

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

May 17, 2018, 11:30 – 1:00

WebEx

Welcome

Guidance Development

FDA MDUFA Performance — Actions through March 31, 2018

- Report on decision goals for 2nd Quarter FY 2018.

Qualitative Update on Finances – 2nd Quarter FY 2018

- User fee receipts through the 2nd Quarter FY 2018.
- Number of discretionary fee waivers or reductions granted by type of submission.

CDRH Registration and Listing

- Report on registration and listing.

CDRH Training update

Reminder: Set date for 3rd Quarter 2018 meeting

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Medical Devices

Guidance Documents

Pursuant to the MDUFA IV Commitment Letter,¹ 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).²

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2018

#	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	User Fees and Refunds for De Novo Classification Requests - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM576306	10/02/2017	Yes	No	N/A	A-List
2	Q1	User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345633	10/02/2017	Yes	No	N/A	A-List
3	Q1	FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089734	10/02/2017	Yes	No	N/A	A-List
4	Q1	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 www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM576305	10/02/2017	Yes	No	N/A	A-List

¹ www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf; see section VI (Performance Reports)

² www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm580172.htm

5	Q1	User Fees for 513(g) Requests for Information - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209858	10/02/2017	Yes	No	N/A	A-List
6	Q1	User Fees and Refunds for Premarket Notification Submissions (510(k)s) - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345931	10/02/2017	Yes	No	N/A	A-List
7	Q1	FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738	10/02/2017	Yes	No	N/A	A-List
8	Q1	Administrative Procedures for CLIA Categorization - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM070889	10/02/2017	No	No	N/A	A-List
9	Q1	Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176	10/02/2017	Yes	No	N/A	A-List
10	Q1	Display Devices for Diagnostic Radiology - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM484914	10/02/2017	No	No	N/A	N/A
11	Q1	Classification and Requirements for Laser Illuminated Projectors (LIPs) (Laser Notice No. 57) - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM578044	10/02/2017	No	No	N/A	N/A
12	Q1	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM578118	10/02/2017	Yes	No	N/A	N/A

13	Q1	Breakthrough Devices Program - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664	10/25/2017	Yes	Statute	Sec. 515B(f) of the FD&C Act	N/A
14	Q1	Deciding When to Submit a 510(k) for a Software Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514737	10/25/2017	Yes	Commitment Letter	Section I.2	N/A
15	Q1	Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514771	10/25/2017	Yes	Statute	Sec. 3059(b) of the 21 st Century Cures Act	N/A
16	Q1	Acceptance Review for De Novo Classification Requests - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM582251	10/30/2017	Yes	Commitment Letter	Section E	N/A
17	Q1	Manufacturers Sharing Patient-Specific Information from Medical Devices with Patients Upon Request - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM505756	10/30/2017	No	No	N/A	N/A
18	Q1	De Novo Classification Process (Evaluation of Automatic Class III Designation) - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080197	10/30/2017	Yes	No	N/A	N/A
19	Q1	Product Labeling for Certain Ultrasonic Surgical Aspirator Devices - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM528182	10/30/2017	Yes	No	N/A	N/A
20	Q1	Evaluation of Devices Used with Regenerative Medicine Advanced Therapies; Draft Guidance for Industry www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585417.pdf	11/17/2017	Yes	Statute	Section 3034 of 21st Century Cures Act	N/A

21	Q1	Unique Device Identification: Direct Marking of Devices - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452262	11/17/2017	No	No	N/A	N/A
22	Q1	Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM302938	11/28/2017	Yes	No	N/A	N/A
23	Q1	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586502	11/29/2017	No	No	N/A	N/A
24	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 www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586506	11/29/2017	No	Statute	Sec. 3057 of the 21 st Century Cures Act	N/A
25	Q1	Technical Considerations for Additive Manufactured Medical Devices - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM499809	12/05/2017	Yes	No	N/A	N/A
26	Q1	FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions - Guidance for Sponsors, Clinical Investigators, Industry, Institutional Review Boards, and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM504091	12/05/2017	Yes	No	N/A	N/A
27	Q1	Software as a Medical Device (SAMD): Clinical Evaluation - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904	12/08/2017	Yes	No	N/A	N/A

28	Q1	Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820	12/08/2017	Yes	No	N/A	N/A
29	Q1	Clinical and Patient Decision Support Software - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587819	12/08/2017	Yes	No	N/A	N/A
30	Q1	The Least Burdensome Provisions: Concept and Principles - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914	12/15/2017	Yes	No	N/A	A-List
31	Q1	Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM071465	12/18/2017	Yes	No	N/A	B-List
32	Q1	Investigational IVDs Used in Clinical Investigations of Therapeutic Products - Draft Guidance for Industry, Food and Drug Administration Staff, Sponsors, and Institutional Review Boards www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM589083	12/18/2017	Yes	No	N/A	N/A
33	Q1	Medical Device Accessories - Describing Accessories and Classification Pathways - Guidance for Industry and FDA Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672	12/20/2017	Yes	No	N/A	A-List
34	Q2	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices - Immediately in Effect Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340	1/16/2018	No	No	N/A	A-List
35	Q2	Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56) - Draft Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592775	1/19/2018	No	No	N/A	N/A

