

## **Agenda for Quarterly Meeting on MDUFA IV (FY 2018-2022)**

### **Performance**

**November 15, 2019, 2:00 – 3:30**

**WebEx**

**Welcome**

**Summary of Performance Data**

**Guidance Development  
Report on ASCA program**

**Quality Management Update**

#### **Qualitative Update on Finances – 4<sup>th</sup> Quarter FY 2019**

- Fee Setting, Fee Collections, and Workload
- How funding is being used to enhance scientific review capacity
  - Hiring
  - Manager to Reviewer Ratio

#### **Other Topics from Industry-**

Industry has requested high level updates on:

Patient Input

RWE

Digital Health

Time Reporting

3<sup>rd</sup> Party Review

**Address specific questions regarding performance data, fee collections,  
registration and listing, or Training**

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## Medical Devices

### Guidance Documents

Pursuant to the MDUFA IV Commitment Letter,<sup>1</sup> the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA IV Commitment Letter are indicated as such. The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).<sup>2</sup>

**Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2019**

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM623529">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM623529</a>	10/18/2018	Yes	No	N/A	A-List
2	Q1	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking - Immediately in Effect Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340</a>	11/05/2018	No	No	N/A	A-List
3	Q1	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586502">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586502</a>	11/29/2018	No	No	N/A	A-List

<sup>1</sup> [www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf](http://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf); see section VI (Performance Reports)

<sup>2</sup> [www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm580172.htm](http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm580172.htm)

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
4	Q1	Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586506">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586506</a>	11/29/2018	No	Yes	Sec. 3057 of the 21st Century Cures Act	A-List
5	Q1	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626742">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626742</a>	11/30/2018	Yes	No	N/A	A-List
6	Q1	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626743">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626743</a>	11/30/2018	Yes	No	N/A	A-List
7	Q1	User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345633">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345633</a>	12/12/2018	Yes	No	N/A	A-List
8	Q1	Manufacturing Site Change Supplements: Content and Submission - Final Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM467414">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM467414</a>	12/17/2018	Yes	No	N/A	A-List
9	Q1	Breakthrough Devices Program - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664</a>	12/18/2018	Yes	Yes	Sec. 3051 of the 21st Century Cures Act (Sec. 515B(f) of the FD&C Act)	A-List
10	Q2	Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/coordinated-development-antimicrobial-drugs-and-antimicrobial-susceptibility-test-devices-0">www.fda.gov/regulatory-information/search-fda-guidance-documents/coordinated-development-antimicrobial-drugs-and-antimicrobial-susceptibility-test-devices-0</a>	2/1/2019	Yes	No	N/A	A-List

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11	Q2	Safety and Performance Based Pathway - Guidance for Industry and Food and Drug Administration <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM604195</a>	2/1/2019	Yes	No	N/A	A-List
12	Q2	The Least Burdensome Provisions: Concept and Principles - Guidance for Industry and FDA Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085999">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085999</a>	2/5/2019	Yes	No	N/A	A-List
13	Q2	Principles of Premarket Pathways for Combination Products Draft Guidance for Industry and FDA Staff <a href="http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM630458.pdf">www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM630458.pdf</a>	2/6/2019	Yes	No	N/A	N/A
14	Q2	Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM407292">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM407292</a>	2/8/2019	Yes	No	N/A	N/A
15	Q2	Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Guidance for Industry <a href="http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585417">www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585417</a>	2/15/2019	Yes	Yes	Sec. 3034 of the 21st Century Cures Act	N/A
16	Q2	Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631397">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631397</a>	2/19/2019	No	Yes	Sec. 702 of FDARA (Sec. 704 of the FD&C Act)	A-List
17	Q2	Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368</a>	2/21/2019	Yes	No	N/A	N/A
18	Q2	Refuse to Accept Policy for 510(k)s - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014</a>	2/21/2019	Yes	No	N/A	N/A

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q2	Implanted Brain-Computer Interface (BCI) Devices for Patients with Paralysis or Amputation - Non-clinical Testing and Clinical Considerations - Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631786">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM631786</a>	2/25/2019	Yes	No	N/A	B-List
20	Q2	Release of ORA Laboratory Analytical Results to the Responsible Party: Guidance for FDA Staff <a href="http://www.fda.gov/RegulatoryInformation/Guidances/UCM633645">www.fda.gov/RegulatoryInformation/Guidances/UCM633645</a>	3/1/2019	No	No	N/A	N/A
21	Q2	Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices) - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM381491">www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM381491</a>	3/15/2019	Yes	No	N/A	N/A
22	Q2	A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers: Draft Guidance for Industry <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/risk-based-approach-monitoring-clinical-investigations-questions-and-answers">www.fda.gov/regulatory-information/search-fda-guidance-documents/risk-based-approach-monitoring-clinical-investigations-questions-and-answers</a>	3/15/2019	Yes	No	N/A	N/A
23	Q2	Review and Update of Device Establishment Inspection Processes and Standards Draft Guidance <a href="http://www.fda.gov/RegulatoryInformation/Guidances/UCM634774">www.fda.gov/RegulatoryInformation/Guidances/UCM634774</a>	3/29/2019	No	Yes	Sec. 702 of FDARA (Sec. 704 of the FD&C Act)	N/A
24	Q3	Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-non-clinical-assessment-medical-devices-containing-nitinol">www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-non-clinical-assessment-medical-devices-containing-nitinol</a>	4/19/2019	Yes	No	N/A	N/A
25	Q3	Technical Performance Assessment of Quantitative Imaging in Device Premarket Submissions: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-performance-assessment-quantitative-imaging-device-premarket-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-performance-assessment-quantitative-imaging-device-premarket-submissions</a>	4/19/2019	Yes	No	N/A	N/A

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26	Q3	Compliance Policy for Combination Product Postmarketing Safety Reporting: Immediately in Effect Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-combination-product-postmarketing-safety-reporting">www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-combination-product-postmarketing-safety-reporting</a>	4/21/2019	No	No	N/A	N/A
27	Q3	Surgical Staplers and Staples for Internal Use - Labeling Recommendations: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations">www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations</a>	4/24/2019	Yes	No	N/A	A-List
28	Q3	Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/characterization-ultrahigh-molecular-weight-polyethylene-uhmwpe-used-orthopedic-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/characterization-ultrahigh-molecular-weight-polyethylene-uhmwpe-used-orthopedic-devices</a>	4/26/2019	Yes	No	N/A	N/A
29	Q3	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket">www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket</a>	4/26/2019	Yes	No	N/A	N/A
30	Q3	Unique Device Identification: Convenience Kits : Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-convenience-kits">www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-convenience-kits</a>	4/26/2019	No	No	N/A	B-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
31	Q3	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program</a>	5/07/2019	Yes	Yes	Section II.A. of the MDUFA IV Commitment Letter	A-List
32	Q3	Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57): Guidance for Industry and Food and Drug Administration <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-and-requirements-laser-illuminated-projectors-lips-laser-notice-no-57">www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-and-requirements-laser-illuminated-projectors-lips-laser-notice-no-57</a>	5/08/2019	No	No	N/A	N/A
33	Q3	Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56): Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56">www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56</a>	5/08/2019	No	No	N/A	N/A
34	Q3	Medical X-Ray Imaging Devices Conformance with IEC Standards: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards">www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards</a>	5/08/2019	Yes	No	N/A	B-List
35	Q3	Policy Clarification for Certain Fluoroscopic Equipment Requirements: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-certain-fluoroscopic-equipment-requirements">www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-certain-fluoroscopic-equipment-requirements</a>	5/08/2019	Yes	No	N/A	N/A
36	Q3	Utilizing Animal Studies to Evaluate Organ Preservation Devices: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/utilizing-animal-studies-evaluate-organ-preservation-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/utilizing-animal-studies-evaluate-organ-preservation-devices</a>	5/08/2019	Yes	No	N/A	B-List



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37	Q3	Mouse Embryo Assay for Assisted Reproduction Technology Devices <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/mouse-embryo-assay-assisted-reproduction-technology-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/mouse-embryo-assay-assisted-reproduction-technology-devices</a>	6/13/2019	Yes	No	N/A	N/A
38	Q3	Testing for Biotin Interference in In Vitro Diagnostic Devices: Draft Guidance for Industry <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-biotin-interference-vitro-diagnostic-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-biotin-interference-vitro-diagnostic-devices</a>	6/13/2019	Yes	No	N/A	N/A
39	Q3	Clinical Investigations for Prostate Tissue Ablation Devices: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-investigations-prostate-tissue-ablation-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-investigations-prostate-tissue-ablation-devices</a>	6/26/2019	Yes	No	N/A	N/A
40	Q3	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers">www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers</a>	6/27/2019	Yes	No	N/A	N/A
41 <sup>3</sup>	Q4	Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a">www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a</a>	7/2/2019	No	No	N/A	N/A
42 <sup>3</sup>	Q4	Center for Devices and Radiological Health (CDRH) Appeals Processes: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes">www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes</a>	7/2/2019	No	No	N/A	N/A

<sup>3</sup> This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2).

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43	Q4	Live Case Presentations During Investigational Device Exemption (IDE) Clinical Trials: Guidance for Institutional Review Boards, Industry, Clinical Investigators, and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/live-case-presentations-during-investigational-device-exemption-ide-clinical-trials">www.fda.gov/regulatory-information/search-fda-guidance-documents/live-case-presentations-during-investigational-device-exemption-ide-clinical-trials</a>	7/11/2019	Yes	No	N/A	N/A
44	Q4	Postmarketing Safety Reporting for Combination Products: Guidance for Industry and FDA Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/metal-expandable-biliary-stents-premarket-notification-510k-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/metal-expandable-biliary-stents-premarket-notification-510k-submissions</a>	7/23/2019	No	No	N/A	N/A
45	Q4	Metal Expandable Biliary Stents - Premarket Notification (510(k)) Submissions: Guidance for Industry and Food and Drug Administration Staff <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/metal-expandable-biliary-stents-premarket-notification-510k-submissions">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/metal-expandable-biliary-stents-premarket-notification-510k-submissions</a>	7/26/2019	Yes	No	N/A	N/A
46	Q4	Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment">www.fda.gov/regulatory-information/search-fda-guidance-documents/testing-and-labeling-medical-devices-safety-magnetic-resonance-mr-environment</a>	8/2/2019	Yes	No	N/A	N/A
47 <sup>3</sup>	Q4	Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications: Guidance for Industry and Food and Drug Administration Staff <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/factors-consider-when-making-benefit-risk-determinations-medical-device-premarket-approval-and-de</a>	8/30/2019	Yes	No	N/A	N/A

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48	Q4	Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-uncertainty-making-benefit-risk-determinations-medical-device-premarket-approvals-de">www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-uncertainty-making-benefit-risk-determinations-medical-device-premarket-approvals-de</a>	8/30/2019	Yes	No	N/A	A-List
49 <sup>3</sup>	Q4	Humanitarian Use Device (HUD) Designations : Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-use-device-hud-designations">www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-use-device-hud-designations</a>	9/5/2019	Yes	No	N/A	N/A
50	Q4	Humanitarian Device Exemption (HDE) Program: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program</a>	9/6/2019	Yes	No	N/A	A-List
51 <sup>3</sup>	Q4	User Fees and Refunds for De Novo Classification Requests: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-de-novo-classification-requests">www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-de-novo-classification-requests</a>	9/9/2019	No	No	N/A	N/A
52 <sup>3</sup>	Q4	FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals">www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals</a>	9/9/2019	Yes	No	N/A	N/A
53	Q4	Acceptance Review for De Novo Classification Requests: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests">www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests</a>	9/9/2019	Yes	Yes	Sec. II. E. of the MDUFA Commitment Letter	N/A

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
54	Q4	The Special 510(k) Program: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program</a>	9/13/2019	Yes	No	N/A	A-List
55 <sup>3</sup>	Q4	The Abbreviated 510(k) Program: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program</a>	9/13/2019	Yes	No	N/A	N/A
56 <sup>3</sup>	Q4	Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks">www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks</a>	9/13/2019	Yes	No	N/A	N/A
57 <sup>3</sup>	Q4	Format for Traditional and Abbreviated 510(k)s: Guidance for Industry and FDA Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks">www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks</a>	9/13/2019	Yes	No	N/A	N/A
58	Q4	Safer Technologies Program for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/safer-technologies-program-medical-devices</a>	9/19/2019	Yes	No	N/A	N/A
59 <sup>3</sup>	Q4	Safety and Performance Based Pathway: Guidance for Industry and Food and Drug Administration <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway">www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway</a>	9/20/2019	Yes	No	N/A	N/A
60	Q4	Spinal Plating Systems - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/spinal-plating-systems-performance-criteria-safety-and-performance-based-pathway">www.fda.gov/regulatory-information/search-fda-guidance-documents/spinal-plating-systems-performance-criteria-safety-and-performance-based-pathway</a>	9/20/2019	Yes	No	N/A	N/A

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
61	Q4	Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance">www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance</a>	9/20/2019	Yes	No	N/A	N/A
62	Q4	Cutaneous Electrodes for Recording Purposes - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/cutaneous-electrodes-recording-purposes-performance-criteria-safety-and-performance-based-pathway">www.fda.gov/regulatory-information/search-fda-guidance-documents/cutaneous-electrodes-recording-purposes-performance-criteria-safety-and-performance-based-pathway</a>	9/20/2019	Yes	No	N/A	N/A
63	Q4	Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/conventional-foley-catheters-performance-criteria-safety-and-performance-based-pathway">www.fda.gov/regulatory-information/search-fda-guidance-documents/conventional-foley-catheters-performance-criteria-safety-and-performance-based-pathway</a>	9/20/2019	Yes	No	N/A	N/A
64	Q4	The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program</a>	9/23/2019	Yes	Yes	Sec. 205 of the FDA Reauthorization Act of 2017 and Sec. IV. D. of the MDUFA Commitment Letter	A-List
65	Q4	Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations: Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations">www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations</a>	9/24/2019	No	N	N/A	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
66	Q4	Providing Regulatory Submissions for Medical Devices in Electronic Format - Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab">www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab</a>	9/26/2019	Yes	Yes	Sec. 207 of the FDA Reauthorization Act of 2017 and Sec. III. C. of the MDUFA Commitment Letter	N/A
67 <sup>3</sup>	Q4	Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications">www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications</a>	9/27/2019	Yes	No	N/A	N/A
68 <sup>3</sup>	Q4	Off-The-Shelf Software Use in Medical Devices: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices</a>	9/27/2019	Yes	No	N/A	N/A
69 <sup>3</sup>	Q4	Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices</a>	9/27/2019	Yes	No	N/A	N/A
70 <sup>3</sup>	Q4	General Wellness: Policy for Low Risk Devices: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices</a>	9/27/2019	Yes	No	N/A	N/A

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
71	Q4	Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act">www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act</a>	9/27/2019	Yes	No	N/A	A-List
72	Q4	Clinical Decision Support Software: Draft Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software">www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software</a>	9/27/2019	Yes	No	N/A	A-List

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**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA IV CDRH Performance Data  
----Action through 30 September 2019**

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## Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology Devices
DIHD	Division of Immunology and Hematology Devices
DMD	Division of Microbiology Devices
DMGP	Division of Molecular Genetics and Pathology
DNPM	Division of Neurological and Physical Medicine Devices
DOD	Division of Orthopedic Devices
DOED	Division of Ophthalmic and Ear, Nose and Throat Devices
DRGUD	Division of Reproductive, Gastro-Renal, and Urological Devices
DRH	Division of Radiological Health
DSD	Division of Surgical Devices
IDE	Investigational Device Exemption
IVD	In Vitro Diagnostic
LDT	Laboratory Developed Test
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
ODE	Office of Device Evaluation
OIR	Office of In Vitro Diagnostics and Radiological Health
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

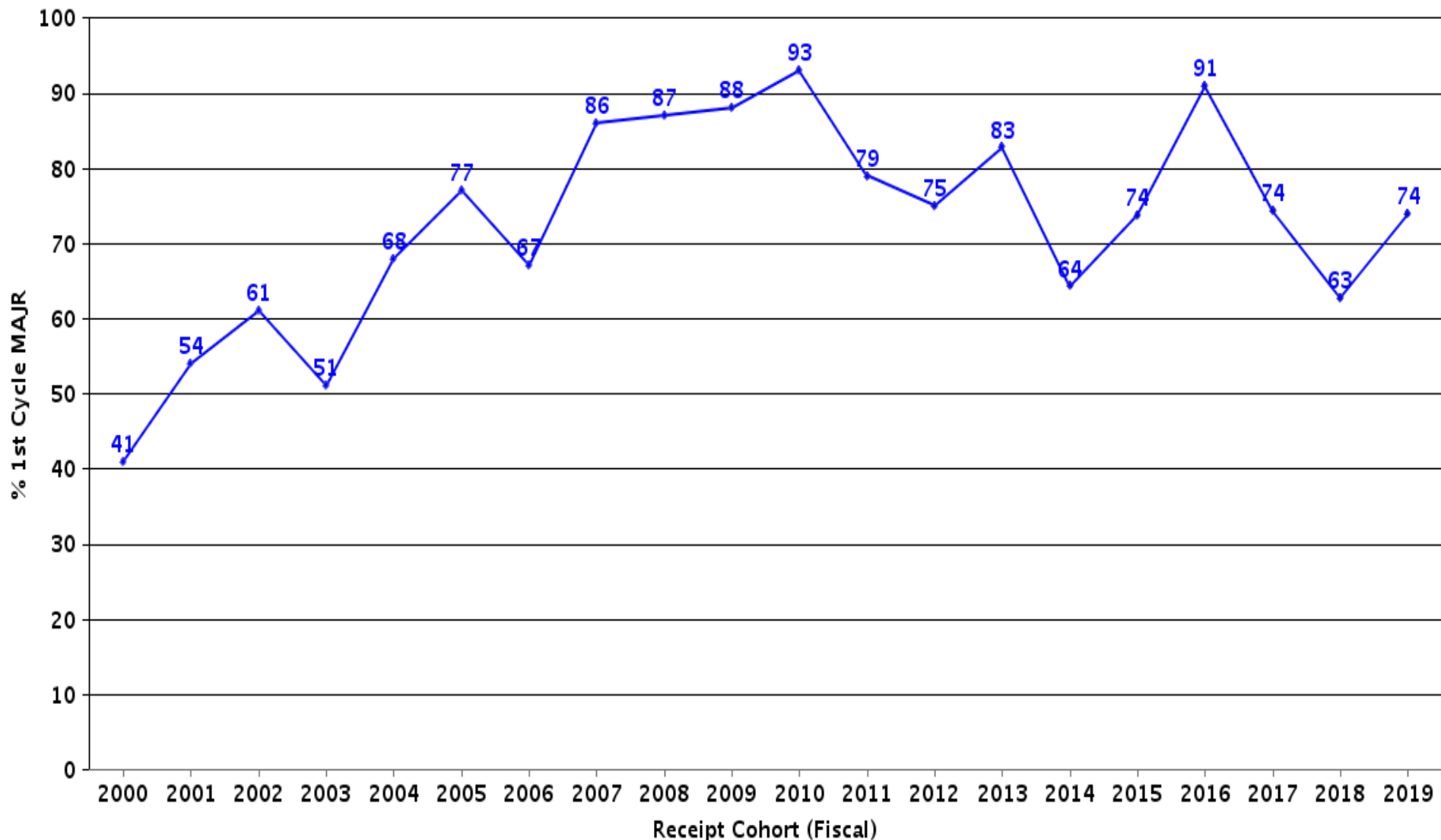
**Note: Data may change in subsequent quarterly and annual reports.**



PMA's

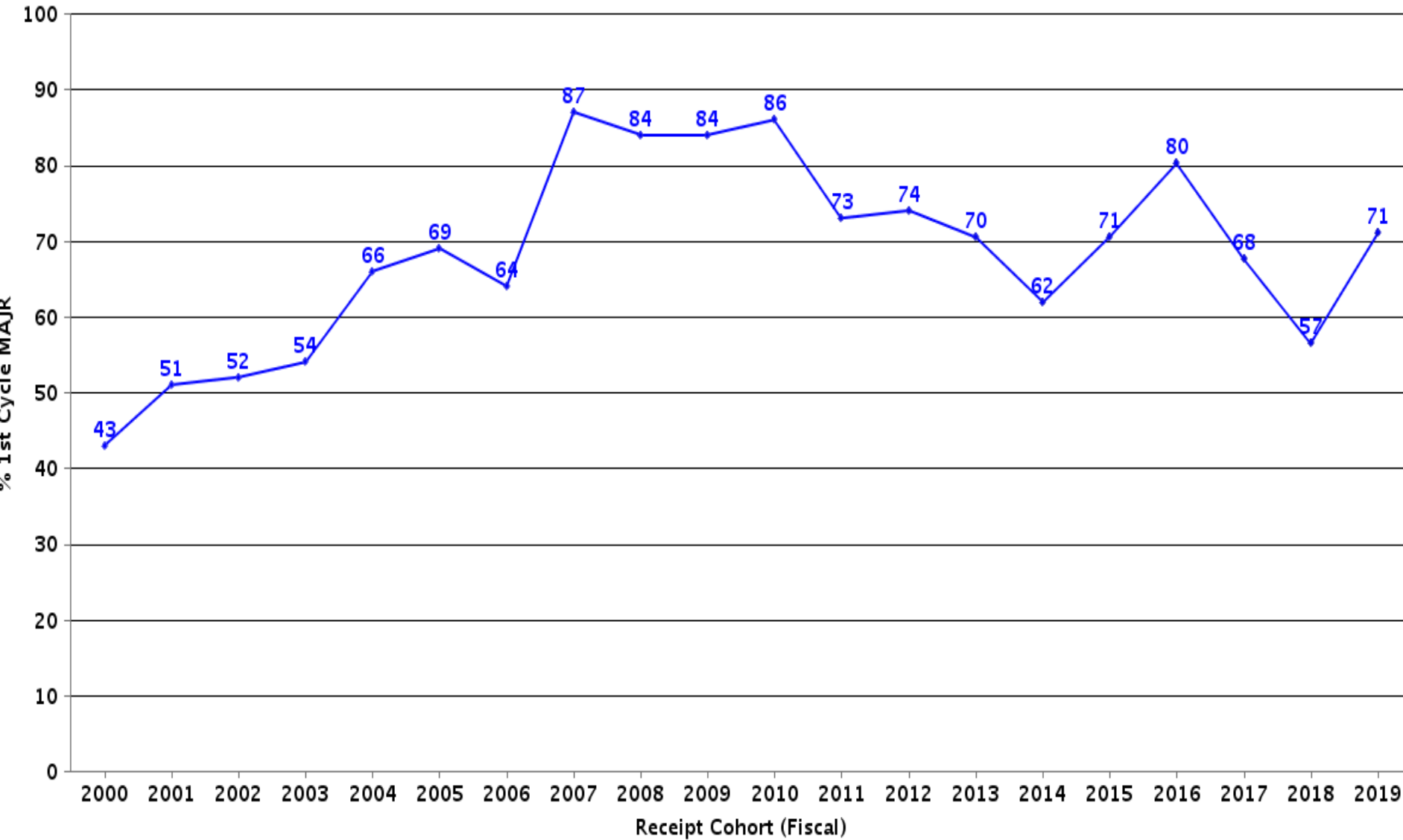
Q4FY19

# PMA Originals Filed As Of 6/30/19: 1st Cycle Major Deficiency Rate as of 9/30/19



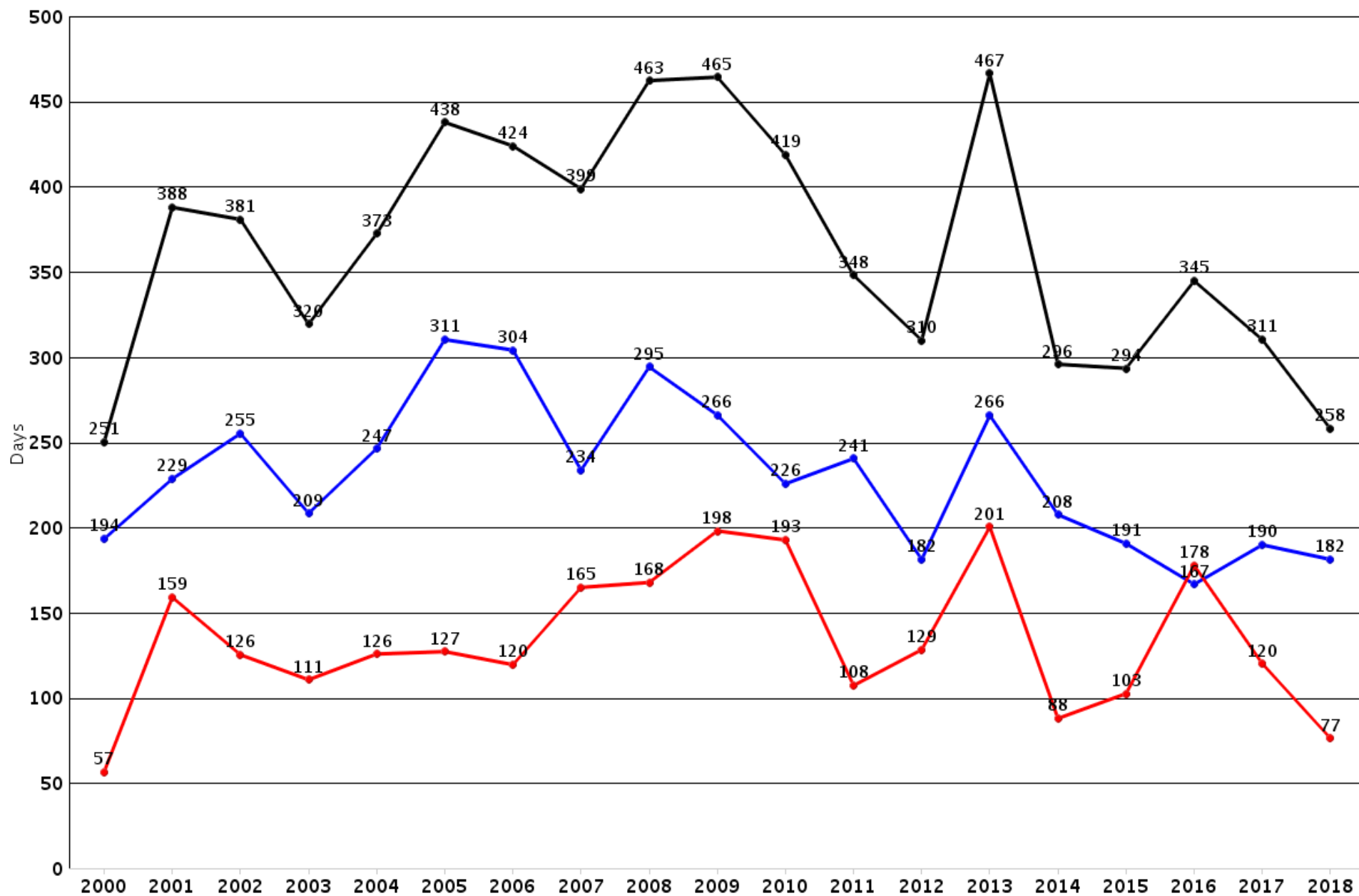
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/19. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

PMA Originals and Panel Track Supplements Filed As Of 6/30/19: 1st Cycle Major Deficiency Rate as of 9/30/19



Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 6/30/19. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

PMA Originals Filed As Of 09/30/2019: Average Time to MDUFA Decision

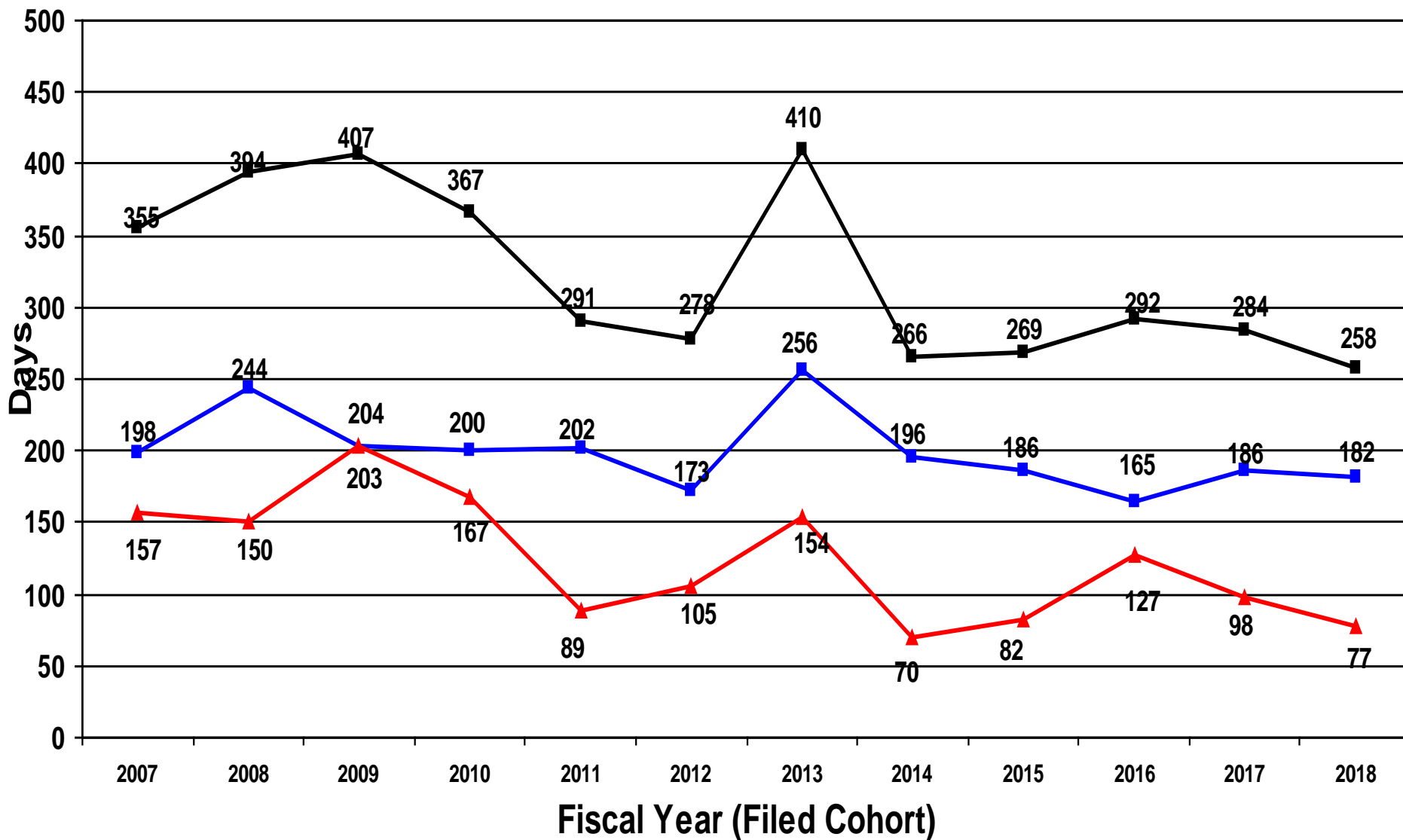


Cohorts not yet closed: 2018: 88.37%

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● Avg FDA Days to MDUFA PMAO ● Avg MFR Days to MDUFA PMAO ● Avg Total Days to MDUFA PMAO

# PMA Originals Filed as of 09/30/2019: Average Time to MDUFA Decision Comparison of Cohorts at 88.4% Closure



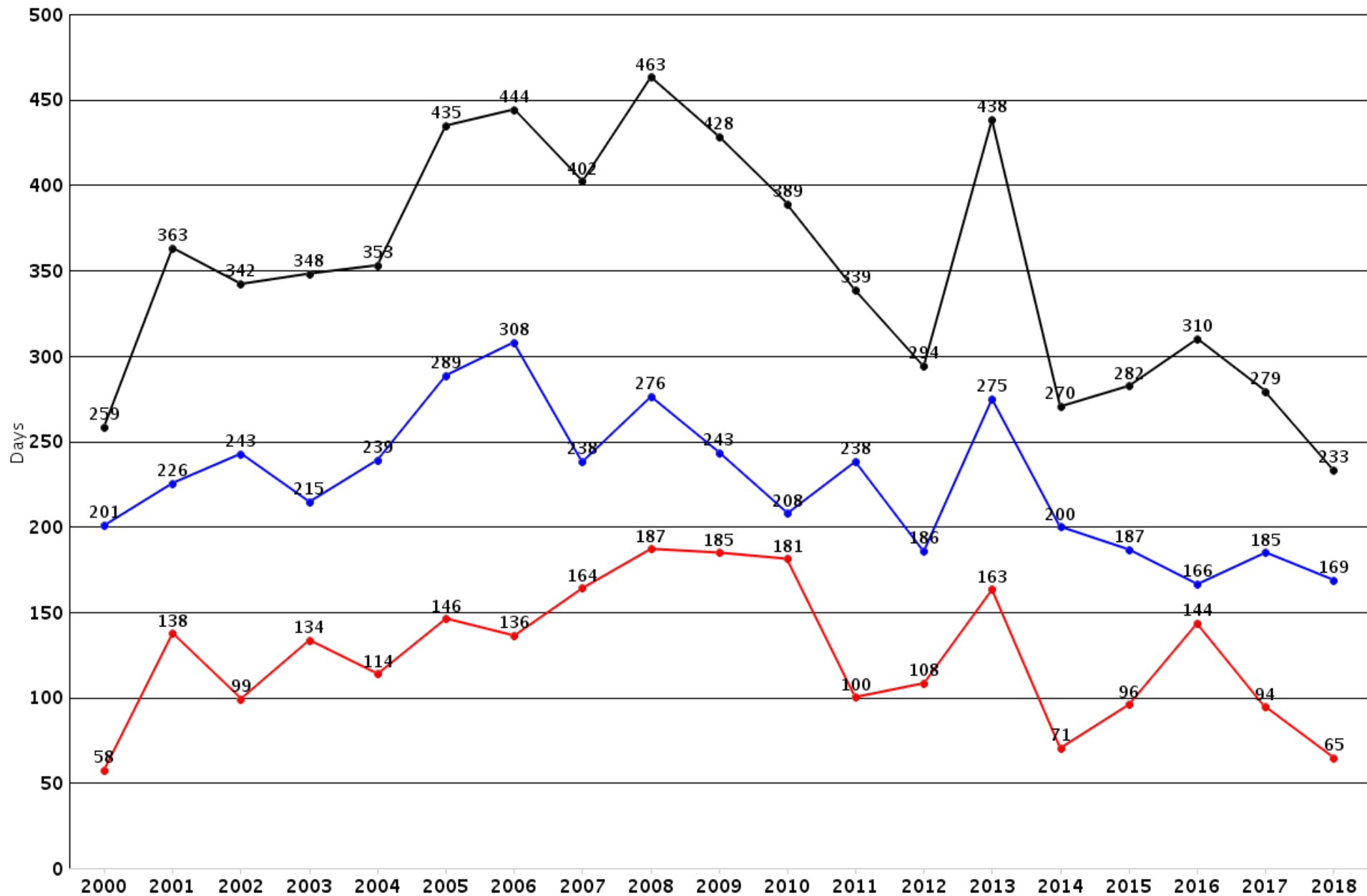
■ Avg Total Days PMAO

■ Avg FDA Days PMAO

▲ Avg Applicant Days PMAO

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# PMA Originals and Panel Track Supplements Filed As Of 09/30/2019: Average Time to MDUFA Decision

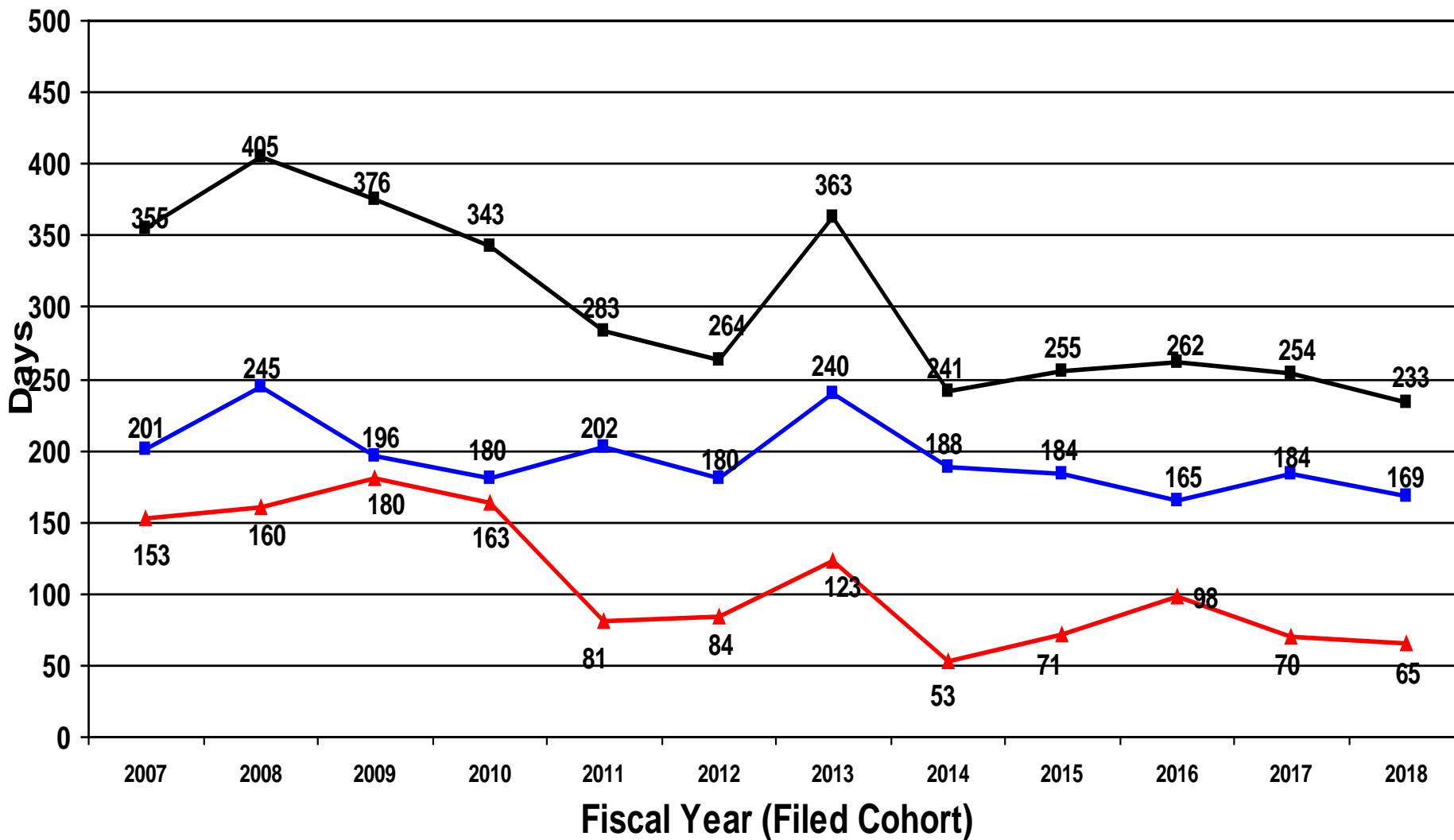


Cohorts not yet closed: 2018: 88.57%

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● Avg FDA Days to MDUFA PMAO-PTS ● Avg MFR Days to MDUFA PMAO-PTS ● Avg Total Days to MDUFA PMAO-PTS

PMA Originals and Panel Track Supplements Filed as of 09/30/2019: Average  
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Comparison of Cohorts at 88.6% Closure

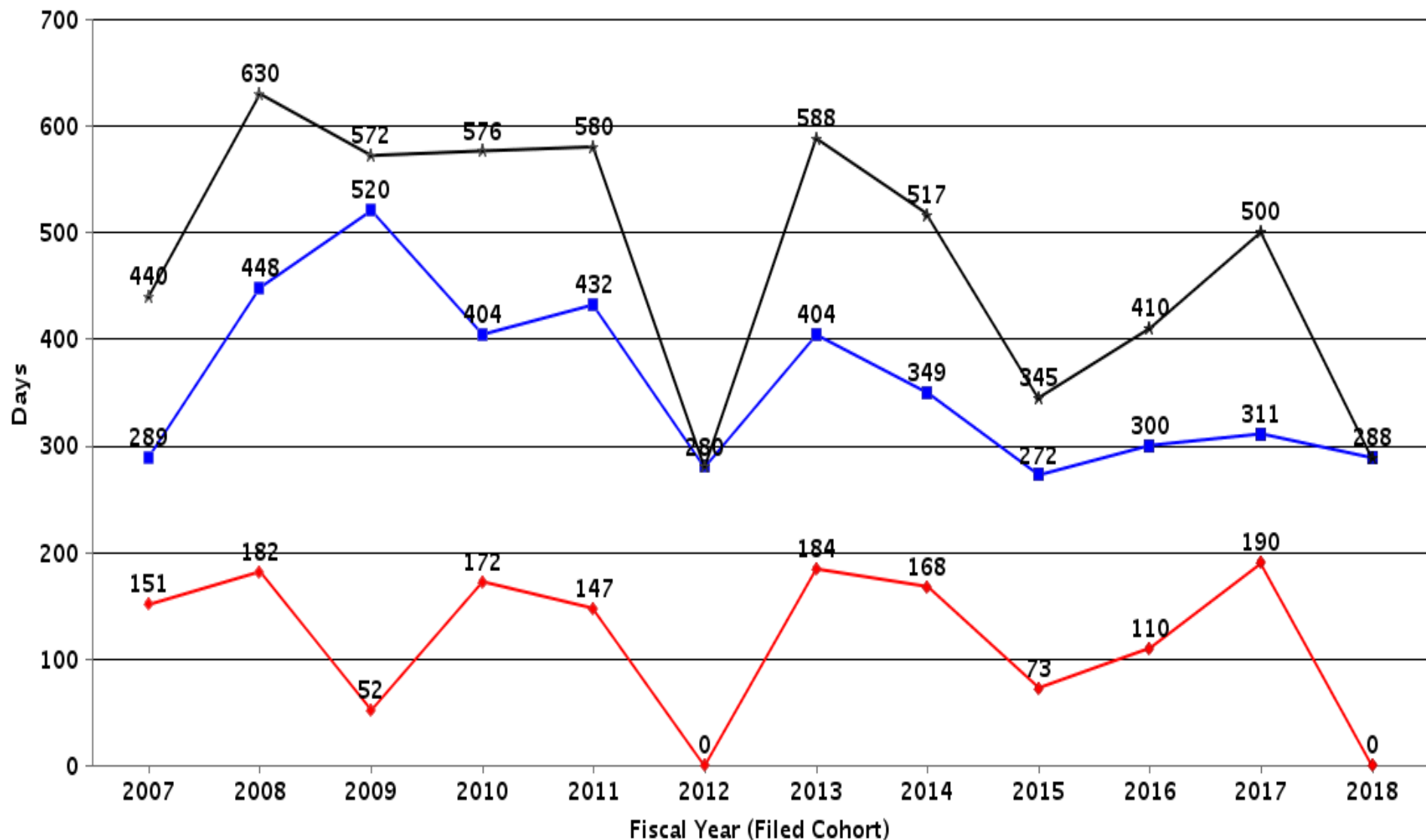


—■— Avg Total Days PMAO-PTS

—■— Avg FDA Days PMAO-PTS

—▲— Avg Applicant Days PMAO-PTS

PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2019/09/30

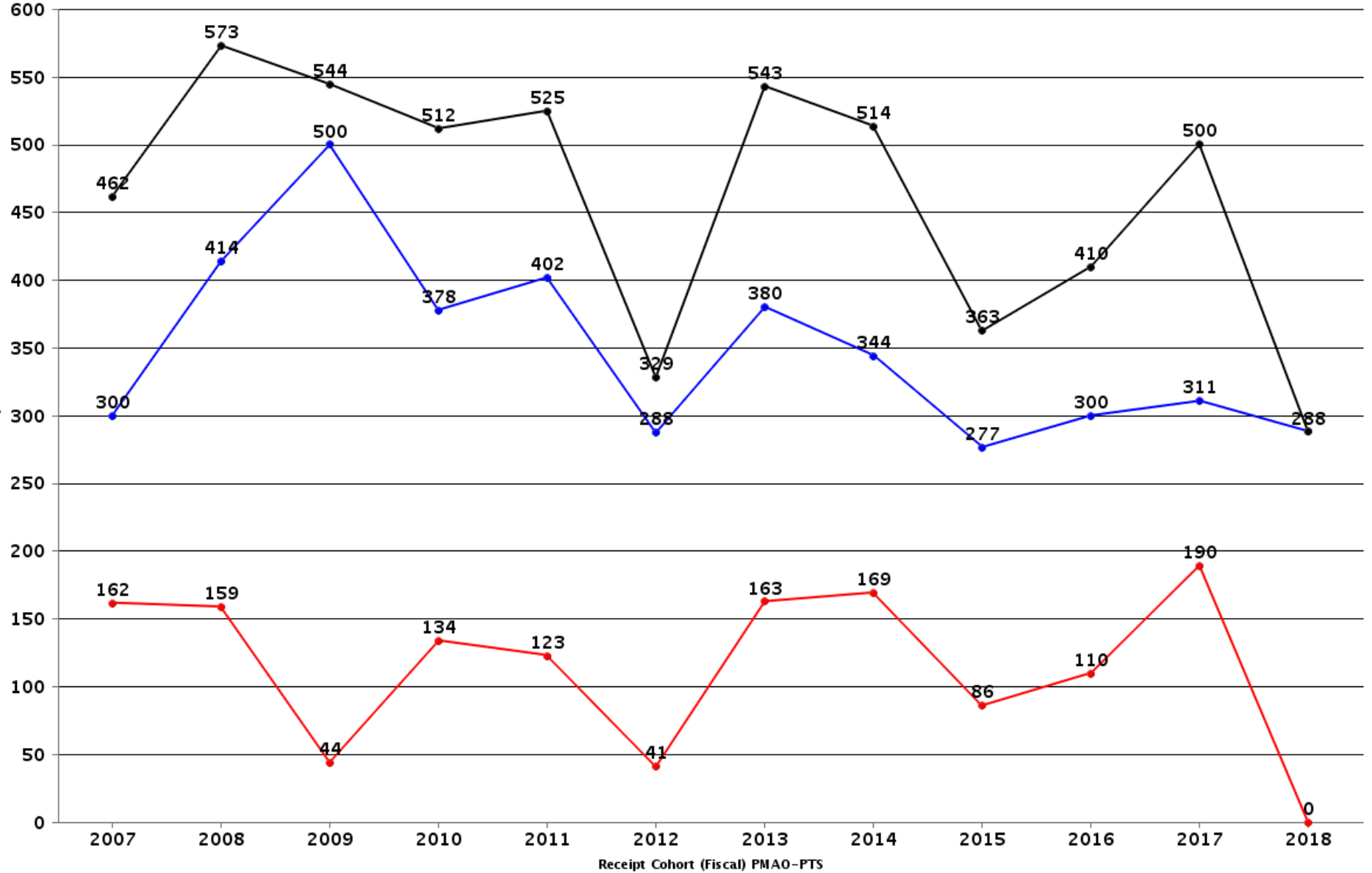


Numbers Filed: 2007 = 7; 2008 = 7; 2009 = 6; 2010 = 7; 2011 = 11; 2012 = 1; 2013 = 11; 2014 = 5; 2015 = 5; 2016 = 1; 2017 = 5; 2018 = 4

■ Avg FDA Days to MDUFA Decision PMAO ♦ Avg MFR Days to MDUFA Decision PMAO ★ Avg Total Days to MDUFA Decision PMAO



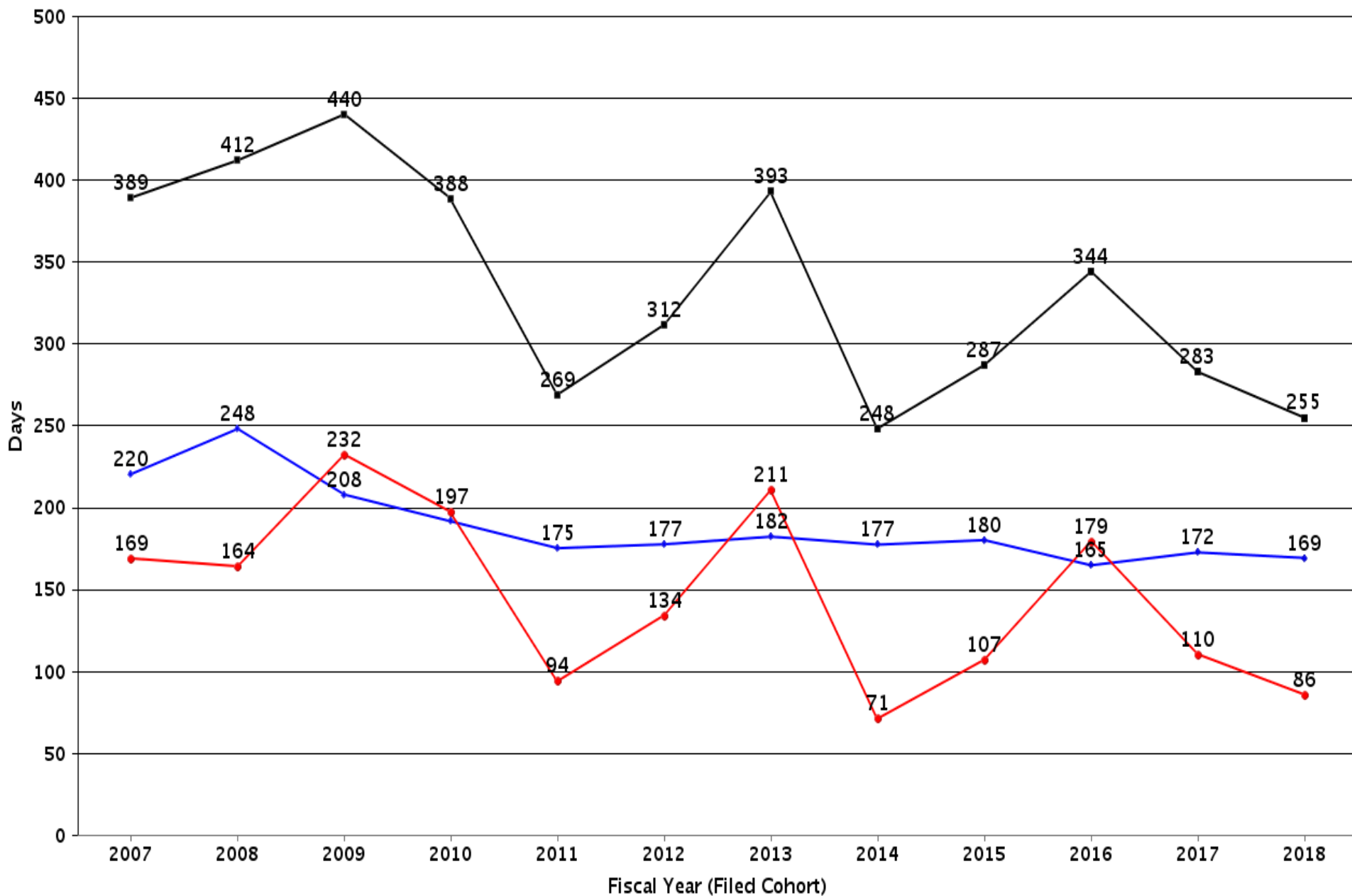
PMA Originals and Panel Track Supplements With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2019/09/30



Numbers Filed: 2007 = 8; 2008 = 8; 2009 = 7; 2010 = 9; 2011 = 14; 2012 = 2; 2013 = 17; 2014 = 6; 2015 = 6; 2016 = 1; 2017 = 5; 2018 = 4

● Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ● Avg Total Days to MDUFA Decision PMAO-PTS

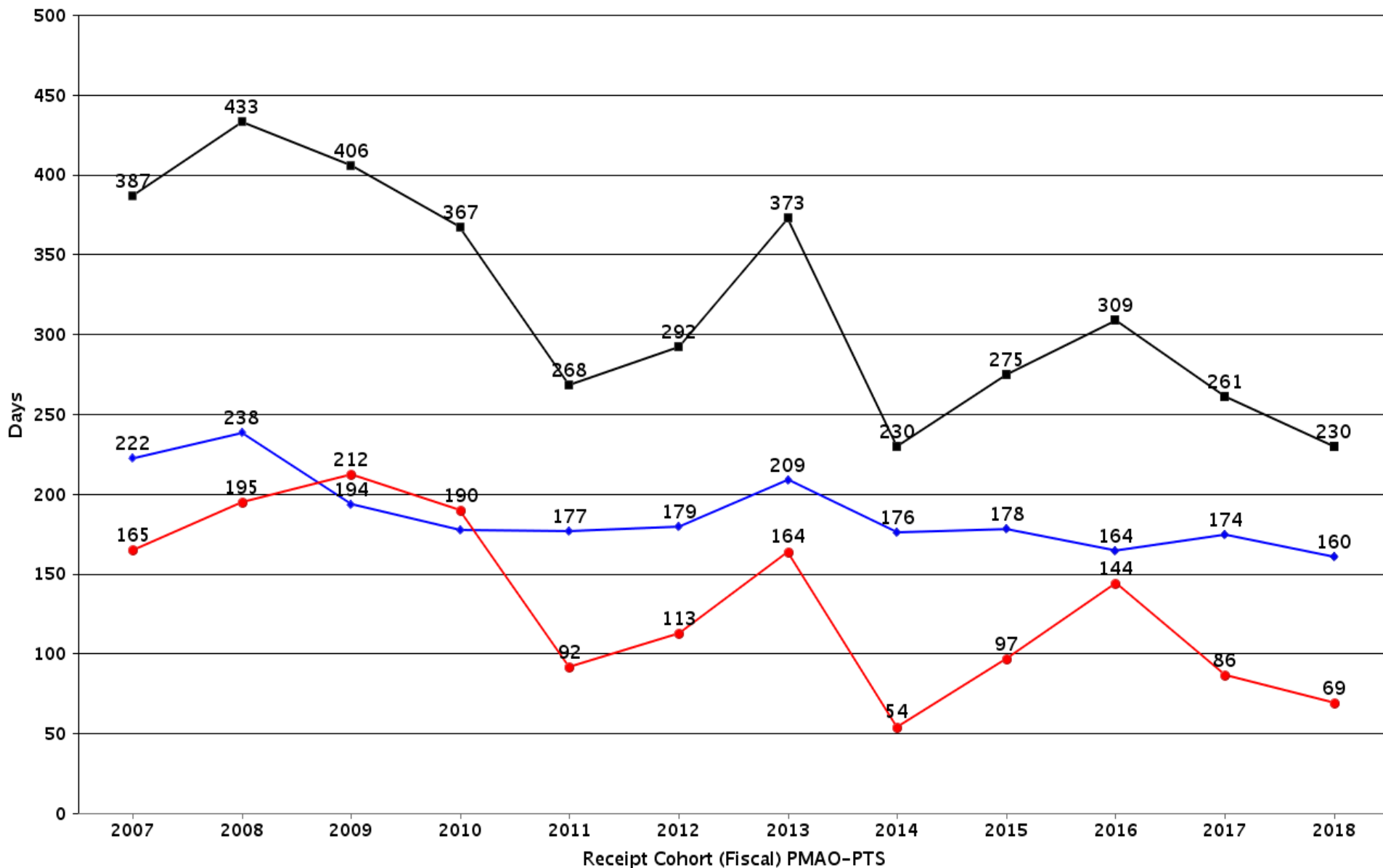
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.