36	Q2	Refuse to Accept Policy for 510(k)s - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014	1/30/2018	Yes	No	N/A	N/A
37	Q2	Acceptance and Filing Reviews for Premarket Approval Applications (PMAs) - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313368	1/30/2018	Yes	No	N/A	N/A
38	Q2	Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions - Guidance for Industry and Food and Drug Administration Staff www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM597273	2/21/2018	Yes	No	N/A	N/A

**Quarterly Update on
Medical Device Performance Goals ----
MDUFA IV CDRH Performance Data
----Action through 31 March 2018**

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Acronyms and Abbreviations

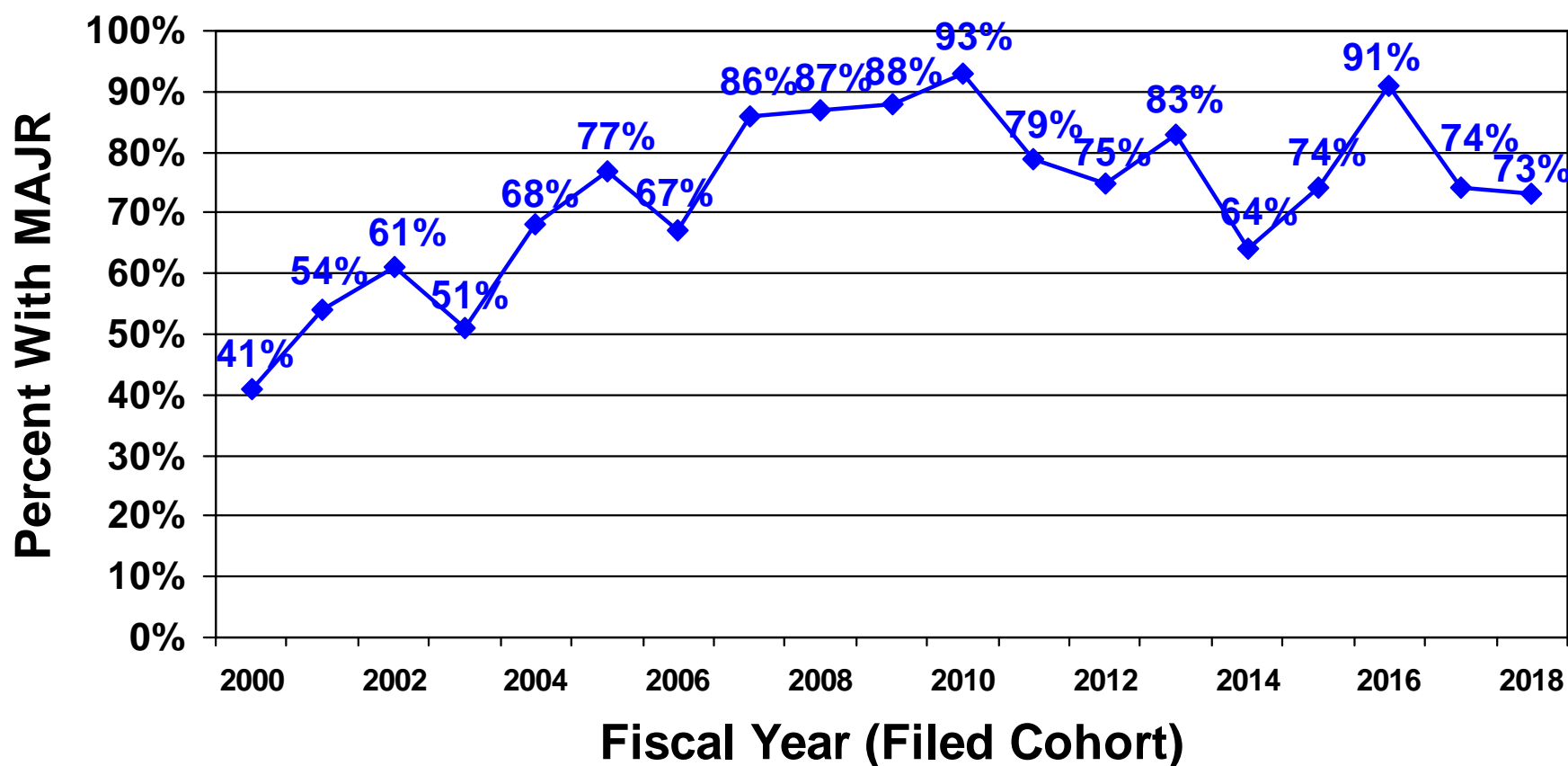
510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology 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

Q2FY18

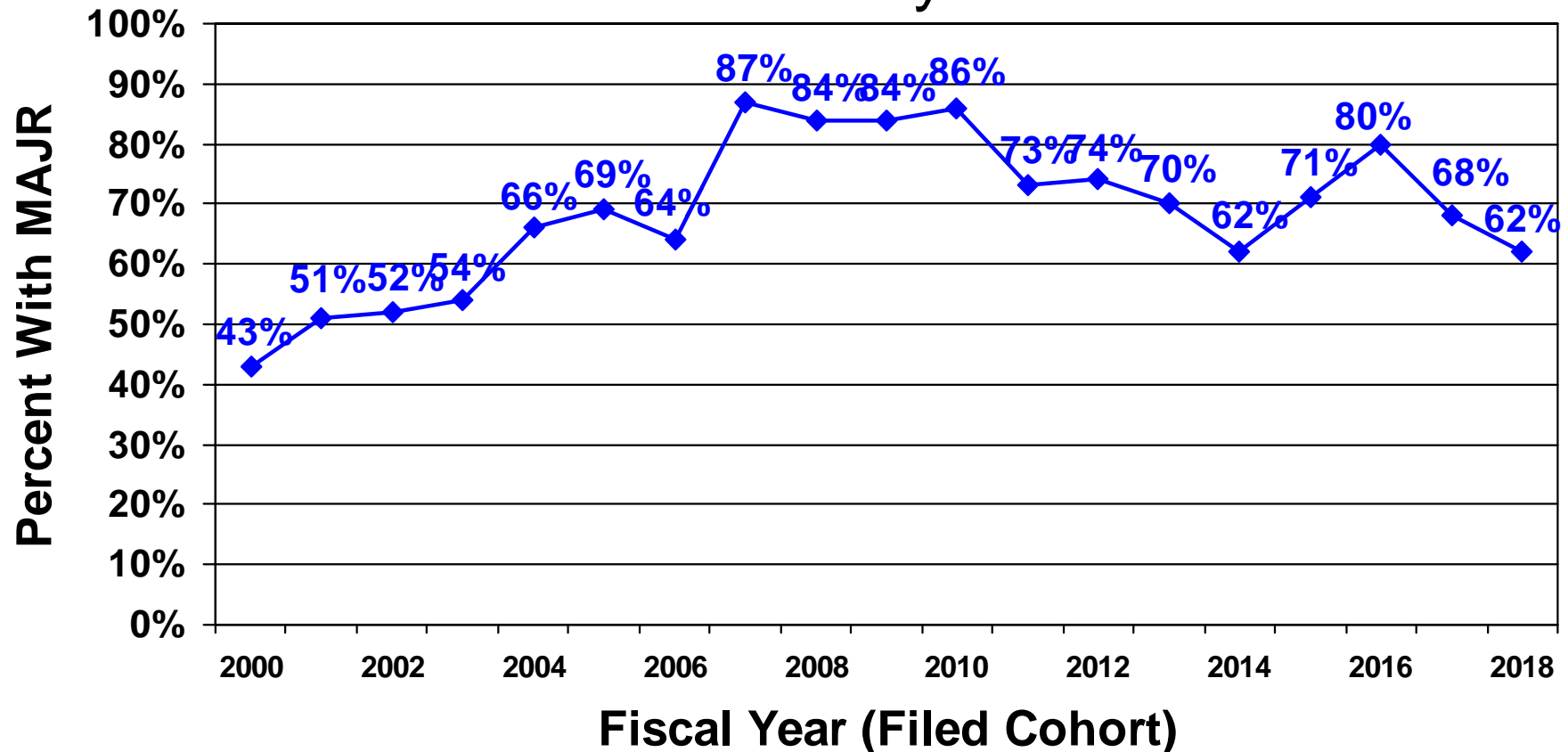
Percent of PMA Originals With Major Deficiency Letter on 1st* FDA Review Cycle*



- 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.

*Includes original PMAs filed as of 12/31/2017. Note that for the latest FY filed cohort, a Substantive Interaction of “Proceed Interactively” was considered to complete the first cycle.

Percent of PMA Originals and Panel Track Supplements With Major Deficiency Letter on 1st* FDA Review Cycle**