Numbers Filed: 2007 = 28; 2008 = 23; 2009 = 26; 2010 = 36; 2011 = 32; 2012 = 23; 2013 = 18; 2014 = 23; 2015 = 37; 2016 = 54; 2017 = 45; 2018 = 39

◆ Avg FDA Days to MDUFA Decision PMAO ● Avg MFR Days to MDUFA Decision PMAO ■ Avg Total Days to MDUFA Decision PMAO

PMA Originals and Panel Track Supplements: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2019/09/30



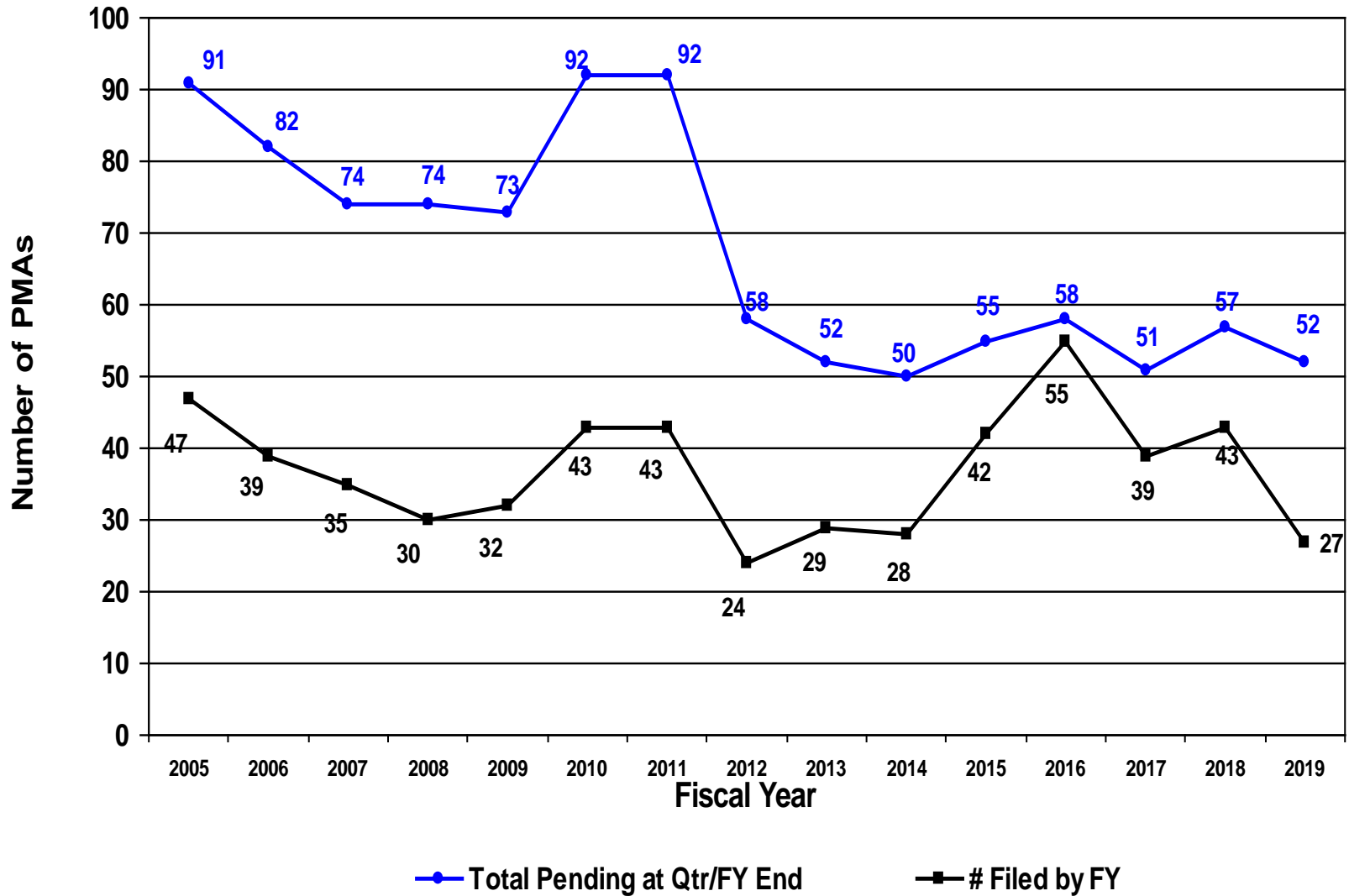
Numbers Filed: 2007 = 31; 2008 = 29; 2009 = 36; 2010 = 50; 2011 = 37; 2012 = 32; 2013 = 27; 2014 = 36; 2015 = 62; 2016 = 70; 2017 = 60; 2018 = 66

◆ Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ■ Avg Total Days to MDUFA Decision PMAO-PTS

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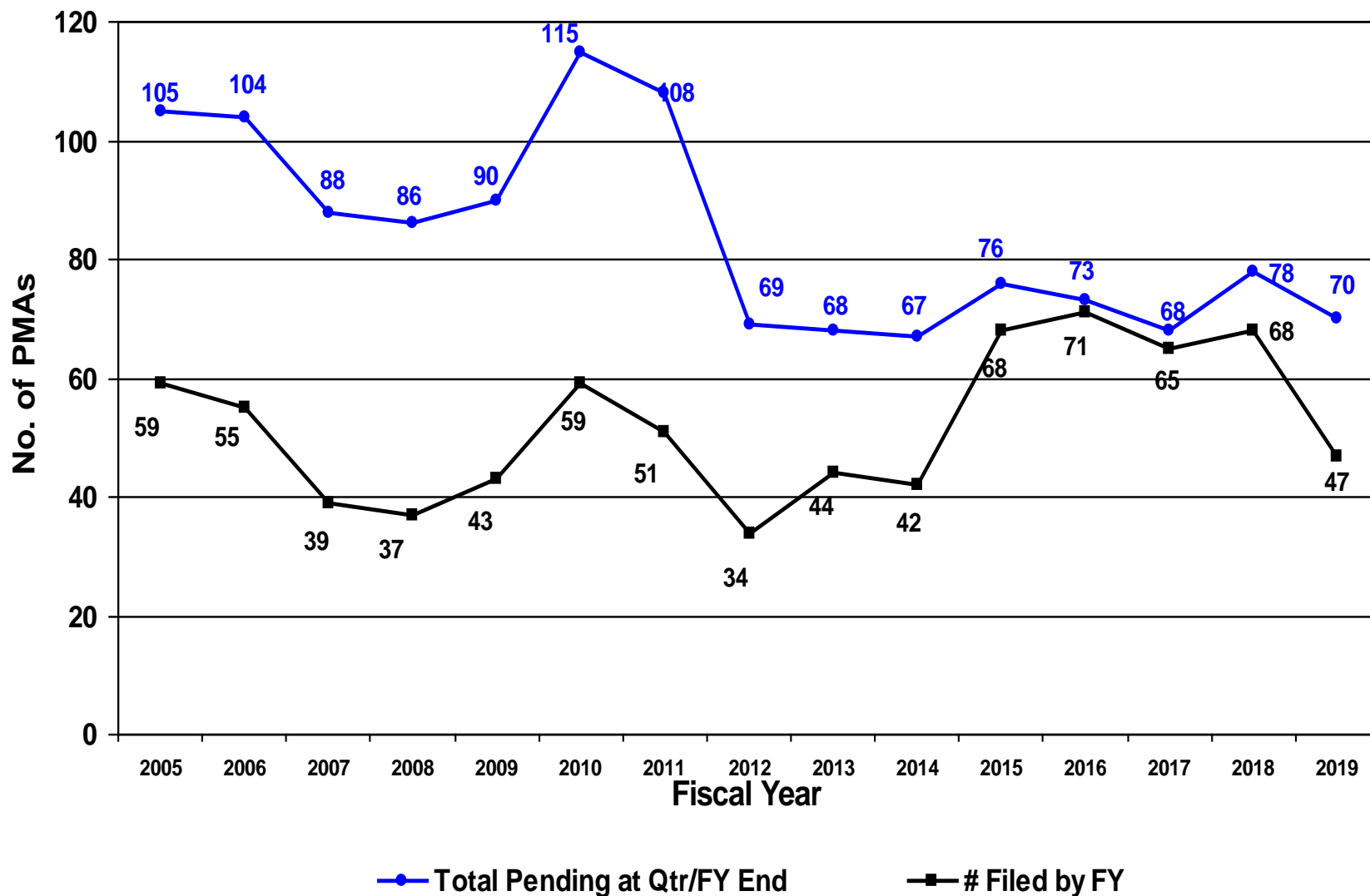
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

## PMA Originals Pending\* at End of Quarter/Year



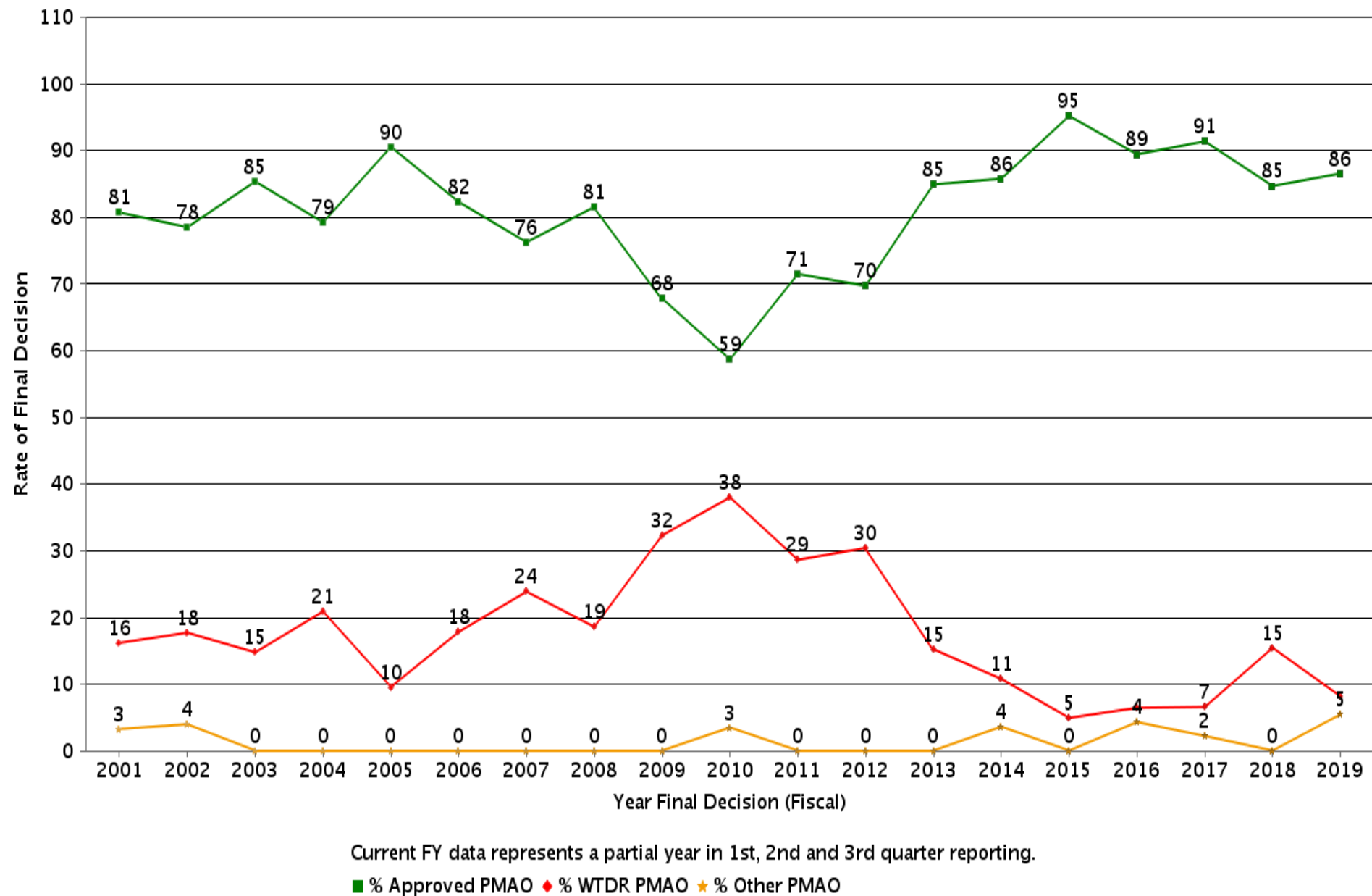
\*Original PMAs under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

## PMA Originals and Panel Track Supplements Pending\* at End of Quarter/Year



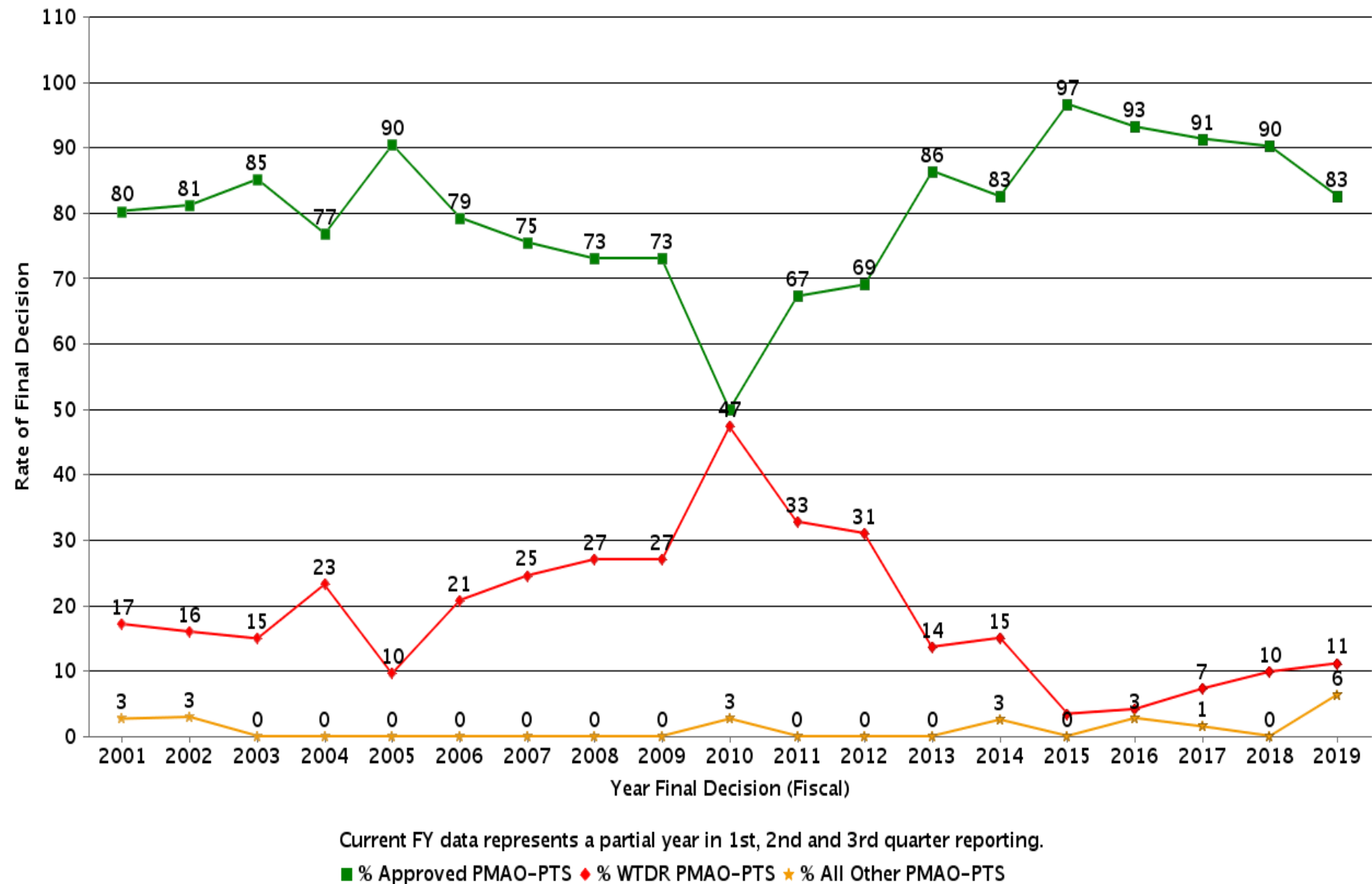
\*Original PMAs/PTS under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

PMA Originals Rates of Approval, Withdrawal and Other Decisions by FY of Final Decision



Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions from FY16 onward

PMA Originals and Panel Track Supplements Rates of Approval, Withdrawal and Other Decisions by FY of Final Decision

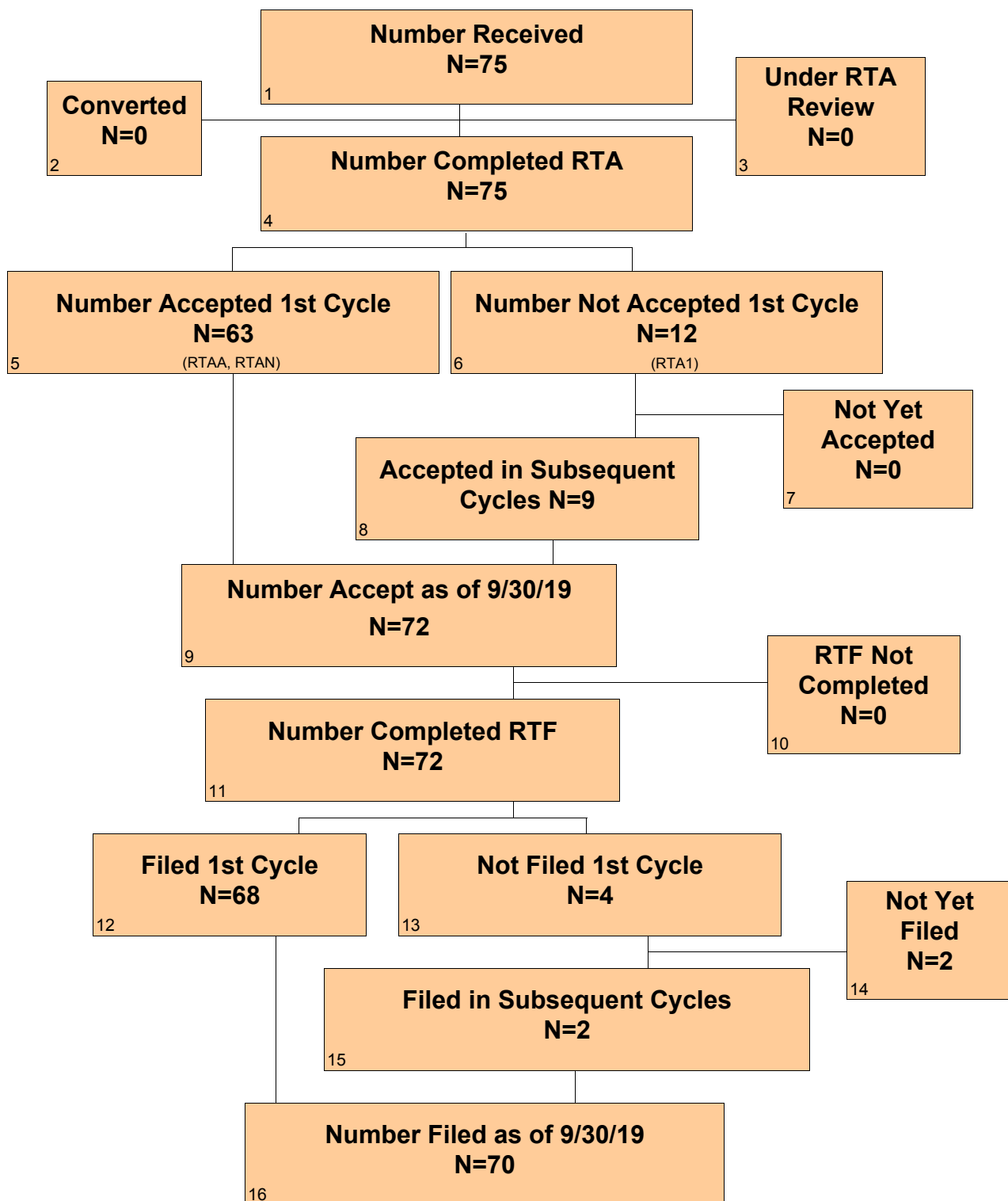


Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions from FY16 onward

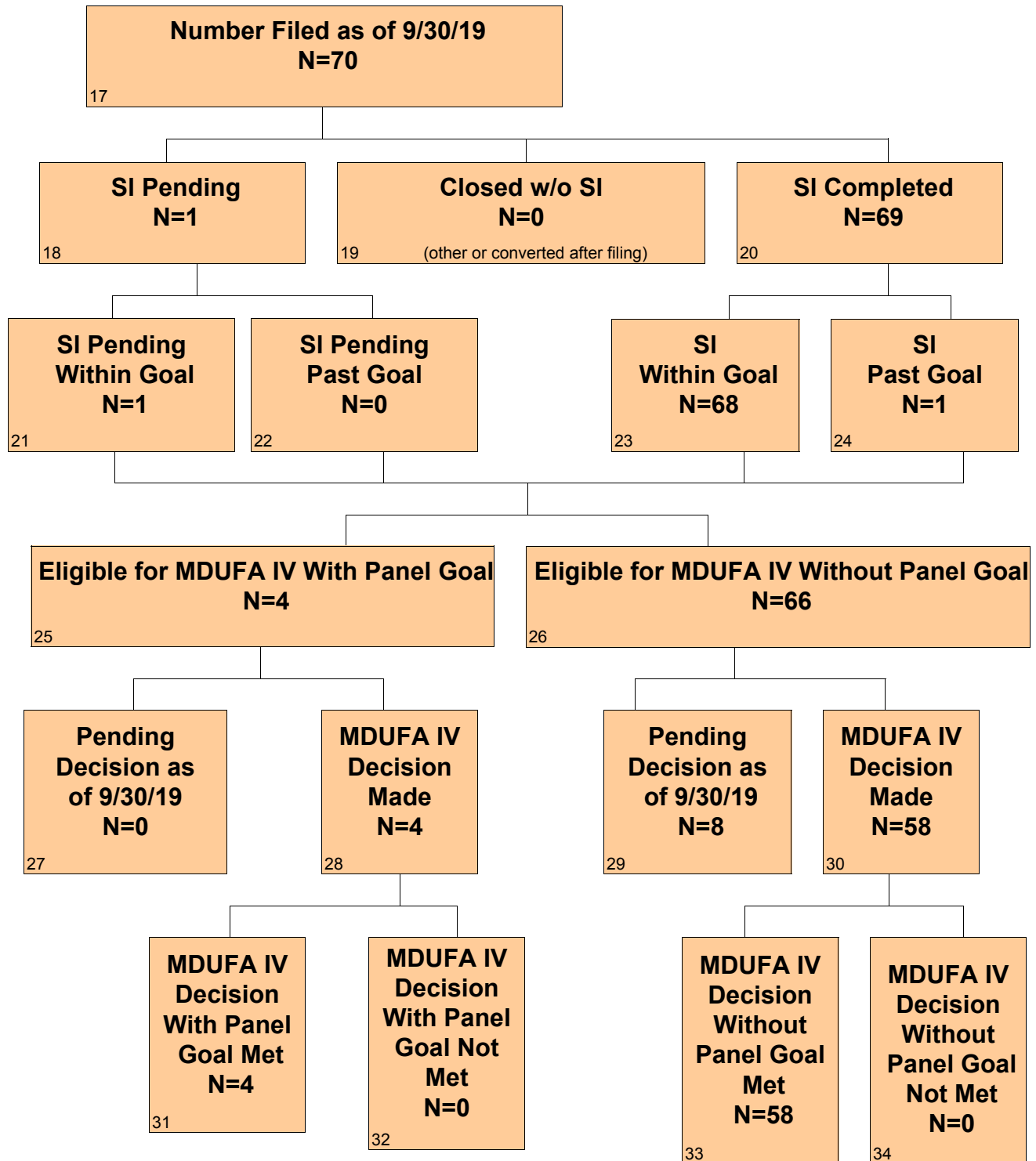
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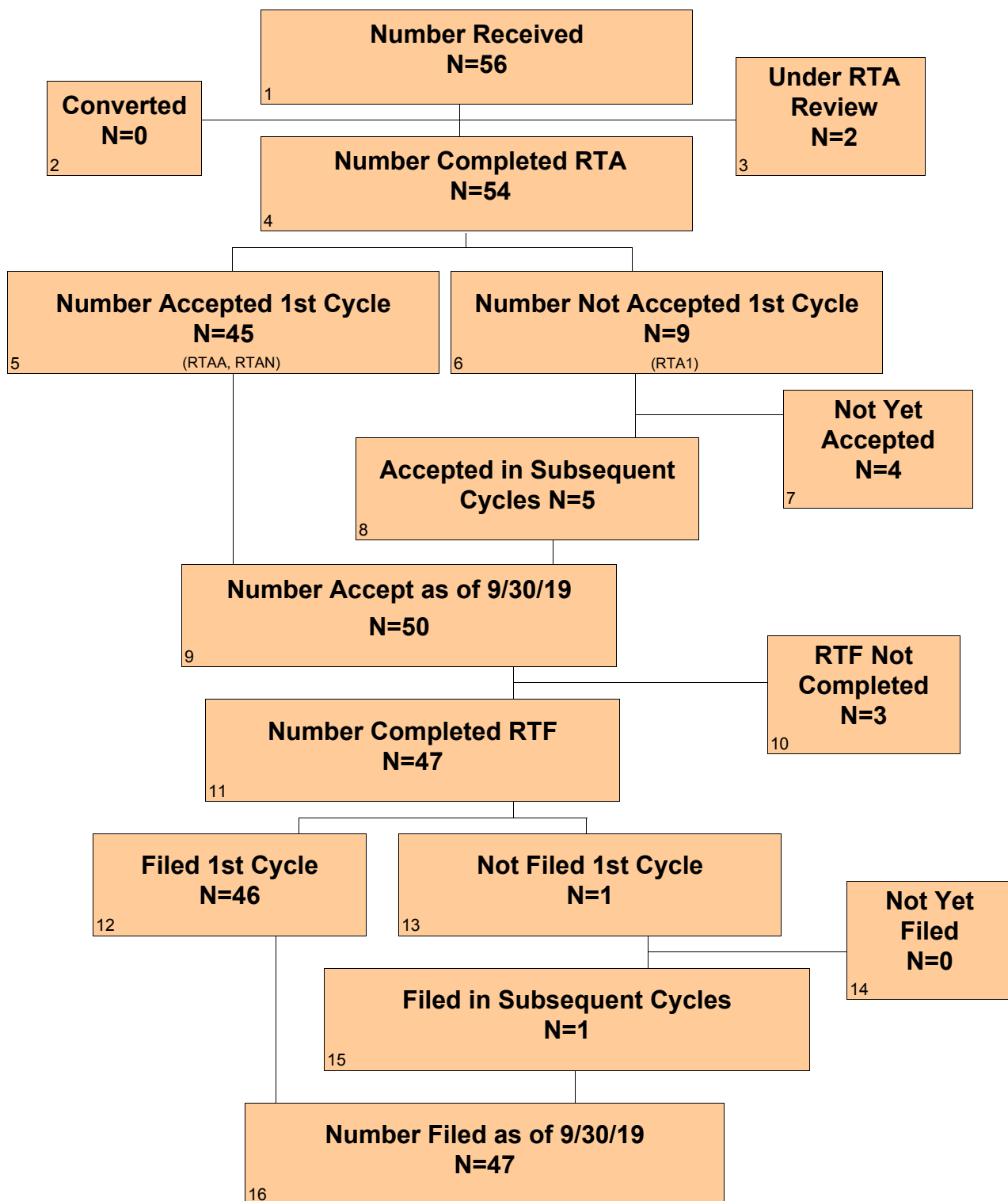
# CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/19



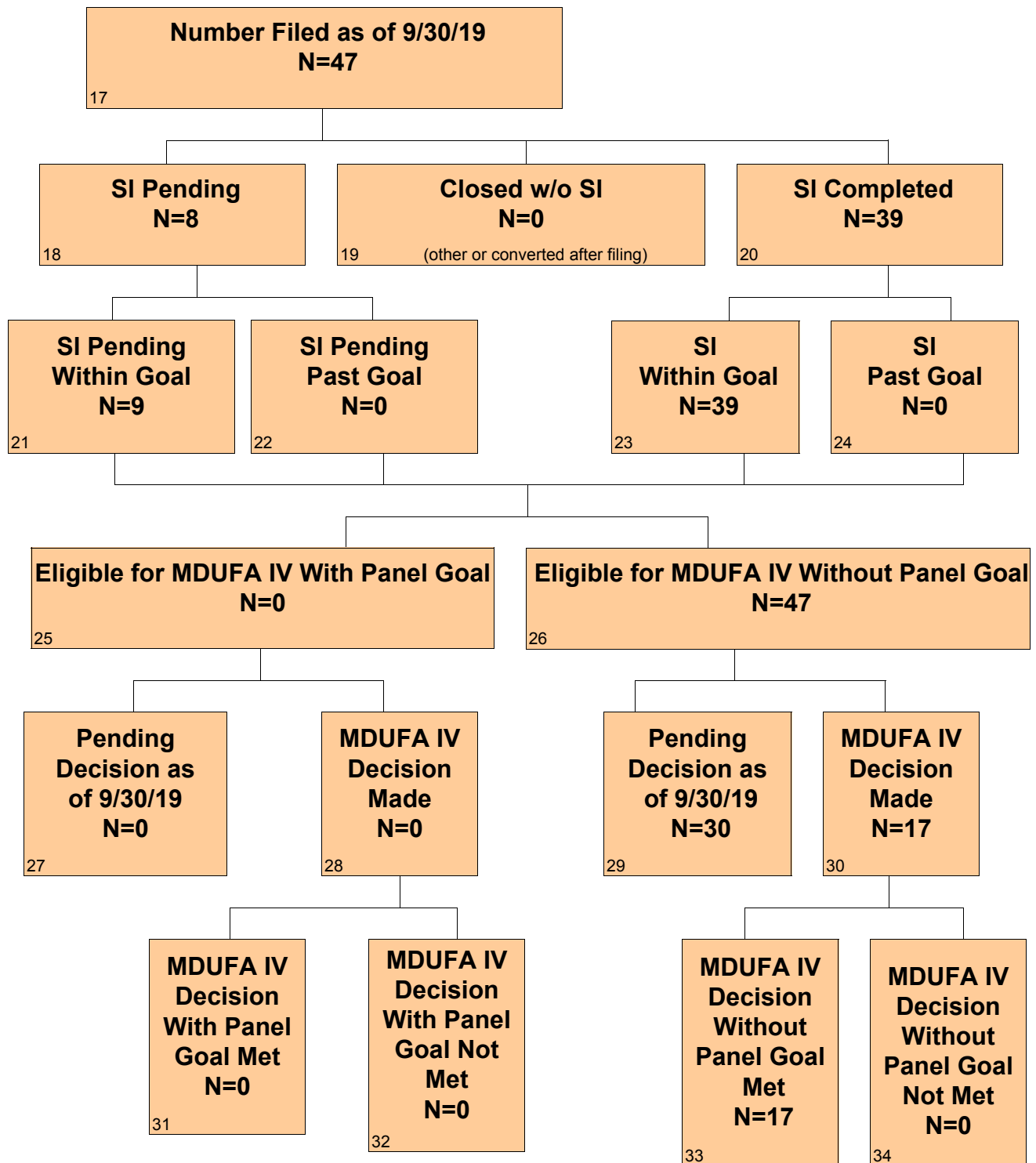
# CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/19 Continued



# CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/19



# CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/19 Continued



## Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

Table 1.1 CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	75	56			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	62	44			
Number Without a RTA Review and > 15 Days Since Date Received	1	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted for Filing Review	12	9			
Rate of Submissions Not Accepted for Filing Review	16.00%	16.67%			

Table 1.2 CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	75	56			
Number Accepted	63	45			
Completed RTF	72	47			
Number Not Filed	4	1			
Rate of Submissions Not Filed	5.56%	2.13%			

Table 1.3 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction

### Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	70	47			
SI Goal Met	68	39			
SI Goal Not Met	1	0			
SI Pending Within Goal	1	8			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.55%	100%			

**Table 1.4 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	69	39			
Average Number of FDA Days to Substantive Interaction	86.81	90.47			
20th Percentile FDA Days to Substantive Interaction	84	86			
40th Percentile FDA Days to Substantive Interaction	88	88			
60th Percentile FDA Days to Substantive Interaction	90	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	178	246			

**Table 1.5 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	66	47			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	58	17			
MDUFA IV Decision Goal Met	58	17			
PMAs Pending MDUFA IV Decision	8	30			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	4	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	4	0			
MDUFA IV Decision Goal Met	4	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**

**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	58	17			
<b>Average FDA Days to MDUFA IV Decision</b>	160.45	154.94			
20th Percentile FDA Days to MDUFA IV Decision	133	130			
40th Percentile FDA Days to MDUFA IV Decision	176	147			
60th Percentile FDA Days to MDUFA IV Decision	178	176			
80th Percentile FDA Days to MDUFA IV Decision	180	180			
Maximum FDA Days to MDUFA IV Decision	279	180			
<b>Average Industry Days to MDUFA IV Decision</b>	70.40	33.65			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	2			
60th Percentile Industry Days to MDUFA IV Decision	75	28			
80th Percentile Industry Days to MDUFA IV Decision	140	68			
Maximum Industry Days to MDUFA IV Decision	301	149			
<b>Average Total Days to MDUFA IV Decision</b>	230.84	188.59			
20th Percentile Total Days to MDUFA IV Decision	163	138			
40th Percentile Total Days to MDUFA IV Decision	180	155			
60th Percentile Total Days to MDUFA IV Decision	249	194			
80th Percentile Total Days to MDUFA IV Decision	314	248			
Maximum Total Days to MDUFA IV Decision	481	328			

**Table 1.8 CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	4	0			
<b>Average FDA Days to MDUFA IV Decision</b>	288.25	0.00			
20th Percentile FDA Days to MDUFA IV Decision	267	0			
40th Percentile FDA Days to MDUFA IV Decision	315	0			
60th Percentile FDA Days to MDUFA IV Decision	319	0			
80th Percentile FDA Days to MDUFA IV Decision	321	0			
Maximum FDA Days to MDUFA IV Decision	322	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	288.25	0.00			
20th Percentile Total Days to MDUFA IV Decision	267	0			
40th Percentile Total Days to MDUFA IV Decision	315	0			
60th Percentile Total Days to MDUFA IV Decision	319	0			
80th Percentile Total Days to MDUFA IV Decision	321	0			
Maximum Total Days to MDUFA IV Decision	322	0			



**Table 1.9 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)****Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	66	47			
Number with MDUFA IV Decision	58	17			
Number of Withdrawal	6	0			
Number of Not Approvable	8	4			
Number of Deleted	0	0			
Rate of Withdrawal	10.34%	0%			
Rate of Not Approvable	13.79%	23.53%			

**Table 1.10 CDRH - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	0			
Number With MDUFA IV Decision	4	0			
Number of Withdrawal	0	0			
Number of Not Approvable	3	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	75.00%	N/A			

**Table 1.11 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 CDRH - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	1			
MDUFA IV Decision Goal Met	1	1			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

\*Includes submission that went to panel

**Table 1.14 CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	14			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	13	6			
MDUFA IV Decision Goal Met	13	6			
PMAs Pending MDUFA IV Decision	2	8			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

\*Includes submission that went to panel

## Section 1 PMA Original and Panel-Track Supplements - Office Level Metric

**Table 1.1 ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	58	35			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	45	27			
Number Without a RTA Review and > 15 Days Since Date Received	1	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	12	7			
Rate of Submissions Not Accepted for Filing Review	20.69%	20.00%			

**Table 1.2 ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	58	35			
Number Accepted	46	28			
Completed RTF	55	30			
Number Not Filed	4	1			
Rate of Submissions Not Filed	7.27%	3.33%			

**Table 1.3 ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	53	30			
SI Goal Met	51	22			
SI Goal Not Met	1	0			
SI Pending Within Goal	1	8			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.08%	100%			

**Table 1.4 ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction  
Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	52	22			
Average Number of FDA Days to Substantive Interaction	87.63	92.62			
20th Percentile FDA Days to Substantive Interaction	86	86			
40th Percentile FDA Days to Substantive Interaction	88	88			
60th Percentile FDA Days to Substantive Interaction	90	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	178	246			

**Table 1.5 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	49	30			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	43	10			
MDUFA IV Decision Goal Met	43	10			
PMAs Pending MDUFA IV Decision	6	20			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)  
MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	4	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	4	0			
MDUFA IV Decision Goal Met	4	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	43	10			
<b>Average FDA Days to MDUFA IV Decision</b>	175.65	167.10			
20th Percentile FDA Days to MDUFA IV Decision	173	151			
40th Percentile FDA Days to MDUFA IV Decision	178	177			
60th Percentile FDA Days to MDUFA IV Decision	180	179			
80th Percentile FDA Days to MDUFA IV Decision	180	180			
Maximum FDA Days to MDUFA IV Decision	279	180			
<b>Average Industry Days to MDUFA IV Decision</b>	75.49	42.30			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	5	14			
60th Percentile Industry Days to MDUFA IV Decision	84	45			
80th Percentile Industry Days to MDUFA IV Decision	154	73			
Maximum Industry Days to MDUFA IV Decision	301	149			
<b>Average Total Days to MDUFA IV Decision</b>	251.14	209.40			
20th Percentile Total Days to MDUFA IV Decision	177	151			
40th Percentile Total Days to MDUFA IV Decision	180	194			
60th Percentile Total Days to MDUFA IV Decision	259	224			
80th Percentile Total Days to MDUFA IV Decision	332	252			
Maximum Total Days to MDUFA IV Decision	481	328			

Table 1.8 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)

## Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	4	0			
<b>Average FDA Days to MDUFA IV Decision</b>	288.25	0.00			
20th Percentile FDA Days to MDUFA IV Decision	267	0			
40th Percentile FDA Days to MDUFA IV Decision	315	0			
60th Percentile FDA Days to MDUFA IV Decision	319	0			
80th Percentile FDA Days to MDUFA IV Decision	321	0			
Maximum FDA Days to MDUFA IV Decision	322	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	288.25	0.00			
20th Percentile Total Days to MDUFA IV Decision	267	0			
40th Percentile Total Days to MDUFA IV Decision	315	0			
60th Percentile Total Days to MDUFA IV Decision	319	0			
80th Percentile Total Days to MDUFA IV Decision	321	0			
Maximum Total Days to MDUFA IV Decision	322	0			

**Table 1.9 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)****Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	49	30			
Number with MDUFA IV Decision	43	10			
Number of Withdrawal	1	0			
Number of Not Approvable	6	3			
Number of Deleted	0	0			
Rate of Withdrawal	2.33%	0%			
Rate of Not Approvable	13.95%	30.00%			

**Table 1.10 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	0			
Number With MDUFA IV Decision	4	0			
Number of Withdrawal	0	0			
Number of Not Approvable	3	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	75.00%	N/A			

**Table 1.11 ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel



**Table 1.1 OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	21			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	17	17			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted for Filing Review	0	2			
Rate of Submissions Not Accepted for Filing Review	0%	10.53%			

**Table 1.2 OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	21			
Number Accepted	17	17			
Completed RTF	17	17			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	17	17			
SI Goal Met	17	17			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction  
Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	17	17			
Average Number of FDA Days to Substantive Interaction	84.29	87.82			
20th Percentile FDA Days to Substantive Interaction	84	87			
40th Percentile FDA Days to Substantive Interaction	87	88			
60th Percentile FDA Days to Substantive Interaction	89	89			
80th Percentile FDA Days to Substantive Interaction	90	89			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)  
MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	17	17			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	15	7			
MDUFA IV Decision Goal Met	15	7			
PMAs Pending MDUFA IV Decision	2	10			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA  
IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	15	7			
<b>Average FDA Days to MDUFA IV Decision</b>	116.87	137.57			
20th Percentile FDA Days to MDUFA IV Decision	89	125			
40th Percentile FDA Days to MDUFA IV Decision	90	132			
60th Percentile FDA Days to MDUFA IV Decision	123	141			
80th Percentile FDA Days to MDUFA IV Decision	155	153			
Maximum FDA Days to MDUFA IV Decision	180	176			
<b>Average Industry Days to MDUFA IV Decision</b>	55.80	21.29			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	66	10			
80th Percentile Industry Days to MDUFA IV Decision	94	45			
Maximum Industry Days to MDUFA IV Decision	268	81			
<b>Average Total Days to MDUFA IV Decision</b>	172.67	158.86			
20th Percentile Total Days to MDUFA IV Decision	90	130			
40th Percentile Total Days to MDUFA IV Decision	126	148			
60th Percentile Total Days to MDUFA IV Decision	181	155			
80th Percentile Total Days to MDUFA IV Decision	249	173			
Maximum Total Days to MDUFA IV Decision	448	257			

**Table 1.8 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**  
**Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	17	17			
Number with MDUFA IV Decision	15	7			
Number of Withdrawal	5	0			
Number of Not Approvable	2	1			
Number of Deleted	0	0			
Rate of Withdrawal	33.33%	0%			
Rate of Not Approvable	13.33%	14.29%			

**Table 1.10 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)**  
**Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	1			
MDUFA IV Decision Goal Met	1	1			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

\*Includes submission that went to panel

**Table 1.14 OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	14			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	13	6			
MDUFA IV Decision Goal Met	13	6			
PMAs Pending MDUFA IV Decision	2	8			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

\*Includes submission that went to panel

**Table 1.1 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	3	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of Submissions Not Accepted for Filing Review	0%	100%			

**Table 1.2 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Number Accepted	3	0			
Completed RTF	3	1			
Number Not Filed	0	1			
Rate of Submissions Not Filed	0%	100%			

**Table 1.3 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	3	1			
SI Goal Met	3	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	3	1			
Average Number of FDA Days to Substantive Interaction	86.67	90.00			
20th Percentile FDA Days to Substantive Interaction	84	90			
40th Percentile FDA Days to Substantive Interaction	88	90			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	3	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	0			
MDUFA IV Decision Goal Met	3	0			
PMAs Pending MDUFA IV Decision	0	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			



**Table 1.7 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	3	0			
<b>Average FDA Days to MDUFA IV Decision</b>	176.67	0.00			
20th Percentile FDA Days to MDUFA IV Decision	174	0			
40th Percentile FDA Days to MDUFA IV Decision	177	0			
60th Percentile FDA Days to MDUFA IV Decision	178	0			
80th Percentile FDA Days to MDUFA IV Decision	179	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	130.33	0.00			
20th Percentile Industry Days to MDUFA IV Decision	48	0			
40th Percentile Industry Days to MDUFA IV Decision	95	0			
60th Percentile Industry Days to MDUFA IV Decision	150	0			
80th Percentile Industry Days to MDUFA IV Decision	211	0			
Maximum Industry Days to MDUFA IV Decision	272	0			
<b>Average Total Days to MDUFA IV Decision</b>	307.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	226	0			
40th Percentile Total Days to MDUFA IV Decision	275	0			
60th Percentile Total Days to MDUFA IV Decision	328	0			
80th Percentile Total Days to MDUFA IV Decision	386	0			
Maximum Total Days to MDUFA IV Decision	444	0			

**Table 1.8 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	3	1			
Number with MDUFA IV Decision	3	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	33.33%	N/A			

**Table 1.10 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DAGRID - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DAGRID - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.1 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	14			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	20	11			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	3	3			
Rate of Submissions Not Accepted for Filing Review	13.04%	21.43%			

**Table 1.2 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	14			
Number Accepted	20	11			
Completed RTF	22	11			
Number Not Filed	1	0			
Rate of Submissions Not Filed	4.55%	0%			