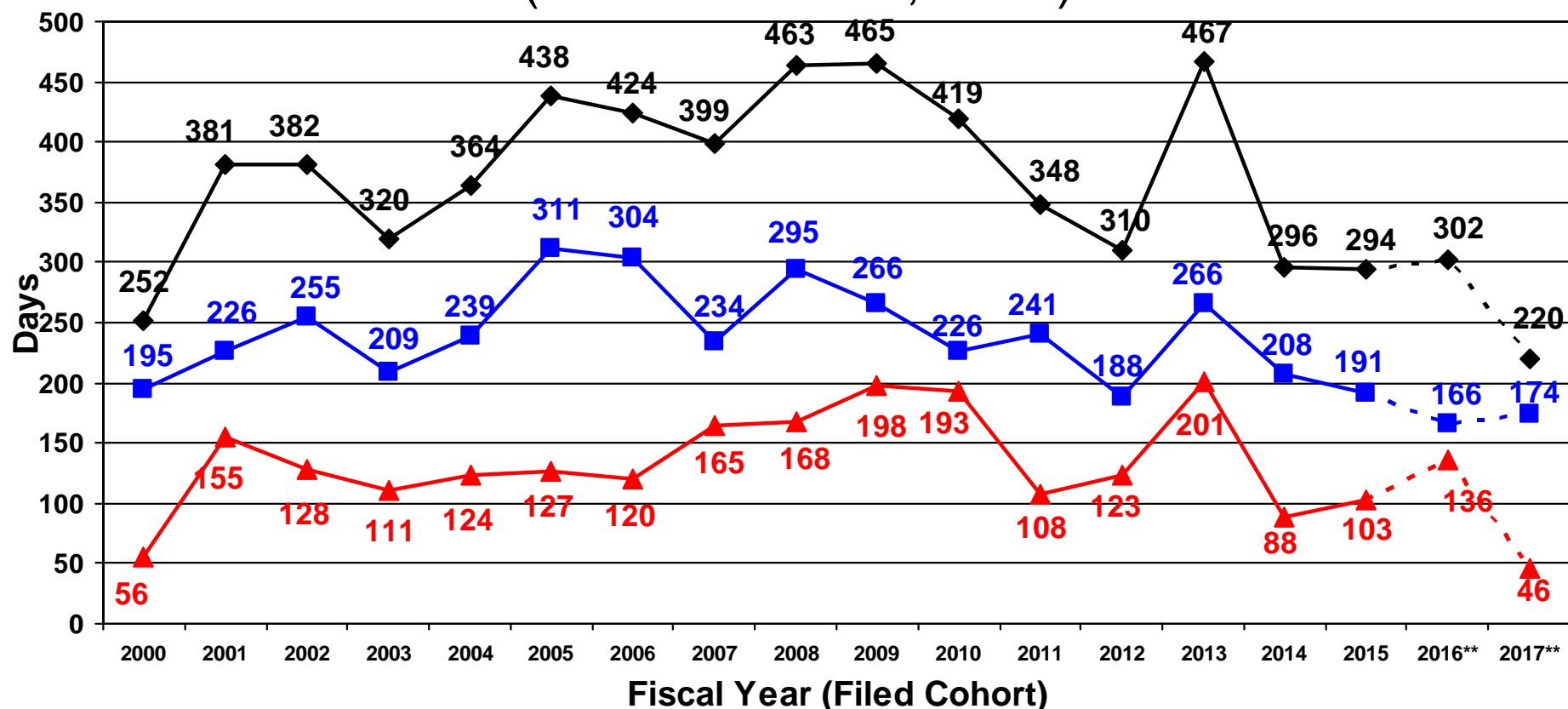


*Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle as of the date specified.

**Includes original PMAs/PTS filed as of 12/31/2017. Note that for the latest FY cohort, a Substantive Interaction of “Proceed Interactively” was considered to complete the first cycle.

Average Time to MDUFA Decision: PMA Originals*

(As of March 31, 2018)