**Table 1.3 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	22	11			
SI Goal Met	21	9			
SI Goal Not Met	0	0			
SI Pending Within Goal	1	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	21	9			
Average Number of FDA Days to Substantive Interaction	83.05	83.11			
20th Percentile FDA Days to Substantive Interaction	84	77			
40th Percentile FDA Days to Substantive Interaction	87	87			
60th Percentile FDA Days to Substantive Interaction	89	88			
80th Percentile FDA Days to Substantive Interaction	90	89			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	21	11			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	20	5			
MDUFA IV Decision Goal Met	20	5			
PMAs Pending MDUFA IV Decision	1	6			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	20	5			
<b>Average FDA Days to MDUFA IV Decision</b>	173.70	154.40			
20th Percentile FDA Days to MDUFA IV Decision	161	135			
40th Percentile FDA Days to MDUFA IV Decision	178	147			
60th Percentile FDA Days to MDUFA IV Decision	178	162			
80th Percentile FDA Days to MDUFA IV Decision	180	176			
Maximum FDA Days to MDUFA IV Decision	279	178			
<b>Average Industry Days to MDUFA IV Decision</b>	50.15	28.80			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	45	24			
80th Percentile Industry Days to MDUFA IV Decision	104	65			
Maximum Industry Days to MDUFA IV Decision	162	83			
<b>Average Total Days to MDUFA IV Decision</b>	223.85	183.20			
20th Percentile Total Days to MDUFA IV Decision	167	135			
40th Percentile Total Days to MDUFA IV Decision	180	147			
60th Percentile Total Days to MDUFA IV Decision	225	188			
80th Percentile Total Days to MDUFA IV Decision	326	243			
Maximum Total Days to MDUFA IV Decision	340	258			

**Table 1.8 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	197	0			
40th Percentile FDA Days to MDUFA IV Decision	197	0			
60th Percentile FDA Days to MDUFA IV Decision	197	0			
80th Percentile FDA Days to MDUFA IV Decision	197	0			
Maximum FDA Days to MDUFA IV Decision	197	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	197.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	197	0			
40th Percentile Total Days to MDUFA IV Decision	197	0			
60th Percentile Total Days to MDUFA IV Decision	197	0			
80th Percentile Total Days to MDUFA IV Decision	197	0			
Maximum Total Days to MDUFA IV Decision	197	0			



**Table 1.9 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	21	11			
Number with MDUFA IV Decision	20	5			
Number of Withdrawal	0	0			
Number of Not Approvable	1	1			
Number of Deleted	0	0			
Rate of Withdrawal	0%	0%			
Rate of Not Approvable	5.00%	20.00%			

**Table 1.10 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0			
Number With MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DCD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DCD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.1 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	5			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	3	4			
Number Without a RTA Review and > 15 Days Since Date Received	0	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of Submissions Not Accepted for Filing Review	25.00%	0%			

**Table 1.2 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	5			
Number Accepted	3	5			
Completed RTF	4	5			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	4	5			
SI Goal Met	3	3			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	75.00%	100%			

**Table 1.4 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	4	3			
Average Number of FDA Days to Substantive Interaction	90.50	81.67			
20th Percentile FDA Days to Substantive Interaction	90	75			
40th Percentile FDA Days to Substantive Interaction	90	85			
60th Percentile FDA Days to Substantive Interaction	90	90			
80th Percentile FDA Days to Substantive Interaction	91	90			
Maximum FDA Days to Substantive Interaction	92	90			

**Table 1.5 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	4	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	2	1			
MDUFA IV Decision Goal Met	2	1			
PMAs Pending MDUFA IV Decision	2	4			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	2	1			
<b>Average FDA Days to MDUFA IV Decision</b>	180.00	180.00			
20th Percentile FDA Days to MDUFA IV Decision	180	180			
40th Percentile FDA Days to MDUFA IV Decision	180	180			
60th Percentile FDA Days to MDUFA IV Decision	180	180			
80th Percentile FDA Days to MDUFA IV Decision	180	180			
Maximum FDA Days to MDUFA IV Decision	180	180			
<b>Average Industry Days to MDUFA IV Decision</b>	47.00	34.00			
20th Percentile Industry Days to MDUFA IV Decision	19	34			
40th Percentile Industry Days to MDUFA IV Decision	38	34			
60th Percentile Industry Days to MDUFA IV Decision	56	34			
80th Percentile Industry Days to MDUFA IV Decision	75	34			
Maximum Industry Days to MDUFA IV Decision	94	34			
<b>Average Total Days to MDUFA IV Decision</b>	227.00	214.00			
20th Percentile Total Days to MDUFA IV Decision	199	214			
40th Percentile Total Days to MDUFA IV Decision	218	214			
60th Percentile Total Days to MDUFA IV Decision	236	214			
80th Percentile Total Days to MDUFA IV Decision	255	214			
Maximum Total Days to MDUFA IV Decision	274	214			

**Table 1.8 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	5			
Number with MDUFA IV Decision	2	1			
Number of Withdrawal	0	0			
Number of Not Approvable	0	1			
Number of Deleted	0	0			
Rate of Withdrawal	0%	0%			
Rate of Not Approvable	0%	100%			

**Table 1.10 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DNPMD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DNPMD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel



**Table 1.1 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance**

**Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	4			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	2	2			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	2			
Rate of Submissions Not Accepted for Filing Review	0%	50.00%			

**Table 1.2 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review**

**Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	4			
Number Accepted	2	2			
Completed RTF	2	3			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive**

**Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	3			
SI Goal Met	2	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	2			
Average Number of FDA Days to Substantive Interaction	86.50	89.50			
20th Percentile FDA Days to Substantive Interaction	84	89			
40th Percentile FDA Days to Substantive Interaction	86	89			
60th Percentile FDA Days to Substantive Interaction	87	90			
80th Percentile FDA Days to Substantive Interaction	89	90			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	2	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	2	1			
MDUFA IV Decision Goal Met	2	1			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	2	1			
<b>Average FDA Days to MDUFA IV Decision</b>	180.00	179.00			
20th Percentile FDA Days to MDUFA IV Decision	180	179			
40th Percentile FDA Days to MDUFA IV Decision	180	179			
60th Percentile FDA Days to MDUFA IV Decision	180	179			
80th Percentile FDA Days to MDUFA IV Decision	180	179			
Maximum FDA Days to MDUFA IV Decision	180	179			
<b>Average Industry Days to MDUFA IV Decision</b>	141.50	149.00			
20th Percentile Industry Days to MDUFA IV Decision	57	149			
40th Percentile Industry Days to MDUFA IV Decision	113	149			
60th Percentile Industry Days to MDUFA IV Decision	170	149			
80th Percentile Industry Days to MDUFA IV Decision	226	149			
Maximum Industry Days to MDUFA IV Decision	283	149			
<b>Average Total Days to MDUFA IV Decision</b>	321.50	328.00			
20th Percentile Total Days to MDUFA IV Decision	237	328			
40th Percentile Total Days to MDUFA IV Decision	293	328			
60th Percentile Total Days to MDUFA IV Decision	350	328			
80th Percentile Total Days to MDUFA IV Decision	406	328			
Maximum Total Days to MDUFA IV Decision	463	328			

**Table 1.8 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3			
Number with MDUFA IV Decision	2	1			
Number of Withdrawal	0	0			
Number of Not Approvable	0	1			
Number of Deleted	0	0			
Rate of Withdrawal	0%	0%			
Rate of Not Approvable	0%	100%			

**Table 1.10 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DOD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DOD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.1 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	6			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	6			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	5	0			
Rate of Submissions Not Accepted for Filing Review	38.46%	0%			

**Table 1.2 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	6			
Number Accepted	8	6			
Completed RTF	13	6			
Number Not Filed	1	0			
Rate of Submissions Not Filed	7.69%	0%			

**Table 1.3 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	13	6			
SI Goal Met	13	4			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	13	4			
Average Number of FDA Days to Substantive Interaction	87.23	88.50			
20th Percentile FDA Days to Substantive Interaction	86	87			
40th Percentile FDA Days to Substantive Interaction	87	88			
60th Percentile FDA Days to Substantive Interaction	89	90			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	13	6			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	10	2			
MDUFA IV Decision Goal Met	10	2			
PMAs Pending MDUFA IV Decision	3	4			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			



**Table 1.7 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	10	2			
<b>Average FDA Days to MDUFA IV Decision</b>	178.00	180.00			
20th Percentile FDA Days to MDUFA IV Decision	177	180			
40th Percentile FDA Days to MDUFA IV Decision	177	180			
60th Percentile FDA Days to MDUFA IV Decision	179	180			
80th Percentile FDA Days to MDUFA IV Decision	180	180			
Maximum FDA Days to MDUFA IV Decision	180	180			
<b>Average Industry Days to MDUFA IV Decision</b>	95.80	45.00			
20th Percentile Industry Days to MDUFA IV Decision	0	30			
40th Percentile Industry Days to MDUFA IV Decision	0	40			
60th Percentile Industry Days to MDUFA IV Decision	90	50			
80th Percentile Industry Days to MDUFA IV Decision	200	60			
Maximum Industry Days to MDUFA IV Decision	301	70			
<b>Average Total Days to MDUFA IV Decision</b>	273.80	225.00			
20th Percentile Total Days to MDUFA IV Decision	177	210			
40th Percentile Total Days to MDUFA IV Decision	180	220			
60th Percentile Total Days to MDUFA IV Decision	268	230			
80th Percentile Total Days to MDUFA IV Decision	378	240			
Maximum Total Days to MDUFA IV Decision	481	250			

**Table 1.8 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	13	6			
Number with MDUFA IV Decision	10	2			
Number of Withdrawal	0	0			
Number of Not Approvable	3	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	0%			
Rate of Not Approvable	30.00%	0%			

**Table 1.10 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DOED - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DOED - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.1 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	10	3			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	3			
Number Without a RTA Review and > 15 Days Since Date Received	1	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of Submissions Not Accepted for Filing Review	10.00%	0%			

**Table 1.2 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	10	3			
Number Accepted	9	3			
Completed RTF	10	3			
Number Not Filed	2	0			
Rate of Submissions Not Filed	20.00%	0%			

**Table 1.3 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	3			
SI Goal Met	8	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	8	3			
Average Number of FDA Days to Substantive Interaction	99.50	139.67			
20th Percentile FDA Days to Substantive Interaction	87	86			
40th Percentile FDA Days to Substantive Interaction	88	87			
60th Percentile FDA Days to Substantive Interaction	90	119			
80th Percentile FDA Days to Substantive Interaction	91	182			
Maximum FDA Days to Substantive Interaction	178	246			

**Table 1.5 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	5	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	1			
MDUFA IV Decision Goal Met	5	1			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	3	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	0			
MDUFA IV Decision Goal Met	3	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	5	1			
<b>Average FDA Days to MDUFA IV Decision</b>	178.00	180.00			
20th Percentile FDA Days to MDUFA IV Decision	159	180			
40th Percentile FDA Days to MDUFA IV Decision	177	180			
60th Percentile FDA Days to MDUFA IV Decision	179	180			
80th Percentile FDA Days to MDUFA IV Decision	197	180			
Maximum FDA Days to MDUFA IV Decision	266	180			
<b>Average Industry Days to MDUFA IV Decision</b>	102.20	6.00			
20th Percentile Industry Days to MDUFA IV Decision	77	6			
40th Percentile Industry Days to MDUFA IV Decision	97	6			
60th Percentile Industry Days to MDUFA IV Decision	108	6			
80th Percentile Industry Days to MDUFA IV Decision	122	6			
Maximum Industry Days to MDUFA IV Decision	163	6			
<b>Average Total Days to MDUFA IV Decision</b>	280.20	186.00			
20th Percentile Total Days to MDUFA IV Decision	248	186			
40th Percentile Total Days to MDUFA IV Decision	270	186			
60th Percentile Total Days to MDUFA IV Decision	285	186			
80th Percentile Total Days to MDUFA IV Decision	302	186			
Maximum Total Days to MDUFA IV Decision	350	186			

**Table 1.8 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	3	0			
<b>Average FDA Days to MDUFA IV Decision</b>	318.67	0.00			
20th Percentile FDA Days to MDUFA IV Decision	316	0			
40th Percentile FDA Days to MDUFA IV Decision	319	0			
60th Percentile FDA Days to MDUFA IV Decision	320	0			
80th Percentile FDA Days to MDUFA IV Decision	321	0			
Maximum FDA Days to MDUFA IV Decision	322	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	318.67	0.00			
20th Percentile Total Days to MDUFA IV Decision	316	0			
40th Percentile Total Days to MDUFA IV Decision	319	0			
60th Percentile Total Days to MDUFA IV Decision	320	0			
80th Percentile Total Days to MDUFA IV Decision	321	0			
Maximum Total Days to MDUFA IV Decision	322	0			



**Table 1.9 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	3			
Number with MDUFA IV Decision	5	1			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	20.00%	0%			
Rate of Not Approvable	0%	0%			

**Table 1.10 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	3	0			
Number With MDUFA IV Decision	3	0			
Number of Withdrawal	0	0			
Number of Not Approvable	3	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	100%	N/A			

**Table 1.11 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DRGUD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DRGUD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.1 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	1			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	2	1			
Rate of Submissions Not Accepted for Filing Review	66.67%	50.00%			

**Table 1.2 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2			
Number Accepted	1	1			
Completed RTF	1	1			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	1			
SI Goal Met	1	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	1	0			
Average Number of FDA Days to Substantive Interaction	88.00	0.00			
20th Percentile FDA Days to Substantive Interaction	88	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	88	0			
80th Percentile FDA Days to Substantive Interaction	88	0			
Maximum FDA Days to Substantive Interaction	88	0			

**Table 1.5 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	1	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	159.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	159	0			
40th Percentile FDA Days to MDUFA IV Decision	159	0			
60th Percentile FDA Days to MDUFA IV Decision	159	0			
80th Percentile FDA Days to MDUFA IV Decision	159	0			
Maximum FDA Days to MDUFA IV Decision	159	0			
<b>Average Industry Days to MDUFA IV Decision</b>	6.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	6	0			
40th Percentile Industry Days to MDUFA IV Decision	6	0			
60th Percentile Industry Days to MDUFA IV Decision	6	0			
80th Percentile Industry Days to MDUFA IV Decision	6	0			
Maximum Industry Days to MDUFA IV Decision	6	0			
<b>Average Total Days to MDUFA IV Decision</b>	165.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	165	0			
40th Percentile Total Days to MDUFA IV Decision	165	0			
60th Percentile Total Days to MDUFA IV Decision	165	0			
80th Percentile Total Days to MDUFA IV Decision	165	0			
Maximum Total Days to MDUFA IV Decision	165	0			

**Table 1.8 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	1			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	100%	N/A			

**Table 1.10 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DSD - ODE - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DSD - ODE - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A			
Non-MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision	N/A	N/A			
MDUFA IV Decision Goal Met	N/A	N/A			
PMAs Pending MDUFA IV Decision	N/A	N/A			
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel



**Table 1.1 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	2			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	5	2			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	0%			

**Table 1.2 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	2			
Number Accepted	5	2			
Completed RTF	5	2			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	5	2			
SI Goal Met	5	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	5	2			
Average Number of FDA Days to Substantive Interaction	88.20	87.50			
20th Percentile FDA Days to Substantive Interaction	86	87			
40th Percentile FDA Days to Substantive Interaction	89	87			
60th Percentile FDA Days to Substantive Interaction	90	88			
80th Percentile FDA Days to Substantive Interaction	90	88			
Maximum FDA Days to Substantive Interaction	90	88			

**Table 1.5 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	5	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	1			
MDUFA IV Decision Goal Met	5	1			
PMAs Pending MDUFA IV Decision	0	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	5	1			
<b>Average FDA Days to MDUFA IV Decision</b>	105.00	125.00			
20th Percentile FDA Days to MDUFA IV Decision	89	125			
40th Percentile FDA Days to MDUFA IV Decision	90	125			
60th Percentile FDA Days to MDUFA IV Decision	100	125			
80th Percentile FDA Days to MDUFA IV Decision	121	125			
Maximum FDA Days to MDUFA IV Decision	146	125			
<b>Average Industry Days to MDUFA IV Decision</b>	22.20	52.00			
20th Percentile Industry Days to MDUFA IV Decision	0	52			
40th Percentile Industry Days to MDUFA IV Decision	0	52			
60th Percentile Industry Days to MDUFA IV Decision	0	52			
80th Percentile Industry Days to MDUFA IV Decision	22	52			
Maximum Industry Days to MDUFA IV Decision	111	52			
<b>Average Total Days to MDUFA IV Decision</b>	127.20	177.00			
20th Percentile Total Days to MDUFA IV Decision	90	177			
40th Percentile Total Days to MDUFA IV Decision	105	177			
60th Percentile Total Days to MDUFA IV Decision	127	177			
80th Percentile Total Days to MDUFA IV Decision	156	177			
Maximum Total Days to MDUFA IV Decision	195	177			

**Table 1.8 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	2			
Number with MDUFA IV Decision	5	1			
Number of Withdrawal	1	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	20.00%	0%			
Rate of Not Approvable	20.00%	0%			

**Table 1.10 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DCTD - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DCTD - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	5	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	1			
MDUFA IV Decision Goal Met	5	1			
PMAs Pending MDUFA IV Decision	0	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

\*Includes submission that went to panel

**Table 1.1 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of Submissions Not Accepted for Filing Review	0%	100%			

**Table 1.2 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	1			
Number Accepted	1	0			
Completed RTF	1	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

**Table 1.3 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	0			
SI Goal Met	1	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	1	0			
Average Number of FDA Days to Substantive Interaction	90.00	0.00			
20th Percentile FDA Days to Substantive Interaction	90	0			
40th Percentile FDA Days to Substantive Interaction	90	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

**Table 1.5 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			



**Table 1.7 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	180.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	180	0			
40th Percentile FDA Days to MDUFA IV Decision	180	0			
60th Percentile FDA Days to MDUFA IV Decision	180	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
<b>Average Industry Days to MDUFA IV Decision</b>	268.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	268	0			
40th Percentile Industry Days to MDUFA IV Decision	268	0			
60th Percentile Industry Days to MDUFA IV Decision	268	0			
80th Percentile Industry Days to MDUFA IV Decision	268	0			
Maximum Industry Days to MDUFA IV Decision	268	0			
<b>Average Total Days to MDUFA IV Decision</b>	448.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	448	0			
40th Percentile Total Days to MDUFA IV Decision	448	0			
60th Percentile Total Days to MDUFA IV Decision	448	0			
80th Percentile Total Days to MDUFA IV Decision	448	0			
Maximum Total Days to MDUFA IV Decision	448	0			

**Table 1.8 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DIHD - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DIHD - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

\*Includes submission that went to panel

**Table 1.1 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	8			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	2	7			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	0%			

**Table 1.2 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	8			
Number Accepted	2	7			
Completed RTF	2	7			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	7			
SI Goal Met	2	7			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	7			
Average Number of FDA Days to Substantive Interaction	84.00	87.86			
20th Percentile FDA Days to Substantive Interaction	84	88			
40th Percentile FDA Days to Substantive Interaction	84	88			
60th Percentile FDA Days to Substantive Interaction	84	88			
80th Percentile FDA Days to Substantive Interaction	84	89			
Maximum FDA Days to Substantive Interaction	84	90			

**Table 1.5 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	2	7			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	2	7			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.6 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.8 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			



**Table 1.9 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	7			
Number with MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DMD - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 DMD - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	2	7			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	2	7			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.1 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	10			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	8			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	0	1			
Rate of Submissions Not Accepted for Filing Review	0%	11.11%			

**Table 1.2 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	10			
Number Accepted	8	8			
Completed RTF	8	8			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

**Table 1.3 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	8			
SI Goal Met	8	8			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	8	8			
Average Number of FDA Days to Substantive Interaction	83.88	87.88			
20th Percentile FDA Days to Substantive Interaction	86	86			
40th Percentile FDA Days to Substantive Interaction	88	89			
60th Percentile FDA Days to Substantive Interaction	88	89			
80th Percentile FDA Days to Substantive Interaction	90	90			
Maximum FDA Days to Substantive Interaction	90	90			

**Table 1.5 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	8	8			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	8	6			
MDUFA IV Decision Goal Met	8	6			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 1.6 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	8	6			
<b>Average FDA Days to MDUFA IV Decision</b>	123.13	139.67			
20th Percentile FDA Days to MDUFA IV Decision	90	127			
40th Percentile FDA Days to MDUFA IV Decision	108	139			
60th Percentile FDA Days to MDUFA IV Decision	137	143			
80th Percentile FDA Days to MDUFA IV Decision	166	155			
Maximum FDA Days to MDUFA IV Decision	180	176			
<b>Average Industry Days to MDUFA IV Decision</b>	57.25	16.17			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	48	0			
60th Percentile Industry Days to MDUFA IV Decision	75	0			
80th Percentile Industry Days to MDUFA IV Decision	84	16			
Maximum Industry Days to MDUFA IV Decision	158	81			
<b>Average Total Days to MDUFA IV Decision</b>	180.38	155.83			
20th Percentile Total Days to MDUFA IV Decision	108	127			
40th Percentile Total Days to MDUFA IV Decision	164	143			
60th Percentile Total Days to MDUFA IV Decision	230	155			
80th Percentile Total Days to MDUFA IV Decision	250	155			
Maximum Total Days to MDUFA IV Decision	270	257			

**Table 1.8 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	8	8			
Number with MDUFA IV Decision	8	6			
Number of Withdrawal	3	0			
Number of Not Approvable	1	1			
Number of Deleted	0	0			
Rate of Withdrawal	37.50%	0%			
Rate of Not Approvable	12.50%	16.67%			

**Table 1.10 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DMGP - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	1			
MDUFA IV Decision Goal Met	1	1			
PMAs Pending MDUFA IV Decision	0	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

\*Includes submission that went to panel

**Table 1.14 DMGP - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	7	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	7	5			
MDUFA IV Decision Goal Met	7	5			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

\*Includes submission that went to panel



**Table 1.1 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	N/A			

**Table 1.2 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0			
Number Accepted	1	0			
Completed RTF	1	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

**Table 1.3 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	0			
SI Goal Met	1	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	1	0			
Average Number of FDA Days to Substantive Interaction	63.00	0.00			
20th Percentile FDA Days to Substantive Interaction	63	0			
40th Percentile FDA Days to Substantive Interaction	63	0			
60th Percentile FDA Days to Substantive Interaction	63	0			
80th Percentile FDA Days to Substantive Interaction	63	0			
Maximum FDA Days to Substantive Interaction	63	0			

**Table 1.5 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>	<b>90% Within 180 FDA Days</b>
Number of PMAs Filed	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>	<b>90% Within 320 FDA Days</b>
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	63.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	63	0			
40th Percentile FDA Days to MDUFA IV Decision	63	0			
60th Percentile FDA Days to MDUFA IV Decision	63	0			
80th Percentile FDA Days to MDUFA IV Decision	63	0			
Maximum FDA Days to MDUFA IV Decision	63	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	63.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	63	0			
40th Percentile Total Days to MDUFA IV Decision	63	0			
60th Percentile Total Days to MDUFA IV Decision	63	0			
80th Percentile Total Days to MDUFA IV Decision	63	0			
Maximum Total Days to MDUFA IV Decision	63	0			

**Table 1.8 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review)**  
**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	1	0			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	1	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	100%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.12 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 1.13 DRH - OIR - CDRH - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

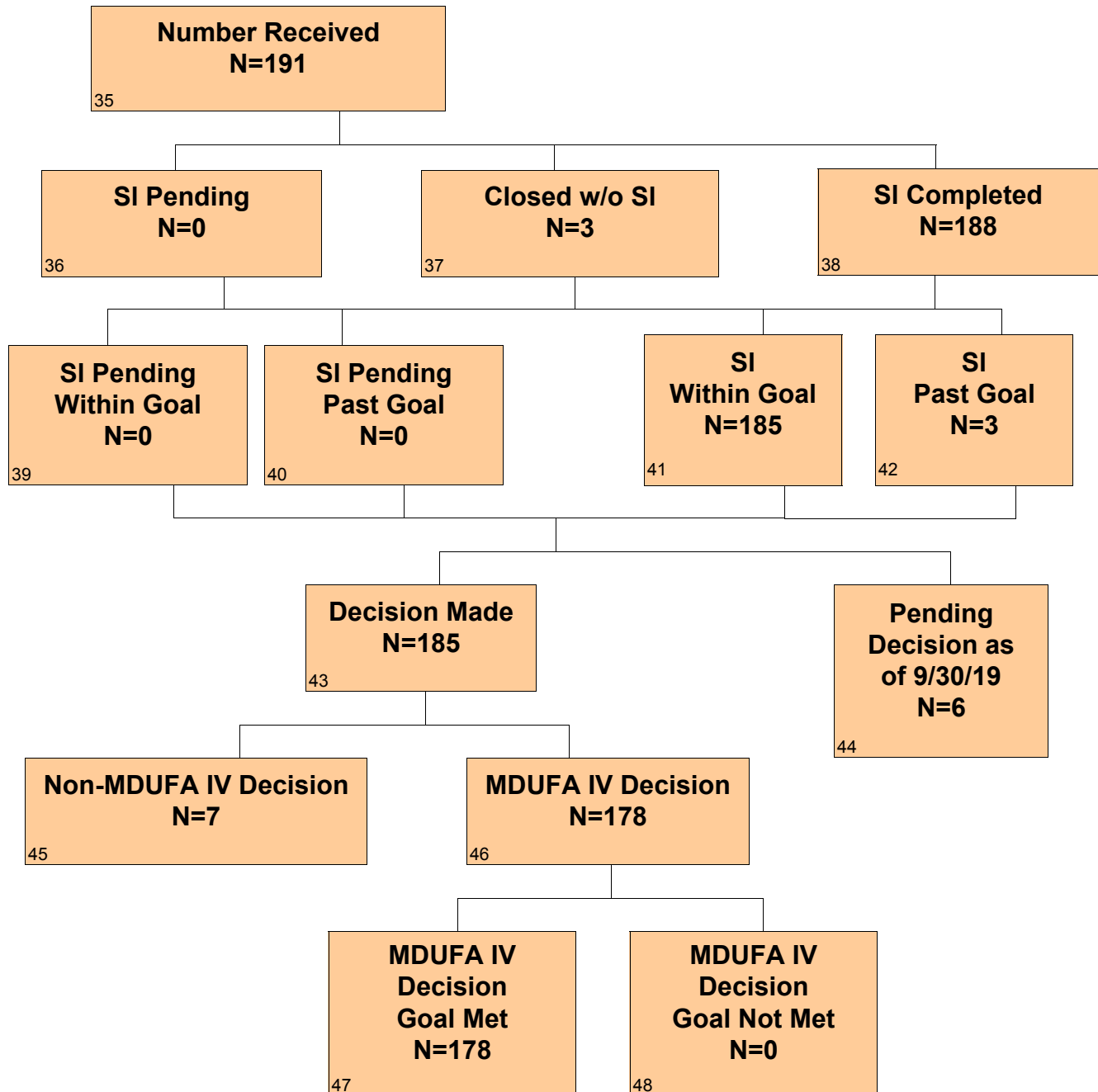
**Table 1.14 DRH - OIR - CDRH - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

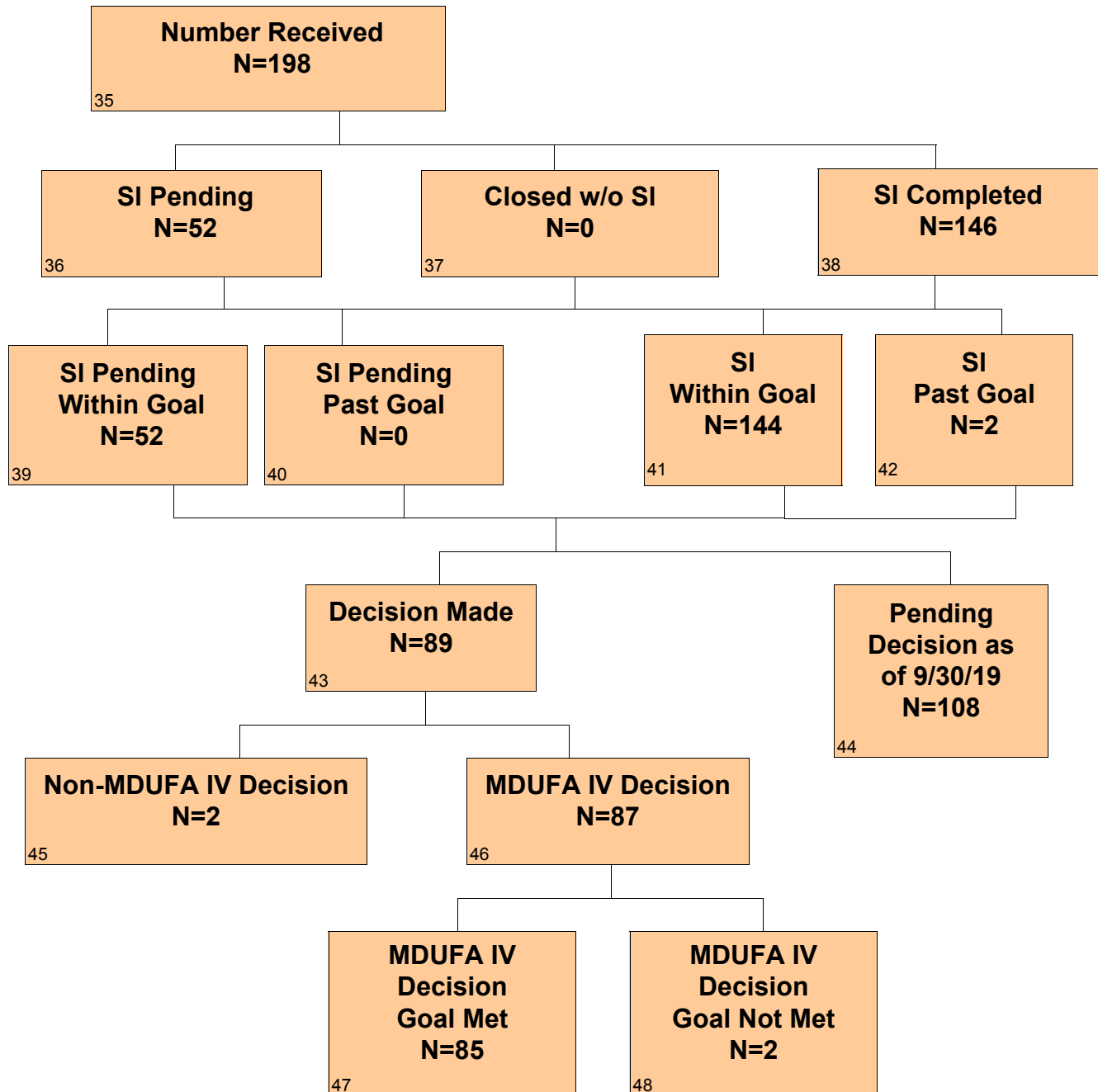
# CDRH PMA 180 Day Supplements - FY 2018 as of 9/30/19

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# CDRH PMA 180 Day Supplements - FY 2019 as of 9/30/19

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## Section 2 PMA 180-Day Supplements - Center Level Metric

Table 2.1 CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	191	198			
SI Goal Met	185	144			
SI Goal Not Met	3	2			
SI Pending Within Goal	0	52			
SI Pending Past Goal	0	0			
Closed Without SI	3	0			
Current SI Performance Percent Goal Met	98.40%	98.63%			

Table 2.2 CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	191	198			
Non-MDUFA IV Decision	7	2			
MDUFA IV Decision	178	87			
MDUFA IV Decision Goal Met	178	85			
Supplements Pending MDUFA IV Decision	6	109			
Supplements Pending MDUFA IV Decision Past Goal	2	2			
Current Performance Percent Goal Met	98.89%	95.51%			

Table 2.3 CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	191	198			
Number with MDUFA IV Decision	178	87			
Number of Not Approvable	13	1			
Rate of Not Approvable	7.30%	1.15%			

Table 2.4 CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	4			
Mean FDA Days for Submissions that Missed the Goal	219.00	206.50			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Office Level Metric

**Table 2.1 ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	154	172			
SI Goal Met	149	121			
SI Goal Not Met	2	2			
SI Pending Within Goal	0	49			
SI Pending Past Goal	0	0			
Closed Without SI	3	0			
Current SI Performance Percent Goal Met	98.68%	98.37%			

**Table 2.2 ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	154	172			
Non-MDUFA IV Decision	4	2			
MDUFA IV Decision	144	73			
MDUFA IV Decision Goal Met	144	71			
Supplements Pending MDUFA IV Decision	6	97			
Supplements Pending MDUFA IV Decision Past Goal	2	2			
Current Performance Percent Goal Met	98.63%	94.67%			

**Table 2.3 ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	154	172			
Number with MDUFA IV Decision	144	73			
Number of Not Approvable	9	0			
Rate of Not Approvable	6.25%	0%			

**Table 2.4 ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	4			
Mean FDA Days for Submissions that Missed the Goal	219.00	206.50			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Office Level Metric

**Table 2.1 OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	37	26			
SI Goal Met	36	23			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	97.30%	100%			

**Table 2.2 OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	37	26			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision	34	14			
MDUFA IV Decision Goal Met	34	14			
Supplements Pending MDUFA IV Decision	0	12			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 2.3 OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	37	26			
Number with MDUFA IV Decision	34	14			
Number of Not Approvable	4	1			
Rate of Not Approvable	11.76%	7.14%			

**Table 2.4 OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DAGRID - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	9	11			
SI Goal Met	8	6			
SI Goal Not Met	1	1			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	88.89%	85.71%			

Table 2.2 DAGRID - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	9	11			
Non-MDUFA IV Decision	0	1			
MDUFA IV Decision	9	4			
MDUFA IV Decision Goal Met	9	4			
Supplements Pending MDUFA IV Decision	0	6			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DAGRID - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	11			
Number with MDUFA IV Decision	9	4			
Number of Not Approvable	1	0			
Rate of Not Approvable	11.11%	0%			

Table 2.4 DAGRID - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DCD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	94	88			
SI Goal Met	91	64			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	24			
SI Pending Past Goal	0	0			
Closed Without SI	2	0			
Current SI Performance Percent Goal Met	98.91%	100%			

Table 2.2 DCD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	94	88			
Non-MDUFA IV Decision	2	1			
MDUFA IV Decision	90	39			
MDUFA IV Decision Goal Met	90	39			
Supplements Pending MDUFA IV Decision	2	48			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DCD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	94	88			
Number with MDUFA IV Decision	90	39			
Number of Not Approvable	6	0			
Rate of Not Approvable	6.67%	0%			

Table 2.4 DCD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DNPMD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	13	16			
SI Goal Met	12	13			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	1	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DNPMD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	13	16			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	11	7			
MDUFA IV Decision Goal Met	11	7			
Supplements Pending MDUFA IV Decision	1	9			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DNPMD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	16			
Number with MDUFA IV Decision	11	7			
Number of Not Approvable	2	0			
Rate of Not Approvable	18.18%	0%			

Table 2.4 DNPMD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DOD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	6			
SI Goal Met	1	5			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DOD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	1	6			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	4			
MDUFA IV Decision Goal Met	1	4			
Supplements Pending MDUFA IV Decision	0	2			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DOD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	6			
Number with MDUFA IV Decision	1	4			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

Table 2.4 DOD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DOED - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	16	31			
SI Goal Met	16	19			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	12			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DOED - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	16	31			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	16	13			
MDUFA IV Decision Goal Met	16	13			
Supplements Pending MDUFA IV Decision	0	18			
Supplements Pending MDUFA IV Decision Past Goal	0	1			
Current Performance Percent Goal Met	100%	92.86%			

Table 2.3 DOED - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	31			
Number with MDUFA IV Decision	16	13			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

Table 2.4 DOED - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1			
Mean FDA Days for Submissions that Missed the Goal	0	265.00			
Mean Industry Days for Submissions that Missed the Goal	0	0			



## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DRGUD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	10	10			
SI Goal Met	10	7			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DRGUD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	10	10			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	10	1			
MDUFA IV Decision Goal Met	10	1			
Supplements Pending MDUFA IV Decision	0	9			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DRGUD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	10	10			
Number with MDUFA IV Decision	10	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

Table 2.4 DRGUD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DSD - ODE - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	11	10			
SI Goal Met	11	7			
SI Goal Not Met	0	1			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	87.50%			

Table 2.2 DSD - ODE - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	11	10			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	7	5			
MDUFA IV Decision Goal Met	7	3			
Supplements Pending MDUFA IV Decision	3	5			
Supplements Pending MDUFA IV Decision Past Goal	2	1			
Current Performance Percent Goal Met	77.78%	50.00%			

Table 2.3 DSD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	11	10			
Number with MDUFA IV Decision	7	5			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

Table 2.4 DSD - ODE - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	3			
Mean FDA Days for Submissions that Missed the Goal	219.00	187.00			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DCTD - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	11	4			
SI Goal Met	11	4			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DCTD - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	11	4			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	10	4			
MDUFA IV Decision Goal Met	10	4			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DCTD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	11	4			
Number with MDUFA IV Decision	10	4			
Number of Not Approvable	1	0			
Rate of Not Approvable	10.00%	0%			

Table 2.4 DCTD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DIHD - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	3	1			
SI Goal Met	3	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DIHD - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	3	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	1			
MDUFA IV Decision Goal Met	3	1			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

Table 2.3 DIHD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Number with MDUFA IV Decision	3	1			
Number of Not Approvable	2	0			
Rate of Not Approvable	66.67%	0%			

Table 2.4 DIHD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

Table 2.1 DMD - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	7			
SI Goal Met	8	4			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

Table 2.2 DMD - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	7			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	8	0			
MDUFA IV Decision Goal Met	8	0			
Supplements Pending MDUFA IV Decision	0	7			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

Table 2.3 DMD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	7			
Number with MDUFA IV Decision	8	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

Table 2.4 DMD - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

**Table 2.1 DMGP - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	13	11			
SI Goal Met	12	11			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	92.31%	100%			

**Table 2.2 DMGP - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	13	11			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	12	8			
MDUFA IV Decision Goal Met	12	8			
Supplements Pending MDUFA IV Decision	0	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 2.3 DMGP - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	11			
Number with MDUFA IV Decision	12	8			
Number of Not Approvable	1	1			
Rate of Not Approvable	8.33%	12.50%			

**Table 2.4 DMGP - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

## Section 2 PMA 180-Day Supplements - Division Level Metric

**Table 2.1 DRH - OIR - CDRH - PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	3			
SI Goal Met	2	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 2.2 DRH - OIR - CDRH - PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	2	3			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	1	1			
MDUFA IV Decision Goal Met	1	1			
Supplements Pending MDUFA IV Decision	0	2			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 2.3 DRH - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	3			
Number with MDUFA IV Decision	1	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 2.4 DRH - OIR - CDRH - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

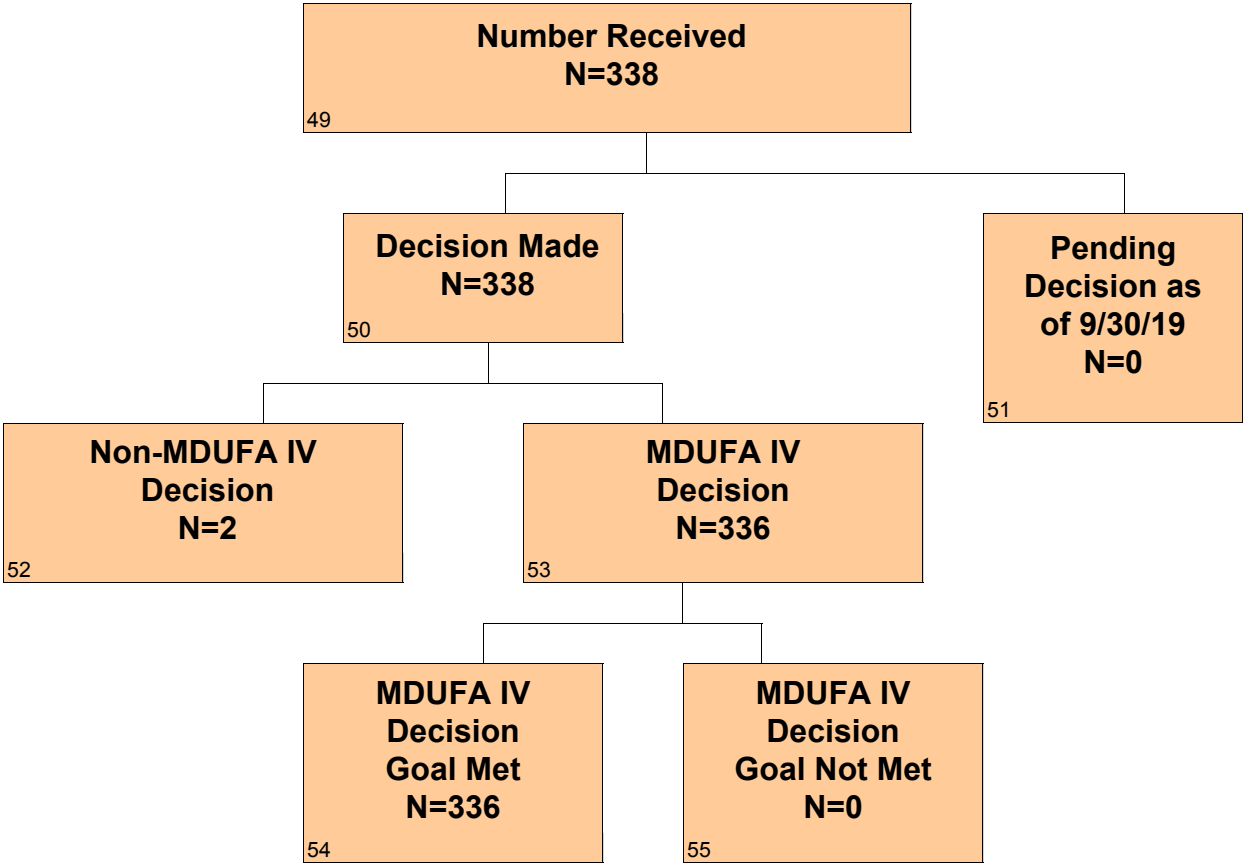
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

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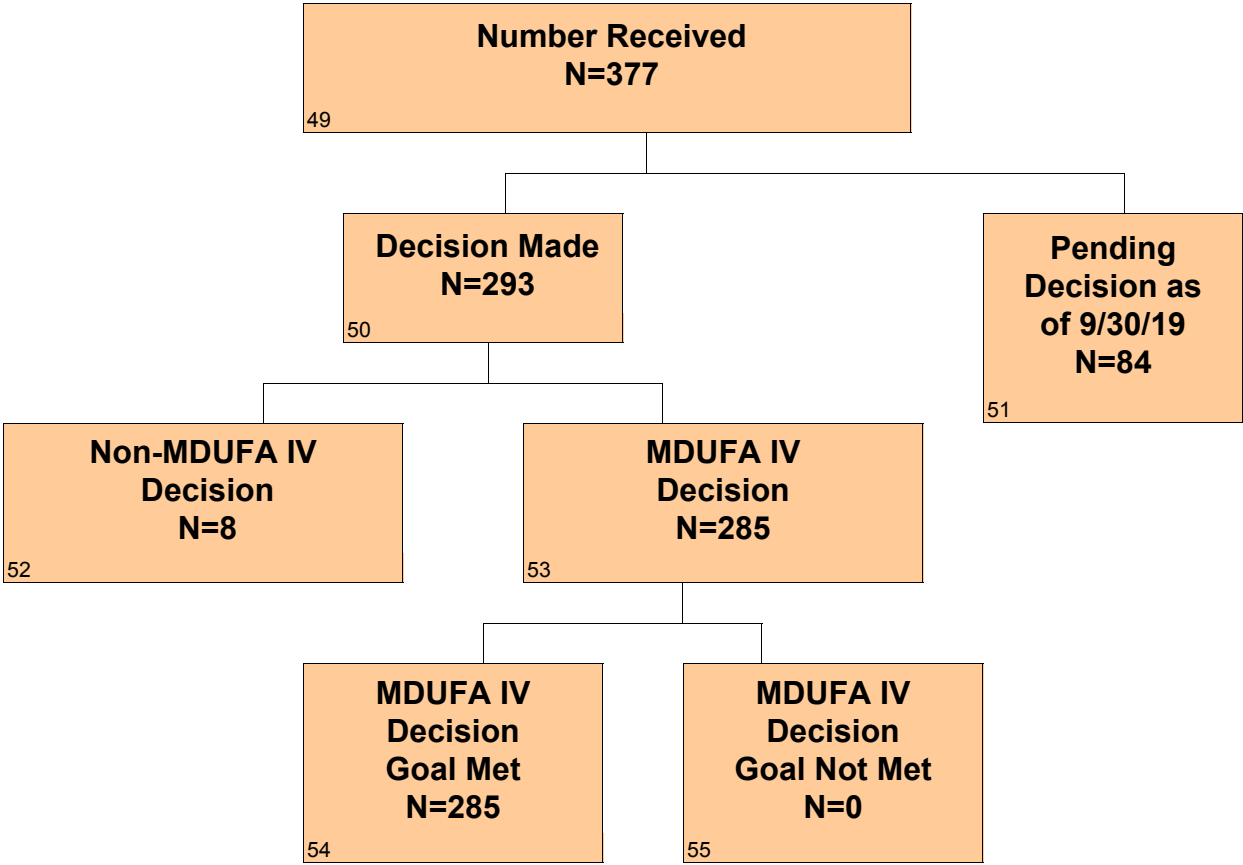
# CDRH PMA Real Time Supplements - FY 2018 as of 9/30/19

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# CDRH PMA Real Time Supplements - FY 2019 as of 9/30/19

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### Section 3 PMA Real-Time Supplements - Center Level Metric

**Table 3.1 CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	338	377			
Non-MDUFA IV Decision	2	8			
MDUFA IV Decision	336	285			
MDUFA IV Decision Goal Met	336	285			
Supplements Pending MDUFA IV Decision	0	84			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	338	377			
Number With MDUFA IV Decision	336	285			
Number of Not Approvable	20	25			
Rate of Not Approvable	5.95%	8.77%			

**Table 3.3 CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Office Level Metric

**Table 3.1 ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	243	328			
Non-MDUFA IV Decision	1	5			
MDUFA IV Decision	242	245			
MDUFA IV Decision Goal Met	242	245			
Supplements Pending MDUFA IV Decision	0	78			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	243	328			
Number With MDUFA IV Decision	242	245			
Number of Not Approvable	20	24			
Rate of Not Approvable	8.26%	9.80%			

**Table 3.3 ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Office Level Metric

**Table 3.1 OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	95	49			
Non-MDUFA IV Decision	1	3			
MDUFA IV Decision	94	40			
MDUFA IV Decision Goal Met	94	40			
Supplements Pending MDUFA IV Decision	0	6			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	95	49			
Number With MDUFA IV Decision	94	40			
Number of Not Approvable	0	1			
Rate of Not Approvable	0%	2.50%			

**Table 3.3 OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DAGRID - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	9	20			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	9	10			
MDUFA IV Decision Goal Met	9	10			
Supplements Pending MDUFA IV Decision	0	10			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DAGRID - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	20			
Number with MDUFA IV Decision	9	10			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DAGRID - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DCD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	154	173			
Non-MDUFA IV Decision	0	2			
MDUFA IV Decision	154	138			
MDUFA IV Decision Goal Met	154	138			
Supplements Pending MDUFA IV Decision	0	33			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DCD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	154	173			
Number with MDUFA IV Decision	154	138			
Number of Not Approvable	12	14			
Rate of Not Approvable	7.79%	10.14%			

**Table 3.3 DCD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DNPMD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision**

**Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	16	34			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	16	26			
MDUFA IV Decision Goal Met	16	26			
Supplements Pending MDUFA IV Decision	0	8			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DNPMD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	34			
Number with MDUFA IV Decision	16	26			
Number of Not Approvable	0	2			
Rate of Not Approvable	0%	7.69%			

**Table 3.3 DNPMD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			



### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DOD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	17	22			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	17	14			
MDUFA IV Decision Goal Met	17	14			
Supplements Pending MDUFA IV Decision	0	8			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DOD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	22			
Number with MDUFA IV Decision	17	14			
Number of Not Approvable	2	2			
Rate of Not Approvable	11.76%	14.29%			

**Table 3.3 DOD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DOED - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	19	34			
Non-MDUFA IV Decision	0	2			
MDUFA IV Decision	19	23			
MDUFA IV Decision Goal Met	19	23			
Supplements Pending MDUFA IV Decision	0	9			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DOED - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	19	34			
Number with MDUFA IV Decision	19	23			
Number of Not Approvable	1	1			
Rate of Not Approvable	5.26%	4.35%			

**Table 3.3 DOED - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DRGUD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	15	27			
Non-MDUFA IV Decision	0	1			
MDUFA IV Decision	15	20			
MDUFA IV Decision Goal Met	15	20			
Supplements Pending MDUFA IV Decision	0	6			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DRGUD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	15	27			
Number with MDUFA IV Decision	15	20			
Number of Not Approvable	1	5			
Rate of Not Approvable	6.67%	25.00%			

**Table 3.3 DRGUD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DSD - ODE - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	13	18			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	12	14			
MDUFA IV Decision Goal Met	12	14			
Supplements Pending MDUFA IV Decision	0	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DSD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	18			
Number with MDUFA IV Decision	12	14			
Number of Not Approvable	4	0			
Rate of Not Approvable	33.33%	0%			

**Table 3.3 DSD - ODE - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DCTD - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	28	14			
Non-MDUFA IV Decision	0	3			
MDUFA IV Decision	28	11			
MDUFA IV Decision Goal Met	28	11			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DCTD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	28	14			
Number with MDUFA IV Decision	28	11			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DCTD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DIHD - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	18	11			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	18	11			
MDUFA IV Decision Goal Met	18	11			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DIHD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	18	11			
Number with MDUFA IV Decision	18	11			
Number of Not Approvable	0	1			
Rate of Not Approvable	0%	9.09%			

**Table 3.3 DIHD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DMD - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	38	12			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	38	12			
MDUFA IV Decision Goal Met	38	12			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DMD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	38	12			
Number with MDUFA IV Decision	38	12			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DMD - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DMGP - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	9	11			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	8	6			
MDUFA IV Decision Goal Met	8	6			
Supplements Pending MDUFA IV Decision	0	5			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 DMGP - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	11			
Number with MDUFA IV Decision	8	6			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 DMGP - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			



### Section 3 PMA Real-Time Supplements - Division Level Metric

**Table 3.1 DRH - OIR - CDRH - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	2	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	2	0			
MDUFA IV Decision Goal Met	2	0			
Supplements Pending MDUFA IV Decision	0	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 3.2 DRH - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	1			
Number with MDUFA IV Decision	2	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 3.3 DRH - OIR - CDRH - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

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## **Section 4 Pre-Market Report Submissions**

There were no pre-market reports received by FDA between October 1, 2018 and September 30, 2019.