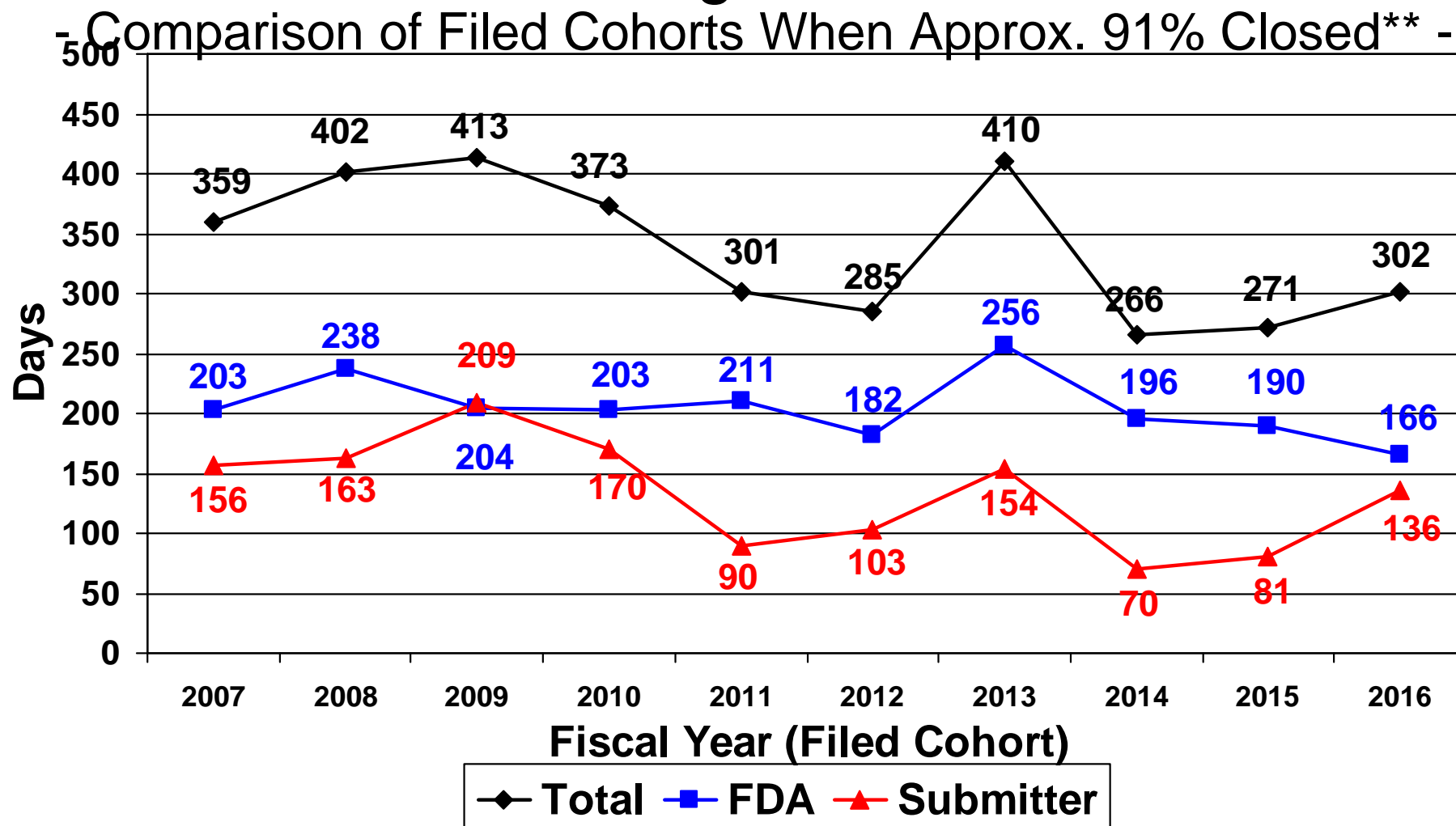


◆ Total ■ FDA ▲ Submitter

*Includes original PMAs filed as of 3/31/2018; times may not add to total due to rounding

** Cohort still open, average times will increase. Percent of cohort with MDUFA decision: FY16 = 91% (50/55); FY17 = 62% (24/39).