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## Section 5 PMA Annual Metrics and Goals

**Table 5.1 CDRH – PMAs (All Review Tracks) Annual General Metrics – PMAs Received by Type**

PMA Submissions Received	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Report Submissions	0	0			
Original PMAs (Panel) – Priority	1	0			
Original PMAs (No Panel) – Priority	3	2			
Original PMAs (Panel) – Non-Priority	3	0			
Original PMAs (No Panel) – Non-Priority	40	33			
Panel-Tracked Supplements (Panel) – Priority	0	0			
Panel-Tracked Supplements (No Panel) – Priority	2	1			
Panel-Tracked Supplements (Panel) – Non-Priority	0	0			
Panel-Tracked Supplements (No Panel) – Non-Priority	26	20			
PMA Modules	63	73			
180-Day Supplements	191	198			
Real-Time Supplements	338	378			

**Table 5.2 CDRH – PMA Originals and Panel Tracked Supplements Annual Shared Outcome Goal – Percent Cohorts Closed**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	70	47			
Number with a decision (MDUFA or Non-MDUFA)	62	17			
% of FY closed	88.57%	36.17%			

**Table 5.3 CDRH – PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision**

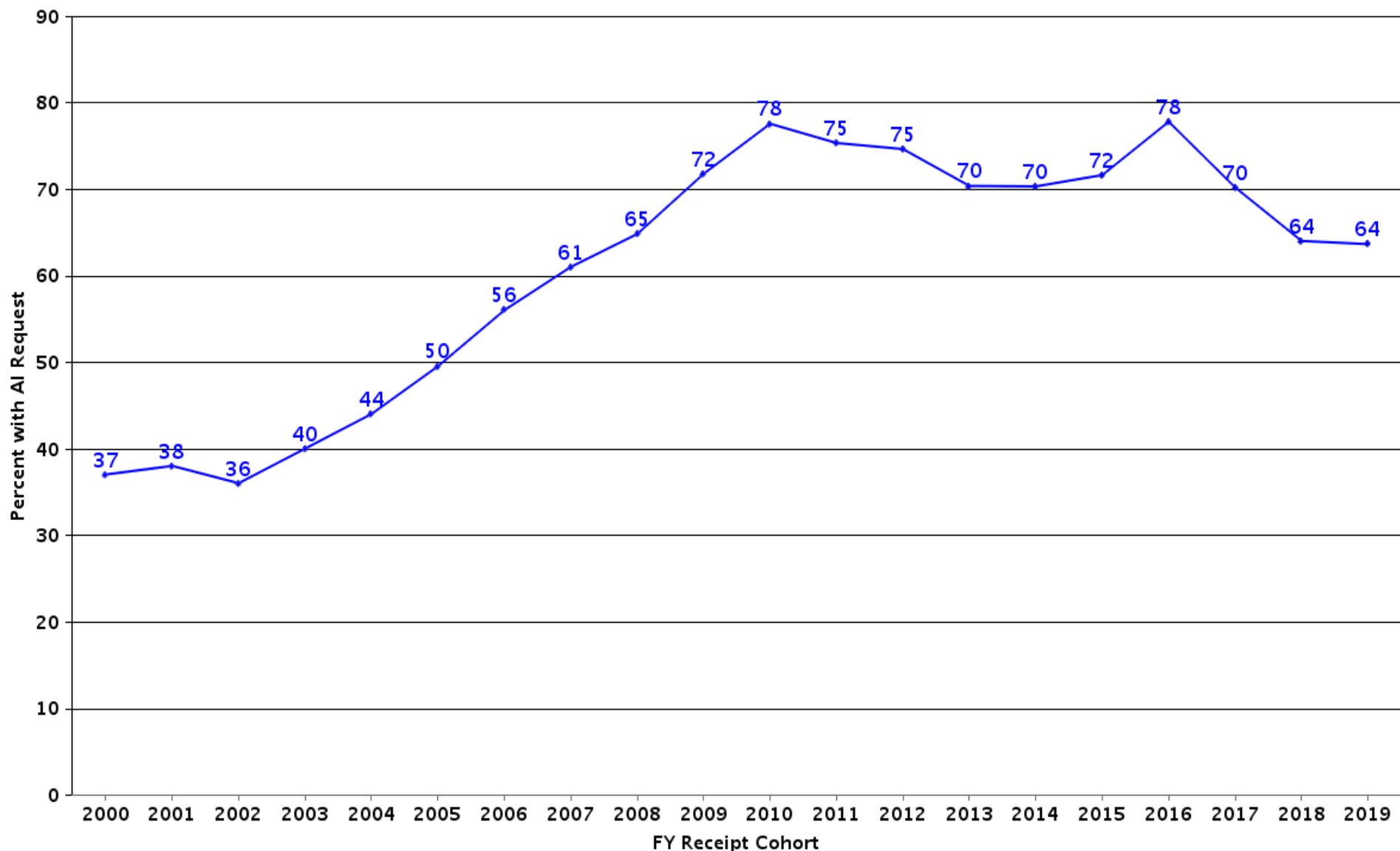
Performance Metric	FY 2018 3 year cohort 320 days	FY 2019 3 year cohort 315 days	FY 2020 3 year cohort 310 days	FY 2021 3 year cohort 300 days	FY 2022 3 year cohort 290 days
Number with a MDUFA decision	198	144			
Number with a MDUFA decision after trimming the upper and lower 5%	178	130			
Three-year Rolling Average Total Time to MDUFA decision	N/A	N/A			

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510(k)s

Q4FY19

## Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle

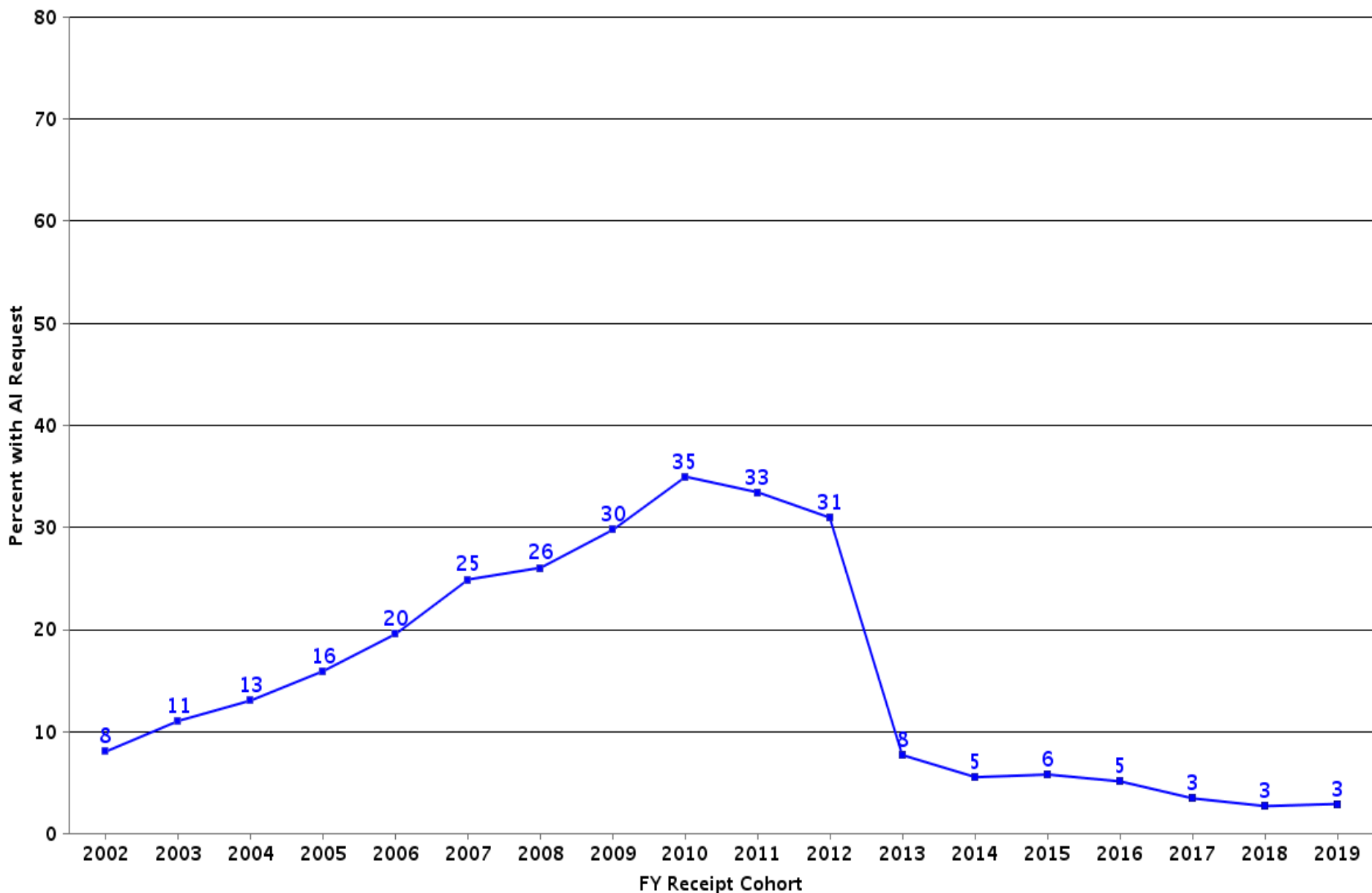


AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 7/31/19

◆ % with 1st Cycle AI Request



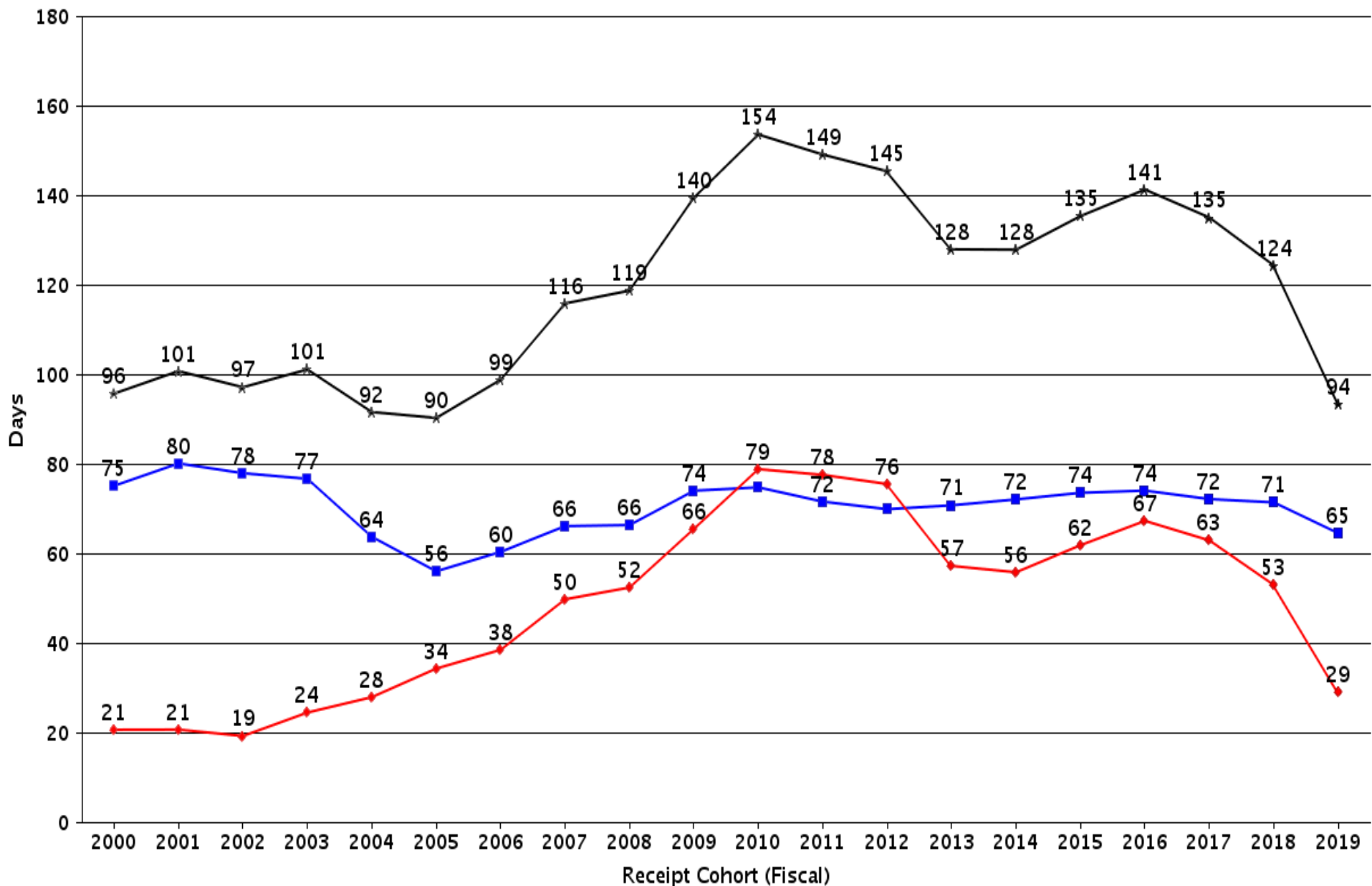
# Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as complete.

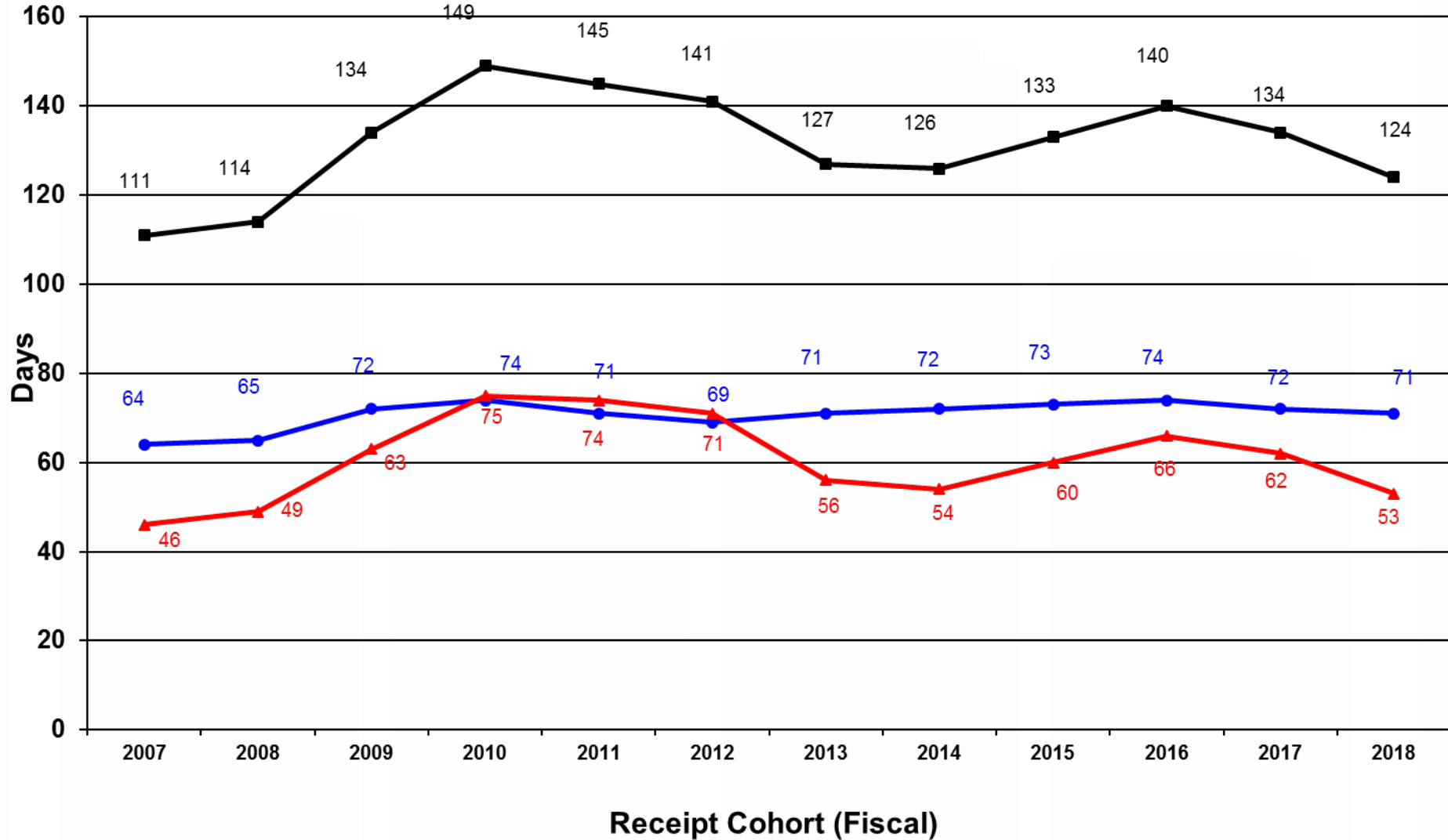
■ % with 2nd Cycle AI Request

# 510(k) Average Days to MDUFA (SE/NSE) Decision as of: 9/30/19



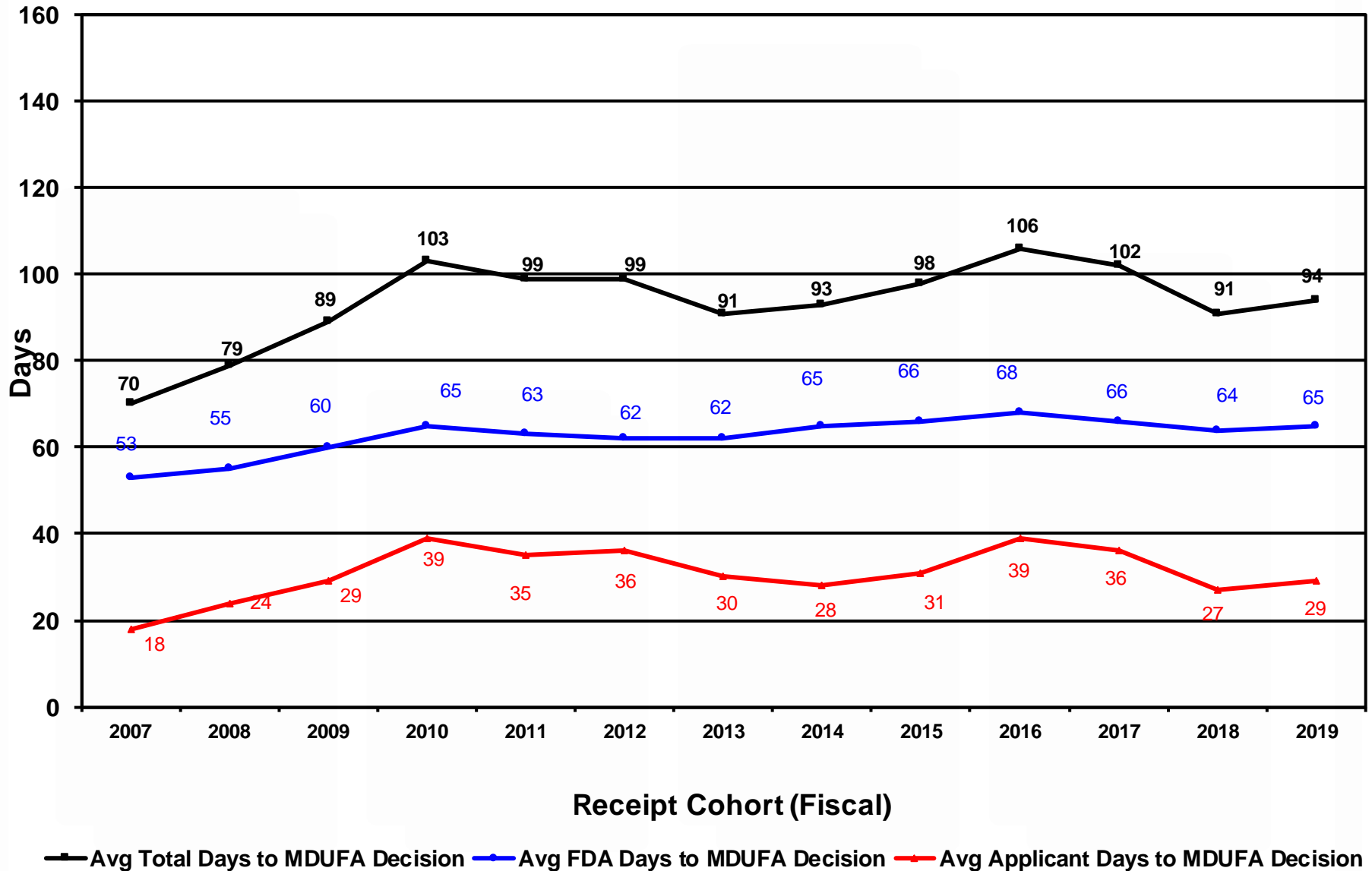
Cohorts not yet closed: 2017: 99.97%; 2018: 98.5%; 2019: 58.36%

# 510(k) Average Days to MDUFA (SE/NSE) Decision Comparison of Receipt Cohorts at 98.5% Closure



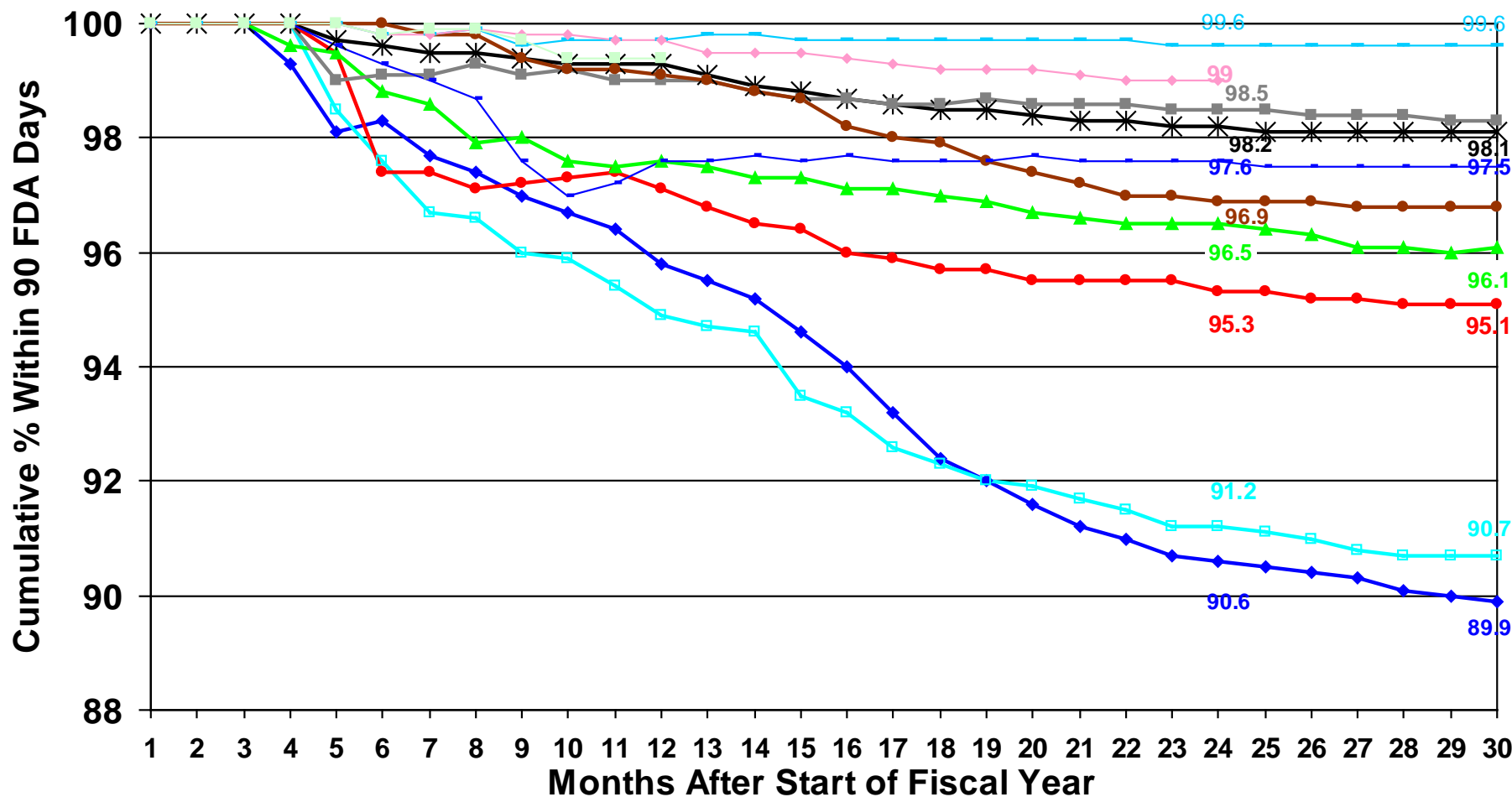
■ Avg Total Days to MDUFA Decision 
 ● Avg FDA Days to MDUFA Decision 
 ▲ Avg Applicant Days to MDUFA Decision

# 510(k) Average Days to MDUFA (SE/NSE) Decision Comparison of Receipt Cohorts at 58.4% Closure



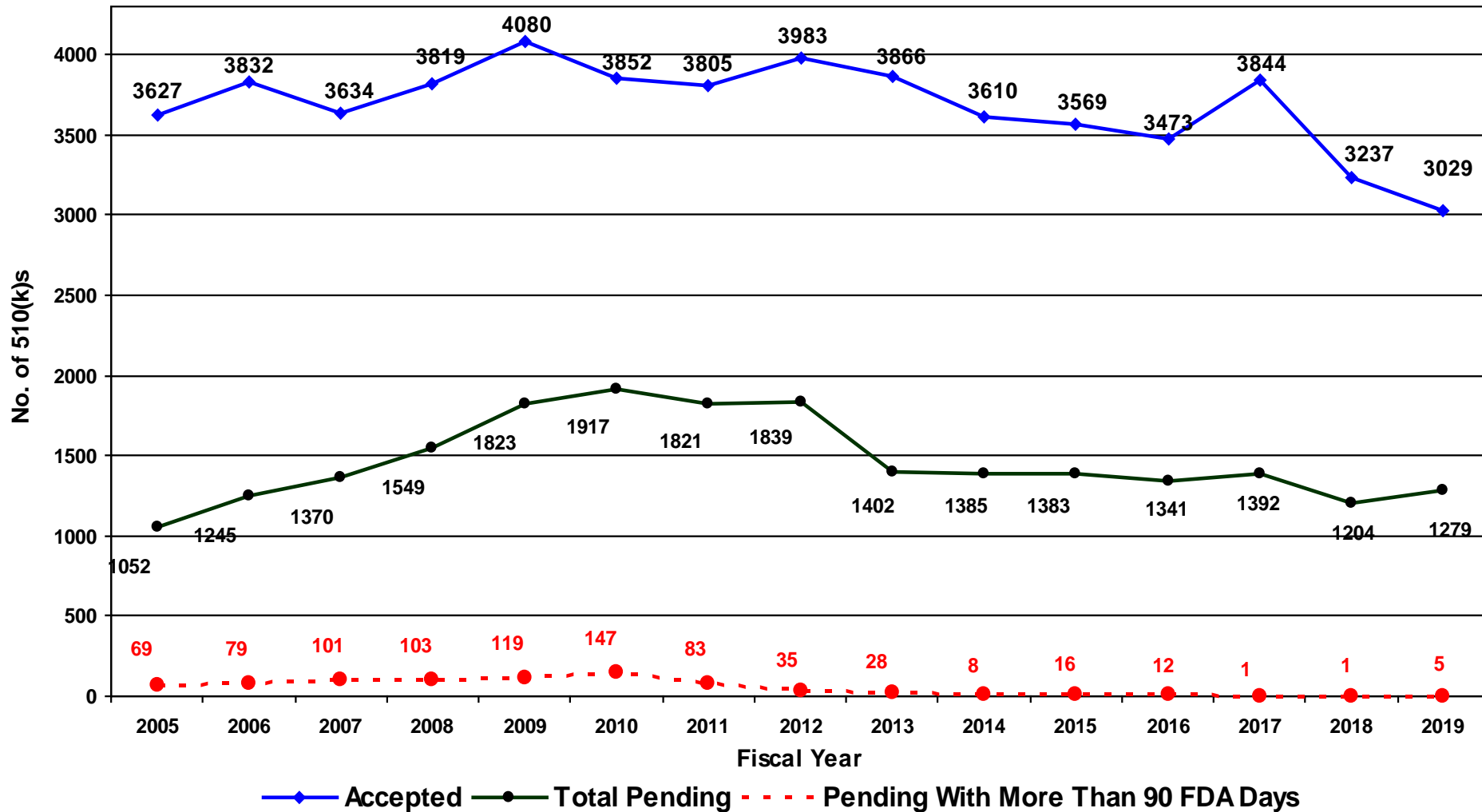
# Trend in 510(k) MDUFA Decision Goal Performance

## Comparison of FY09 - FY19 Receipt Cohorts



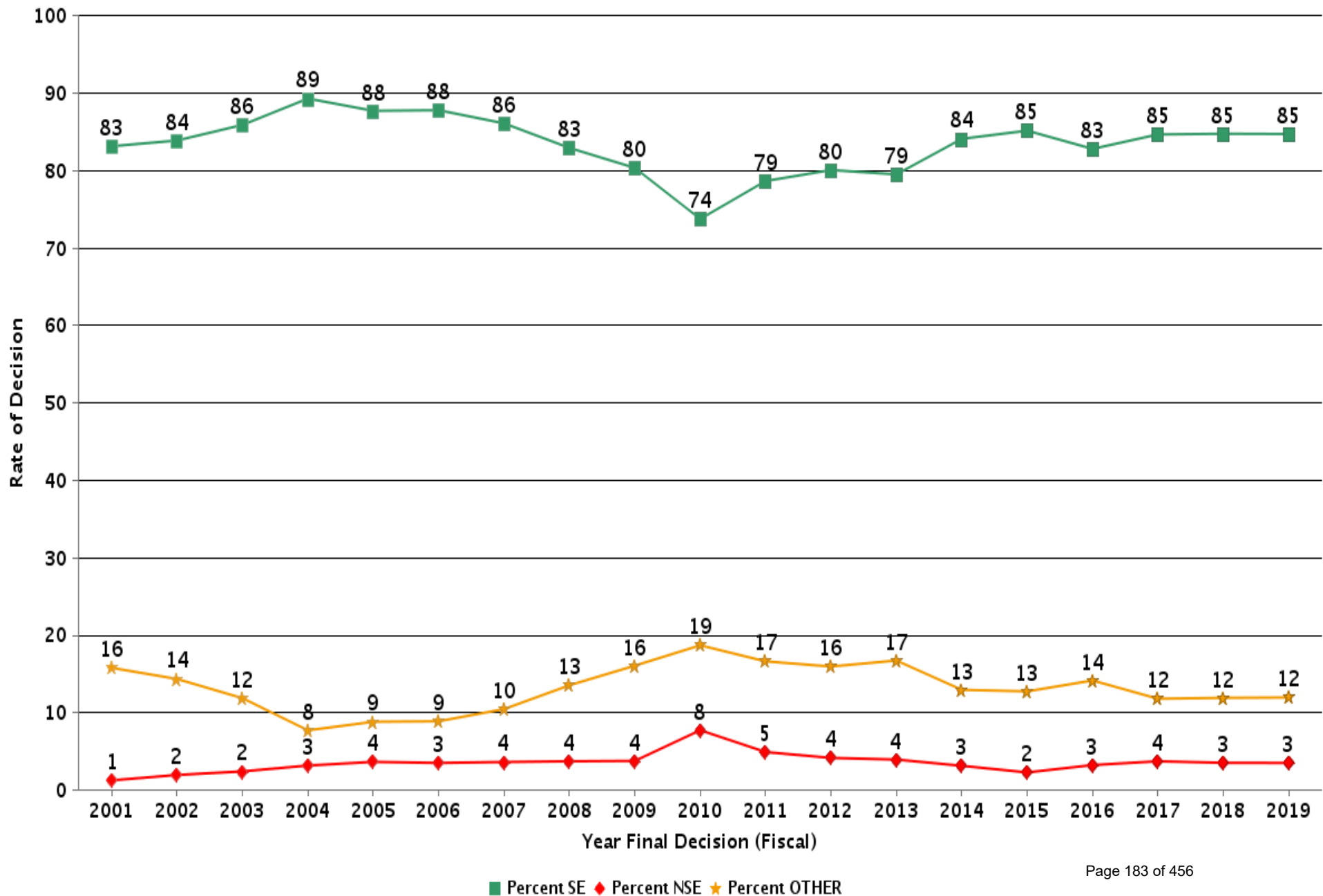
- FY09 Receipt Cohort
- FY10 Receipt Cohort
- FY11 Receipt Cohort
- FY12 Receipt Cohort
- FY13 Receipt Cohort
- FY14 Receipt Cohort
- FY15 Receipt Cohort
- FY16 Receipt Cohort
- FY17 Receipt Cohort
- FY18 Receipt Cohort
- FY19 Receipt Cohort

# 510(k)s Pending at End of Quarter/Year



“Pending” means 510ks under review or on hold following a positive RTA decision (FY13 and later).

# Rates of SE, NSE and Other Decisions by FY of Decision



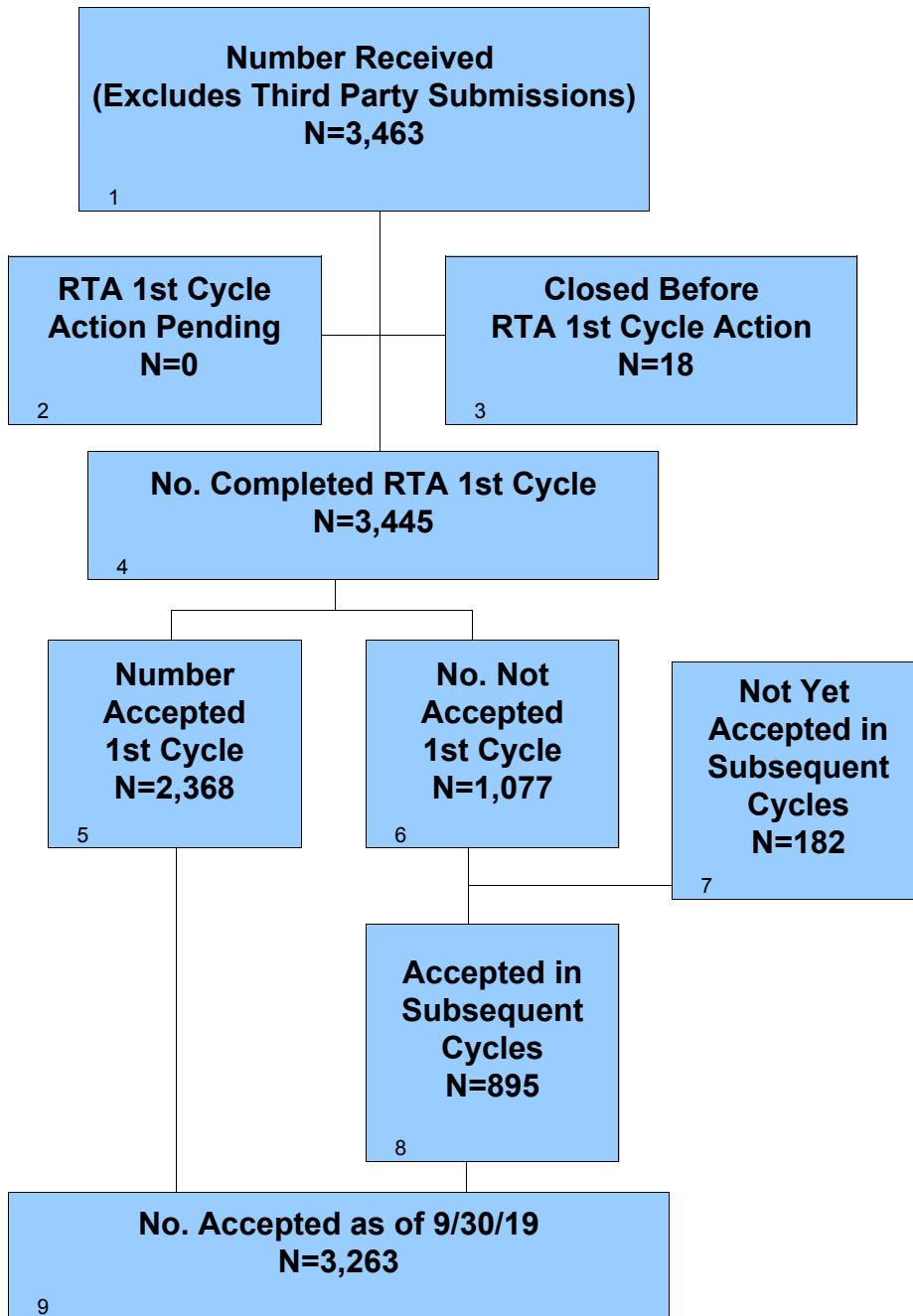
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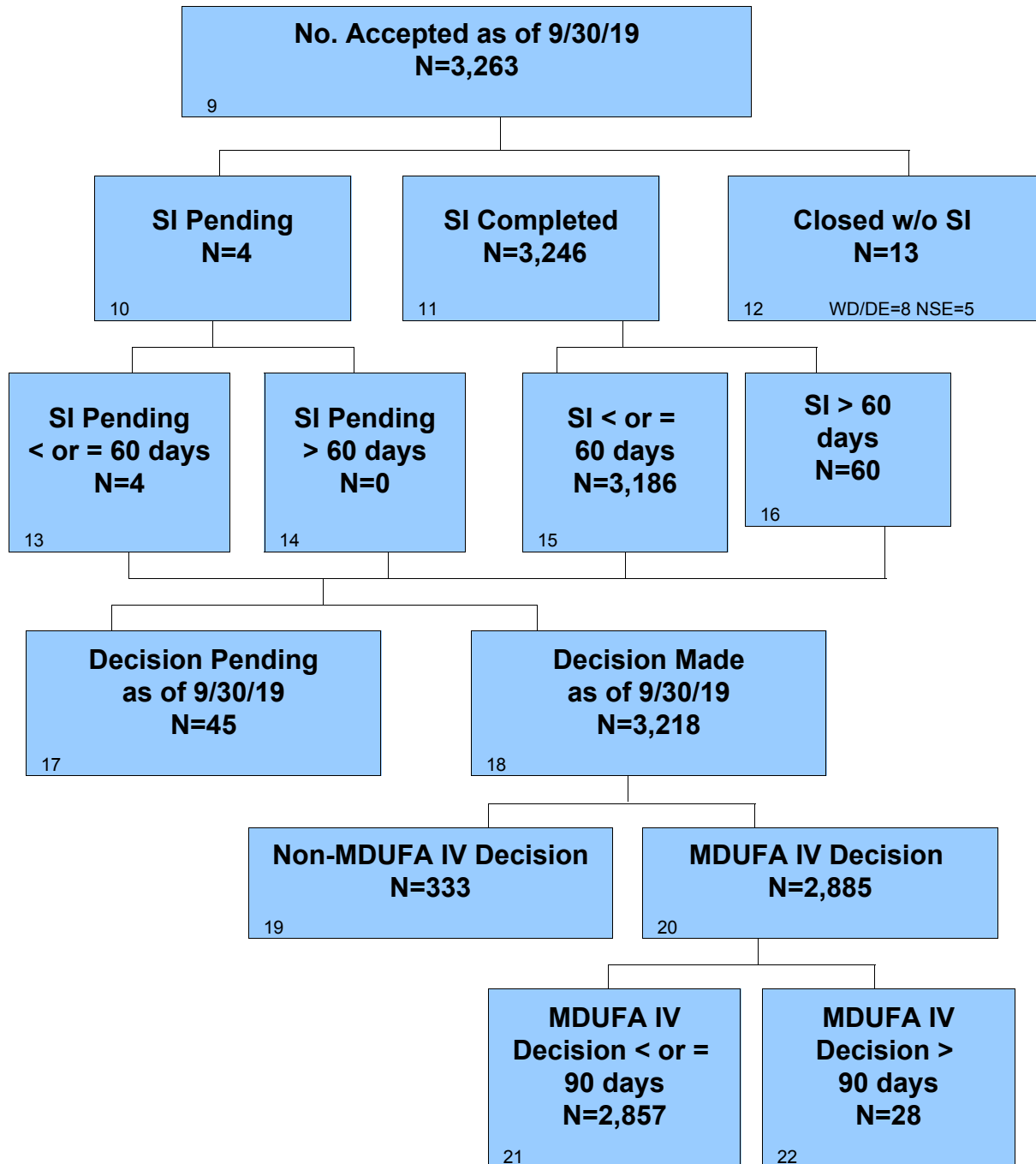
# CDRH 510(k)s - FY 2018

## as of 9/30/19

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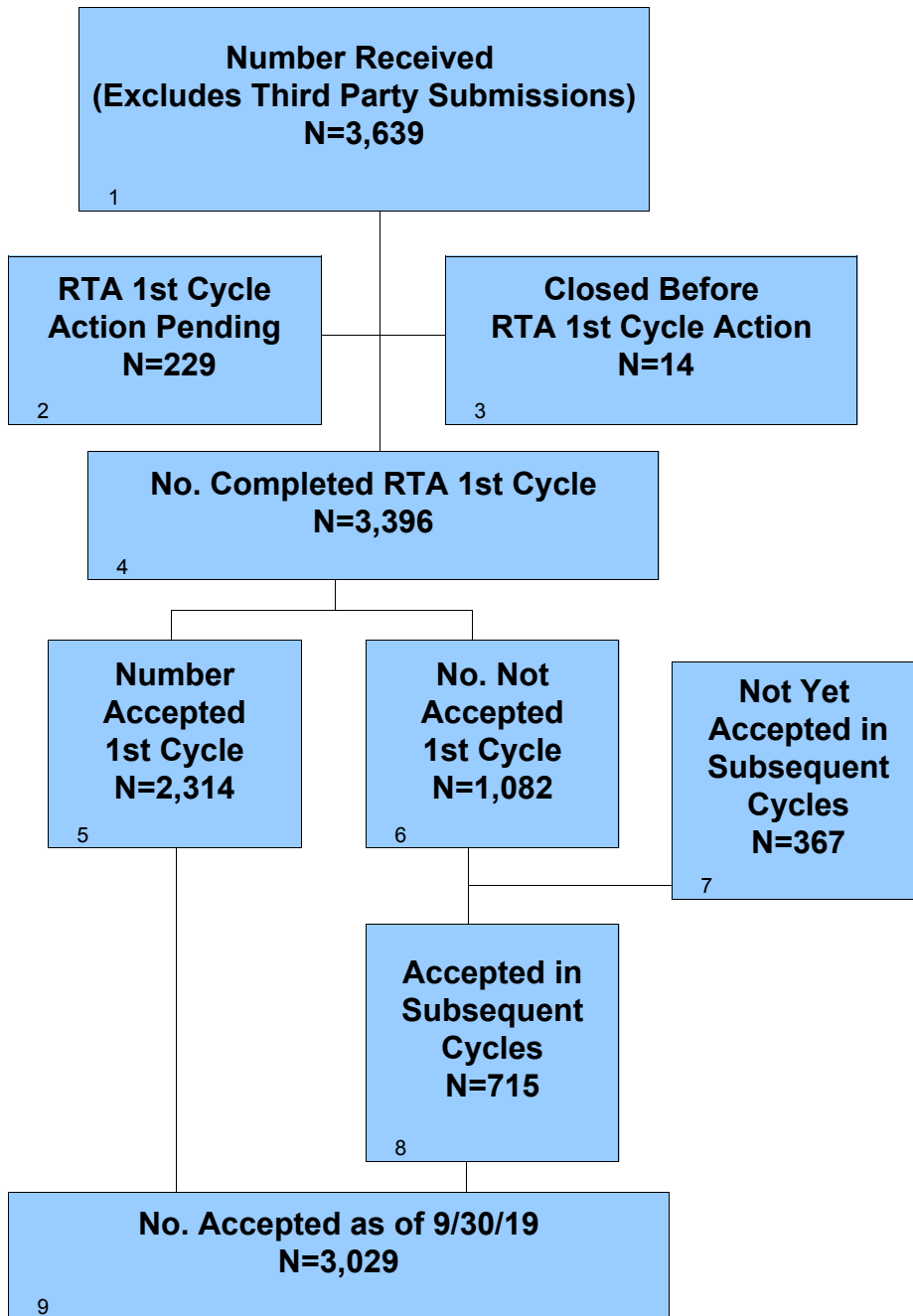
# CDRH 510(k)s - FY 2018 as of 9/30/19 Continued



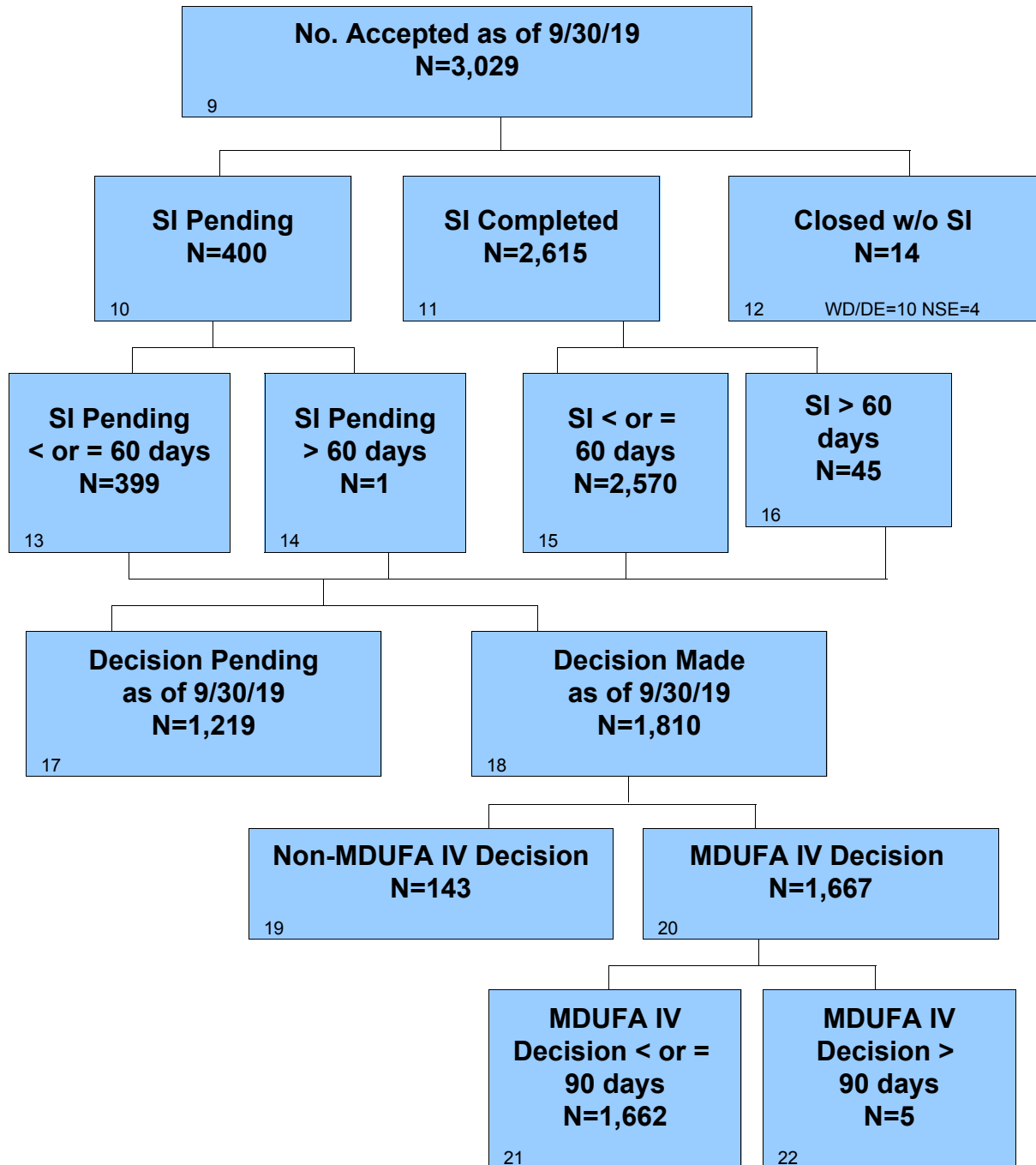
# CDRH 510(k)s - FY 2019

## as of 9/30/19

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# CDRH 510(k)s - FY 2019 as of 9/30/19 Continued



## Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

**Table 6.1 CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3463	3639			
Closed Before RTA Action	18	14			
Number Accepted	2353	2262			
Number Without a RTA Review and > 15 Days Since Date Received	15	52			
Number Without a RTA Review and <= 15 Days Since Date Received	0	229			
Number Not Accepted	1077	1082			
Rate of Submissions Not Accepted for Review	31.26%	31.86%			

**Table 6.2 CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	3263	3029			
Deleted or Withdrawn Prior to SI	8	10			
SI Within 60 FDA Days	3186	2570			
SI Over 60 FDA Days	60	45			
SI Pending Within 60 FDA Days	4	399			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	5	4			
Current SI Performance Percent Within 60 FDA Days	98.00%	98.09%			

**Table 6.3 CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	3246	2615			
Average Number of FDA Days to Substantive Interaction	51.00	50.45			
20th Percentile FDA Days to Substantive Interaction	43	34			
40th Percentile FDA Days to Substantive Interaction	55	55			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	86	90			

**Table 6.4 CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	3263	3029			
Non-MDUFA IV Decision	333	143			
MDUFA IV Decision (SE/NSE)	2885	1667			
MDUFA IV Decision Within 90 FDA Days	2857	1662			
510(k)s Pending MDUFA IV Decision	45	1219			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	1	4			
Current Performance Percent Within 90 FDA Days	99.00%	99.46%			

**Table 6.5 CDRH - 510(k) Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.62	1.46			
Number With MDUFA IV Decision	2885	1667			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	72.37	65.86			
20th Percentile FDA Days to MDUFA IV Decision	54	30			
40th Percentile FDA Days to MDUFA IV Decision	79	60			
60th Percentile FDA Days to MDUFA IV Decision	87	85			
80th Percentile FDA Days to MDUFA IV Decision	89	89			
Maximum FDA Days to MDUFA IV Decision	170	145			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	53.38	29.40			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	3	0			
60th Percentile Industry Days to MDUFA IV Decision	42	13			
80th Percentile Industry Days to MDUFA IV Decision	123	56			
Maximum Industry Days to MDUFA IV Decision	389	194			
<b>Average Number of Total Days to MDUFA IV Decision</b>	125.75	95.26			
20th Percentile Total Days to MDUFA IV Decision	57	30			
40th Percentile Total Days to MDUFA IV Decision	89	70			
60th Percentile Total Days to MDUFA IV Decision	127	90			
80th Percentile Total Days to MDUFA IV Decision	209	140			
Maximum Total Days to MDUFA IV Decision	479	282			

**Table 6.6 CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	3263	3029			
Number With MDUFA IV Decision	2885	1667			
Number of SE Decision	2771	1641			
Number of NSE Decision	114	26			
Number of Withdrawal	181	90			
Number of Deleted	143	39			
Rate of SE Decision	96.05%	98.44%			
Rate of NSE Decision	3.95%	1.56%			
Rate of Withdrawal	5.55%	2.97%			
Rate of Deleted	4.38%	1.29%			

**Table 6.7 CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	28	5			
Mean FDA Days for Submissions that Missed the Goal	107.50	112.40			
Mean Industry Days for Submissions that Missed the Goal	121.00	67.80			



**Table 6.8 CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	2	1			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	1	0			
MDUFA IV Decision Within 90 FDA Days	1	0			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	N/A			

**Table 6.9 CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	272	256			
Non-MDUFA IV Decision	39	14			
MDUFA IV Decision (SE/NSE)	231	157			
MDUFA IV Decision Within 90 FDA Days	230	157			
510(k)s Pending MDUFA IV Decision	2	85			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.57%	100%			

## Section 6 510(k) Office Level Metric (Excludes Third Party Review)

**Table 6.1 ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2782	2955			
Closed Before RTA Action	15	10			
Number Accepted	1760	1741			
Number Without a RTA and > 15 Days Since Date Received	13	45			
Number Without a RTA and <= 15 Days Since Date Received	0	201			
Number Not Accepted	994	958			
Rate of Submissions Not Accepted For Review	35.92%	34.91%			

**Table 6.2 ODE - CDRH - 510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	2604	2428			
Deleted or Withdrawn Prior to SI	6	9			
SI Within 60 FDA Days	2531	2042			
SI Over 60 FDA Days	59	44			
SI Pending Within 60 FDA Days	4	331			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	4	1			
Current SI Performance Percent Within 60 FDA Days	97.57%	97.80%			

**Table 6.3 ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	2590	2086			
Average Number of FDA Days to Substantive Interaction	52.13	51.61			
20th Percentile FDA Days to Substantive Interaction	47	43			
40th Percentile FDA Days to Substantive Interaction	56	56			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	86	90			

**Table 6.4 ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	2604	2428			
Non-MDUFA IV Decision	279	114			
MDUFA IV Decision (SE/NSE)	2282	1275			
MDUFA IV Decision Within 90 FDA Days	2255	1270			
510(k)s Pending MDUFA IV Decision	43	1039			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	1	4			
Current Performance Percent Within 90 FDA Days	98.77%	99.30%			

Table 6.5 ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.65	1.51			
Number With MDUFA IV Decision	2282	1275			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	74.53	68.53			
20th Percentile FDA Days to MDUFA IV Decision	57	39			
40th Percentile FDA Days to MDUFA IV Decision	82	68			
60th Percentile FDA Days to MDUFA IV Decision	88	87			
80th Percentile FDA Days to MDUFA IV Decision	90	89			
Maximum FDA Days to MDUFA IV Decision	170	145			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	56.17	32.14			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	10	0			
60th Percentile Industry Days to MDUFA IV Decision	46	19			
80th Percentile Industry Days to MDUFA IV Decision	129	60			
Maximum Industry Days to MDUFA IV Decision	389	194			
<b>Average Number of Total Days to MDUFA IV Decision</b>	130.70	100.67			
20th Percentile Total Days to MDUFA IV Decision	60	43			
40th Percentile Total Days to MDUFA IV Decision	90	82			
60th Percentile Total Days to MDUFA IV Decision	131	100			
80th Percentile Total Days to MDUFA IV Decision	215	146			
Maximum Total Days to MDUFA IV Decision	479	282			

**Table 6.6 ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	2604	2428			
Number With MDUFA IV Decision	2282	1275			
Number of SE Decision	2190	1255			
Number of NSE Decision	92	20			
Number of Withdrawal	148	82			
Number of Deleted	125	26			
Rate of SE Decision	95.97%	98.43%			
Rate of NSE Decision	4.03%	1.57%			
Rate of Withdrawal	5.68%	3.38%			
Rate of Deleted	4.80%	1.07%			

**Table 6.7 ODE - CDRH - 510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	27	5			
Mean FDA Days for Submissions that Missed the Goal	108.04	112.40			
Mean Industry Days for Submissions that Missed the Goal	118.00	67.80			

**Table 6.8 ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Office Level Metric (Excludes Third Party Review)

**Table 6.1 OIR - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	681	684			
Closed Before RTA Action	3	4			
Number Accepted	593	521			
Number Without a RTA and > 15 Days Since Date Received	2	7			
Number Without a RTA and <= 15 Days Since Date Received	0	28			
Number Not Accepted	83	124			
Rate of Submissions Not Accepted For Review	12.24%	19.02%			

**Table 6.2 OIR - CDRH - 510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	659	601			
Deleted or Withdrawn Prior to SI	2	1			
SI Within 60 FDA Days	655	528			
SI Over 60 FDA Days	1	1			
SI Pending Within 60 FDA Days	0	68			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	3			
Current SI Performance Percent Within 60 FDA Days	99.70%	99.25%			

**Table 6.3 OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	656	529			
Average Number of FDA Days to Substantive Interaction	46.54	45.84			
20th Percentile FDA Days to Substantive Interaction	30	29			
40th Percentile FDA Days to Substantive Interaction	48	48			
60th Percentile FDA Days to Substantive Interaction	56	55			
80th Percentile FDA Days to Substantive Interaction	58	58			
Maximum FDA Days to Substantive Interaction	61	61			

**Table 6.4 OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	659	601			
Non-MDUFA IV Decision	54	29			
MDUFA IV Decision (SE/NSE)	603	392			
MDUFA IV Decision Within 90 FDA Days	602	392			
510(k)s Pending MDUFA IV Decision	2	180			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.83%	100%			



Table 6.5 OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.51	1.28			
Number With MDUFA IV Decision	603	392			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	64.21	57.18			
20th Percentile FDA Days to MDUFA IV Decision	30	28			
40th Percentile FDA Days to MDUFA IV Decision	59	51			
60th Percentile FDA Days to MDUFA IV Decision	81	69			
80th Percentile FDA Days to MDUFA IV Decision	88	86			
Maximum FDA Days to MDUFA IV Decision	93	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	42.78	20.48			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	25	0			
80th Percentile Industry Days to MDUFA IV Decision	91	34			
Maximum Industry Days to MDUFA IV Decision	231	181			
<b>Average Number of Total Days to MDUFA IV Decision</b>	106.99	77.67			
20th Percentile Total Days to MDUFA IV Decision	30	28			
40th Percentile Total Days to MDUFA IV Decision	72	52			
60th Percentile Total Days to MDUFA IV Decision	104	80			
80th Percentile Total Days to MDUFA IV Decision	177	108			
Maximum Total Days to MDUFA IV Decision	321	269			

**Table 6.6 OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	659	601			
Number With MDUFA IV Decision	603	392			
Number of SE Decision	581	386			
Number of NSE Decision	22	6			
Number of Withdrawal	33	8			
Number of Deleted	18	13			
Rate of SE Decision	96.35%	98.47%			
Rate of NSE Decision	3.65%	1.53%			
Rate of Withdrawal	5.01%	1.33%			
Rate of Deleted	2.73%	2.16%			

**Table 6.7 OIR - CDRH - 510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	93.00	0			
Mean Industry Days for Submissions that Missed the Goal	202.00	0			

**Table 6.8 OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	2	1			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	1	0			
MDUFA IV Decision Within 90 FDA Days	1	0			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	N/A			

**Table 6.9 OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	272	256			
Non-MDUFA IV Decision	39	14			
MDUFA IV Decision (SE/NSE)	231	157			
MDUFA IV Decision Within 90 FDA Days	230	157			
510(k)s Pending MDUFA IV Decision	2	85			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.57%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DAGRID - ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	695	760			
Closed Before RTA Action	3	1			
Number Accepted	262	268			
Number Without a RTA and > 15 Days Since Date Received	3	15			
Number Without a RTA and <= 15 Days Since Date Received	0	58			
Number Not Accepted	427	418			
Rate of Submissions Not Accepted for Review	61.71%	59.63%			

**Table 6.2 DAGRID - ODE - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	614	558			
Deleted or Withdrawn Prior to SI	0	2			
SI Within 60 FDA Days	595	415			
SI Over 60 FDA Days	16	26			
SI Pending Within 60 FDA Days	3	113			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	0	1			
Current SI Performance Percent Within 60 FDA Days	97.38%	93.68%			

**Table 6.3 DAGRID - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	611	441			
Average Number of FDA Days to Substantive Interaction	55.56	55.32			
20th Percentile FDA Days to Substantive Interaction	54	54			
40th Percentile FDA Days to Substantive Interaction	57	58			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	78	87			

**Table 6.4 DAGRID - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	614	558			
Non-MDUFA IV Decision	87	20			
MDUFA IV Decision (SE/NSE)	504	221			
MDUFA IV Decision Within 90 FDA Days	498	221			
510(k)s Pending MDUFA IV Decision	23	317			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	1	1			
Current Performance Percent Within 90 FDA Days	98.61%	99.55%			

Table 6.5 DAGRID - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.76	1.57			
Number With MDUFA IV Decision	504	221			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	82.80	77.49			
20th Percentile FDA Days to MDUFA IV Decision	80	71			
40th Percentile FDA Days to MDUFA IV Decision	87	84			
60th Percentile FDA Days to MDUFA IV Decision	89	88			
80th Percentile FDA Days to MDUFA IV Decision	90	90			
Maximum FDA Days to MDUFA IV Decision	148	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	72.06	36.15			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	29	0			
60th Percentile Industry Days to MDUFA IV Decision	76	29			
80th Percentile Industry Days to MDUFA IV Decision	155	74			
Maximum Industry Days to MDUFA IV Decision	389	184			
<b>Average Number of Total Days to MDUFA IV Decision</b>	154.86	113.65			
20th Percentile Total Days to MDUFA IV Decision	87	80			
40th Percentile Total Days to MDUFA IV Decision	114	90			
60th Percentile Total Days to MDUFA IV Decision	162	111			
80th Percentile Total Days to MDUFA IV Decision	242	154			
Maximum Total Days to MDUFA IV Decision	479	274			

**Table 6.6 DAGRID - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	614	558			
Number With MDUFA IV Decision	504	221			
Number of SE Decision	480	219			
Number of NSE Decision	24	2			
Number of Withdrawal	43	13			
Number of Deleted	44	5			
Rate of SE Decision	95.24%	99.10%			
Rate of NSE Decision	4.76%	0.90%			
Rate of Withdrawal	7.00%	2.33%			
Rate of Deleted	7.17%	0.90%			

**Table 6.7 DAGRID - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	6	0			
Mean FDA Days for Submissions that Missed the Goal	109.00	0			
Mean Industry Days for Submissions that Missed the Goal	126.00	0			

**Table 6.8 DAGRID - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DAGRID - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			



## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DCD - ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	357	377			
Closed Before RTA Action	4	2			
Number Accepted	237	252			
Number Without a RTA and > 15 Days Since Date Received	2	10			
Number Without a RTA and <= 15 Days Since Date Received	0	21			
Number Not Accepted	114	92			
Rate of Submissions Not Accepted for Review	32.29%	25.99%			

**Table 6.2 DCD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	341	337			
Deleted or Withdrawn Prior to SI	4	0			
SI Within 60 FDA Days	323	298			
SI Over 60 FDA Days	13	7			
SI Pending Within 60 FDA Days	1	32			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.13%	97.70%			

**Table 6.3 DCD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	336	305			
Average Number of FDA Days to Substantive Interaction	49.71	50.36			
20th Percentile FDA Days to Substantive Interaction	30	30			
40th Percentile FDA Days to Substantive Interaction	53	56			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	83	71			

**Table 6.4 DCD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	341	337			
Non-MDUFA IV Decision	30	21			
MDUFA IV Decision (SE/NSE)	307	193			
MDUFA IV Decision Within 90 FDA Days	301	192			
510(k)s Pending MDUFA IV Decision	4	123			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1			
Current Performance Percent Within 90 FDA Days	98.05%	98.97%			

Table 6.5 DCD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.70	1.55			
Number With MDUFA IV Decision	307	193			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	71.57	64.88			
20th Percentile FDA Days to MDUFA IV Decision	49	30			
40th Percentile FDA Days to MDUFA IV Decision	80	59			
60th Percentile FDA Days to MDUFA IV Decision	87	85			
80th Percentile FDA Days to MDUFA IV Decision	90	89			
Maximum FDA Days to MDUFA IV Decision	159	102			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	64.15	37.53			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	19	0			
60th Percentile Industry Days to MDUFA IV Decision	64	27			
80th Percentile Industry Days to MDUFA IV Decision	146	79			
Maximum Industry Days to MDUFA IV Decision	292	182			
<b>Average Number of Total Days to MDUFA IV Decision</b>	135.72	102.40			
20th Percentile Total Days to MDUFA IV Decision	54	30			
40th Percentile Total Days to MDUFA IV Decision	102	63			
60th Percentile Total Days to MDUFA IV Decision	146	109			
80th Percentile Total Days to MDUFA IV Decision	225	163			
Maximum Total Days to MDUFA IV Decision	370	281			

**Table 6.6 DCD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	341	337			
Number With MDUFA IV Decision	307	193			
Number of SE Decision	290	186			
Number of NSE Decision	17	7			
Number of Withdrawal	19	16			
Number of Deleted	9	4			
Rate of SE Decision	94.46%	96.37%			
Rate of NSE Decision	5.54%	3.63%			
Rate of Withdrawal	5.57%	4.75%			
Rate of Deleted	2.64%	1.19%			

**Table 6.7 DCD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	6	1			
Mean FDA Days for Submissions that Missed the Goal	107.17	102.00			
Mean Industry Days for Submissions that Missed the Goal	131.50	179.00			

**Table 6.8 DCD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DCD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DNPMD - ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	260	276			
Closed Before RTA Action	3	0			
Number Accepted	147	137			
Number Without a RTA and > 15 Days Since Date Received	3	7			
Number Without a RTA and <= 15 Days Since Date Received	0	27			
Number Not Accepted	107	105			
Rate of Submissions Not Accepted for Review	41.63%	42.17%			

**Table 6.2 DNPMD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	233	206			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	229	184			
SI Over 60 FDA Days	4	0			
SI Pending Within 60 FDA Days	0	22			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	98.28%	100%			

**Table 6.3 DNPMD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	233	184			
Average Number of FDA Days to Substantive Interaction	53.86	54.10			
20th Percentile FDA Days to Substantive Interaction	53	54			
40th Percentile FDA Days to Substantive Interaction	58	58			
60th Percentile FDA Days to Substantive Interaction	60	60			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	86	60			

**Table 6.4 DNPMD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	233	206			
Non-MDUFA IV Decision	27	10			
MDUFA IV Decision (SE/NSE)	201	112			
MDUFA IV Decision Within 90 FDA Days	196	108			
510(k)s Pending MDUFA IV Decision	5	84			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1			
Current Performance Percent Within 90 FDA Days	97.51%	95.58%			

Table 6.5 DNPMD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.52	1.52			
Number With MDUFA IV Decision	201	112			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	76.34	75.59			
20th Percentile FDA Days to MDUFA IV Decision	60	55			
40th Percentile FDA Days to MDUFA IV Decision	86	87			
60th Percentile FDA Days to MDUFA IV Decision	89	89			
80th Percentile FDA Days to MDUFA IV Decision	90	90			
Maximum FDA Days to MDUFA IV Decision	170	145			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	41.95	32.41			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	38	22			
80th Percentile Industry Days to MDUFA IV Decision	82	68			
Maximum Industry Days to MDUFA IV Decision	187	194			
<b>Average Number of Total Days to MDUFA IV Decision</b>	118.29	108.00			
20th Percentile Total Days to MDUFA IV Decision	61	56			
40th Percentile Total Days to MDUFA IV Decision	89	89			
60th Percentile Total Days to MDUFA IV Decision	117	111			
80th Percentile Total Days to MDUFA IV Decision	170	157			
Maximum Total Days to MDUFA IV Decision	346	282			



**Table 6.6 DNPMD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	233	206			
Number With MDUFA IV Decision	201	112			
Number of SE Decision	193	111			
Number of NSE Decision	8	1			
Number of Withdrawal	16	8			
Number of Deleted	8	2			
Rate of SE Decision	96.02%	99.11%			
Rate of NSE Decision	3.98%	0.89%			
Rate of Withdrawal	6.87%	3.88%			
Rate of Deleted	3.43%	0.97%			

**Table 6.7 DNPMD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	5	4			
Mean FDA Days for Submissions that Missed the Goal	111.40	115.00			
Mean Industry Days for Submissions that Missed the Goal	80.60	40.00			

**Table 6.8 DNPMD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DNPMD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DOD - ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	606	630			
Closed Before RTA Action	2	4			
Number Accepted	466	467			
Number Without a RTA and > 15 Days Since Date Received	0	5			
Number Without a RTA and <= 15 Days Since Date Received	0	31			
Number Not Accepted	138	123			
Rate of Submissions Not Accepted for Review	22.85%	20.67%			

**Table 6.2 DOD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	594	575			
Deleted or Withdrawn Prior to SI	0	2			
SI Within 60 FDA Days	575	504			
SI Over 60 FDA Days	19	2			
SI Pending Within 60 FDA Days	0	67			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.80%	99.60%			

**Table 6.3 DOD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	594	506			
Average Number of FDA Days to Substantive Interaction	50.43	49.00			
20th Percentile FDA Days to Substantive Interaction	39	30			
40th Percentile FDA Days to Substantive Interaction	55	55			
60th Percentile FDA Days to Substantive Interaction	57	58			
80th Percentile FDA Days to Substantive Interaction	59	60			
Maximum FDA Days to Substantive Interaction	78	64			

**Table 6.4 DOD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	594	575			
Non-MDUFA IV Decision	40	23			
MDUFA IV Decision (SE/NSE)	550	352			
MDUFA IV Decision Within 90 FDA Days	548	352			
510(k)s Pending MDUFA IV Decision	4	200			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.64%	100%			

Table 6.5 DOD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.67	1.52			
Number With MDUFA IV Decision	550	352			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	71.26	65.36			
20th Percentile FDA Days to MDUFA IV Decision	52	30			
40th Percentile FDA Days to MDUFA IV Decision	74	60			
60th Percentile FDA Days to MDUFA IV Decision	86	85			
80th Percentile FDA Days to MDUFA IV Decision	89	89			
Maximum FDA Days to MDUFA IV Decision	135	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	47.71	24.30			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	9	0			
60th Percentile Industry Days to MDUFA IV Decision	33	14			
80th Percentile Industry Days to MDUFA IV Decision	102	42			
Maximum Industry Days to MDUFA IV Decision	316	180			
<b>Average Number of Total Days to MDUFA IV Decision</b>	118.97	89.66			
20th Percentile Total Days to MDUFA IV Decision	57	31			
40th Percentile Total Days to MDUFA IV Decision	86	69			
60th Percentile Total Days to MDUFA IV Decision	115	90			
80th Percentile Total Days to MDUFA IV Decision	183	130			
Maximum Total Days to MDUFA IV Decision	400	269			

**Table 6.6 DOD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	594	575			
Number With MDUFA IV Decision	550	352			
Number of SE Decision	536	348			
Number of NSE Decision	14	4			
Number of Withdrawal	24	19			
Number of Deleted	16	4			
Rate of SE Decision	97.45%	98.86%			
Rate of NSE Decision	2.55%	1.14%			
Rate of Withdrawal	4.04%	3.30%			
Rate of Deleted	2.69%	0.70%			

**Table 6.7 DOD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	0			
Mean FDA Days for Submissions that Missed the Goal	117.50	0			
Mean Industry Days for Submissions that Missed the Goal	208.50	0			

**Table 6.8 DOD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DOD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DOED - ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	140	124			
Closed Before RTA Action	0	1			
Number Accepted	112	91			
Number Without a RTA and > 15 Days Since Date Received	0	2			
Number Without a RTA and <= 15 Days Since Date Received	0	5			
Number Not Accepted	28	25			
Rate of Submissions Not Accepted for Review	20.00%	21.19%			

**Table 6.2 DOED - ODE - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	137	110			
Deleted or Withdrawn Prior to SI	2	2			
SI Within 60 FDA Days	134	87			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	21			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	99.26%	100%			



**Table 6.3 DOED - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	134	87			
Average Number of FDA Days to Substantive Interaction	51.84	49.76			
20th Percentile FDA Days to Substantive Interaction	48	44			
40th Percentile FDA Days to Substantive Interaction	53	52			
60th Percentile FDA Days to Substantive Interaction	57	56			
80th Percentile FDA Days to Substantive Interaction	59	60			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 DOED - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	137	110			
Non-MDUFA IV Decision	17	5			
MDUFA IV Decision (SE/NSE)	120	61			
MDUFA IV Decision Within 90 FDA Days	120	61			
510(k)s Pending MDUFA IV Decision	0	44			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DOED - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.44	1.48			
Number With MDUFA IV Decision	120	61			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	71.02	66.11			
20th Percentile FDA Days to MDUFA IV Decision	52	49			
40th Percentile FDA Days to MDUFA IV Decision	66	59			
60th Percentile FDA Days to MDUFA IV Decision	86	86			
80th Percentile FDA Days to MDUFA IV Decision	90	89			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	36.19	38.69			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	14	25			
80th Percentile Industry Days to MDUFA IV Decision	82	69			
Maximum Industry Days to MDUFA IV Decision	180	180			
<b>Average Number of Total Days to MDUFA IV Decision</b>	107.21	104.80			
20th Percentile Total Days to MDUFA IV Decision	52	49			
40th Percentile Total Days to MDUFA IV Decision	72	60			
60th Percentile Total Days to MDUFA IV Decision	100	107			
80th Percentile Total Days to MDUFA IV Decision	167	148			
Maximum Total Days to MDUFA IV Decision	270	270			

**Table 6.6 DOED - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	137	110			
Number With MDUFA IV Decision	120	61			
Number of SE Decision	118	60			
Number of NSE Decision	2	1			
Number of Withdrawal	8	3			
Number of Deleted	9	2			
Rate of SE Decision	98.33%	98.36%			
Rate of NSE Decision	1.67%	1.64%			
Rate of Withdrawal	5.84%	2.73%			
Rate of Deleted	6.57%	1.82%			

**Table 6.7 DOED - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DOED - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DOED - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DRGUD - ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	309	326			
Closed Before RTA Action	1	2			
Number Accepted	250	245			
Number Without a RTA and > 15 Days Since Date Received	0	2			
Number Without a RTA and <= 15 Days Since Date Received	0	23			
Number Not Accepted	58	54			
Rate of Submissions Not Accepted for Review	18.83%	17.94%			

**Table 6.2 DRGUD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	299	283			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	293	250			
SI Over 60 FDA Days	3	1			
SI Pending Within 60 FDA Days	0	32			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	3	0			
Current SI Performance Percent Within 60 FDA Days	97.99%	99.60%			

**Table 6.3 DRGUD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	296	251			
Average Number of FDA Days to Substantive Interaction	49.88	50.59			
20th Percentile FDA Days to Substantive Interaction	42	42			
40th Percentile FDA Days to Substantive Interaction	52	55			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	64	61			

**Table 6.4 DRGUD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	299	283			
Non-MDUFA IV Decision	26	14			
MDUFA IV Decision (SE/NSE)	272	139			
MDUFA IV Decision Within 90 FDA Days	271	139			
510(k)s Pending MDUFA IV Decision	1	130			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.63%	100%			

**Table 6.5 DRGUD - ODE - CDRH - 510(k) Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.68	1.63			
Number With MDUFA IV Decision	272	139			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	72.95	69.52			
20th Percentile FDA Days to MDUFA IV Decision	57	47			
40th Percentile FDA Days to MDUFA IV Decision	79	73			
60th Percentile FDA Days to MDUFA IV Decision	88	87			
80th Percentile FDA Days to MDUFA IV Decision	89	89			
Maximum FDA Days to MDUFA IV Decision	92	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	70.50	49.19			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	20	7			
60th Percentile Industry Days to MDUFA IV Decision	79	42			
80th Percentile Industry Days to MDUFA IV Decision	167	103			
Maximum Industry Days to MDUFA IV Decision	186	181			
<b>Average Number of Total Days to MDUFA IV Decision</b>	143.45	118.71			
20th Percentile Total Days to MDUFA IV Decision	60	47			
40th Percentile Total Days to MDUFA IV Decision	98	90			
60th Percentile Total Days to MDUFA IV Decision	158	126			
80th Percentile Total Days to MDUFA IV Decision	249	189			
Maximum Total Days to MDUFA IV Decision	274	271			

**Table 6.6 DRGUD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	299	283			
Number With MDUFA IV Decision	272	139			
Number of SE Decision	255	138			
Number of NSE Decision	17	1			
Number of Withdrawal	12	8			
Number of Deleted	14	5			
Rate of SE Decision	93.75%	99.28%			
Rate of NSE Decision	6.25%	0.72%			
Rate of Withdrawal	4.01%	2.83%			
Rate of Deleted	4.68%	1.77%			

**Table 6.7 DRGUD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	92.00	0			
Mean Industry Days for Submissions that Missed the Goal	35.00	0			



**Table 6.8 DRGUD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DRGUD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DSD - ODE - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	415	462			
Closed Before RTA Action	2	0			
Number Accepted	286	281			
Number Without a RTA and > 15 Days Since Date Received	5	4			
Number Without a RTA and <= 15 Days Since Date Received	0	36			
Number Not Accepted	122	141			
Rate of Submissions Not Accepted for Review	29.54%	33.10%			

**Table 6.2 DSD - ODE - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	386	359			
Deleted or Withdrawn Prior to SI	0	3			
SI Within 60 FDA Days	382	304			
SI Over 60 FDA Days	4	8			
SI Pending Within 60 FDA Days	0	44			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	98.96%	97.44%			

**Table 6.3 DSD - ODE - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	386	312			
Average Number of FDA Days to Substantive Interaction	52.23	51.70			
20th Percentile FDA Days to Substantive Interaction	49	43			
40th Percentile FDA Days to Substantive Interaction	57	56			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	69	90			

**Table 6.4 DSD - ODE - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	386	359			
Non-MDUFA IV Decision	52	21			
MDUFA IV Decision (SE/NSE)	328	197			
MDUFA IV Decision Within 90 FDA Days	321	197			
510(k)s Pending MDUFA IV Decision	6	141			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	1			
Current Performance Percent Within 90 FDA Days	97.87%	99.49%			

Table 6.5 DSD - ODE - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.51	1.33			
Number With MDUFA IV Decision	328	197			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	71.56	63.76			
20th Percentile FDA Days to MDUFA IV Decision	54	30			
40th Percentile FDA Days to MDUFA IV Decision	77	58			
60th Percentile FDA Days to MDUFA IV Decision	87	82			
80th Percentile FDA Days to MDUFA IV Decision	89	88			
Maximum FDA Days to MDUFA IV Decision	163	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	42.64	22.18			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	22	0			
80th Percentile Industry Days to MDUFA IV Decision	91	33			
Maximum Industry Days to MDUFA IV Decision	366	182			
<b>Average Number of Total Days to MDUFA IV Decision</b>	114.20	85.94			
20th Percentile Total Days to MDUFA IV Decision	56	30			
40th Percentile Total Days to MDUFA IV Decision	85	58			
60th Percentile Total Days to MDUFA IV Decision	101	87			
80th Percentile Total Days to MDUFA IV Decision	178	117			
Maximum Total Days to MDUFA IV Decision	455	269			

**Table 6.6 DSD - ODE - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	386	359			
Number With MDUFA IV Decision	328	197			
Number of SE Decision	318	193			
Number of NSE Decision	10	4			
Number of Withdrawal	26	15			
Number of Deleted	25	4			
Rate of SE Decision	96.95%	97.97%			
Rate of NSE Decision	3.05%	2.03%			
Rate of Withdrawal	6.74%	4.18%			
Rate of Deleted	6.48%	1.11%			

**Table 6.7 DSD - ODE - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	7	0			
Mean FDA Days for Submissions that Missed the Goal	105.14	0			
Mean Industry Days for Submissions that Missed the Goal	112.29	0			

**Table 6.8 DSD - ODE - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DSD - ODE - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DCTD - OIR - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	143	126			
Closed Before RTA Action	3	3			
Number Accepted	110	87			
Number Without a RTA and > 15 Days Since Date Received	1	1			
Number Without a RTA and <= 15 Days Since Date Received	0	8			
Number Not Accepted	29	27			
Rate of Submissions Not Accepted for Review	20.71%	23.48%			

**Table 6.2 DCTD - OIR - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	134	104			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	133	89			
SI Over 60 FDA Days	0	1			
SI Pending Within 60 FDA Days	0	12			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	2			
Current SI Performance Percent Within 60 FDA Days	99.25%	96.74%			

**Table 6.3 DCTD - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	133	90			
Average Number of FDA Days to Substantive Interaction	49.81	47.77			
20th Percentile FDA Days to Substantive Interaction	44	30			
40th Percentile FDA Days to Substantive Interaction	51	49			
60th Percentile FDA Days to Substantive Interaction	56	58			
80th Percentile FDA Days to Substantive Interaction	59	60			
Maximum FDA Days to Substantive Interaction	60	61			

**Table 6.4 DCTD - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	134	104			
Non-MDUFA IV Decision	31	9			
MDUFA IV Decision (SE/NSE)	101	52			
MDUFA IV Decision Within 90 FDA Days	101	52			
510(k)s Pending MDUFA IV Decision	2	43			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			



Table 6.5 DCTD - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.69	1.15			
Number With MDUFA IV Decision	101	52			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	74.18	55.88			
20th Percentile FDA Days to MDUFA IV Decision	56	29			
40th Percentile FDA Days to MDUFA IV Decision	85	54			
60th Percentile FDA Days to MDUFA IV Decision	88	60			
80th Percentile FDA Days to MDUFA IV Decision	90	87			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	78.05	13.65			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	24	0			
60th Percentile Industry Days to MDUFA IV Decision	111	0			
80th Percentile Industry Days to MDUFA IV Decision	174	0			
Maximum Industry Days to MDUFA IV Decision	231	179			
<b>Average Number of Total Days to MDUFA IV Decision</b>	152.23	69.54			
20th Percentile Total Days to MDUFA IV Decision	56	29			
40th Percentile Total Days to MDUFA IV Decision	110	54			
60th Percentile Total Days to MDUFA IV Decision	192	60			
80th Percentile Total Days to MDUFA IV Decision	258	89			
Maximum Total Days to MDUFA IV Decision	321	269			

**Table 6.6 DCTD - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	134	104			
Number With MDUFA IV Decision	101	52			
Number of SE Decision	95	49			
Number of NSE Decision	6	3			
Number of Withdrawal	21	1			
Number of Deleted	9	8			
Rate of SE Decision	94.06%	94.23%			
Rate of NSE Decision	5.94%	5.77%			
Rate of Withdrawal	15.67%	0.96%			
Rate of Deleted	6.72%	7.69%			

**Table 6.7 DCTD - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DCTD - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DCTD - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	134	104			
Non-MDUFA IV Decision	31	9			
MDUFA IV Decision (SE/NSE)	101	52			
MDUFA IV Decision Within 90 FDA Days	101	52			
510(k)s Pending MDUFA IV Decision	2	43			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DIHD - OIR - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	50	64			
Closed Before RTA Action	0	0			
Number Accepted	43	40			
Number Without a RTA and > 15 Days Since Date Received	0	2			
Number Without a RTA and <= 15 Days Since Date Received	0	2			
Number Not Accepted	7	20			
Rate of Submissions Not Accepted for Review	14.00%	32.26%			

**Table 6.2 DIHD - OIR - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	46	48			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	44	45			
SI Over 60 FDA Days	1	0			
SI Pending Within 60 FDA Days	0	3			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.78%	100%			

**Table 6.3 DIHD - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	45	45			
Average Number of FDA Days to Substantive Interaction	52.67	50.84			
20th Percentile FDA Days to Substantive Interaction	48	30			
40th Percentile FDA Days to Substantive Interaction	57	57			
60th Percentile FDA Days to Substantive Interaction	59	59			
80th Percentile FDA Days to Substantive Interaction	60	60			
Maximum FDA Days to Substantive Interaction	61	60			

**Table 6.4 DIHD - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	46	48			
Non-MDUFA IV Decision	3	2			
MDUFA IV Decision (SE/NSE)	43	28			
MDUFA IV Decision Within 90 FDA Days	42	28			
510(k)s Pending MDUFA IV Decision	0	18			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	97.67%	100%			

Table 6.5 DIHD - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.56	1.25			
Number With MDUFA IV Decision	43	28			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	76.81	64.36			
20th Percentile FDA Days to MDUFA IV Decision	71	29			
40th Percentile FDA Days to MDUFA IV Decision	88	57			
60th Percentile FDA Days to MDUFA IV Decision	89	89			
80th Percentile FDA Days to MDUFA IV Decision	90	90			
Maximum FDA Days to MDUFA IV Decision	93	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	69.02	32.36			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	84	0			
80th Percentile Industry Days to MDUFA IV Decision	169	84			
Maximum Industry Days to MDUFA IV Decision	202	180			
<b>Average Number of Total Days to MDUFA IV Decision</b>	145.84	96.71			
20th Percentile Total Days to MDUFA IV Decision	76	29			
40th Percentile Total Days to MDUFA IV Decision	90	67			
60th Percentile Total Days to MDUFA IV Decision	174	90			
80th Percentile Total Days to MDUFA IV Decision	256	172			
Maximum Total Days to MDUFA IV Decision	295	269			

**Table 6.6 DIHD - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	46	48			
Number With MDUFA IV Decision	43	28			
Number of SE Decision	39	28			
Number of NSE Decision	4	0			
Number of Withdrawal	2	1			
Number of Deleted	1	1			
Rate of SE Decision	90.70%	100%			
Rate of NSE Decision	9.30%	0%			
Rate of Withdrawal	4.35%	2.08%			
Rate of Deleted	2.17%	2.08%			

**Table 6.7 DIHD - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	93.00	0			
Mean Industry Days for Submissions that Missed the Goal	202.00	0			

**Table 6.8 DIHD - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DIHD - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	46	48			
Non-MDUFA IV Decision	3	2			
MDUFA IV Decision (SE/NSE)	43	28			
MDUFA IV Decision Within 90 FDA Days	42	28			
510(k)s Pending MDUFA IV Decision	0	18			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	97.67%	100%			



## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DMD - OIR - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	89	96			
Closed Before RTA Action	0	0			
Number Accepted	86	90			
Number Without a RTA and > 15 Days Since Date Received	0	1			
Number Without a RTA and <= 15 Days Since Date Received	0	2			
Number Not Accepted	3	3			
Rate of Submissions Not Accepted for Review	3.37%	3.19%			

**Table 6.2 DMD - OIR - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	87	94			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	87	84			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	10			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

**Table 6.3 DMD - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	87	84			
Average Number of FDA Days to Substantive Interaction	50.67	47.94			
20th Percentile FDA Days to Substantive Interaction	41	32			
40th Percentile FDA Days to Substantive Interaction	57	52			
60th Percentile FDA Days to Substantive Interaction	58	57			
80th Percentile FDA Days to Substantive Interaction	59	59			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 DMD - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	87	94			
Non-MDUFA IV Decision	4	2			
MDUFA IV Decision (SE/NSE)	83	70			
MDUFA IV Decision Within 90 FDA Days	83	70			
510(k)s Pending MDUFA IV Decision	0	22			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DMD - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.25	1.10			
Number With MDUFA IV Decision	83	70			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	70.00	63.40			
20th Percentile FDA Days to MDUFA IV Decision	42	35			
40th Percentile FDA Days to MDUFA IV Decision	81	57			
60th Percentile FDA Days to MDUFA IV Decision	87	81			
80th Percentile FDA Days to MDUFA IV Decision	89	87			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	27.66	4.76			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	69	0			
Maximum Industry Days to MDUFA IV Decision	181	88			
<b>Average Number of Total Days to MDUFA IV Decision</b>	97.66	68.16			
20th Percentile Total Days to MDUFA IV Decision	45	37			
40th Percentile Total Days to MDUFA IV Decision	84	59			
60th Percentile Total Days to MDUFA IV Decision	88	82			
80th Percentile Total Days to MDUFA IV Decision	150	87			
Maximum Total Days to MDUFA IV Decision	271	172			

**Table 6.6 DMD - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	87	94			
Number With MDUFA IV Decision	83	70			
Number of SE Decision	83	70			
Number of NSE Decision	0	0			
Number of Withdrawal	2	1			
Number of Deleted	2	1			
Rate of SE Decision	100%	100%			
Rate of NSE Decision	0%	0%			
Rate of Withdrawal	2.30%	1.06%			
Rate of Deleted	2.30%	1.06%			

**Table 6.7 DMD - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DMD - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	1	0			
MDUFA IV Decision Within 90 FDA Days	1	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	N/A			

**Table 6.9 DMD - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	86	94			
Non-MDUFA IV Decision	4	2			
MDUFA IV Decision (SE/NSE)	82	70			
MDUFA IV Decision Within 90 FDA Days	82	70			
510(k)s Pending MDUFA IV Decision	0	22			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DMGP - OIR - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	13			
Closed Before RTA Action	0	0			
Number Accepted	6	11			
Number Without a RTA and > 15 Days Since Date Received	0	0			
Number Without a RTA and <= 15 Days Since Date Received	0	0			
Number Not Accepted	2	2			
Rate of Submissions Not Accepted for Review	25.00%	15.38%			

**Table 6.2 DMGP - OIR - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	7	11			
Deleted or Withdrawn Prior to SI	0	1			
SI Within 60 FDA Days	7	9			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	0			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	1			
Current SI Performance Percent Within 60 FDA Days	100%	90.00%			

**Table 6.3 DMGP - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	7	9			
Average Number of FDA Days to Substantive Interaction	50.00	46.22			
20th Percentile FDA Days to Substantive Interaction	42	30			
40th Percentile FDA Days to Substantive Interaction	55	47			
60th Percentile FDA Days to Substantive Interaction	58	55			
80th Percentile FDA Days to Substantive Interaction	59	57			
Maximum FDA Days to Substantive Interaction	59	60			

**Table 6.4 DMGP - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	7	11			
Non-MDUFA IV Decision	2	1			
MDUFA IV Decision (SE/NSE)	5	7			
MDUFA IV Decision Within 90 FDA Days	5	7			
510(k)s Pending MDUFA IV Decision	0	3			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DMGP - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.80	1.29			
Number With MDUFA IV Decision	5	7			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	65.20	59.14			
20th Percentile FDA Days to MDUFA IV Decision	45	30			
40th Percentile FDA Days to MDUFA IV Decision	56	42			
60th Percentile FDA Days to MDUFA IV Decision	72	77			
80th Percentile FDA Days to MDUFA IV Decision	88	88			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	74.40	26.43			
20th Percentile Industry Days to MDUFA IV Decision	7	0			
40th Percentile Industry Days to MDUFA IV Decision	28	0			
60th Percentile Industry Days to MDUFA IV Decision	81	0			
80th Percentile Industry Days to MDUFA IV Decision	150	15			
Maximum Industry Days to MDUFA IV Decision	180	166			
<b>Average Number of Total Days to MDUFA IV Decision</b>	139.60	85.57			
20th Percentile Total Days to MDUFA IV Decision	65	30			
40th Percentile Total Days to MDUFA IV Decision	81	42			
60th Percentile Total Days to MDUFA IV Decision	145	78			
80th Percentile Total Days to MDUFA IV Decision	240	104			
Maximum Total Days to MDUFA IV Decision	268	254			



**Table 6.6 DMGP - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	7	11			
Number With MDUFA IV Decision	5	7			
Number of SE Decision	4	6			
Number of NSE Decision	1	1			
Number of Withdrawal	1	1			
Number of Deleted	1	0			
Rate of SE Decision	80.00%	85.71%			
Rate of NSE Decision	20.00%	14.29%			
Rate of Withdrawal	14.29%	9.09%			
Rate of Deleted	14.29%	0%			

**Table 6.7 DMGP - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DMGP - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	1	1			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DMGP - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	6	10			
Non-MDUFA IV Decision	1	1			
MDUFA IV Decision (SE/NSE)	5	7			
MDUFA IV Decision Within 90 FDA Days	5	7			
510(k)s Pending MDUFA IV Decision	0	2			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

## Section 6 510(k) Division Level Metric (Excludes Third Party Review)

**Table 6.1 DRH - OIR - CDRH - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	391	385			
Closed Before RTA Action	0	1			
Number Accepted	348	293			
Number Without a RTA and > 15 Days Since Date Received	1	3			
Number Without a RTA and <= 15 Days Since Date Received	0	16			
Number Not Accepted	42	72			
Rate of Submissions Not Accepted for Review	10.74%	19.57%			

**Table 6.2 DRH - OIR - CDRH - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	385	344			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	384	301			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	43			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

**Table 6.3 DRH - OIR - CDRH - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interactions	384	301			
Average Number of FDA Days to Substantive Interaction	43.70	43.93			
20th Percentile FDA Days to Substantive Interaction	29	28			
40th Percentile FDA Days to Substantive Interaction	42	45			
60th Percentile FDA Days to Substantive Interaction	52	53			
80th Percentile FDA Days to Substantive Interaction	57	57			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 DRH - OIR - CDRH - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	385	344			
Non-MDUFA IV Decision	14	15			
MDUFA IV Decision (SE/NSE)	371	235			
MDUFA IV Decision Within 90 FDA Days	371	235			
510(k)s Pending MDUFA IV Decision	0	94			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 DRH - OIR - CDRH - 510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.37			
Number With MDUFA IV Decision	371	235			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	58.72	54.71			
20th Percentile FDA Days to MDUFA IV Decision	30	28			
40th Percentile FDA Days to MDUFA IV Decision	55	49			
60th Percentile FDA Days to MDUFA IV Decision	73	65			
80th Percentile FDA Days to MDUFA IV Decision	84	84			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	33.09	25.09			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	19	0			
80th Percentile Industry Days to MDUFA IV Decision	56	46			
Maximum Industry Days to MDUFA IV Decision	181	181			
<b>Average Number of Total Days to MDUFA IV Decision</b>	91.81	79.79			
20th Percentile Total Days to MDUFA IV Decision	30	28			
40th Percentile Total Days to MDUFA IV Decision	58	49			
60th Percentile Total Days to MDUFA IV Decision	93	79			
80th Percentile Total Days to MDUFA IV Decision	138	122			
Maximum Total Days to MDUFA IV Decision	270	268			

**Table 6.6 DRH - OIR - CDRH - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	385	344			
Number With MDUFA IV Decision	371	235			
Number of SE Decision	360	233			
Number of NSE Decision	11	2			
Number of Withdrawal	7	4			
Number of Deleted	5	3			
Rate of SE Decision	97.04%	99.15%			
Rate of NSE Decision	2.96%	0.85%			
Rate of Withdrawal	1.82%	1.16%			
Rate of Deleted	1.30%	0.87%			

**Table 6.7 DRH - OIR - CDRH - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 DRH - OIR - CDRH - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 DRH - OIR - CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

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## Section 7 510(k) Annual General Metrics

**Table 7.1 CDRH - 510(k) Annual General Metrics - 510(k)s Received by Type**

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	3,338	3,107			
Number of Traditional Submissions	2,776	2,514			
Number of Special Submissions	419	462			
Number of Abbreviated Submissions	68	53			
Average Number of Days to Accept/Refuse to Accept	10.57	11.00			
Number of Third Party Submissions	75	78			

**Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal**

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	124 Days	120 Days	116 Days	112 Days	108 Days
Number Accepted	3,338	3,107			
Currently Under Review	45	1,232			
Number With Non-MDUFA IV Decision	338	148			
Number With MDUFA IV Decision	2,955	1,727			
Percent of Cohort Closed	98.50%	58.36%			
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	N/A	N/A			
Average Total Time to MDUFA IV Decision	N/A	N/A			

**Table 7.3 CDRH - 510(k) Third Party Performance**

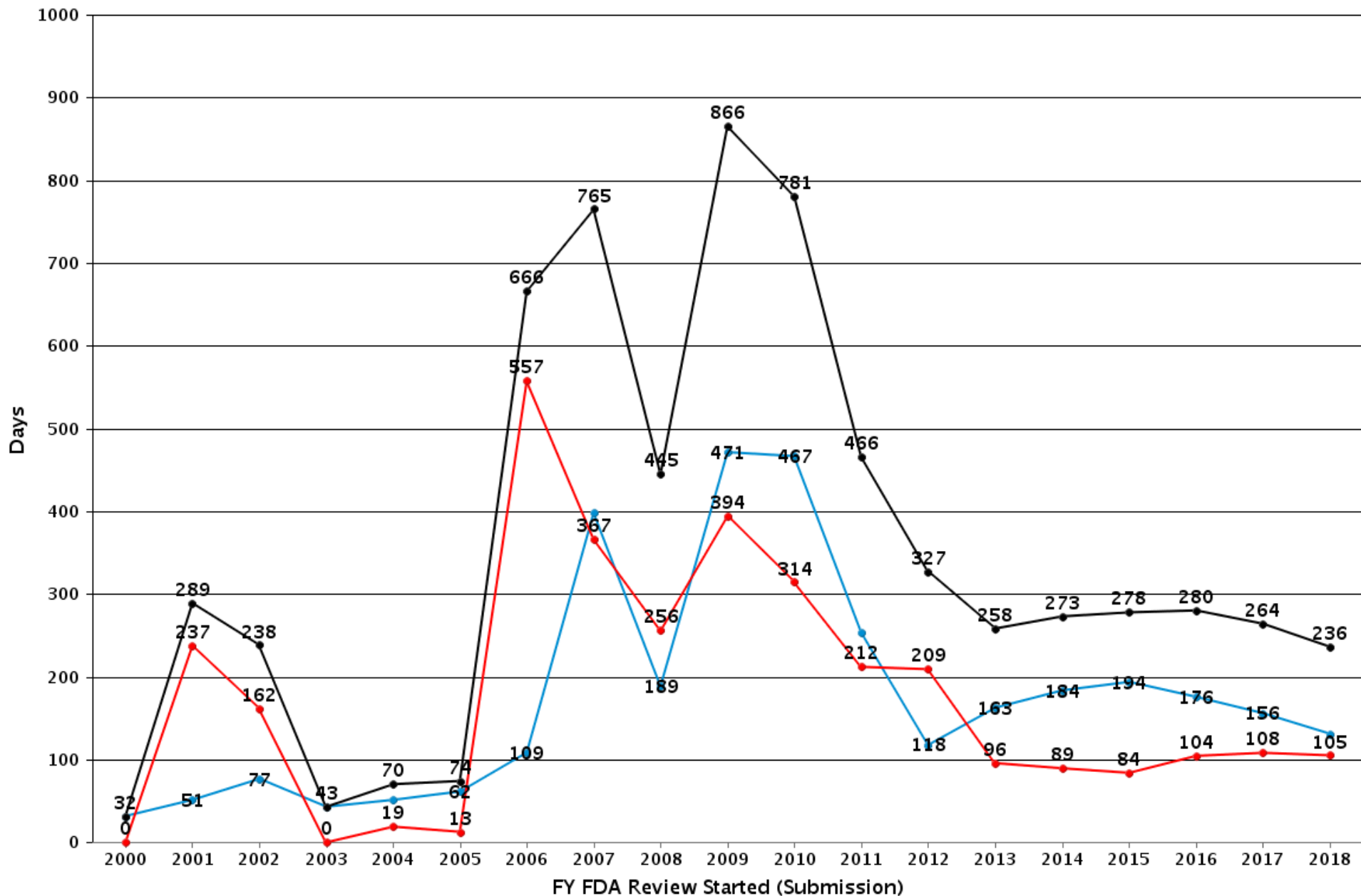
Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Third Party Submissions	75	78			
90th Percentile FDA Days to MDUFA IV Decision	55.40	30.60			