Average Time to MDUFA Decision: PMA Originals*

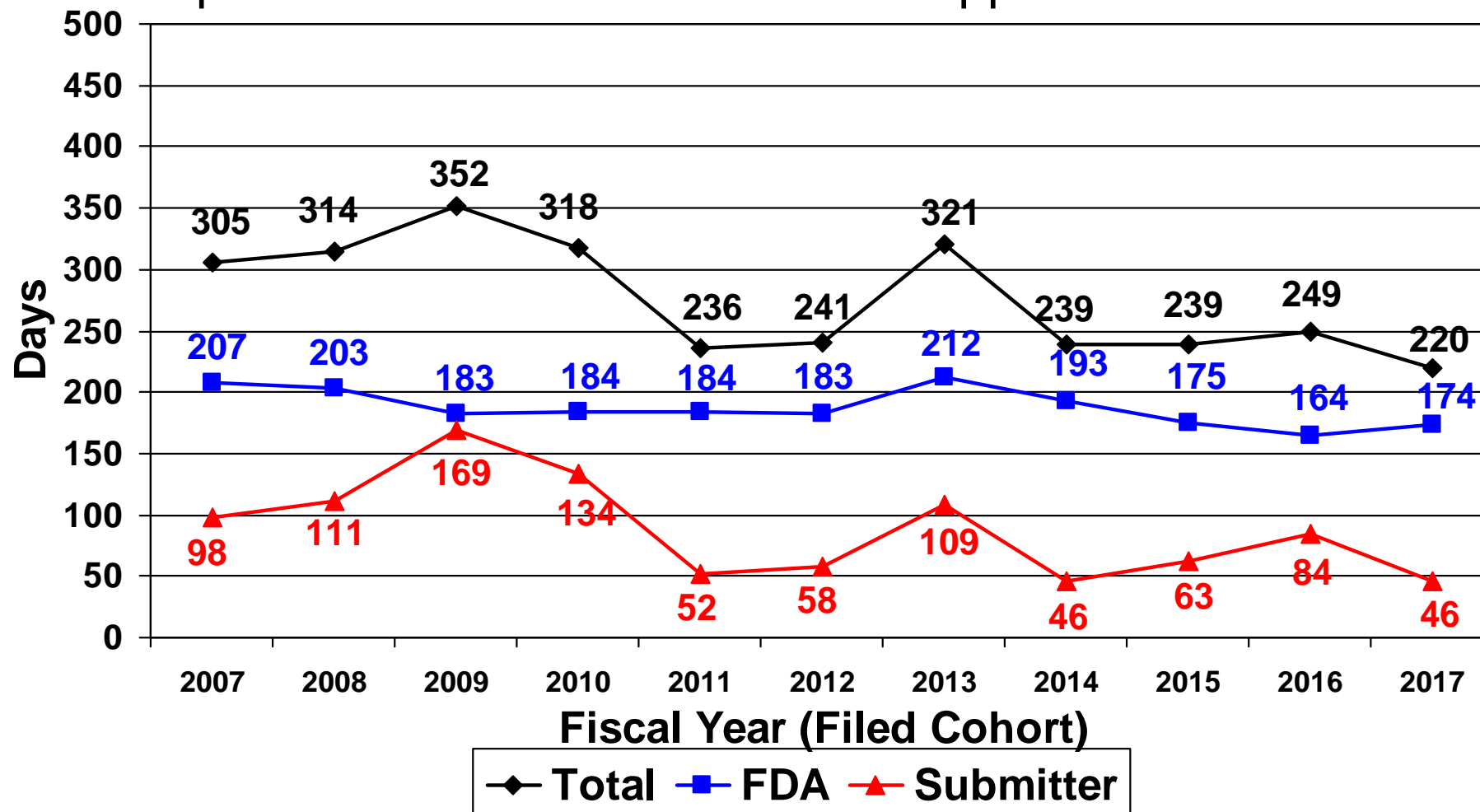


*Includes original PMAs only; times may not add to total due to rounding

**Proportion of cohort closed with MDUFA decision: FY16: 50/55; FY15: 38/42; FY14: 25/28; FY13: 26/29; FY12: 22/24; FY11: 39/43; FY10: 39/43; FY09: 29/32; FY08: 27/30; FY07: 32/35