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# De Novos

## Q4FY19

# De Novo Average Days to MDUFA Decision as of: 9/30/19



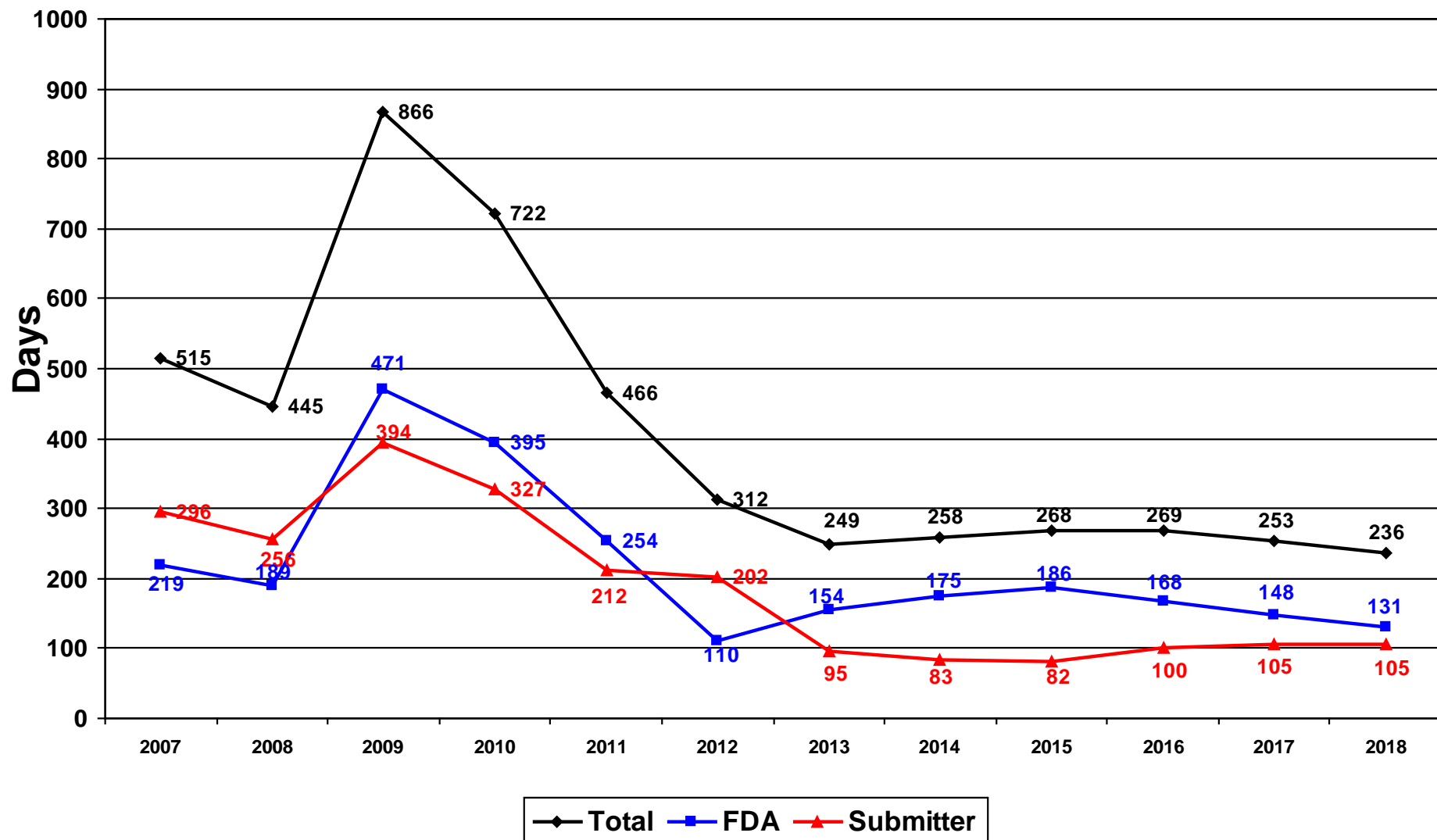
Cohorts not yet closed: 2018: 98.21%

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● Avg FDA Days to MDUFA ● Avg MFR Days to MDUFA ● Avg Total Days to MDUFA

# Average Time to MDUFA Decision: De Novos\*

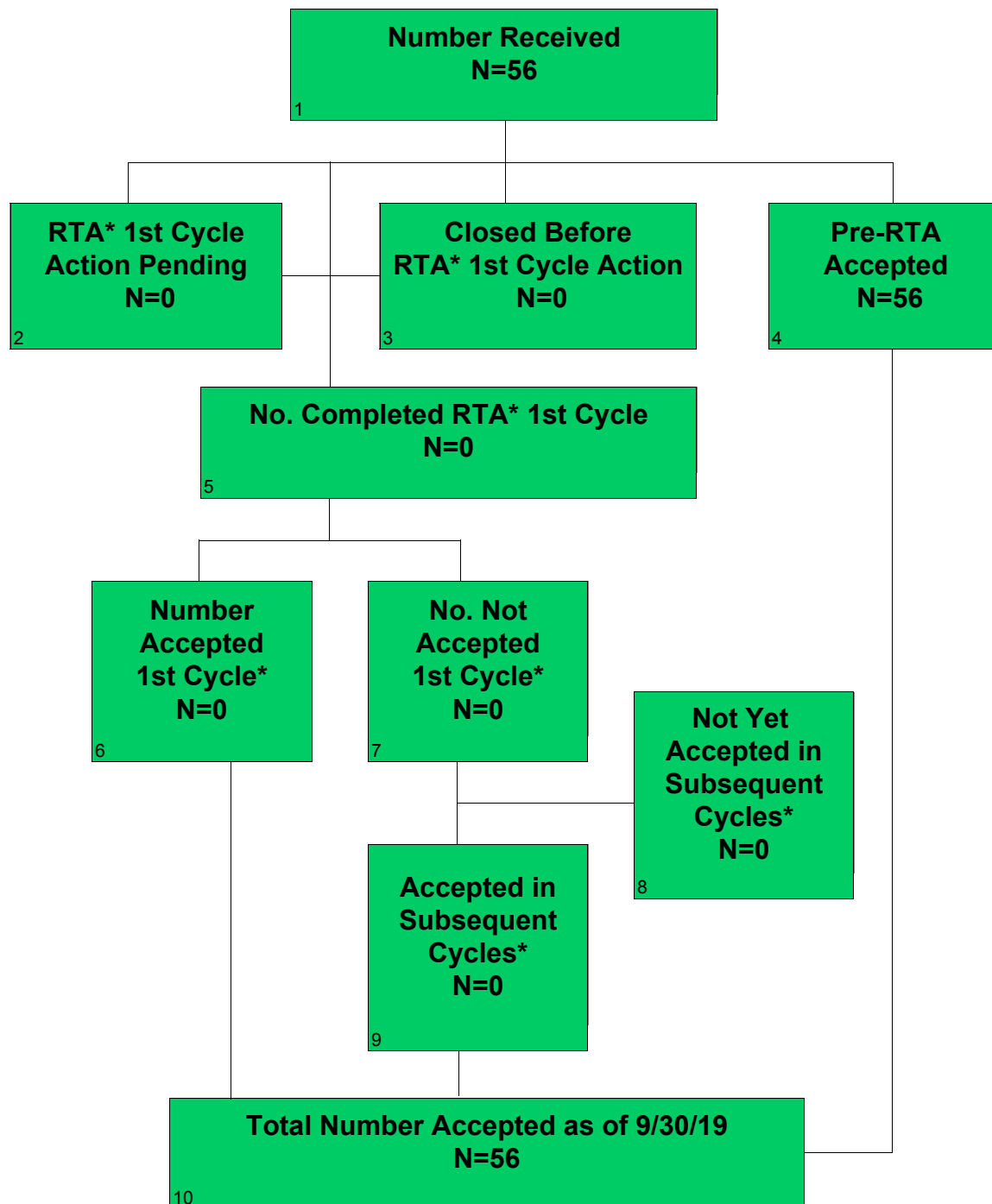
(98.2% closure comparison)



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# CDRH De Novo - FY 2018 as of 9/30/19

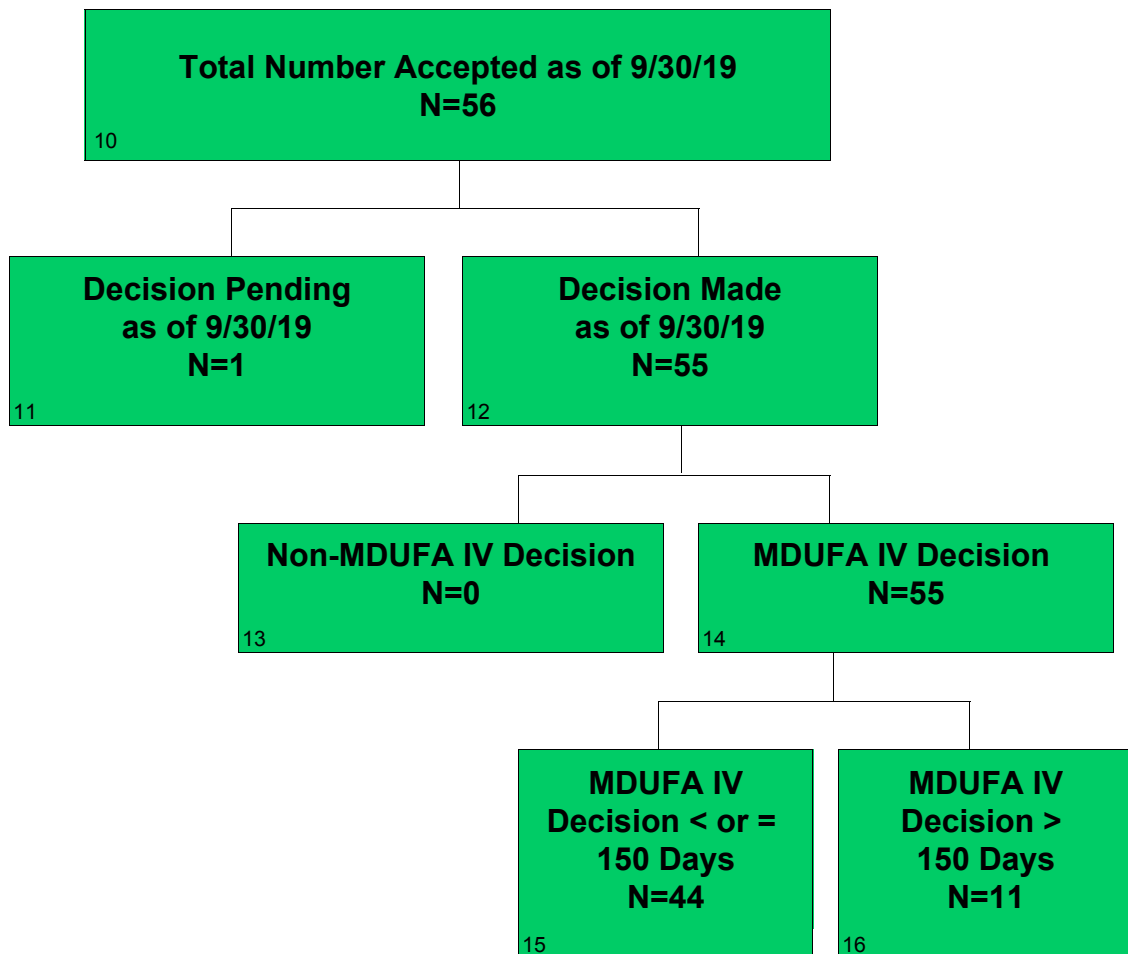
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\* RTA was implemented on TBD, thus RTA metrics include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

# CDRH De Novo - FY 2018 as of 9/30/19 Continued

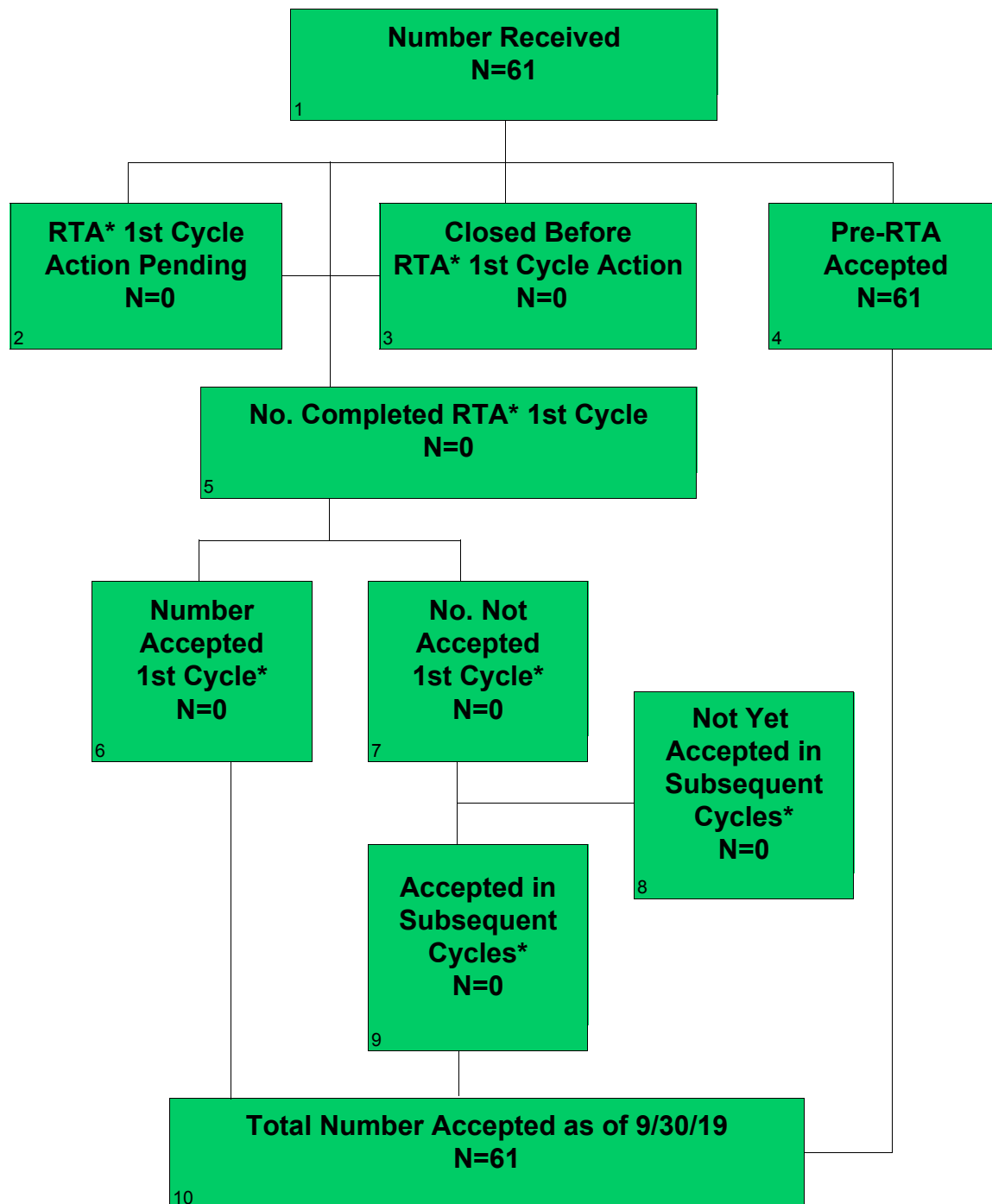
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# CDRH De Novo - FY 2019 as of 9/30/19

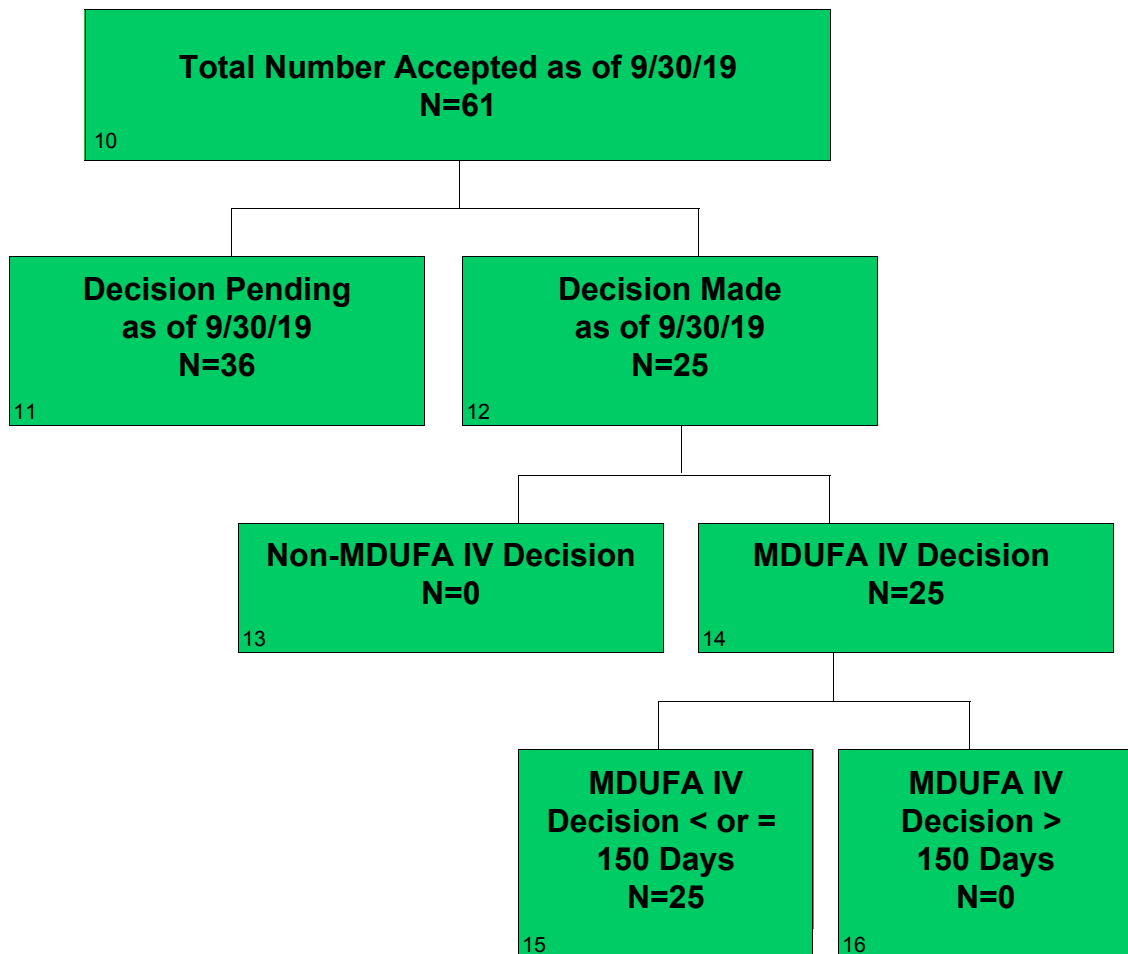
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\* RTA was implemented on TBD, thus RTA metrics include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

# CDRH De Novo - FY 2019 as of 9/30/19 Continued

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## Section 8 De Novo Center Level Metrics

**Table 8.1 CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	56	61			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	56	61			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	55	25			
MDUFA IV Decisions Within 150 FDA Days	44	25			
De Novos Pending MDUFA IV Decision	1	36			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	80.00%	100%			

**Table 8.3 CDRH - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.58	1.20			
Number With MDUFA IV Decision	55	25			
<b>Average FDA Days to MDUFA IV Decision</b>	131.15	101.28			
20th Percentile FDA Days to MDUFA IV Decision	82	66			
40th Percentile FDA Days to MDUFA IV Decision	146	86			
60th Percentile FDA Days to MDUFA IV Decision	150	128			
80th Percentile FDA Days to MDUFA IV Decision	150	148			
Maximum FDA Days to MDUFA IV Decision	254	150			
<b>Average Industry Days to MDUFA IV Decision</b>	105.05	18.52			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	77	0			
60th Percentile Industry Days to MDUFA IV Decision	165	0			
80th Percentile Industry Days to MDUFA IV Decision	179	9			
Maximum Industry Days to MDUFA IV Decision	217	153			
<b>Average Total Days to MDUFA IV Decision</b>	236.20	119.80			
20th Percentile Total Days to MDUFA IV Decision	143	66			
40th Percentile Total Days to MDUFA IV Decision	250	86			
60th Percentile Total Days to MDUFA IV Decision	292	128			
80th Percentile Total Days to MDUFA IV Decision	322	159			
Maximum Total Days to MDUFA IV Decision	400	303			

**Table 8.4 CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	56	61			
Number With MDUFA IV Decisions	55	25			
Number With Granted Decisions	25	5			
Number With Declined Decisions	15	10			
Number of Withdrawals	10	10			
Number Deleted	5	0			
Rate of Granted Decisions	45.45%	20.00%			
Rate of Declined Decisions	27.27%	40.00%			
Rate of Withdrawals	18.18%	40.00%			
Rate of Deleted	9.09%	0%			

**Table 8.5 CDRH - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	11	0			
Mean FDA Days for Submissions that Missed the Goal	192.45	0			
Mean Industry Days for Submissions that Missed the Goal	127.27	0			

**Table 8.6 CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	2			
MDUFA IV Decisions Within 150 FDA Days	1	2			
De Novos Pending MDUFA IV Decision	0	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.7 CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	15	5			
MDUFA IV Decisions Within 150 FDA Days	15	5			
De Novos Pending MDUFA IV Decision	0	9			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

## Section 8 - De Novo Office Level Metrics

**Table 8.1 ODE - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	39	41			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 ODE - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	39	41			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	38	18			
MDUFA IV Decisions Within 150 FDA Days	27	18			
De Novos Pending MDUFA IV Decision	1	23			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	71.05%	100%			

**Table 8.3 ODE - CDRH - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.63	1.28			
Number With MDUFA IV Decision	38	18			
<b>Average FDA Days to MDUFA IV Decision</b>	133.82	111.11			
20th Percentile FDA Days to MDUFA IV Decision	79	75			
40th Percentile FDA Days to MDUFA IV Decision	148	98			
60th Percentile FDA Days to MDUFA IV Decision	150	132			
80th Percentile FDA Days to MDUFA IV Decision	160	148			
Maximum FDA Days to MDUFA IV Decision	254	150			
<b>Average Industry Days to MDUFA IV Decision</b>	106.47	25.72			
20th Percentile Industry Days to MDUFA IV Decision	6	0			
40th Percentile Industry Days to MDUFA IV Decision	82	0			
60th Percentile Industry Days to MDUFA IV Decision	164	0			
80th Percentile Industry Days to MDUFA IV Decision	179	62			
Maximum Industry Days to MDUFA IV Decision	217	153			
<b>Average Total Days to MDUFA IV Decision</b>	240.29	136.83			
20th Percentile Total Days to MDUFA IV Decision	154	75			
40th Percentile Total Days to MDUFA IV Decision	254	98			
60th Percentile Total Days to MDUFA IV Decision	296	132			
80th Percentile Total Days to MDUFA IV Decision	323	211			
Maximum Total Days to MDUFA IV Decision	400	303			

**Table 8.4 ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	39	41			
Number With MDUFA IV Decisions	38	18			
Number With Granted Decisions	15	3			
Number With Declined Decisions	14	10			
Number of Withdrawals	5	5			
Number Deleted	4	0			
Rate of Granted Decisions	39.47%	16.67%			
Rate of Declined Decisions	36.84%	55.56%			
Rate of Withdrawals	13.16%	27.78%			
Rate of Deleted	10.53%	0%			

**Table 8.5 ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	11	0			
Mean FDA Days for Submissions That Missed the Goal	192.45	0			
Mean Industry Days for Submissions That Missed the Goal	127.27	0			

**Table 8.6 ODE - CDRH - LDT De Novo MDUFA IV Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 ODE - CDRH - Conventional IV (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			



## Section 8 - De Novo Office Level Metrics

Table 8.1 OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	20			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	17	20			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	17	7			
MDUFA IV Decisions Within 150 FDA Days	17	7			
De Novos Pending MDUFA IV Decision	0	13			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 OIR - CDRH - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.47	1.00			
Number With MDUFA IV Decision	17	7			
<b>Average FDA Days to MDUFA IV Decision</b>	125.18	76.00			
20th Percentile FDA Days to MDUFA IV Decision	108	21			
40th Percentile FDA Days to MDUFA IV Decision	127	43			
60th Percentile FDA Days to MDUFA IV Decision	146	90			
80th Percentile FDA Days to MDUFA IV Decision	150	140			
Maximum FDA Days to MDUFA IV Decision	150	150			
<b>Average Industry Days to MDUFA IV Decision</b>	101.88	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	84	0			
60th Percentile Industry Days to MDUFA IV Decision	169	0			
80th Percentile Industry Days to MDUFA IV Decision	179	0			
Maximum Industry Days to MDUFA IV Decision	189	0			
<b>Average Total Days to MDUFA IV Decision</b>	227.06	76.00			
20th Percentile Total Days to MDUFA IV Decision	137	21			
40th Percentile Total Days to MDUFA IV Decision	183	43			
60th Percentile Total Days to MDUFA IV Decision	277	90			
80th Percentile Total Days to MDUFA IV Decision	313	140			
Maximum Total Days to MDUFA IV Decision	327	150			

**Table 8.4 OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	17	20			
Number With MDUFA IV Decisions	17	7			
Number With Granted Decisions	10	2			
Number With Declined Decisions	1	0			
Number of Withdrawals	5	5			
Number Deleted	1	0			
Rate of Granted Decisions	58.82%	28.57%			
Rate of Declined Decisions	5.88%	0%			
Rate of Withdrawals	29.41%	71.43%			
Rate of Deleted	5.88%	0%			

**Table 8.5 OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	0	0			
Mean Industry Days for Submissions That Missed the Goal	0	0			

**Table 8.6 OIR - CDRH - LDT De Novo MDUFA IV Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	2			
MDUFA IV Decisions Within 150 FDA Days	1	2			
De Novos Pending MDUFA IV Decision	0	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.7 OIR - CDRH - Conventional IV (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	15	5			
MDUFA IV Decisions Within 150 FDA Days	15	5			
De Novos Pending MDUFA IV Decision	0	9			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DAGRID - ODE - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	4			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DAGRID - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	3	4			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	4			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	33.33%	N/A			

**Table 8.3 DAGRID - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	2.00	0			
Number with MDUFA IV Decision	3	0			
<b>Average FDA Days to MDUFA IV Decision</b>	169.33	0			
20th Percentile FDA Days to MDUFA IV Decision	156	0			
40th Percentile FDA Days to MDUFA IV Decision	161	0			
60th Percentile FDA Days to MDUFA IV Decision	170	0			
80th Percentile FDA Days to MDUFA IV Decision	182	0			
Maximum FDA Days to MDUFA IV Decision	194	0			
<b>Average Industry Days to MDUFA IV Decision</b>	83.67	0			
20th Percentile Industry Days to MDUFA IV Decision	34	0			
40th Percentile Industry Days to MDUFA IV Decision	45	0			
60th Percentile Industry Days to MDUFA IV Decision	76	0			
80th Percentile Industry Days to MDUFA IV Decision	127	0			
Maximum Industry Days to MDUFA IV Decision	177	0			
<b>Average Total Days to MDUFA IV Decision</b>	253.00	0			
20th Percentile Total Days to MDUFA IV Decision	202	0			
40th Percentile Total Days to MDUFA IV Decision	231	0			
60th Percentile Total Days to MDUFA IV Decision	264	0			
80th Percentile Total Days to MDUFA IV Decision	303	0			
Maximum Total Days to MDUFA IV Decision	341	0			

**Table 8.4 DAGRID - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	3	4			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	2	0			
Number with Declined Decisions	1	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	66.67%	N/A			
Rate of Declined Decisions	33.33%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	N/A			

**Table 8.5 DAGRID - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Perform:**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	0			
Mean FDA Days for Submissions that Missed the Goal	179.00	0			
Mean Industry Days for Submissions that Missed the Goal	114.00	0			

**Table 8.6 DAGRID - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DAGRID - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Me**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DCD - ODE - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	9			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DCD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	9			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	5	6			
MDUFA IV Decisions Within 150 FDA Days	5	6			
De Novos Pending MDUFA IV Decision	0	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 DCD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.20	1.33			
Number with MDUFA IV Decision	5	6			
<b>Average FDA Days to MDUFA IV Decision</b>	74.00	123.17			
20th Percentile FDA Days to MDUFA IV Decision	32	99			
40th Percentile FDA Days to MDUFA IV Decision	58	129			
60th Percentile FDA Days to MDUFA IV Decision	79	146			
80th Percentile FDA Days to MDUFA IV Decision	98	148			
Maximum FDA Days to MDUFA IV Decision	148	150			
<b>Average Industry Days to MDUFA IV Decision</b>	112.40	37.67			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	98	0			
60th Percentile Industry Days to MDUFA IV Decision	171	0			
80th Percentile Industry Days to MDUFA IV Decision	188	73			
Maximum Industry Days to MDUFA IV Decision	217	153			
<b>Average Total Days to MDUFA IV Decision</b>	186.40	160.83			
20th Percentile Total Days to MDUFA IV Decision	32	99			
40th Percentile Total Days to MDUFA IV Decision	173	129			
60th Percentile Total Days to MDUFA IV Decision	277	146			
80th Percentile Total Days to MDUFA IV Decision	296	221			
Maximum Total Days to MDUFA IV Decision	312	303			



**Table 8.4 DCD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	9			
Number with MDUFA IV Decision	5	6			
Number with Granted Decisions	3	0			
Number with Declined Decisions	0	5			
Number of Withdrawals	0	1			
Number Deleted	2	0			
Rate of Granted Decisions	60.00%	0%			
Rate of Declined Decisions	0%	83.33%			
Rate of Withdrawals	0%	16.67%			
Rate of Deleted	40.00%	0%			

**Table 8.5 DCD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DCD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DCD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DNPMD - ODE - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	6			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DNPMD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	13	6			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	13	5			
MDUFA IV Decisions Within 150 FDA Days	9	5			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	69.23%	100%			

**Table 8.3 DNPMD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.77	1.40			
Number with MDUFA IV Decision	13	5			
<b>Average FDA Days to MDUFA IV Decision</b>	153.00	108.80			
20th Percentile FDA Days to MDUFA IV Decision	104	69			
40th Percentile FDA Days to MDUFA IV Decision	148	107			
60th Percentile FDA Days to MDUFA IV Decision	150	136			
80th Percentile FDA Days to MDUFA IV Decision	219	149			
Maximum FDA Days to MDUFA IV Decision	254	150			
<b>Average Industry Days to MDUFA IV Decision</b>	106.08	24.20			
20th Percentile Industry Days to MDUFA IV Decision	39	0			
40th Percentile Industry Days to MDUFA IV Decision	82	0			
60th Percentile Industry Days to MDUFA IV Decision	164	18			
80th Percentile Industry Days to MDUFA IV Decision	174	51			
Maximum Industry Days to MDUFA IV Decision	183	76			
<b>Average Total Days to MDUFA IV Decision</b>	259.08	133.00			
20th Percentile Total Days to MDUFA IV Decision	226	69			
40th Percentile Total Days to MDUFA IV Decision	266	107			
60th Percentile Total Days to MDUFA IV Decision	316	154			
80th Percentile Total Days to MDUFA IV Decision	323	201			
Maximum Total Days to MDUFA IV Decision	371	225			

**Table 8.4 DNPMD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	13	6			
Number with MDUFA IV Decision	13	5			
Number with Granted Decisions	3	2			
Number with Declined Decisions	7	0			
Number of Withdrawals	3	3			
Number Deleted	0	0			
Rate of Granted Decisions	23.08%	40.00%			
Rate of Declined Decisions	53.85%	0%			
Rate of Withdrawals	23.08%	60.00%			
Rate of Deleted	0%	0%			

**Table 8.5 DNPMD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	4	0			
Mean FDA Days for Submissions that Missed the Goal	229.25	0			
Mean Industry Days for Submissions that Missed the Goal	82.75	0			

**Table 8.6 DNPMD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DNPMD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Met**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DOD - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	4			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DOD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	4			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	2			
MDUFA IV Decisions Within 150 FDA Days	3	2			
De Novos Pending MDUFA IV Decision	0	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	75.00%	100%			

**Table 8.3 DOD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.50	1.50			
Number with MDUFA IV Decision	4	2			
<b>Average FDA Days to MDUFA IV Decision</b>	133.25	109.00			
20th Percentile FDA Days to MDUFA IV Decision	122	89			
40th Percentile FDA Days to MDUFA IV Decision	148	102			
60th Percentile FDA Days to MDUFA IV Decision	150	116			
80th Percentile FDA Days to MDUFA IV Decision	150	129			
Maximum FDA Days to MDUFA IV Decision	151	143			
<b>Average Industry Days to MDUFA IV Decision</b>	161.00	58.00			
20th Percentile Industry Days to MDUFA IV Decision	149	23			
40th Percentile Industry Days to MDUFA IV Decision	179	46			
60th Percentile Industry Days to MDUFA IV Decision	180	70			
80th Percentile Industry Days to MDUFA IV Decision	180	93			
Maximum Industry Days to MDUFA IV Decision	181	116			
<b>Average Total Days to MDUFA IV Decision</b>	294.25	167.00			
20th Percentile Total Days to MDUFA IV Decision	260	112			
40th Percentile Total Days to MDUFA IV Decision	278	149			
60th Percentile Total Days to MDUFA IV Decision	316	185			
80th Percentile Total Days to MDUFA IV Decision	330	222			
Maximum Total Days to MDUFA IV Decision	331	259			

**Table 8.4 DOD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	4			
Number with MDUFA IV Decision	4	2			
Number with Granted Decisions	1	0			
Number with Declined Decisions	1	2			
Number of Withdrawals	1	0			
Number Deleted	1	0			
Rate of Granted Decisions	25.00%	0%			
Rate of Declined Decisions	25.00%	100%			
Rate of Withdrawals	25.00%	0%			
Rate of Deleted	25.00%	0%			

**Table 8.5 DOD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	151.00	0			
Mean Industry Days for Submissions that Missed the Goal	180.00	0			

**Table 8.6 DOD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DOD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DOED - ODE - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	2			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DOED - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	0			
MDUFA IV Decisions Within 150 FDA Days	3	0			
De Novos Pending MDUFA IV Decision	1	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	75.00%	N/A			



**Table 8.3 DOED - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.50	0			
Number with MDUFA IV Decision	4	0			
<b>Average FDA Days to MDUFA IV Decision</b>	137.00	0			
20th Percentile FDA Days to MDUFA IV Decision	122	0			
40th Percentile FDA Days to MDUFA IV Decision	148	0			
60th Percentile FDA Days to MDUFA IV Decision	149	0			
80th Percentile FDA Days to MDUFA IV Decision	156	0			
Maximum FDA Days to MDUFA IV Decision	166	0			
<b>Average Industry Days to MDUFA IV Decision</b>	52.25	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	11	0			
60th Percentile Industry Days to MDUFA IV Decision	45	0			
80th Percentile Industry Days to MDUFA IV Decision	95	0			
Maximum Industry Days to MDUFA IV Decision	153	0			
<b>Average Total Days to MDUFA IV Decision</b>	189.25	0			
20th Percentile Total Days to MDUFA IV Decision	122	0			
40th Percentile Total Days to MDUFA IV Decision	159	0			
60th Percentile Total Days to MDUFA IV Decision	194	0			
80th Percentile Total Days to MDUFA IV Decision	251	0			
Maximum Total Days to MDUFA IV Decision	319	0			

**Table 8.4 DOED - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	2			
Number with MDUFA IV Decision	4	0			
Number with Granted Decisions	3	0			
Number with Declined Decisions	1	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	75.00%	N/A			
Rate of Declined Decisions	25.00%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	N/A			

**Table 8.5 DOED - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performan**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	166.00	0			
Mean Industry Days for Submissions that Missed the Goal	153.00	0			

**Table 8.6 DOED - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DOED - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metri**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DRGUD - ODE - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	10			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DRGUD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	4	10			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	2			
MDUFA IV Decisions Within 150 FDA Days	3	2			
De Novos Pending MDUFA IV Decision	0	8			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	75.00%	100%			

**Table 8.3 DRGUD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.50	1.00			
Number with MDUFA IV Decision	4	2			
<b>Average FDA Days to MDUFA IV Decision</b>	100.00	111.50			
20th Percentile FDA Days to MDUFA IV Decision	57	90			
40th Percentile FDA Days to MDUFA IV Decision	97	104			
60th Percentile FDA Days to MDUFA IV Decision	135	119			
80th Percentile FDA Days to MDUFA IV Decision	149	133			
Maximum FDA Days to MDUFA IV Decision	151	148			
<b>Average Industry Days to MDUFA IV Decision</b>	136.75	0			
20th Percentile Industry Days to MDUFA IV Decision	100	0			
40th Percentile Industry Days to MDUFA IV Decision	169	0			
60th Percentile Industry Days to MDUFA IV Decision	175	0			
80th Percentile Industry Days to MDUFA IV Decision	187	0			
Maximum Industry Days to MDUFA IV Decision	203	0			
<b>Average Total Days to MDUFA IV Decision</b>	236.75	111.5			
20th Percentile Total Days to MDUFA IV Decision	179	90			
40th Percentile Total Days to MDUFA IV Decision	293	104			
60th Percentile Total Days to MDUFA IV Decision	312	119			
80th Percentile Total Days to MDUFA IV Decision	321	133			
Maximum Total Days to MDUFA IV Decision	325	148			

**Table 8.4 DRGUD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	10			
Number with MDUFA IV Decision	4	2			
Number with Granted Decisions	0	1			
Number with Declined Decisions	3	1			
Number of Withdrawals	0	0			
Number Deleted	1	0			
Rate of Granted Decisions	0%	50.00%			
Rate of Declined Decisions	75.00%	50.00%			
Rate of Withdrawals	0%	0%			
Rate of Deleted	25.00%	0%			

**Table 8.5 DRGUD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	151.00	0			
Mean Industry Days for Submissions that Missed the Goal	167.00	0			

**Table 8.6 DRGUD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DRGUD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Met**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DSD - ODE - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	6			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DSD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	6			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	5	3			
MDUFA IV Decisions Within 150 FDA Days	3	3			
De Novos Pending MDUFA IV Decision	0	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	60.00%	100%			

**Table 8.3 DSD - ODE - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.80	1.00			
Number with MDUFA IV Decision	5	3			
<b>Average FDA Days to MDUFA IV Decision</b>	147.40	92.00			
20th Percentile FDA Days to MDUFA IV Decision	133	83			
40th Percentile FDA Days to MDUFA IV Decision	150	90			
60th Percentile FDA Days to MDUFA IV Decision	151	96			
80th Percentile FDA Days to MDUFA IV Decision	167	101			
Maximum FDA Days to MDUFA IV Decision	221	107			
<b>Average Industry Days to MDUFA IV Decision</b>	90.80	0			
20th Percentile Industry Days to MDUFA IV Decision	12	0			
40th Percentile Industry Days to MDUFA IV Decision	65	0			
60th Percentile Industry Days to MDUFA IV Decision	124	0			
80th Percentile Industry Days to MDUFA IV Decision	165	0			
Maximum Industry Days to MDUFA IV Decision	179	0			
<b>Average Total Days to MDUFA IV Decision</b>	238.20	92.00			
20th Percentile Total Days to MDUFA IV Decision	145	83			
40th Percentile Total Days to MDUFA IV Decision	215	90			
60th Percentile Total Days to MDUFA IV Decision	275	96			
80th Percentile Total Days to MDUFA IV Decision	332	101			
Maximum Total Days to MDUFA IV Decision	400	107			

**Table 8.4 DSD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	6			
Number with MDUFA IV Decision	5	3			
Number with Granted Decisions	3	0			
Number with Declined Decisions	1	2			
Number of Withdrawals	1	1			
Number Deleted	0	0			
Rate of Granted Decisions	60.00%	0%			
Rate of Declined Decisions	20.00%	66.67%			
Rate of Withdrawals	20.00%	33.33%			
Rate of Deleted	0%	0%			

**Table 8.5 DSD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	0			
Mean FDA Days for Submissions that Missed the Goal	187.00	0			
Mean Industry Days for Submissions that Missed the Goal	170.50	0			

**Table 8.6 DSD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DSD - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			



## Section 8 - De Novo Division Level Metrics

**Table 8.1 DCTD - OIR - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	7	8			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DCTD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	7	8			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	7	3			
MDUFA IV Decisions Within 150 FDA Days	7	3			
De Novos Pending MDUFA IV Decision	0	5			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 DCTD - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.57	1.00			
Number with MDUFA IV Decision	7	3			
<b>Average FDA Days to MDUFA IV Decision</b>	136.86	107.33			
20th Percentile FDA Days to MDUFA IV Decision	124	82			
40th Percentile FDA Days to MDUFA IV Decision	138	99			
60th Percentile FDA Days to MDUFA IV Decision	148	116			
80th Percentile FDA Days to MDUFA IV Decision	150	133			
Maximum FDA Days to MDUFA IV Decision	150	150			
<b>Average Industry Days to MDUFA IV Decision</b>	87.57	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	48	0			
60th Percentile Industry Days to MDUFA IV Decision	127	0			
80th Percentile Industry Days to MDUFA IV Decision	170	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
<b>Average Total Days to MDUFA IV Decision</b>	224.43	107.33			
20th Percentile Total Days to MDUFA IV Decision	147	82			
40th Percentile Total Days to MDUFA IV Decision	197	99			
60th Percentile Total Days to MDUFA IV Decision	277	116			
80th Percentile Total Days to MDUFA IV Decision	299	133			
Maximum Total Days to MDUFA IV Decision	312	150			

**Table 8.4 DCTD - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	7	8			
Number with MDUFA IV Decision	7	3			
Number with Granted Decisions	5	1			
Number with Declined Decisions	0	0			
Number of Withdrawals	2	2			
Number Deleted	0	0			
Rate of Granted Decisions	71.43%	33.33%			
Rate of Declined Decisions	0%	0%			
Rate of Withdrawals	28.57%	66.67%			
Rate of Deleted	0%	0%			

**Table 8.5 DCTD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DCTD - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DCTD - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metric**

Performance Metric			FY 2020	FY 2021	FY 2022
De Novos Accepted	7	8			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	7	3			
MDUFA IV Decisions Within 150 FDA Days	7	3			
De Novos Pending MDUFA IV Decision	0	5			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DIHD - OIR - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DIHD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	3	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	1			
MDUFA IV Decisions Within 150 FDA Days	3	1			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 DIHD - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.67	1.00			
Number with MDUFA IV Decision	3	1			
<b>Average FDA Days to MDUFA IV Decision</b>	119	29			
20th Percentile FDA Days to MDUFA IV Decision	98	29			
40th Percentile FDA Days to MDUFA IV Decision	121	29			
60th Percentile FDA Days to MDUFA IV Decision	136	29			
80th Percentile FDA Days to MDUFA IV Decision	143	29			
Maximum FDA Days to MDUFA IV Decision	150	29			
<b>Average Industry Days to MDUFA IV Decision</b>	172.67	0			
20th Percentile Industry Days to MDUFA IV Decision	167	0			
40th Percentile Industry Days to MDUFA IV Decision	173	0			
60th Percentile Industry Days to MDUFA IV Decision	177	0			
80th Percentile Industry Days to MDUFA IV Decision	179	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
<b>Average Total Days to MDUFA IV Decision</b>	291.67	29.00			
20th Percentile Total Days to MDUFA IV Decision	267	29			
40th Percentile Total Days to MDUFA IV Decision	298	29			
60th Percentile Total Days to MDUFA IV Decision	316	29			
80th Percentile Total Days to MDUFA IV Decision	321	29			
Maximum Total Days to MDUFA IV Decision	326	29			

**Table 8.4 DIHD - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	3	2			
Number with MDUFA IV Decision	3	1			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	2	1			
Number Deleted	0	0			
Rate of Granted Decisions	33.33%	0%			
Rate of Declined Decisions	0%	0%			
Rate of Withdrawals	66.67%	100%			
Rate of Deleted	0%	0%			

**Table 8.5 DIHD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DIHD - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	1			
MDUFA IV Decisions Within 150 FDA Days	0	1			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	100%			

**Table 8.7 DIHD - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	3	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	3	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

## Section 8 - De Novo Division Level Metrics

Table 8.1 DMD - OIR - CDRH - De Novo Acceptance Review Decision\*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	4			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 DMD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	4			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	5	1			
MDUFA IV Decisions Within 150 FDA Days	5	1			
De Novos Pending MDUFA IV Decision	0	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 DMD - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.40	1.00			
Number with MDUFA IV Decision	5	1			
<b>Average FDA Days to MDUFA IV Decision</b>	128.60	148.00			
20th Percentile FDA Days to MDUFA IV Decision	113	148			
40th Percentile FDA Days to MDUFA IV Decision	136	148			
60th Percentile FDA Days to MDUFA IV Decision	147	148			
80th Percentile FDA Days to MDUFA IV Decision	150	148			
Maximum FDA Days to MDUFA IV Decision	150	148			
<b>Average Industry Days to MDUFA IV Decision</b>	82.40	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	36	0			
60th Percentile Industry Days to MDUFA IV Decision	106	0			
80th Percentile Industry Days to MDUFA IV Decision	175	0			
Maximum Industry Days to MDUFA IV Decision	177	0			
<b>Average Total Days to MDUFA IV Decision</b>	211.00	148.00			
20th Percentile Total Days to MDUFA IV Decision	133	148			
40th Percentile Total Days to MDUFA IV Decision	141	148			
60th Percentile Total Days to MDUFA IV Decision	217	148			
80th Percentile Total Days to MDUFA IV Decision	325	148			
Maximum Total Days to MDUFA IV Decision	327	148			



**Table 8.4 DMD - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	4			
Number with MDUFA IV Decision	5	1			
Number with Granted Decisions	3	1			
Number with Declined Decisions	1	0			
Number of Withdrawals	1	0			
Number Deleted	0	0			
Rate of Granted Decisions	60.00%	100%			
Rate of Declined Decisions	20.00%	0%			
Rate of Withdrawals	20.00%	0%			
Rate of Deleted	0%	0%			

**Table 8.5 DMD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DMD - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 DMD - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	3			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	5	1			
MDUFA IV Decisions Within 150 FDA Days	5	1			
De Novos Pending MDUFA IV Decision	0	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DMGP - OIR - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	5			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DMGP - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	1	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	2			
MDUFA IV Decisions Within 150 FDA Days	1	2			
De Novos Pending MDUFA IV Decision	0	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.3 DMGP - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.00	1.00			
Number with MDUFA IV Decision	1	2			
<b>Average FDA Days to MDUFA IV Decision</b>	62.00	16.50			
20th Percentile FDA Days to MDUFA IV Decision	62	15			
40th Percentile FDA Days to MDUFA IV Decision	62	16			
60th Percentile FDA Days to MDUFA IV Decision	62	17			
80th Percentile FDA Days to MDUFA IV Decision	62	18			
Maximum FDA Days to MDUFA IV Decision	62	19			
<b>Average Industry Days to MDUFA IV Decision</b>	189.00	0			
20th Percentile Industry Days to MDUFA IV Decision	189	0			
40th Percentile Industry Days to MDUFA IV Decision	189	0			
60th Percentile Industry Days to MDUFA IV Decision	189	0			
80th Percentile Industry Days to MDUFA IV Decision	189	0			
Maximum Industry Days to MDUFA IV Decision	189	0			
<b>Average Total Days to MDUFA IV Decision</b>	251.00	16.50			
20th Percentile Total Days to MDUFA IV Decision	251	15			
40th Percentile Total Days to MDUFA IV Decision	251	16			
60th Percentile Total Days to MDUFA IV Decision	251	17			
80th Percentile Total Days to MDUFA IV Decision	251	18			
Maximum Total Days to MDUFA IV Decision	251	19			

**Table 8.4 DMGP - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5			
Number with MDUFA IV Decision	1	2			
Number with Granted Decisions	0	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	2			
Number Deleted	1	0			
Rate of Granted Decisions	0%	0%			
Rate of Declined Decisions	0%	0%			
Rate of Withdrawals	0%	100%			
Rate of Deleted	100%	0%			

**Table 8.5 DMGP - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DMGP - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	1			
MDUFA IV Decisions Within 150 FDA Days	1	1			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	100%			

**Table 8.7 DMGP - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	3			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	1			
MDUFA IV Decisions Within 150 FDA Days	0	1			
De Novos Pending MDUFA IV Decision	0	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	100%			

## Section 8 - De Novo Division Level Metrics

**Table 8.1 DRH - OIR - CDRH - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	1			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA was implemented on TBD, thus RTA metrics in table 8.1 include only De Novos received on or after TBD. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 DRH - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	1	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

**Table 8.3 DRH - OIR - CDRH - De Novo Time to MDUFA IV Decisions**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.00	0			
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	108.00	0			
20th Percentile FDA Days to MDUFA IV Decision	108	0			
40th Percentile FDA Days to MDUFA IV Decision	108	0			
60th Percentile FDA Days to MDUFA IV Decision	108	0			
80th Percentile FDA Days to MDUFA IV Decision	108	0			
Maximum FDA Days to MDUFA IV Decision	108	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0	0			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	108.00	0			
20th Percentile Total Days to MDUFA IV Decision	108	0			
40th Percentile Total Days to MDUFA IV Decision	108	0			
60th Percentile Total Days to MDUFA IV Decision	108	0			
80th Percentile Total Days to MDUFA IV Decision	108	0			
Maximum Total Days to MDUFA IV Decision	108	0			

**Table 8.4 DRH - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	1			
Number with MDUFA IV Decision	1	0			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	100%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	N/A			

**Table 8.5 DRH - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 8.6 DRH - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

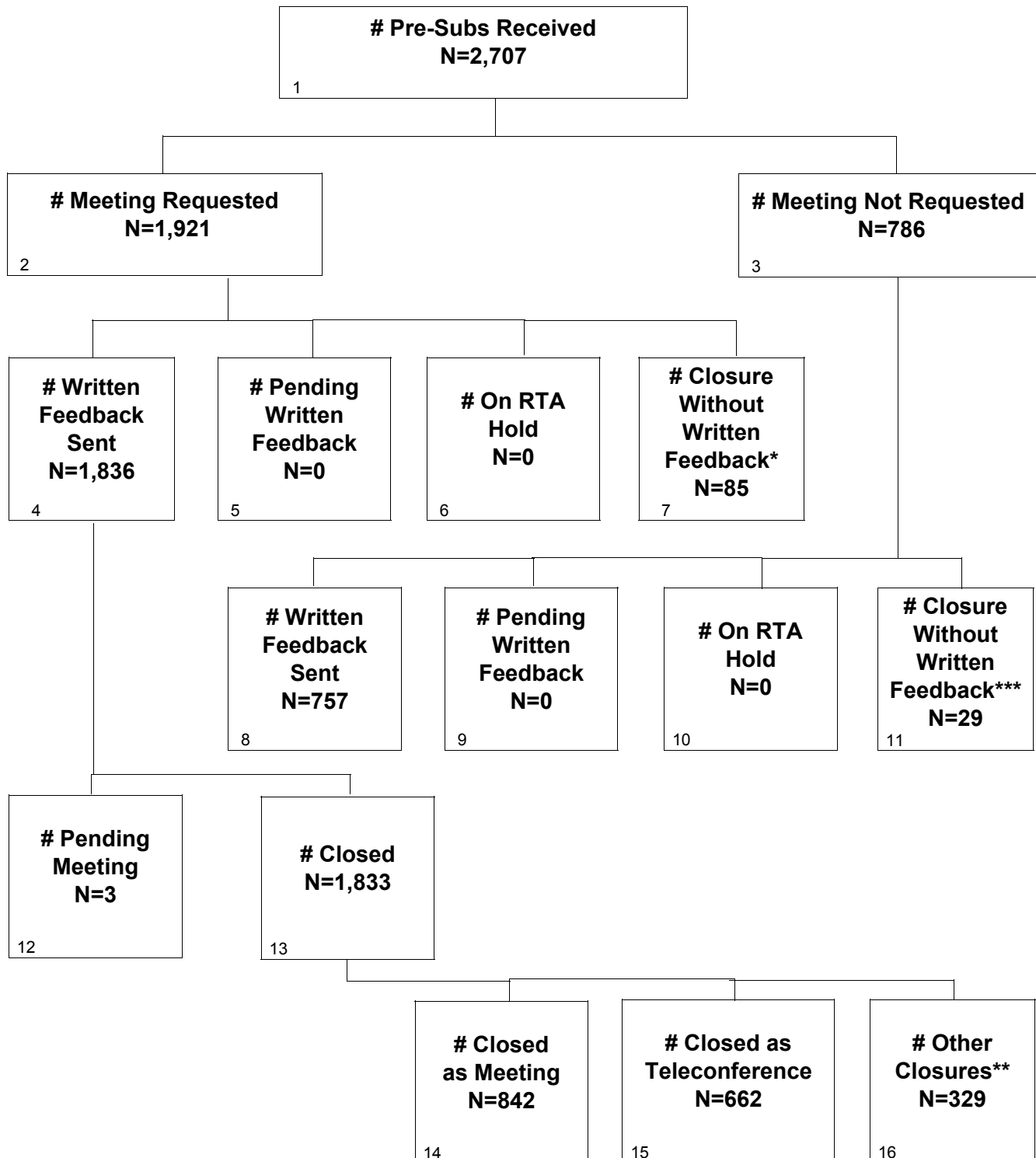
**Table 8.7 DRH - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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# CDRH Pre-Sub - FY 2018 as of 9/30/19



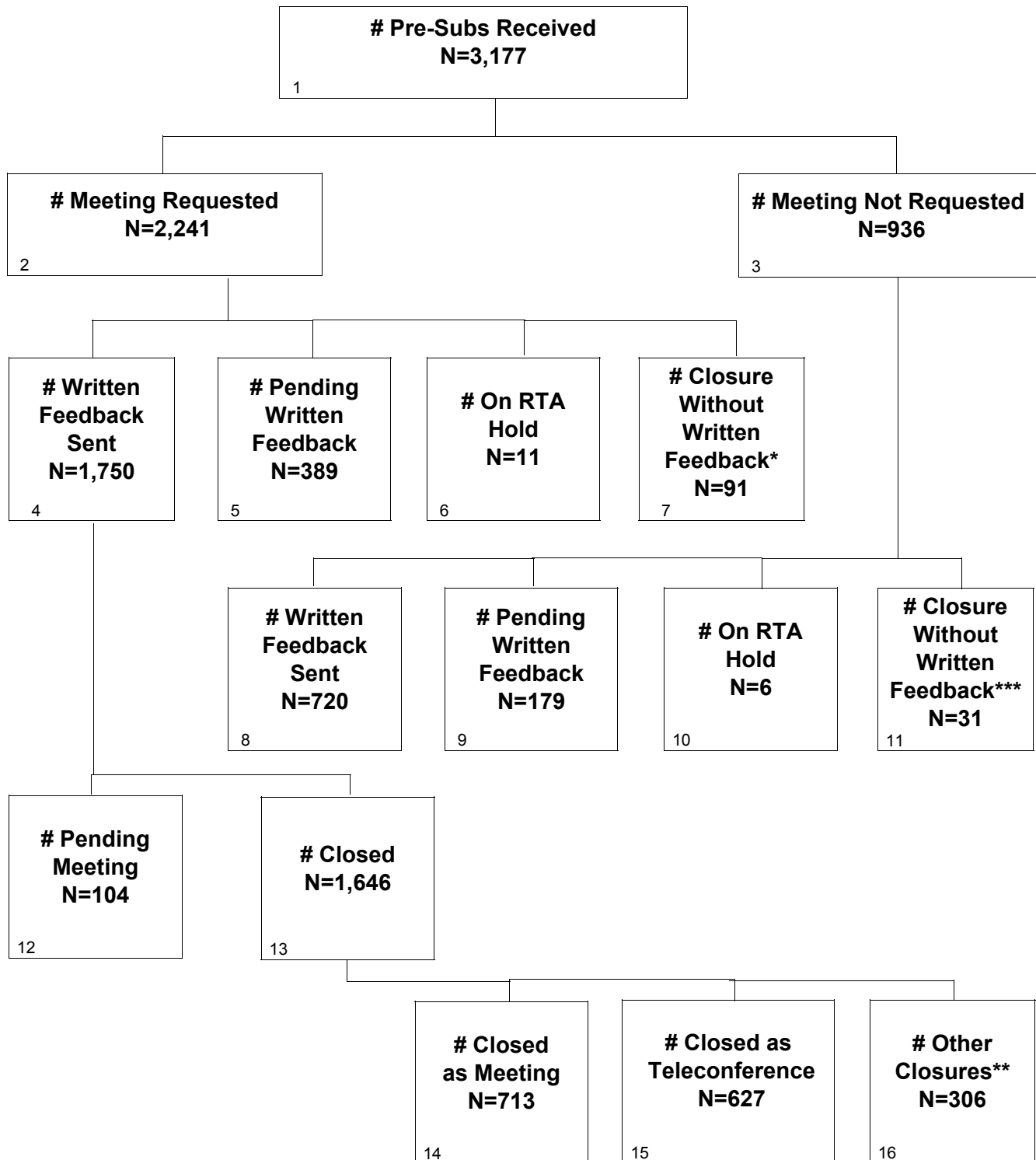
\* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

\*\* Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

\*\*\* Closures include JTRX, JPND, DELE & WTDR

# CDRH Pre-Sub - FY 2019

## as of 9/30/19



\* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

\*\* Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

\*\*\* Closures include JTRX, JPND, DELE & WTDR

## Section 9 Pre-Sub Center Level Metrics

**Table 9.1 CDRH - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2,707	3,177			
Closed Before RTA Action	27	39			
Number Accepted First RTA Cycle	2,565	2,906			
Number Without a RTA Review and > 15 Days Since Date Received	49	66			
Number Without a RTA Review and <= 15 Days Since Date Received	0	107			
Number Not Accepted	66	59			
Rate of Submissions Not Accepted for Review	2.46%	1.95%			

**Table 9.2 CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	2,594	2,470			
Written Feedback Provided Within MDUFA IV Goal	2,439	2,341			

**Table 9.3 CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	2,594	2,470			
Average FDA Days to Written Feedback	58.86	58.76			
20th Percentile FDA Days to Written Feedback	49	48			
40th Percentile FDA Days to Written Feedback	59	59			
60th Percentile FDA Days to Written Feedback	65	65			
80th Percentile FDA Days to Written Feedback	69	70			
Maximum FDA Days to Written Feedback	172	178			

**Table 9.4 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	37	41			
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.07			

**Table 9.5 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	1,504	1,340			
Meeting Minutes Submitted Within 15 Days of Meeting	971	841			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	54			
Meeting Minutes Past 15 Days of Meeting	481	387			
Meeting Minutes Not Submitted and >15 Days Since Meeting	52	58			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.56%	65.40%			

## Section 9 Pre-Sub Office Level Metrics

**Table 9.1 ODE - CDRH - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1,817	2,081			
Closed Before RTA Action	19	29			
Number Accepted First RTA Cycle	1,691	1,865			
Number Without a RTA Review and > 15 Days Since Date Received	49	53			
Number Without a RTA Review and <= 15 Days Since Date Received	0	82			
Number Not Accepted	58	52			
Rate of Submissions Not Accepted for Review	3.23%	2.64%			

**Table 9.2 ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	1,722	1,577			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	1,571	1,456			

**Table 9.3 ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	1,722	1,577			
Average FDA Days to Written Feedback	59.62	60.51			
20th Percentile FDA Days to Written Feedback	49	51			
40th Percentile FDA Days to Written Feedback	59	61			
60th Percentile FDA Days to Written Feedback	65	66			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	172	178			

**Table 9.4 ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	31	36			
Average Days to Scheduling for Meetings Scheduled After Day 30	35.94	36.14			

**Table 9.5 ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	1,029	868			
Meeting Minutes Submitted Within 15 Days of Meeting	667	541			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	37			
Meeting Minutes Past 15 Days of Meeting	327	249			
Meeting Minutes Not Submitted and >15 Days Since Meeting	35	41			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.82%	65.10%			

## Section 9 Pre-Sub Office Level Metrics

**Table 9.1 OIR - CDRH - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	890	1,096			
Closed Before RTA Action	8	10			
Number Accepted First RTA Cycle	874	1,041			
Number Without a RTA Review and > 15 Days Since Date Received	0	13			
Number Without a RTA Review and <= 15 Days Since Date Received	0	25			
Number Not Accepted	8	7			
Rate of Submissions Not Accepted for Review	0.91%	0.66%			

**Table 9.2 OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	872	893			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	868	885			

**Table 9.3 OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	872	893			
Average FDA Days to Written Feedback	57.36	55.65			
20th Percentile FDA Days to Written Feedback	48	44			
40th Percentile FDA Days to Written Feedback	57	56			
60th Percentile FDA Days to Written Feedback	63	63			
80th Percentile FDA Days to Written Feedback	68	68			
Maximum FDA Days to Written Feedback	85	91			

**Table 9.4 OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	6	5			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.83	35.60			

**Table 9.5 OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	475	472			
Meeting Minutes Submitted Within 15 Days of Meeting	304	300			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	17			
Meeting Minutes Past 15 Days of Meeting	154	138			
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	17			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.00%	65.93%			



## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	333	383			
Closed Before RTA Action	3	6			
Number Accepted First RTA Cycle	285	330			
Number Without a RTA Review and > 15 Days Since Date Received	12	10			
Number Without a RTA Review and <= 15 Days Since Date Received	0	16			
Number Not Accepted	33	21			
Rate of Submissions Not Accepted for Review	10.00%	5.82%			

**Table 9.2 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	301	279			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	254	239			

**Table 9.3 DAGRID - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	301	279			
Average FDA Days to Written Feedback	64.30	62.94			
20th Percentile FDA Days to Written Feedback	57	57			
40th Percentile FDA Days to Written Feedback	64	64			
60th Percentile FDA Days to Written Feedback	68	68			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	168	119			

**Table 9.4 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	10	10			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.30	32.90			

**Table 9.5 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	172	145			
Meeting Minutes Submitted Within 15 Days of Meeting	115	91			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	6			
Meeting Minutes Past 15 Days of Meeting	47	40			
Meeting Minutes Not Submitted and >15 Days Since Meeting	10	8			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	66.86%	65.47%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DCD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	529	573			
Closed Before RTA Action	6	6			
Number Accepted First RTA Cycle	505	521			
Number Without a RTA Review and > 15 Days Since Date Received	12	14			
Number Without a RTA Review and <= 15 Days Since Date Received	0	27			
Number Not Accepted	6	5			
Rate of Submissions Not Accepted for Review	1.15%	0.93%			

**Table 9.2 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	511	449			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	481	430			

**Table 9.3 DCD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	511	449			
Average FDA Days to Written Feedback	53	54.77			
20th Percentile FDA Days to Written Feedback	39	43			
40th Percentile FDA Days to Written Feedback	50	52			
60th Percentile FDA Days to Written Feedback	59	61			
80th Percentile FDA Days to Written Feedback	67	68			
Maximum FDA Days to Written Feedback	91	115			

**Table 9.4 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	8	8			
Average Days to Scheduling for Meetings Scheduled After Day 30	32.13	37.75			

**Table 9.5 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	310	236			
Meeting Minutes Submitted Within 15 Days of Meeting	183	144			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	6			
Meeting Minutes Past 15 Days of Meeting	117	71			
Meeting Minutes Not Submitted and >15 Days Since Meeting	10	15			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	59.03%	62.61%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	249	273			
Closed Before RTA Action	3	2			
Number Accepted First RTA Cycle	232	241			
Number Without a RTA Review and > 15 Days Since Date Received	7	8			
Number Without a RTA Review and <= 15 Days Since Date Received	0	10			
Number Not Accepted	7	12			
Rate of Submissions Not Accepted for Review	2.85%	4.60%			

**Table 9.2 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	210			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	202	182			

**Table 9.3 DNPMD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	210			
Average FDA Days to Written Feedback	64.72	68.63			
20th Percentile FDA Days to Written Feedback	58	62			
40th Percentile FDA Days to Written Feedback	65	67			
60th Percentile FDA Days to Written Feedback	69	70			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	172	178			

**Table 9.4 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	5	6			
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	32.17			

**Table 9.5 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	155	120			
Meeting Minutes Submitted Within 15 Days of Meeting	99	74			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	1			
Meeting Minutes Past 15 Days of Meeting	50	39			
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	6			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.87%	62.18%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DOD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	133	171			
Closed Before RTA Action	1	3			
Number Accepted First RTA Cycle	127	153			
Number Without a RTA Review and > 15 Days Since Date Received	5	6			
Number Without a RTA Review and <= 15 Days Since Date Received	0	7			
Number Not Accepted	0	2			
Rate of Submissions Not Accepted for Review	0%	1.24%			

**Table 9.2 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	130			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	115	120			

**Table 9.3 DOD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	130			
Average FDA Days to Written Feedback	61.91	59.44			
20th Percentile FDA Days to Written Feedback	52	52			
40th Percentile FDA Days to Written Feedback	62	60			
60th Percentile FDA Days to Written Feedback	67	64			
80th Percentile FDA Days to Written Feedback	70	69			
Maximum FDA Days to Written Feedback	106	83			

**Table 9.4 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	4			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	43.75			

**Table 9.5 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	77	64			
Meeting Minutes Submitted Within 15 Days of Meeting	55	38			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	2			
Meeting Minutes Past 15 Days of Meeting	19	19			
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	61.29%			



## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DOED - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	128	176			
Closed Before RTA Action	0	4			
Number Accepted First RTA Cycle	118	154			
Number Without a RTA Review and > 15 Days Since Date Received	5	3			
Number Without a RTA Review and <= 15 Days Since Date Received	0	10			
Number Not Accepted	5	5			
Rate of Submissions Not Accepted for Review	3.91%	3.09%			

**Table 9.2 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	120	125			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	117	125			

**Table 9.3 DOED - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	120	125			
Average FDA Days to Written Feedback	62.38	62.11			
20th Percentile FDA Days to Written Feedback	57	57			
40th Percentile FDA Days to Written Feedback	63	64			
60th Percentile FDA Days to Written Feedback	66	67			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	73	70			

**Table 9.4 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	37.00	38.00			

**Table 9.5 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	78	86			
Meeting Minutes Submitted Within 15 Days of Meeting	57	66			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	21	16			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.08%	79.52%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	231	276			
Closed Before RTA Action	2	4			
Number Accepted First RTA Cycle	225	259			
Number Without a RTA Review and > 15 Days Since Date Received	2	2			
Number Without a RTA Review and <= 15 Days Since Date Received	0	7			
Number Not Accepted	2	4			
Rate of Submissions Not Accepted for Review	0.87%	1.51%			

**Table 9.2 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	224	205			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	218	200			

**Table 9.3 DRGUD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	224	205			
Average FDA Days to Written Feedback	59.80	59.81			
20th Percentile FDA Days to Written Feedback	51	50			
40th Percentile FDA Days to Written Feedback	60	60			
60th Percentile FDA Days to Written Feedback	65	65			
80th Percentile FDA Days to Written Feedback	69	69			
Maximum FDA Days to Written Feedback	156	143			

**Table 9.4 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	1	6			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	37.00			

**Table 9.5 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	129	114			
Meeting Minutes Submitted Within 15 Days of Meeting	78	63			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	11			
Meeting Minutes Past 15 Days of Meeting	50	38			
Meeting Minutes Not Submitted and >15 Days Since Meeting	1	2			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	60.47%	61.17%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DSD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	214	229			
Closed Before RTA Action	4	4			
Number Accepted First RTA Cycle	199	207			
Number Without a RTA Review and > 15 Days Since Date Received	6	10			
Number Without a RTA Review and <= 15 Days Since Date Received	0	5			
Number Not Accepted	5	3			
Rate of Submissions Not Accepted for Review	2.38%	1.36%			

**Table 9.2 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	202	179			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	184	160			

**Table 9.3 DSD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	202	179			
Average FDA Days to Written Feedback	60.19	62.08			
20th Percentile FDA Days to Written Feedback	51	55			
40th Percentile FDA Days to Written Feedback	58	63			
60th Percentile FDA Days to Written Feedback	64	65			
80th Percentile FDA Days to Written Feedback	69	70			
Maximum FDA Days to Written Feedback	121	106			

**Table 9.4 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.50	42.00			

**Table 9.5 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	108	103			
Meeting Minutes Submitted Within 15 Days of Meeting	80	65			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	8			
Meeting Minutes Past 15 Days of Meeting	23	26			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	4			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.07%	68.42%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	226	287			
Closed Before RTA Action	3	3			
Number Accepted First RTA Cycle	222	273			
Number Without a RTA Review and > 15 Days Since Date Received	0	2			
Number Without a RTA Review and <= 15 Days Since Date Received	0	9			
Number Not Accepted	1	0			
Rate of Submissions Not Accepted for Review	0.45%	0%			

**Table 9.2 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	225			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	221	223			

**Table 9.3 DCTD - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	225			
Average FDA Days to Written Feedback	57.17	55.08			
20th Percentile FDA Days to Written Feedback	46	45			
40th Percentile FDA Days to Written Feedback	58	54			
60th Percentile FDA Days to Written Feedback	63	61			
80th Percentile FDA Days to Written Feedback	68	66			
Maximum FDA Days to Written Feedback	71	70			

**Table 9.4 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	36.00	47.00			

**Table 9.5 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	129	133			
Meeting Minutes Submitted Within 15 Days of Meeting	88	81			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	6			
Meeting Minutes Past 15 Days of Meeting	36	41			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	5			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.22%	63.78%			



## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	115	143			
Closed Before RTA Action	4	3			
Number Accepted First RTA Cycle	111	135			
Number Without a RTA Review and > 15 Days Since Date Received	0	4			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted	0	0			
Rate of Submissions Not Accepted for Review	0%	0%			

**Table 9.2 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	110	120			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	109	118			

**Table 9.3 DIHD - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	110	120			
Average FDA Days to Written Feedback	62.63	61.09			
20th Percentile FDA Days to Written Feedback	57	56			
40th Percentile FDA Days to Written Feedback	63	64			
60th Percentile FDA Days to Written Feedback	67	67			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	71	91			

**Table 9.4 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	3			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.33	31.67			

**Table 9.5 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	69	69			
Meeting Minutes Submitted Within 15 Days of Meeting	48	46			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	2			
Meeting Minutes Past 15 Days of Meeting	17	20			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	69.57%	68.66%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DMD - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	224	239			
Closed Before RTA Action	0	0			
Number Accepted First RTA Cycle	223	233			
Number Without a RTA Review and > 15 Days Since Date Received	0	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	4			
Number Not Accepted	1	1			
Rate of Submissions Not Accepted for Review	0.45%	0.43%			

**Table 9.2 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	205			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	221	205			

**Table 9.3 DMD - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	205			
Average FDA Days to Written Feedback	57.66	55.84			
20th Percentile FDA Days to Written Feedback	48	45			
40th Percentile FDA Days to Written Feedback	58	57			
60th Percentile FDA Days to Written Feedback	65	63			
80th Percentile FDA Days to Written Feedback	69	68			
Maximum FDA Days to Written Feedback	85	70			

**Table 9.4 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0	0			

**Table 9.5 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	70	70			
Meeting Minutes Submitted Within 15 Days of Meeting	33	42			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	2			
Meeting Minutes Past 15 Days of Meeting	30	22			
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	4			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	47.14%	61.76%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	193	233			
Closed Before RTA Action	0	1			
Number Accepted First RTA Cycle	192	221			
Number Without a RTA Review and > 15 Days Since Date Received	0	4			
Number Without a RTA Review and <= 15 Days Since Date Received	0	6			
Number Not Accepted	1	1			
Rate of Submissions Not Accepted for Review	0.52%	0.44%			

**Table 9.2 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	191	190			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	191	187			

**Table 9.3 DMGP - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	191	190			
Average FDA Days to Written Feedback	58.07	56.67			
20th Percentile FDA Days to Written Feedback	51	45			
40th Percentile FDA Days to Written Feedback	59	57			
60th Percentile FDA Days to Written Feedback	63	63			
80th Percentile FDA Days to Written Feedback	67	67			
Maximum FDA Days to Written Feedback	70	76			

**Table 9.4 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0	0			

**Table 9.5 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	121	103			
Meeting Minutes Submitted Within 15 Days of Meeting	70	66			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	4			
Meeting Minutes Past 15 Days of Meeting	50	29			
Meeting Minutes Not Submitted and >15 Days Since Meeting	1	4			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	57.85%	66.67%			

## Section 9 Pre-Sub Division Level Metrics

**Table 9.1 DRH - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	132	194			
Closed Before RTA Action	1	3			
Number Accepted First RTA Cycle	126	179			
Number Without a RTA Review and > 15 Days Since Date Received	0	2			
Number Without a RTA Review and <= 15 Days Since Date Received	0	5			
Number Not Accepted	5	5			
Rate of Submissions Not Accepted for Review	3.82%	2.69%			

**Table 9.2 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	153			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	126	152			

**Table 9.3 DRH - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	153			
Average FDA Days to Written Feedback	51.53	50.7			
20th Percentile FDA Days to Written Feedback	43	38			
40th Percentile FDA Days to Written Feedback	49	49			
60th Percentile FDA Days to Written Feedback	56	56			
80th Percentile FDA Days to Written Feedback	61	63			
Maximum FDA Days to Written Feedback	70	70			

**Table 9.4 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	1	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	31.00	36.00			

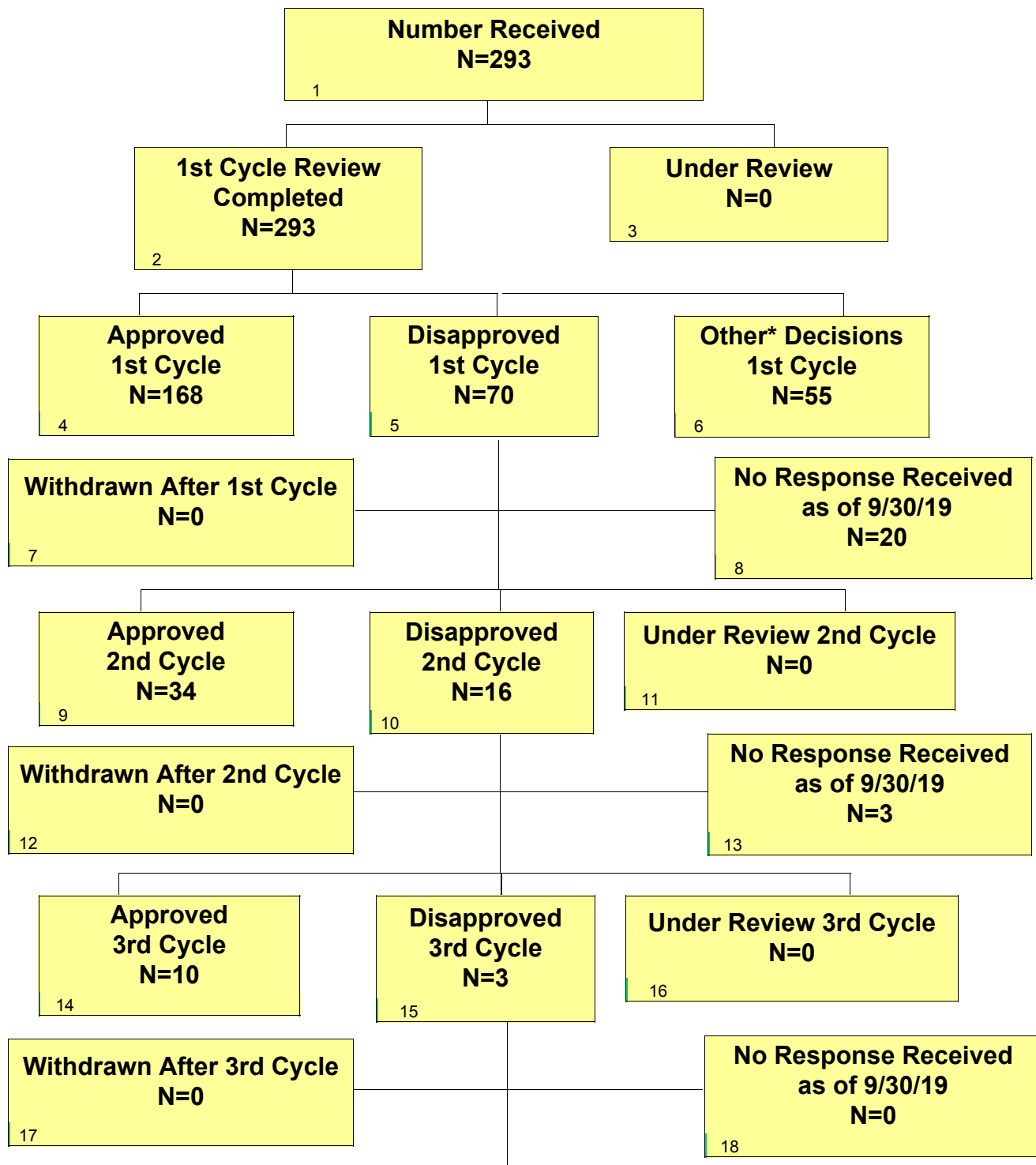
**Table 9.5 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	86	97			
Meeting Minutes Submitted Within 15 Days of Meeting	65	65			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	21	26			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.58%	69.15%			



# CDRH IDEs - FY 2018

## as of 9/30/19

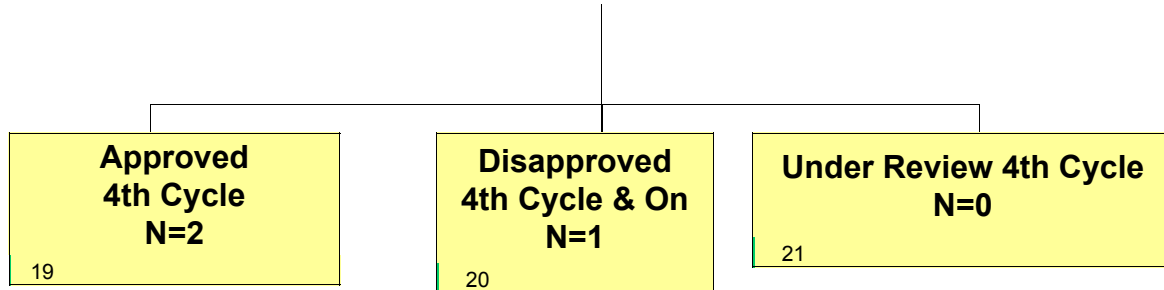


\* Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

# CDRH IDEs - FY 2018

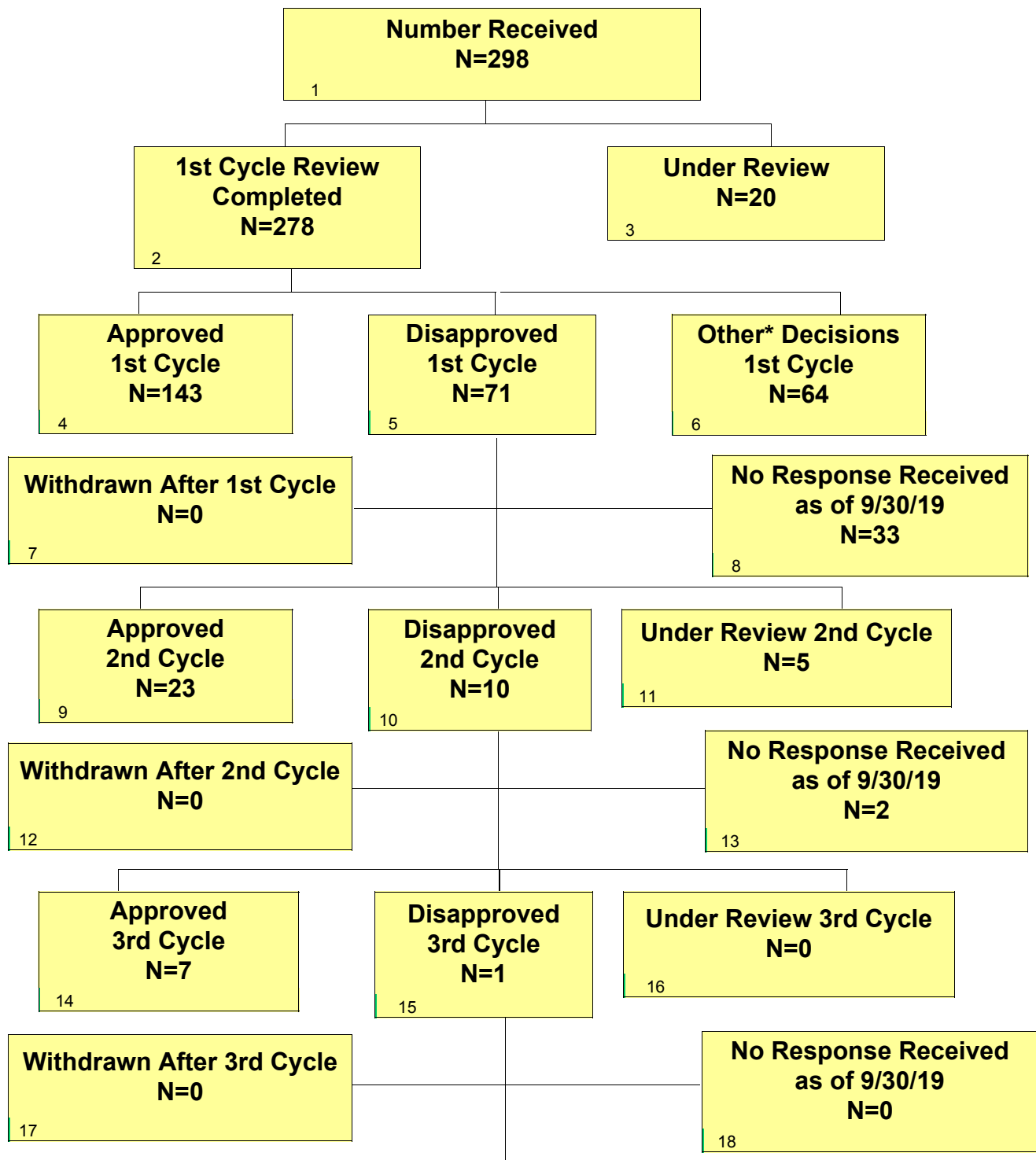
## as of 9/30/19

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# CDRH IDEs - FY 2019

## as of 9/30/19

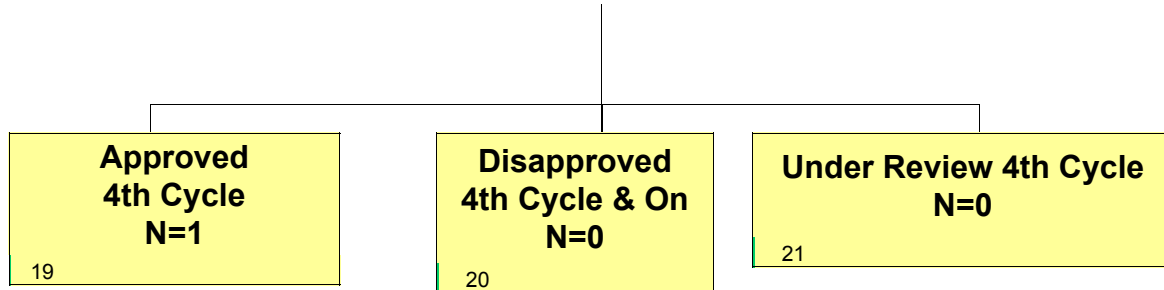


\* Other decisions include withdrawn (N=8), withdrawn and converted (N=36), RTA (N=0), nonsignificant risk device (N=12), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).

# CDRH IDEs - FY 2019

## as of 9/30/19

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## Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	293	298			
Average Number of Cycles to IDE Approval or Conditional Approval	1.30	1.23			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.30	0.23			

## Section 10 IDE - Office Level Metric

Table 10.1 ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	241	249			
Average Number of Cycles to IDE Approval or Conditional Approval	1.37	1.28			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.37	0.28			

## Section 10 IDE - Office Level Metric

Table 10.1 OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	52	49			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DAGRID - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	14	17			
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.10			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.10			

## Section 10 IDE - Division Level Metric

Table 10.1 DCD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	57	57			
Average Number of Cycles to IDE Approval or Conditional Approval	1.57	1.39			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.57	0.39			

## Section 10 IDE - Division Level Metric

Table 10.1 DNPMD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	61	70			
Average Number of Cycles to IDE Approval or Conditional Approval	1.14	1.32			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.14	0.32			

## Section 10 IDE - Division Level Metric

Table 10.1 DOD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	17	11			
Average Number of Cycles to IDE Approval or Conditional Approval	1.17	1.25			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.17	0.25			

## Section 10 IDE - Division Level Metric

Table 10.1 DOED - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	32	23			
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.19			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.19			

## Section 10 IDE - Division Level Metric

Table 10.1 DRGUD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	31	39			
Average Number of Cycles to IDE Approval or Conditional Approval	1.59	1.32			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.59	0.32			

## Section 10 IDE - Division Level Metric

Table 10.1 DSD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	29	32			
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.17			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.17			

## Section 10 IDE - Division Level Metric

Table 10.1 DCTD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	24	24			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DIHD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	1	3			
Average Number of Cycles to IDE Approval or Conditional Approval	N/A	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	N/A	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DMD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	2	2			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	N/A			

## Section 10 IDE - Division Level Metric

Table 10.1 DMGP - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	17	13			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

## Section 10 IDE - Division Level Metric

Table 10.1 DRH - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	8	7			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			



## Section 11 CLIA Waiver Annual Metrics

**Table 11.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	4	8			
Withdrawn prior to SI	0	0			
SI within 90 FDA days	4	5			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	3			
SI pending over 90 FDA days	0	0			
Denial without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	100%			

**Table 11.2.CDRH – CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	4	5			
Average number of FDA days to Substantive Interaction	59.50	53.60			
20th Percentile FDA days to Substantive Interaction	39	42			
40th Percentile FDA days to Substantive Interaction	48	50			
60th Percentile FDA days to Substantive Interaction	67	56			
80th Percentile FDA days to Substantive Interaction	79	71			
Maximum FDA days to Substantive Interaction	88	90			

**Table 11.3.CDRH – CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days
Eligible for MDUFA IV Decisions	4	8			
Non-MDUFA IV Decisions	0	1			
MDUFA IV Decisions	4	4			
MDUFA IV Decisions within 150 FDA Days	4	4			
CLIA Waiver Applications pending MDUFA IV Decision	0	4			
CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	0	0			
Current Performance Percent within 150 FDA Days	100%	100%			

**Table 11.4.CDRH – CLIA Waiver with Panel Review MDUFA Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decisions	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions within 320 FDA Days	0	0			
CLIA Waiver Applications pending MDUFA IV Decision	0	0			
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

**Table 11.5.CDRH – CLIA Waiver (without Panel Review) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA decision	4	4			
<b>Average FDA days to MDUFA IV decision</b>	119.50	50.50			
20th Percentile FDA days to MDUFA IV decision	102	35			
40th Percentile FDA days to MDUFA IV decision	143	49			
60th Percentile FDA days to MDUFA IV decision	145	50			
80th Percentile FDA days to MDUFA IV decision	147	66			
Maximum FDA days to MDUFA IV decision	148	90			
<b>Average Industry days to MDUFA IV decision</b>	150.50	133.25			
20th Percentile Industry days to MDUFA IV decision	86	104			
40th Percentile Industry days to MDUFA IV decision	151	174			
60th Percentile Industry days to MDUFA IV decision	173	179			
80th Percentile Industry days to MDUFA IV decision	219	180			
Maximum Industry days to MDUFA IV decision	278	180			
<b>Average Total days to MDUFA IV decision</b>	270.00	183.75			
20th Percentile Total days to MDUFA IV decision	192	135			
40th Percentile Total days to MDUFA IV decision	236	199			
60th Percentile Total days to MDUFA IV decision	276	217			
80th Percentile Total days to MDUFA IV decision	342	242			
Maximum Total days to MDUFA IV decision	420	270			

**Table 11.6.CDRH – CLIA Waiver (with Panel Review) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA IV decision</b>	0.00	0.00			
20th Percentile FDA days to MDUFA IV decision	0	0			
40th Percentile FDA days to MDUFA IV decision	0	0			
60th Percentile FDA days to MDUFA IV decision	0	0			
80th Percentile FDA days to MDUFA IV decision	0	0			
Maximum FDA days to MDUFA IV decision	0	0			
<b>Average Industry days to MDUFA IV decision</b>	0.00	0.00			
20th Percentile Industry days to MDUFA IV decision	0	0			
40th Percentile Industry days to MDUFA IV decision	0	0			
60th Percentile Industry days to MDUFA IV decision	0	0			
80th Percentile Industry days to MDUFA IV decision	0	0			
Maximum Industry days to MDUFA IV decision	0	0			
<b>Average Total days to MDUFA IV decision</b>	0.00	0.00			
20th Percentile Total days to MDUFA IV decision	0	0			
40th Percentile Total days to MDUFA IV decision	0	0			
60th Percentile Total days to MDUFA IV decision	0	0			
80th Percentile Total days to MDUFA IV decision	0	0			
Maximum Total days to MDUFA IV decision	0	0			

## Section 12 DUAL (510(k) and CLIA Waiver) Annual Metrics

**Table 12.1 CDRH – DUAL (510(k) and CLIA Waiver) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	11	5			
Withdrawn prior to SI	0	0			
SI within 90 FDA days	11	4			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	1			
SI pending over 90 FDA days	0	0			
Denial without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	100%			

**Table 12.2.CDRH –DUAL (510(k) and CLIA Waiver)Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	11	4			
Average number of FDA days to Substantive Interaction	85.18	86.25			
20th Percentile FDA days to Substantive Interaction	84	85			
40th Percentile FDA days to Substantive Interaction	87	88			
60th Percentile FDA days to Substantive Interaction	87	88			
80th Percentile FDA days to Substantive Interaction	88	88			
Maximum FDA days to Substantive Interaction	90	88			

**Table 12.3.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) MDUFA Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Eligible for MDUFA IV Decision	11	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	11	0			
MDUFA IV Decisions within 180 FDA Days	11	0			
CLIA Waiver Applications pending MDUFA IV Decision	0	5			
CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 12.4.CDRH – DUAL (510(k) and CLIA Waiver) (with panel review) MDUFA Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decision	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions with in 320 FDA Days	0	0			
CLIA Waiver Applications pending MDUFA IV Decision	0	0			
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

**Table 12.5.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV decision	11	0			
<b>Average FDA days to MDUFA IV decision</b>	139.64	0.00			
20th Percentile FDA days to MDUFA IV decision	87	0			
40th Percentile FDA days to MDUFA IV decision	140	0			
60th Percentile FDA days to MDUFA IV decision	176	0			
80th Percentile FDA days to MDUFA IV decision	180	0			
Maximum FDA days to MDUFA IV decision	180	0			
<b>Average Industry days to MDUFA IV decision</b>	42.18	0.00			
20th Percentile Industry days to MDUFA IV decision	0	0			
40th Percentile Industry days to MDUFA IV decision	0	0			
60th Percentile Industry days to MDUFA IV decision	0	0			
80th Percentile Industry days to MDUFA IV decision	110	0			
Maximum Industry days to MDUFA IV decision	180	0			
<b>Average Total days to MDUFA IV decision</b>	181.82	0.00			
20th Percentile Total days to MDUFA IV decision	87	0			
40th Percentile Total days to MDUFA IV decision	155	0			
60th Percentile Total days to MDUFA IV decision	177	0			
80th Percentile Total days to MDUFA IV decision	270	0			
Maximum Total days to MDUFA IV decision	354	0			

**Table 12.6.CDRH – DUAL (510(k) and CLIA Waiver) (with Panel Review) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV decision	0	0			
<b>Average FDA days to MDUFA IV decision</b>	0.00	0.00			
20th Percentile FDA days to MDUFA IV decision	0	0			
40th Percentile FDA days to MDUFA IV decision	0	0			
60th Percentile FDA days to MDUFA IV decision	0	0			
80th Percentile FDA days to MDUFA IV decision	0	0			
Maximum FDA days to MDUFA IV decision	0	0			
<b>Average Industry days to MDUFA IV decision</b>	0.00	0.00			
20th Percentile Industry days to MDUFA IV decision	0	0			
40th Percentile Industry days to MDUFA IV decision	0	0			
60th Percentile Industry days to MDUFA IV decision	0	0			
80th Percentile Industry days to MDUFA IV decision	0	0			
Maximum Industry days to MDUFA IV decision	0	0			
<b>Average Total days to MDUFA IV decision</b>	0.00	0.00			
20th Percentile Total days to MDUFA IV decision	0	0			
40th Percentile Total days to MDUFA IV decision	0	0			
60th Percentile Total days to MDUFA IV decision	0	0			
80th Percentile Total days to MDUFA IV decision	0	0			
Maximum Total days to MDUFA IV decision	0	0			



## Appendix A      Variable Definitions

### Section 1      PMA Originals and Panel Track Supplements

**Table 1.1 and Tables 1.1.x      PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number with accepted RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer.
4	Number without RTA Review and > 15 Days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number without RTA Review and <= 15 Days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of submissions not accepted for filing review	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

**Table 1.2 and Tables 1.2.x****PMA Original and Panel Track Supplements – Filing Review  
Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Accepted <sup>#</sup>	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAN decision in the first RTA review cycle entered by reviewer.
3	Number with completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

**Table 1.3 and Tables 1.3.x****PMA Originals & Panel Track Supplements Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under review with no SI past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 1.4 and Tables 1.4.x****PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 1.5 and Tables 1.5.x****PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.6 and Tables 1.6.x****PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.7 and Tables 1.7.x****PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.8 and Tables 1.8.x****PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.9 and Tables 1.9.x****PMA Originals and Panel Track Supplements (without Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable -  
Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number with MDUFA IV decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

**Table 1.10 and Tables 1.10.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).



**Table 1.11 and Tables 1.11.x PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals -  
Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

**Table 1.12 and Tables 1.12.x PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals -  
Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

**Tables 1.13 and Tables 1.13.x LDT PMA Originals & Panel-Track Supplements Metric\* MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

\*Includes submissions that went to panel

**Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements Metric\* MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

\*Includes submissions that went to panel

## Section 2 PMA 180 Day Supplements

**Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA(other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA Decision Performance Goals – Definitions**

#	Measure	Description
1	Supplements filed	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa).
3	MDUFA IV Decisions	Supplements received (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements pending MDUFA IV Decision	Number of supplements received (line 1) that do not have a MDUFA IV decision or a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 2.3 and Tables 2.3.x****PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable – Definitions**

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

**Table 2.4 and Tables 2.4.x****PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

### Section 3 PMA Real Time Supplements

**Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions**

#	Measure	Description
1	Supplements received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) within goal.
5	Supplements pending MDUFA IV Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA IV decision and are not closed with a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable – Definitions**

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

**Table 3.3 and Tables 3.3.x****Real Time PMA Supplements Performance Metrics – Submissions  
Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

## Section 5 PMA Annual Metrics and Goals

**Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions**

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.



**Table 5.2      PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number with a decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

**Table 5.3      PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with MDUFA decision after trimming the upper and lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA IV decision and 5% of submissions with the highest number of Total Days to MDUFA IV decision.
3	Three-year Rolling Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

## Section 6 510(k) MDUFA IV Performance (Quarterly Data Exclude Third Party Review)

**Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision – Definitions**

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision in the first RTA review cycle.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that received a "Did not perform RTA" (RTAN, RTAS or RTAW) decision in the first RTA review cycle. An RTAN decision is automatically recorded by CTS at the end of day 15 of RTA review, if no other RTA decision is made. This RTA decision means that the 510(k) is deemed accepted.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle and have not yet reached the 15 <sup>th</sup> day of that cycle..
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage of the sum of the Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

**Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goal – Definitions**

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions accepted or deemed accepted via the RTA process as of quarter end date (RTAA, RTAN, RTAW or RTAS).
2	Deleted or Withdrawn Prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made as of the quarter end date and before any SI action: WTDR, DELE.
3	SI Within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI Over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI Pending within 60 FDA days	Submissions that are awaiting SI and where 60 days have not yet elapsed.
6	SI Pending over 60 FDA days	Submissions that are under review over 60 FDA days and that do not have an SI.
7	510(k)s NSE Without SI	Number of 510(k) submissions that are closed with an NSE decision (and did not have an SI).
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) expressed as a percentage of the sum of the number of submissions that either had an SI (line 3 and line 4), the number of submissions that received an SI after 60 days had elapsed (line 6), and the number of submissions that were found NSE without first receiving an SI (line 7).

**Table 6.3 and Tables 6.3.x****510(k) Substantive Interaction Metric – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interaction	Number of 510(k) submissions accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to substantive interaction across all 510(k) submissions with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 6.4 and Tables 6.4.x 510(k) MDUFA Decision Performance Goal – Definitions**

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of submissions with MDUFA IV decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA IV Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA IV decision.

**Table 6.6 and Tables 6.6.x****510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decision – Definitions**

#	Measure	Description
1	510(k) Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Number with MDUFA IV Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

**Table 6.7 and Tables 6.7.x****510(k) Performance Metric – Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

**Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA IV Decision Metric – Definitions**

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA IV Decision over 90 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

**Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric – Definitions**

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).



## Section 7    510(k) Annual General Metrics (Annual data includes Third Party reviews)

**Table 7.1            CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

**Table 7.2****CDRH - 510(k) Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions..
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA IV decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA IV Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA IV decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA IV decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA IV Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA IV decision and the 2% of submissions with the highest number of Total Days to MDUFA IV decision.
7	Average Total Time to MDUFA IV decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

**Table 7.3****CDRH - 510(k) Third Party Performance – Definitions**

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90 <sup>th</sup> Percentile FDA Days to MDUFA IV Decision	The 90 <sup>th</sup> percentile of FDA days to MDUFA IV decision on 3 <sup>rd</sup> Party 510(k) submissions received in this fiscal year

## Section 8 De Novo MDUFA IV Performance

**Table 8.1 and Tables 8.1.x De Novo Acceptance Review Decision\* - Definitions**

#	Measure	Description
1	Number Received	Number of De Novo submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN ) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage the sum of the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

\*RTA will be implemented when the guidance, including the submission checklist, is finalized.

**Tables 8.2 and Tables 8.2.x De Novo MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not GrantedDeclined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (GrantedDeclined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA IV Decision over 150 FDA days	Number of submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 8.3 and Tables 8.3.x De Novo Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for De Novos with a MDUFA IV decision (line 2).
2	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA IV decision.

**Table 8.4 and Tables 8.4.x****De Novo Performance Metrics – Rate of Grant, Decline, Withdrawal and Delete Decisions – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA IV Decisions	Number submissions accepted (line 1) that had a MDUFA IV decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA IV decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA IV decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA IV decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA IV decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA IV decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA IV decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA IV decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA IV decision (line 2).