Average Time to MDUFA Decision: PMA Originals*

- Comparison of Filed Cohorts When Approx. 62% Closed** -

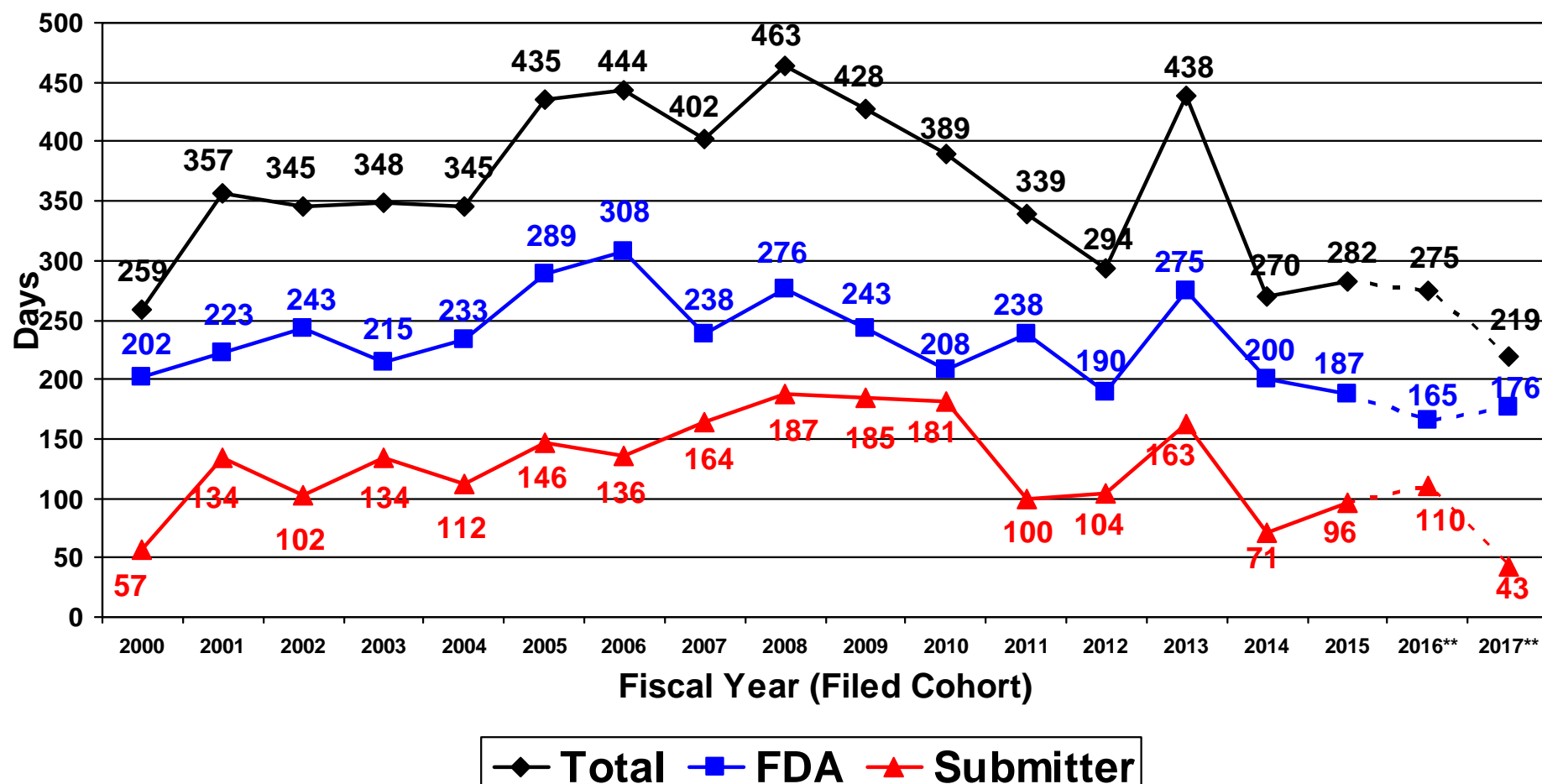


*Includes original PMAs only; times may not add to total due to rounding

**Proportion of cohort closed with MDUFA decision in this comparison: FY17: 21/39; FY16: 30/55; FY15: 23/42; FY14: 15/28; FY13: 16/29; FY12: 13/24; FY11: 23/43; FY10: 23/43; FY09: 17/32; FY08: 16/30; FY07: 19/35

Average Time to MDUFA Decision: PMA Originals and Panel Track Supplements*

(As of March 31, 2018)

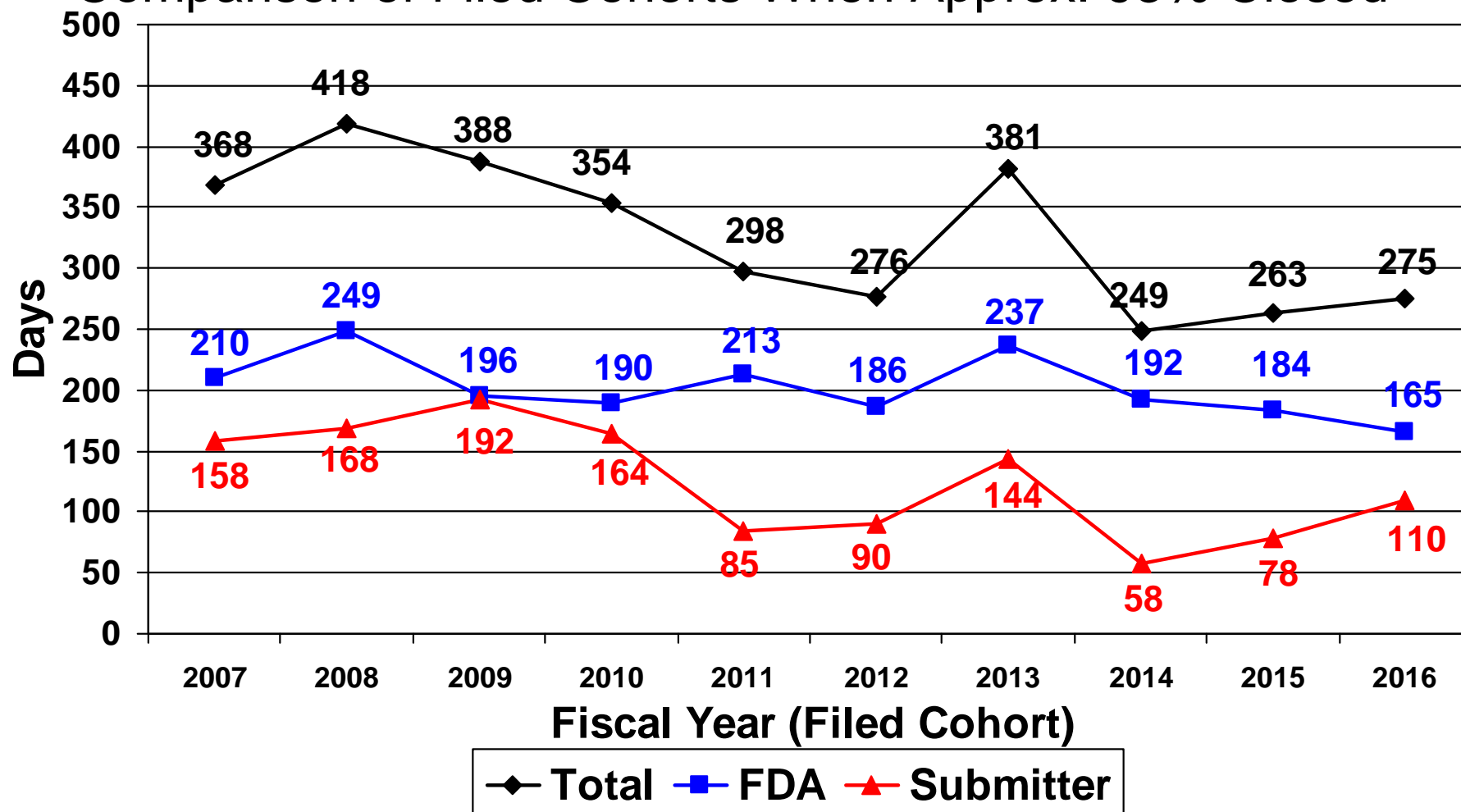


*Includes original PMAs/PTS filed as of 3/31/2018; times may not add to total due to rounding