**Table 8.5 and Tables 8.5.x****De Novo Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of De Novo submissions accepted in this fiscal year that had a MDUFA IV decision with more than 150 FDA days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

**Tables 8.6 and Tables 8.6.x LDT De Novo MDUFA IV Decision Metrics – Definitions**

#	Measure	Description
1	De Novos accepted	Number of De Novo submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV Decision over 150 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

**Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).

**Section 8 Annual Metrics for De Novo Requests**

**Table 8.8 CDRH – Annual General Metric Report for De Novo Requests - Definitions**

#	Measure	Description
1	Number Accepted First RTA Cycle	Number of De Novo submissions accepted in the first RTA cycle in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept*	Average number of days in the first RTA review cycle De Novo submissions..

\*RTA will be implemented when the guidance, including the submission checklist, is finalized.

## Section 9 Pre-Submissions

**Table 9.1 and Tables 9.1.x Pre-Sub Acceptance Review Decision – Definitions**

#	Measure	Description
1	Number Received	Number of Pre-Subs submissions received in this fiscal year.
2	Closed before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that had "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days Since Date Received	Number Received (line 1) that had "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review.
5	Number Without a RTA Review and <= 15 days Since Date Received	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that had "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

**Table 9.2 and Tables 9.2.x Pre-Submissions Performance Metrics – Definitions**

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either "Email Reply" (EMAL) or "Email Feedback Sent Before Meeting" (EMFB) in CTS. EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Written Feedback Provided Within MDUFA IV Goal	Number of Pre-Subs that had Written Feedback sent (line 1) by Day 70 (for Pre-Subs without a meeting request), or by 5 Days before the Meeting Date or Day 70, whichever is sooner (for Pre-Subs with a meeting request).



**Table 9.3 and Tables 9.3.x Pre-Sub Time to MDUFA IV Metrics – Definitions**

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either “Email Reply” (EMAL) or “Email Feedback Sent Before Meeting” (EMFB) EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Average FDA Days to Written Feedback	Average number of days from the start of FDA review to MDUFA IV Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1).
3	20 <sup>th</sup> Percentile FDA Days to Written Feedback	20 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
4	40 <sup>th</sup> Percentile FDA Days to Written Feedback	40 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
5	60 <sup>th</sup> Percentile FDA Days to Written Feedback	60 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
6	80 <sup>th</sup> Percentile FDA Days to Written Feedback	80 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100 <sup>th</sup> percentile) to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).

**Table 9.4 and Tables 9.4.x Pre-Submissions Performance Metrics Meeting Scheduling-Definitions**

#	Measure	Description
1	Meetings Not Scheduled by Day 30	Number of Pre-Subs for which a Meeting was Requested and a Meeting Date was not confirmed by the reviewer in CTS by day 30.
2	Average Days to Scheduling for Meetings Scheduled After Day 30	Average days to confirming a Meeting Date in CTS for Meetings not scheduled by Day 30 (line 1).

**Table 9.5 and Tables 9.5.x****Pre-Submissions Performance Metrics Meeting Minutes- Definitions**

#	Measure	Description
1	Meetings Held	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date.
2	Meeting Minutes Submitted Within 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received within 15 days after Meeting Date.
3	Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and it is still under 15 days since meeting (as of end of quarter).
4	Meeting Minutes Past 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received more than 15 days after Meeting Date.
5	Meeting Minutes Not Submitted and >15 Days Since Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and more than 15 days have passed since the Meeting Date (as of end of quarter).
6	Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	Number of Meeting Minutes received within 15 days (line 2) divided by the total of Number of Meeting Minutes received within 15 days (line 2), Number of Meeting Minutes received past 15 days (line 4), and Number of Meeting Minutes which have not been received and >15 days since Meeting Date (line 5).

**Section 10 IDE Performance Metrics****Table 10.1 IDE Performance Metrics**

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.

## Section 11 CLIA Waiver Annual Metrics

**Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn within 90 FDA days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

**Table 11.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 11.3 CLIA Waiver (without Panel Review) MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn).
3	MDUFA IV Decisions	Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn).
4	MDUFA IV Decisions within 150 FDA Days	Number of submissions with MDUFA IV decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	Number of submissions pending MDUFA IV Decision for more than 150 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA IV Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 11.4 CLIA Waiver (with Panel Review) MDUFA IV Decision Performance Goals) – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn).
3	MDUFA IV Decisions	Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn).
4	MDUFA IV Decisions within 320 FDA Days	Number of submissions with MDUFA IV decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA IV Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

## Section 12 Dual 510(k) and CLIA Waiver Annual Metrics

**Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn prior to 90 days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

**Table 12.2 Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications accepted in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).



**Table 12.3 Dual 510(k) and CLIA Waiver (without panel review) MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with non-MDUFA IV decisions.
3	MDUFA IV Decisions	Number of submissions closed with MDUFA IV decisions.
4	MDUFA IV Decisions within 180 FDA Days	Number of submissions with MDUFA IV decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	Number of submissions pending MDUFA IV Decision for more than 180 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA IV Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA IV Decision Performance Goals – Definitions**

#	Measure	Description
1	Eligible for MDUFA IV Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with non-MDUFA IV decisions.
3	MDUFA IV Decisions	Number of submissions closed with MDUFA IV decisions.
4	MDUFA IV Decisions within 320FDA Days	Number of submissions with MDUFA IV decisions made within 320 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

**Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision), and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA IV Decision – Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision, and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

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**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA IV CBER Performance Data ----  
Actions through 30 Sep 2019**

## Section 1 PMA Original and Panel-Track Supplements - Center Level Metric

**Table 1.1 CBER - PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	3			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	1	1			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	2	1			
Rate of Submissions Not Accepted for Filing Review	67%	50%			

**Table 1.2 CBER - PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	3			
Number Accepted	1	1			
Completed RTF	3	2			
Number Not Filed	1	0			
Rate of Submissions Not Filed	33.33%	0.00%			

**Table 1.3 CBER - PMA Original and Panel-Track Supplements Substantive Interaction**

### Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	2			
SI Goal Met	2	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	100.00%			

**Table 1.4 CBER - PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	2			
Average Number of FDA Days to Substantive Interaction	69.00	86.00			
20th Percentile FDA Days to Substantive Interaction	50.00	82.00			
40th Percentile FDA Days to Substantive Interaction	50.00	82.00			
60th Percentile FDA Days to Substantive Interaction	88.00	90.00			
80th Percentile FDA Days to Substantive Interaction	88.00	90.00			
Maximum FDA Days to Substantive Interaction	88.00	90.00			

**Table 1.5 CBER - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	2	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	1	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

**Table 1.6 CBER - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)**

**Performance Metric - Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number with MDUFA IV Decision	1	0			
<b>Average FDA Days to MDUFA IV Decision</b>	156.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
40th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
60th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
80th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
Maximum FDA Days to MDUFA IV Decision	156.00	0.00			
<b>Average Industry Days to MDUFA IV Decision</b>	105.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
40th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
60th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
80th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
Maximum Industry Days to MDUFA IV Decision	105.00	0.00			
<b>Average Total Days to MDUFA IV Decision</b>	261.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
40th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
60th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
80th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
Maximum Total Days to MDUFA IV Decision	261.00	0.00			



**Table 1.8 CBER - PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 1.9 CBER - PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	2			
Number with MDUFA IV Decision	1	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10 CBER - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	0	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11 CBER - PMA Original and Panel-Track Supplements (Without Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

**Table 1.12 CBER - PMA Original and Panel-Track Supplements (with Panel Review)****Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

**Table 1.13 CBER - LDT PMA Original and Panel-Track Supplements Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

\*Includes submission that went to panel

**Table 1.14 CBER - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements**

**Metric\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	1	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	1	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	0.00%	0.00%			

\*Includes submission that went to panel

## Section 2 PMA 180-Day Supplements - Center Level Metric

**Table 2.1 CBER - PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	5			
SI Goal Met	8	5			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 2.2 CBER - PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	8	3			
MDUFA IV Decision Goal Met	8	3			
Supplements Pending MDUFA IV Decision	0	2			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	100.00%			

**Table 2.3 CBER - PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	5			
Number with MDUFA IV Decision	8	3			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	0.00%			

**Table 2.4 CBER - PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

### Section 3 PMA Real-Time Supplements - Center Level Metric

**Table 3.1 CBER - PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	3	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	2			
MDUFA IV Decision Goal Met	3	2			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2 CBER - PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2			
Number With MDUFA IV Decision	3	2			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3 CBER - PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

## Section 6 510(k) Center Level Metrics (Excludes Third Party Review)

**Table 6.1 CBER - 510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	53	52			
Closed Before RTA Action	0	0			
Number Accepted	40	36			
Number Without a RTA Review and > 15 Days Since Date Received	2	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted	11	14			
Rate of Submissions Not Accepted for Review	20.75%	28.00%			

**Table 6.2 CBER - 510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	49	45			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	49	39			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	6			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

**Table 6.3 CBER - 510(k) Substantive Interaction Metric - Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Number of Substantive Interaction	49	39			
Average Number of FDA Days to Substantive Interaction	50.60	42.18			
20th Percentile FDA Days to Substantive Interaction	43	21			
40th Percentile FDA Days to Substantive Interaction	57	45			
60th Percentile FDA Days to Substantive Interaction	59	58			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	60	60			

**Table 6.4 CBER - 510(k) MDUFA IV Decision Performance Goal**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>	<b>95% Within 90 FDA Days</b>
510(k)s Accepted	49	45			
Non-MDUFA IV Decision	6	1			
MDUFA IV Decision (SE/NSE)	43	26			
MDUFA IV Decision Within 90 FDA Days	43	26			
510(k)s Pending MDUFA IV Decision	0	18			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

**Table 6.5 CBER - 510(k) Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	1.30	1.27			
Number With MDUFA IV Decision	43	26			
<b>Average Number of FDA Days to MDUFA IV Decision</b>	75.12	56.65			
20th Percentile FDA Days to MDUFA IV Decision	65	28			
40th Percentile FDA Days to MDUFA IV Decision	85	30			
60th Percentile FDA Days to MDUFA IV Decision	87	78			
80th Percentile FDA Days to MDUFA IV Decision	90	87			
Maximum FDA Days to MDUFA IV Decision	90	90			
<b>Average Number of Industry Days to MDUFA IV Decision</b>	25.23	22.96			
20th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
40th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
60th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
80th Percentile Industry Days to MDUFA IV Decision	59.00	54.00			
Maximum Industry Days to MDUFA IV Decision	178.00	179.00			
<b>Average Number of Total Days to MDUFA IV Decision</b>	100.37	74.04			
20th Percentile Total Days to MDUFA IV Decision	76	28			
40th Percentile Total Days to MDUFA IV Decision	86	59			
60th Percentile Total Days to MDUFA IV Decision	90	85			
80th Percentile Total Days to MDUFA IV Decision	147	90			
Maximum Total Days to MDUFA IV Decision	268	269			



**Table 6.6 CBER - 510(k) Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	49	45			
Number With MDUFA IV Decision	43	26			
Number of SE Decision	43	26			
Number of NSE Decision	0	0			
Number of Withdrawal	2	1			
Number of Deleted	3	0			
Rate of SE Decision	100%	100%			
Rate of NSE Decision	0%	0%			
Rate of Withdrawal	4%	2%			
Rate of Deleted	6%	0%			

**Table 6.7 CBER - 510(k) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

**Table 6.8 CBER - LDT 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	0	0			
MDUFA IV Decision Within 90 FDA Days	0	0			
510(k)s Pending MDUFA IV Decision	0	0			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	N/A	N/A			

**Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	14	10			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	14	8			
MDUFA IV Decision Within 90 FDA Days	14	8			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	100.00%			

## Section 8 De Novo Center Level Metrics

**Table 8.1 CBER - De Novo Acceptance Review Decision\***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	0	1			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

\* RTA will be implemented when the guidance, including the submission checklist, is finalized.

**Table 8.2 CBER - De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	0	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.3 CBER - De Novo Time to MDUFA IV Decision**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Average Review Cycles	0.00	0.00			
Number With MDUFA IV Decision	0	0			
<b>Average FDA Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
<b>Average Industry Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
<b>Average Total Days to MDUFA IV Decision</b>	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

**Table 8.4 CBER - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1			
Number With MDUFA IV Decisions	0	0			
Number With Granted Decisions	0	0			
Number With Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	N/A	N/A			
Rate of Declined Decisions	N/A	N/A			
Rate of Withdrawals	N/A	N/A			
Rate of Deleted	N/A	N/A			

**Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

**Table 8.6 CBER - LDT De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

**Table 8.7 CBER - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

## Section 9 Pre-Sub Center Level Metrics

**Table 9.1 CBER - Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	76	77			
Closed Before RTA Action	5	3			
Number Accepted First RTA Cycle	69	70			
Number Without a RTA Review and > 15 Days Since Date Received	1	2			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted	1	1			
Rate of Submissions Not Accepted for Review	1.41%	1.37%			

**Table 9.2 CBER - MDUFA IV Pre-Sub Performance Goals**

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	70	57			
Written Feedback Provided Within MDUFA IV Goal	68	55			

**Table 9.3 CBER - Pre-Sub Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	70	57			
Average FDA Days to Written Feedback	57.86	60.14			
20th Percentile FDA Days to Written Feedback	47	54			
40th Percentile FDA Days to Written Feedback	58	60			
60th Percentile FDA Days to Written Feedback	64	63			
80th Percentile FDA Days to Written Feedback	67	68			
Maximum FDA Days to Written Feedback	72	75			

**Table 9.4 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00			

**Table 9.5 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes**

<b>Performance Metric</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Meeting Held	42	26			
Meeting Minutes Submitted Within 15 Days of Meeting	33	22			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	1			
Meeting Minutes Past 15 Days of Meeting	9	2			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	88.00%			



## Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	15	15			
Average Number of Cycles to IDE Approval or Conditional Approval	1.18	1.40			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.18	0.40			

**BLA**  
**CBER – Annual General Metric Report for BLAs**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard BLAs Filed	14	4			
Number of Standard BLA First Actions less than or equal to 10 months	14	1			
Number of Standard BLA First Actions greater than 10 months	0	0			
Number of Standard BLAs Pending	0	3			
Number of Priority BLA Filed	0	0			
Number of Priority BLA First Actions less than or equal to 10 months	0	0			
Number of Priority BLA First Actions greater than 10 months	0	0			
Number of Priority BLAs Pending	0	0			

**BLA Efficacy Supplements**  
**CBER – Annual General Metric Report for BLA Efficacy Supplements**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard Efficacy Supplements Filed	8	2			
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	8	1			
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0			
Number of Standard Efficacy Supplements Pending	0	1			
Number of Priority Efficacy Supplements Filed	0	0			
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0			
Number of Priority Efficacy Supplements First Actions greater than 10 months	0	0			
Number of Priority Efficacy Supplements Pending	0	0			

**BLA Prior Approval Manufacturing Supplements**  
**CBER – Annual General Metric Report for BLA PAS Supplements**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard PAS Supplements Filed	94	49			
Number of Standard PAS Supplements First Actions less than or equal to 4months	94	46			
Number of Standard PAS Supplements First Actions greater than 4 months	0	1			
Number of Standard PAS Supplements Pending	0	2			

**BLA/BLA Resubmissions**  
**CBER – Annual General Metric Report for BLA/BLA Resubmissions**

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## Shared Outcome Goals (FY 2018 – FY 2022)

FDA has 2 shared outcome goals each fiscal year, one for Original PMAs and Panel Track Supplements and one for 510(k)s. FDA committed to report the average TTD within a closed cohort and based on the methodology prescribed in the MDUFA IV commitment letter. A PMA cohort is considered closed when 95% of applications have reached a decision. A 510(k) cohort is considered closed when 99% of accepted submissions have reached a decision. Both the 510(k) and PMA cohorts include submissions reviewed in CDRH and CBER.

As of September 30, 2019, neither the 510(k) nor the PMA cohorts for FY 2018 or FY 2019 have met the decision threshold to calculate the average TTD. FDA will report the average TTD for FY 2018 and FY 2019 in future reports, once the cohorts have met the decision threshold.

### MDUFA IV Shared Outcome Goals

Submission Type	FY 18	FY 19	FY 20	FY 21	FY 22
<b>Original PMAs and Panel-Track PMA Supplements</b>					
Total Time to Decision Goal (Days)	320	315	310	300	290
Current Performance (Days)	*	*			
<b>510(k) Premarket Notifications</b>					
Total Time to Decision Goal (Days)	124	120	116	112	108
Current Performance (Days)	*	*			

\* As of September 30, 2019, fiscal year cohort has not met the decision threshold to calculate performance

## Updated Shared Outcome Goal Performance (FY 2013 – FY 2017)

FDA had 2 shared outcome goals each fiscal year in MDUFA III, one for Original PMAs and Panel Track Supplements and one for 510(k)s. FDA committed to report the average TTD within a closed cohort and based on the methodology prescribed in the MDUFA III commitment letter. A PMA cohort is considered closed when 95% of applications have reached a decision. A 510(k) cohort is considered closed when 99% of accepted submissions have reached a decision. Performance for submission types that are meeting or exceeding the goal as of September 30, 2019, is shown in **bold** text.

As of September 30, 2019, the 510(k) and PMA cohorts for all five years (FY 2013 – 2017) have met the decision threshold to calculate the average TTD and are listed below. FDA did not meet the shared outcome goal for 510(k)s FY 2015, FY 2016, and FY 2017 but met all the PMA and other 510(k) shared outcome goals. The 510(k) goal was missed by one day in FY 2015, eight days in FY 2016, and eight days in FY 2017.

### MDUFA III Shared Outcome Goals

Submission Type	FY 13	FY 14	FY 15	FY 16	FY 17
<b>Original PMAs and Panel Track Supplements</b>					
Total Time to Decision Goal (Days)	395	395	390	390	385
Current Performance (Days)	<b>314</b>	<b>300</b>	<b>293</b>	<b>266</b>	<b>267</b>
<b>510(k)</b>					
Total Time to Decision Goal (Days)	135	135	130	130	124
Current Performance (Days)	<b>124</b>	<b>125</b>	131	138	132

**FY 2019 Medical Device User Fee Collections  
as of September 30th, 2019  
Excludes Unearned Fees**

	<b>Receipts</b>	<b>Refunds</b>	<b>Net</b>	<b>Authorized</b>	<b>% of Authorized</b>
Registration Fees	\$137,430,018	\$369,636	\$137,060,382		
Application Fees	\$65,085,698	\$2,009,691	\$63,076,007		
<b>Total</b>	<b>\$202,515,715</b>	<b>\$2,379,327</b>	<b>\$200,136,389</b>	<b>\$204,730,000</b>	<b>98%</b>

**Medical Device User Fee Collection History  
Excludes Unearned Fees, Includes Refunds**

	<b>FY 2003</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
MD I	\$21,620,549	\$26,281,779	\$31,728,269	\$34,417,751	\$28,031,569
	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
MD II	\$47,719,519	\$57,563,951	\$63,948,268	\$70,153,462	\$65,825,151
	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
MD III	\$101,268,118	\$121,143,525	\$134,512,002	\$146,300,573	\$136,826,013
	<b>FY 2018</b>	<b>FY 2019</b>			
MD IV	\$189,223,210	\$200,136,389			

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**MDUFA IV Commitment Letter - VI. Performance Reports**  
**2.12. Number of discretionary fee waivers or reductions granted by type of submission<sup>1/</sup>**

<b>MDUFA Program (CDRH and CBER combined) Data 4th Quarter FY 2019 by Submission type</b>	<b># Waived</b>	<b># Reduced</b>
<b>Full Fee applications<sup>2/</sup></b>		
PMA	5	4
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
<b>Panel Track Supplements</b>	<b>2</b>	<b>4</b>
<b>De Novo Classification</b>	<b>7</b>	<b>39</b>
<b>180-Day Supplements</b>	<b>1</b>	<b>23</b>
<b>Real-Time Supplements</b>	<b>1</b>	<b>44</b>
<b>510(k)s</b>	<b>40</b>	<b>1567</b>
<b>30-day Notices</b>	<b>6</b>	<b>112</b>
<b>513(g)s</b>	<b>0</b>	<b>54</b>
<b>PMA Annual Report</b>	<b>0</b>	<b>64</b>
<b>Total</b>	<b>62</b>	<b>1,911</b>

<sup>1/</sup> User fees may be waived for several reasons, including but not limited to: the submitter is a State or Federal Government entity who does not intend to distribute the device commercially; the proposed conditions of use for the device involved are solely for a pediatric population; and, the submitter is a small business submitting their first premarket approval application or premarket report. User fees are reduced for small businesses. 510(k)s reviewed through the Third Party Review program are not included because FDA does not collect user fees for 510(k)s reviewed through that program. Counts are cumulative for the Fiscal Year.

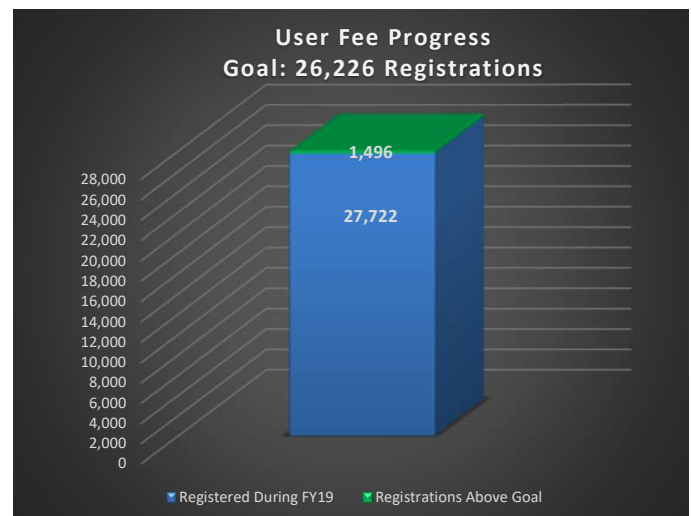
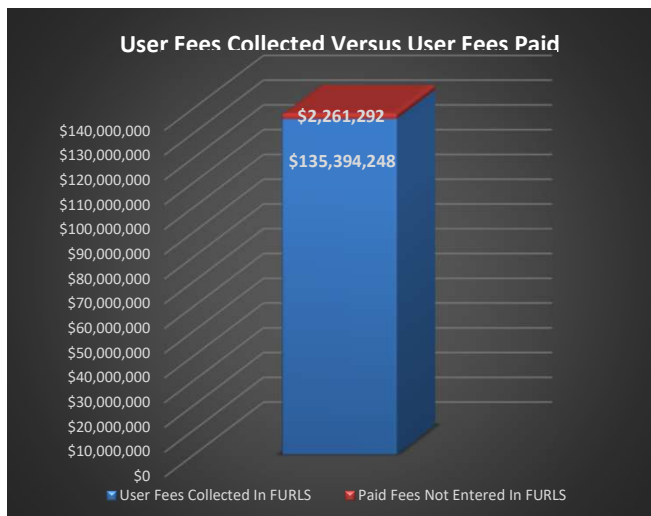
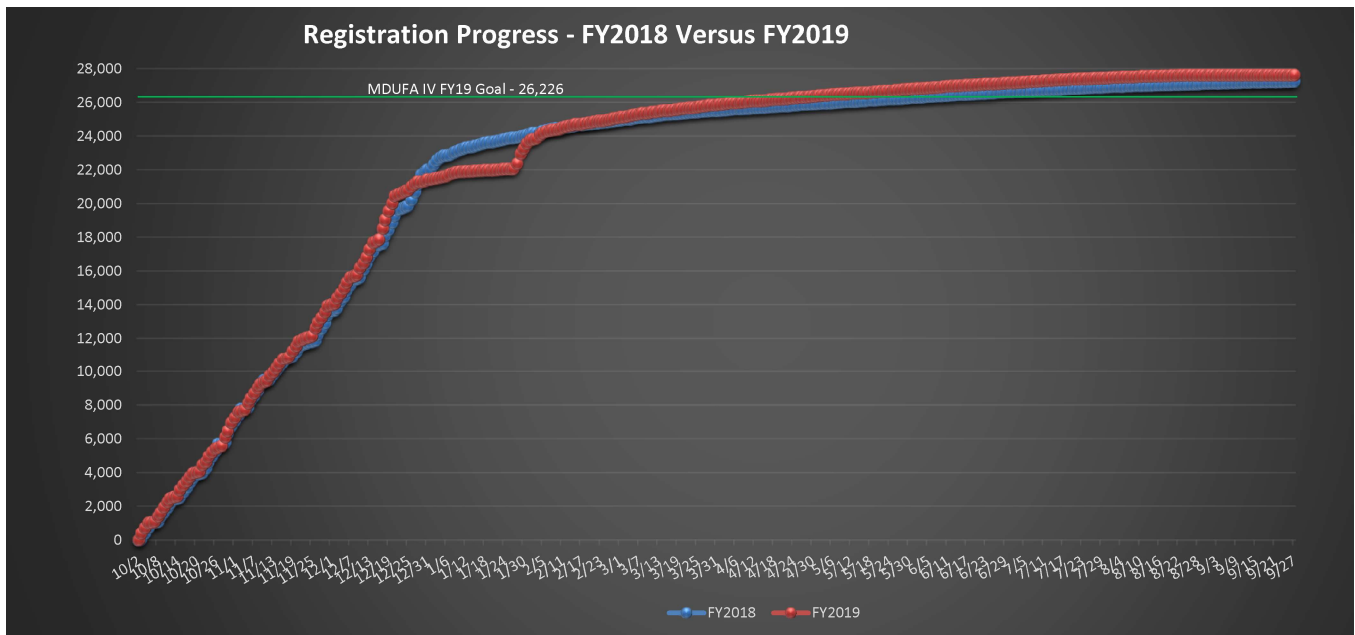
<sup>2/</sup> As specified in the MDUFA 4 Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually. CBER counts are included in 180-Day Supplements (1 Reduced), Real-Time Supplements (1 Reduced), 510(k)s (11 Reduced), 30-day Notices (5 Reduced), and PMA Annual Reports (8 Reduced).

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## MDUFA IV Registrations - 4th Quarter Summary FY2019\*

Current Active Registrations by Type	FY19 Q4			FY18 Year End Active Totals			FY19 vs End FY18
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,266	10,241	16,507	6,199	9,926	16,125	102.37%
Contract Manufacturer	1,121	1,598	2,719	1,113	1,481	2,594	104.82%
Contract Sterilizer	70	138	208	73	140	213	97.65%
Specification Developer	1,711	540	2,251	1,708	502	2,210	101.86%
Reprocessor of Single Use Devices	24	2	26	25	3	28	92.86%
U.S. Manufacturer of Export Only Devices	123	0	123	137		137	89.78%
Repackager/Relabeler	1,136	191	1,327	1,144	185	1,329	99.85%
Remanufacturer	19	9	28	22	13	35	80.00%
Foreign Exporter/Private Label Distributor		1,033	1,032		976	976	105.74%
Initial Importer	3,255		3,255	3,264		3,264	99.72%
Unknown	1	1	2	17	13	30	6.67%
<b>Total:</b>	<b>13,726</b>	<b>13,753</b>	<b>27,479</b>	<b>13,702</b>	<b>13,239</b>	<b>26,941</b>	<b>102.00%</b>

\*Note: This data is current as of 9/27/2019



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# **Center for Devices and Radiological Health Internal Training Summary Report**

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**Q4 FY19**

October 2018 – September 2019

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Prepared by: The Division of Employee Training and Development (DETD)

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As of: 10/25/2019

The FDA continues to invest in internal and external training opportunities supporting medical device regulation. The Division of Employee Training and Development (DETD) is CDRH's internal resource for scientific, regulatory, leadership training, career development programs, and customized learning opportunities. We help further the Center's mission by championing employee growth across the Center's eight offices. Our approach to improving performance combines classroom, experiential, and online learning with mentoring, self-study initiatives, and specialty programs. We are committed to providing CDRH employees with the knowledge and skills needed to maximize their organizational and individual potential.

Table X provides a summary of internal training conducted in CDRH between October 1, 2018 and September 30, 2019. DETD offered 545 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. The training was designed to support the Medical Device User Fee Amendment (MDUFA) goals and program activities.

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**Table X – FY19 CDRH Internal Training Conducted by DETD:***October 1, 2018 and September 30, 2019*

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
<b>Regulatory and Law (LAW) Training</b>	MDUFA IV	5	584	474
	ELP	38	474	7176
	Other LAW	285	8499	8215
<i>LAW Subtotal:</i>		<i>328</i>	<i>9557</i>	<i>15865</i>
<b>Leadership Development Training (LED)</b>	LEAD: Leadership for Managers	59	1530	2656
	Leadership for Non-Managers	13	189	1263
	Other LED	19	340	2096
<i>LED Subtotal:</i>		<i>91</i>	<i>2059</i>	<i>6015</i>
<b>Professional Development (PRO) Training</b>	New Employee Orientation (NEO)	3	72	452
	Other PRO	43	615	6184
<i>PRO Subtotal:</i>		<i>46</i>	<i>687</i>	<i>6636</i>
<b>Center-Specific Information Technology (CIT) Training</b>	Premarket IT	6	288	291
	Other CIT	4	34	20
<i>CIT Subtotal:</i>		<i>10</i>	<i>322</i>	<i>311</i>
<b>Science (SCI) Training</b>	All SCI	70	1893	3759
<i>SCI Subtotal:</i>		<i>70</i>	<i>1893</i>	<i>3759</i>
<b>Grand Total:</b>		<b>545</b>	<b>14518</b>	<b>32586</b>



## CDRH Informal Training

### CDRH Informal Training:

DETD implemented a process for tracking Informal training in 2015. Unlike Formal Center-wide training managed by DETD, Informal training targets specific audiences and addresses specialized training topics. Informal training is offered at the Office, Division and Branch levels and is conducted as on-the-job training, All-Hands meetings, small group sessions and classroom and remote training. Formal and informal training is necessary to meet the mission-critical training needs of Center staff. Examples of informal training content include:

- Additional instruction provided following Formal training (e.g. Medical Device Regulation training)
- Policy change updates (e.g. Technology, MDUFA, new guidance)
- Best practices used in a specific product area

### CDRH Informal Training:

Year	# of Learning Events	Total # of Participants	Total Contact Hours
FY'15	34	1249	3350
FY'16	42	978	2122
FY'17	113	2845	8956
FY'18	61	1692	5650
FY'19	39	575	1170
<b>Total:</b>	<b>289</b>	<b>7339</b>	<b>21248</b>

## Premarket Reviewer Training - RCP

### Reviewer Certification Program (RCP):

The RCP curriculum is a 30.5-hour program consisting of online and classroom courses essential to new reviewers during their first 60 days of hire. The condensed course design results in reviewers receiving the most salient knowledge in a timely fashion. After completion of the RCP, reviewers enroll in advanced courses designed to further enhance their knowledge and skills. The curriculum consists of the following components:

- 11 classroom courses, including a program Orientation and Capstone, totaling 15.5 hours of training
- 15 online courses, totaling 23.5 hours
- 7 Advanced courses, to be taken within a year of employment
- Practical activities and hands-on exercises
- Knowledge assessments

### RCP Training by Cohort: *October 1, 2018 and September 30, 2019*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 1 2018 Cohort	11	11	OC	2	20	26
			OCD	1	12	15
			ODE	5	53	66
			OIR	10	164	202
			OSEL	4	72	88
			Subtotal:	22	321	397
Fall 2 2018 Cohort	11	11	OC	1	5	7
			OCD	2	11	15
			ODE	6	45	52
			OIR	2	30	33
			OSEL	8	59	69
			Subtotal:	19	150	176
Spring 1 2019 Cohort	11	11	OC	2	19	27
			ODE	3	65	83
			OIR	2	38	45
			OSEL	5	106	122
			Subtotal:	12	228	277
Spring 2 2019 Cohort	11	15	OCD	2	28	36
			ODE	8	81	107
			OIR	6	114	149
			OSEL	4	85	107
			Subtotal:	20	308	399
Summer 1 2019 Cohort	11	15	ODE	10	152	208
			OIR	8	121	156
			OSB	1	8	11
			OSEL	3	16	21
			Subtotal:	22	297	396
Summer 2 2019 Cohort	11	15	OC	2	7	12
			ODE	14	219	285
			OIR	1	16	21
			OSEL	8	124	163
			Subtotal:	25	366	481
Total:	66	78	-	120	1670	2126

## Premarket Reviewer Training - ELP

### Experiential Learning Program (ELP):

The Experiential Learning Program (ELP) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the review of resulting medical devices. The Program fosters an understanding of how medical devices are developed, clinically tested, manufactured, and utilized. Staff involved in medical device regulation visit ELP sites identified by training need and selected through a formalized proposal submission process.

### ELP Training Completed: *October 1, 2018 and September 30, 2019*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
38	474	7176	<ul style="list-style-type: none"><li>• Innovation</li><li>• Diagnostic Ultrasound</li><li>• Gene Sequencing</li><li>• Catheter Devices</li><li>• Medical Device Development</li></ul>

### ELP Training Completed by Office: *October 1, 2018 and September 30, 2019*

Office	Total # of Attendees	Total Training Hours
<b>OC</b>	34	512
<b>OCD</b>	18	288
<b>ODE</b>	262	4104
<b>OIR</b>	96	1224
<b>OSB</b>	44	752
<b>OSEL</b>	20	296
<b>Total:</b>	<b>474</b>	<b>7176</b>

## Leadership Training - LEAD

### Leadership Enhancement and Development (LEAD) Program:

The LEAD Program is a mandatory Supervisory Training Program targeting CDRH Supervisors, Managers, and Non-Bargaining Unit Team Leaders. The LEAD curriculum supports the CDRH Management Competencies and addresses the supervisory training requirements as mandated in 5 CFR 412.

### LEAD Training Completed: *October 1, 2018 and September 30, 2019*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
<b>LEAD</b>	59	1530	2656	<ul style="list-style-type: none"> <li>• Diversity, Unconscious Bias</li> <li>• Effective Performance Management</li> <li>• CDRH Manager Orientation Program</li> <li>• Leading Through Change</li> <li>• Leading with Personal Integrity and Ethics</li> <li>• Managing Up, Communicating with your Boss</li> <li>• CDRH Ethics Refresher Series: What is an Outside Activity?</li> </ul>

### LEAD Training Completed by ODE and OIR: *October 1, 2018 and September 30, 2019*

Office	Total # of Managers/Supervisors*	# of Training Participants	Training Hours Required**	% of Required Training Hours Completed
ODE	63	63	1008	74%
OIR	40	40	640	48%
<b>Total:</b>	<b>103</b>	<b>103</b>	<b>1648</b>	<b>61%</b>

\*The number of supervisors may vary by quarter based on the data provided by each Office.

\*\*This data is based on the 16-hour minimum annual training requirement for managers with 3 or more years of experience. New supervisors within the federal government have an additional 24-hour training requirement, for a total of 40 hours.

## Leadership Training - LRP

### Leadership Readiness Program (LRP):

The Leadership Readiness Program (LRP) is a one-year learning opportunity for employees considering a supervisory career path. The LRP facilitates learning in the areas of mentoring, self-study, classroom-based courses, and other practical activities. The target audience is highly motivated, non-managers at the GS 12, 13, and non-supervisory 14 levels or equivalent Commissioned Corps Officers rank, with a minimum of two years of FDA experience. Participants are selected for the one-year program through a competitive process. They remain in their current position and participate in the LRP as a collateral activity.

### LRP Participant Data:

LRP Program Year	Office	# of Enrolled Participants	# of Participant Completions
<b>2006 - 2007</b>	OIVD	3	3
	ODE	13	12
<b>2008 - 2009</b>	OIVD	3	3
	ODE	10	10
	Other	17	16
<b>2010 - 2011</b>	OIVD	3	3
	ODE	9	8
	Other	8	8
<b>2012 - 2013</b>	OIR	3	3
	ODE	6	6
	Other	11	11
<b>2014 - 2015</b>	OIR	2	2
	ODE	6	6
	Other	12	12
<b>2016-2017</b>	OIR	3	3
	ODE	9	9
	Other	8	8
<b>2018-2019</b>	OIR	4	-
	ODE	11	-
	Other	7	-
<b>Total:</b>		<b>148</b>	<b>123</b>

## CDRH Training Courses by Category:

The following section contains a sampling of DETD courses provided during FY19.

### **Regulatory and Law (LAW) Training:**

Benefit-Risk Guidance – Online	This online course outlines the factors to consider when making benefit-risk determinations for Premarket Approval (PMA) applications and De novo petitions.
Master Four-Part Harmony	This course provides instruction on writing deficiencies that are clear, concise, and in the appropriate format.
Master Technical Writing	This course teaches the basic elements of plain language writing and how they are used to write clear and succinct technical documents.
Pre-Submission Program, Meetings with FDA, IDEs, and Clinical Trials	This course provides practical knowledge about the reviewer's roles and responsibilities related to the Pre-submission program, meetings and clinical trials.
Effective Communication Skills for Technical and Scientific Professionals	This course addresses real-world communication strategies for scientific and technical professionals.
Introduction to Premarket Review	This course describes the essential elements in premarket review.
Premarket programs: 510k and 513g	This course provides an understanding of the device classifications.
Conducting 510k Reviews	This course provides an overview of the 510(k) flowchart.
Basics of Writing Consult Requests and Reviews	This course provides examples of the essential elements of a pre-market consulting review.
Premarket Programs: IDEs	This course provides an understanding of the regulatory submission that permits clinical investigation of medical devices.
Premarket Programs: PMA and HDE	This training outlines the types of PMA submissions and the information necessary to determine when a PMA is required.
Premarket Review Clinic	The training prepares the participant to complete the CAPSTONE assignments distributed following completion of the Reviewer Certification Program.
Reviewer Certification CAPSTONE	This training includes interactive sessions that discuss the varying types and requirements of medical device applications.
Regulatory Basics (online)	This training describes the source and effect of law, regulation, and guidance on the work conducted within CDRH.
MDUFA IV Overview	This training provides an overview of the Medical Device User Fee Act of 2017.

Basics of 4-Part Harmony in Lead and Consult Reviews	This training provides participants with instruction on the elements needed to write clear and concise deficiencies.
RCP: Standards Overview	This training provides an overview of Standards and how they are applied.
RCP: Standards Resources and Premarket Use	This training provides participants with instruction on how to find recognized Standards and discusses how Standards are used in premarket submissions.
RCP: Basics of Standards in Premarket Review	This training provides participants with instruction on locating recognized Standards, Standard's guidance, and accessing library resources addressing Standards.
Overview of FOIA	This training provides an overview of FOIA applications and discusses the impact of OPEN Government amendments to FOIA.
SMART Template	This class provides instruction for using a programmed Microsoft Word document to create review documents.
RCP Premarket Program: De Novo Classification	This class describes the legal basis for the De Novo pathway.

### **Leadership Development Training for Managers and Non-Managers (LED) Training:**

Handling People with Diplomacy & Tact	This course provides participants with a big-picture mentality regarding their work and a blueprint for productivity. Participants also learn techniques for empowering their team and holding them accountable.
LEAD: CDRH Manager Orientation Program	This training provides managers with resources to navigate professional development and human resource information for themselves as well as the employees they supervise.
LEAD: Diversity, Unconscious Bias	This course provides organizations with an understanding of unconscious bias, the tools to confront and combat its negative effects; and the ability to recognize when the impact on decision making.
LEAD: Managing Up, Communicating with Your Boss	This course focuses on the skills necessary for managing upward including effective communication, achieving goals and providing constructive feedback.
Negotiating with Confidence	This interactive program enables participants to better communicate their needs and negotiate with confidence using practical application.
Critical Thinking and Problem Solving	This two-day workshop is designed to provide an understanding of the differences between critical thinking styles and how they are applied in the everyday world.

### **Professional Development (PRO) Training:**

Growing Creativity and Innovation	This course explores both the nature and nurture of creativity and innovation and the capacity for putting these vital skills into everyday practice.
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Strategic Planning and Analytical Thinking	This course provides participants with an understanding of the different analytical styles and how they affect and inhibit analytical thinking. Tools used in analytical thinking and ways to increase creative thinking are also addressed.
Critical TOP Thinking	This training provides an overview and tools for Thought Optimized Processing (TOP) Thinking. Participants learn how to accomplish TOP in a pragmatic way while maintaining precision and accuracy. Instruction also addresses the ability to think creatively and critically while ensuring that reasoning is objective.
Influencing Others for High Impact	This seminar focuses on the skills and strategies necessary to increase the likelihood that others will say "yes". The course instruction includes an opportunity to translate theory into practice.

### Science (SCI) Training:

Introduction to Public Health	This course provides the framework for understanding public health concepts, the fundamentals of epidemiology, medical product surveillance systems, and the public health determinants that influence medical device development.
CDRH Laboratory Waste Management – online	This course gives an overview of the requirements for waste handling in CDRH laboratories, as well as a brief description of the laboratory Emergency Procedures.
Regenerative Medicine Series	The Regenerative Medicine Seminar Series offers a variety of seminars that examine the restoration and function of the human form within the context of translational research involving medical devices and biologics.
Reprocessing Medical Devices in Health Care Settings	This course is designed to provide staff involved in medical device regulation with the knowledge necessary to perform routine labeling evaluations based on FDA's 2015 Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

### Center-Specific IT (CIT) Training

Using IT Systems in Premarket Review	This online course is designed to provide an overview of the IT systems used in medical device regulation.
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## CDRH Quality Management and Organizational Excellence (QMOE) Program

FY 2019 Summary

### A. Reporting Requirement

The CDRH Quality Management and Organizational Excellence (QMOE) Program FY 2019 Summary FY 2019 meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:<sup>1</sup>

*“VI. Performance Reports...3. In addition, the Agency will provide the following information on an annual basis... 3.14. Report on quality management program 3.15. Summary of quality system audits...”*

### B. CDRH Quality Management Program

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:<sup>2</sup>

*...The Agency will establish a dedicated Quality Management (QM) Unit that reports directly to the CDRH Director or Deputy Director...*

#### 1. Quality Management Unit Expertise

- **ISO 9001:2015 Quality Management Systems.** All CDRH QMOE Program Staff at the Office of the Center Director satisfactorily completed training associated with quality auditing under an ISO 9001:2015 Quality Management Systems (QMS).
- **Quality Credentials.** Collectively, CDRH QM staff (from the QM Unit and OPEQ QM) hold the following quality-related certifications: ASQ Certified Quality Improvement Associate (CQIA); ASQ Certified Quality Auditor (CQA); ASQ Certified Quality Engineer (CQE); ASQ Certified Manager of Quality and Operational Excellence (CMQOE); ASQ Certified Lean Six Sigma Yellow Belt (CLSSYB); ASQ Certified Lean Six Sigma Green Belt (CLSSGB); and ASQ Bronze Level Kirkpatrick Evaluation Certification Program.

#### 2. Quality Management Training. To support the adoption of quality management across CDRH, the following training was provided in FY 2019:

- ISO 9001:2015 Requirements from A-Z
- ASQ Six Sigma Yellow Belt
- ASQ Six Sigma Green Belt
- ASQ Quality Auditor
- SOP Writing

<sup>1</sup> MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, <https://www.fda.gov/media/102699/download>; page 23; 20/02/2016

<sup>2</sup> MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, <https://www.fda.gov/media/102699/download>; pages 10-11; 20/02/2016

## C. CDRH Quality Management System (QMS)

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:<sup>3</sup>

*“...and establish a quality management framework for the premarket submission process in CDRH. The Framework will include infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation...”*

### 1. ISO 9001:2015 Certification

- In December 2019, the CDRH QMOE Program at the Office of the Center Director attained ISO 9001:2015 certification for the provision of quality management and operational excellence tools and services.
- As of September 30, 2019, the team is preparing for the required yearly surveillance audit, scheduled for November 2019.

### 2. Voice of the Customer

- **Customer Service Survey.** The CDRH customer satisfaction survey is available through the FDA.gov and is included in all CDRH staff email correspondence. Overall, industry satisfaction with CDRH was above 92 percent in FY 2019. The industry submitters continue to positively comment on their satisfaction with the premarket review process.
- **Feedback✓CDRH.** Feedback✓CDRH is the internal system used to collect internal staff input. The input is assigned to offices that assess the need for actions. After feedback is addressed, final resolution is made available to all CDRH staff. In FY 2019 over 25 percent of the feedback received by OPEQ was related to premarket. All feedback was examined and addressed within the established CDRH timelines.

### 3. Document Control

- 3.1.** CDRH Document Control System (DCS) Components. The CDRH Document Control System includes the following components:
- **Document Change Requests (DCRs).** CDRH’s intake system. Minor improvements in FY2019.
  - **SWIFT Docs.** Repository of all CDRH control documents versions in their original form. Minor improvements in FY2019.
  - **CDRH Docs.** Staff access point. Documents are made available to staff through CDRH Docs or through links to CDRH Docs documents from other CDRH sites. Minor improvements in FY2019.
  - **Pilot Docs.** The system houses documents under pilot/being tested. Minor improvements in FY2019.
  - **Transmittal Notices (TNs).** CDRH’s notification system. TN is the QM provided mechanism to announce changes to documents to staff. Minor improvements in FY2019.

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<sup>3</sup> MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, <https://www.fda.gov/media/102699/download>; pages 10-11; 20/02/2016

- 3.2. DCS System – FY 2019 Improvements.** Minor Changes: Changes to QMS infrastructure for ease of use and alignment with the new CDRH organization. Major change: Simplified the CDRH template for controlled documents.
- 3.3. CDRH’s QMS Documentation.** All documents related to the CDRH QMS are being controlled using the CDRH DCS.
- 3.4. Conforming Offices Documentation.** All documents related to the management and execution of the premarket review program processes are being controlled using the CDRH DCS.

#### **4. Internal Audits**

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:<sup>4</sup>

*...At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH’s Corrective and Preventive Action (CAPA) process. FDA will expand the scope of its annual audits as it implements and builds up its auditing capability. As part of these ongoing audits, high-performing premarket review processes utilized in one division will be identified and shared accordingly with other divisions to improve efficiencies and effectiveness. At a minimum, FDA audits in the following areas will be completed by the end of FY 2020: Deficiency Letters and Pre-Submissions. Additional audits in the following areas will be completed by the end of FY 2022: Submission Issue Meetings, Interactive Review, Withdrawals and Special 510(k) conversions...*

- 4.1. Audit Schedule 2020.** Data call for FY 2020 internal audit schedule is planned for November 2019. The following internal audits are already in the FY 2020 schedule:

- Deficiency Letters (follow-up to AF-2018-00003)
- Pre-Submissions (MDUFA Required<sup>4</sup>)
- Focal Point Program – Biocompatibility
- ISO 9001:2015 (External Audit)
- CDRH QMS Core Processes

- 4.2. Internal Audit Schedule FY 2019.**

- Requested input from internal and external customers in December 2018.

- 4.3. 2019 Audits (Final)**

Title	Purpose
AF-2018-00003	Assess use of “Four-Part Harmony” (meets MDUFA commitment for FY 2020 “Deficiency Letter” audit <sup>5</sup> )

<sup>4</sup> MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, <https://www.fda.gov/media/102699/download>; page 11; 20/02/2016

<sup>5</sup> MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, <https://www.fda.gov/media/102699/download>; page 11; 20/02/2016

<b>AF-2018-00004</b>	Internal quality audit; verifying the document control system and record management to ISO 9001:2015 requirements.
<b>AF-2018-00005</b>	Internal quality audit; verifying the internal audit system to ISO 9001:2015 requirements.
<b>AF-2018-00006</b>	Internal quality audit; assess the quality management system (QMS) Scope of Registration found on Doc 1207, <i>CDRH Quality Management Program Scope</i> , (v1.01, effective on 11/09/2018), Section 1.3.
<b>AF-2018-00007</b>	Internal quality audit; verifying the Risk, Nonconformance and Corrective Action systems to ISO 9001:2015 requirements.
<b>AF-2018-00008</b>	Internal quality audit; verifying the Feedback CDRH system to ISO 9001:2015 requirements.
<b>AF-2018-00009</b>	Internal quality audit; verifying the Quality Management Review system to ISO 9001:2015 requirements.

**5. Continual Improvement. In FY 2019, the QM CDRH oversaw the following improvement efforts:**

- 5.1. Assessment of the Management of the Premarket Review Program (Report Published<sup>6</sup>).** FDA completed an independent Third-Party executed assessment, led by the FDA Office of the Commissioner. The assessment covered several topics suggested by industry during the FY 2018 Audit Schedule data call (withdrawal process, deficiency letters, and sponsor communications). With the publication of the report, FDA met the following MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022 requirement:<sup>7</sup>

*“... Independent Assessment of Review Process Management - Phase 1...During the first phase, the contractor will complete an evaluation of FDA’s implementation of the corrective action plan developed in response to recommendations from the MDUFA III independent assessment. For Phase 1, FDA will award the contract by the end of CY2017. The contractor will evaluate the implementation of MDUFA III recommendations and publish a written assessment within 1 year of contract award...”*

- 5.2. Business Process Improvement (BPI; ongoing).** In support of CDRH’s 2018-2020 Simplicity Strategic Priority and Digital Transformation Initiative, this project aims to lean CDRH core businesses processes. Effort objectives include:
- Simplify processes to improve process efficiency, repeatability and effectiveness
  - Support process harmonization to increase standardization
  - Improve **clarity** of process and supporting documents (e.g., Standard Operating Procedures, Work Instructions, etc.)

<sup>6</sup> Link to Report: [Medical Device User Fee Amendments IV Independent Assessment of Food and Drug Administration's Device Review Process Management](https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-review-process-management) or <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2017-mdufa-iv>

<sup>7</sup> MDUFA Performance Goals and Procedures, Fiscal Years 2018 Through 2022, <https://www.fda.gov/media/102699/download>; page 11; 20/02/2016

- In FY 2019, 176 individuals (10% CDRH staff) began executing 27 processes improvement efforts (over 40% of CDRH core Processes), including:
  - Consults
  - Premarket Approval (PMA)
  - 510(k)
  - Pre-Submission (Q-Sub)
  - Staff Training
  - De Novo
  - PAS / 522
  - Pre-EUA / EUA
  - CLIA
  - IDE
  - 513(g)
  - Third Party Review
  - Public Meetings
  - Information Disclosure (FOIA)