** Cohort still open, average times will increase. Percent of cohort closed with MDUFA decision: FY16 = 93% (66/71); FY17 = 71% (46/65)

Average Time to MDUFA Decision: PMA Originals and Panel Track Supplements*

- Comparison of Filed Cohorts When Approx. 93% Closed** -

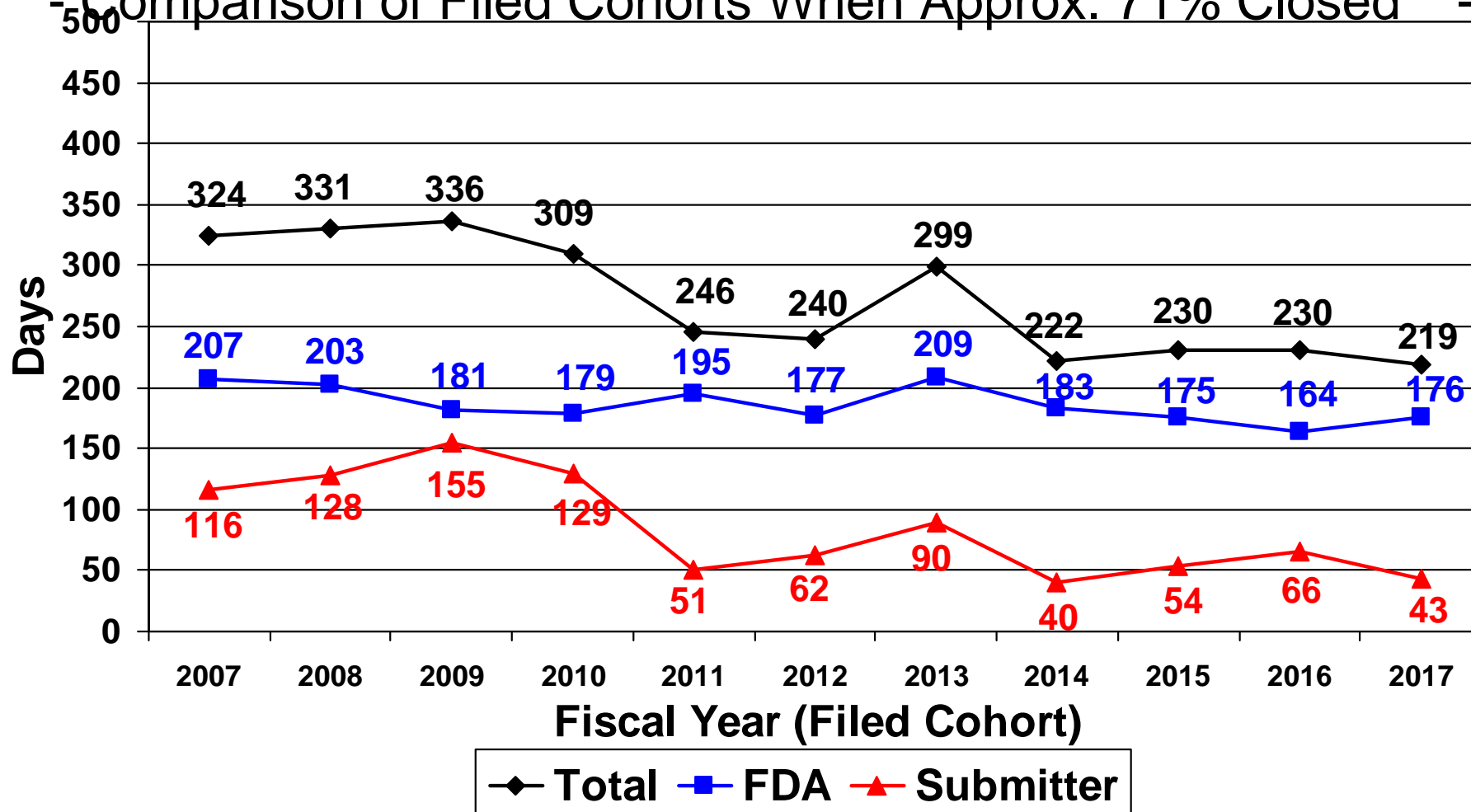


*Includes original PMAs and Panel Track Supplements; times may not add to total due to rounding

**Proportion of cohort closed with MDUFA decision in this comparison: FY16: 66/71; FY15: 63/68; FY14: 39/42; FY13: 41/44 ; FY12: 32/34; FY11: 47/51; FY10: 55/59; FY09: 40/43; FY08: 34/37; FY07: 36/39

Average Time to MDUFA Decision: PMA Originals and Panel Track Supplements*

- Comparison of Filed Cohorts When Approx. 71% Closed** -

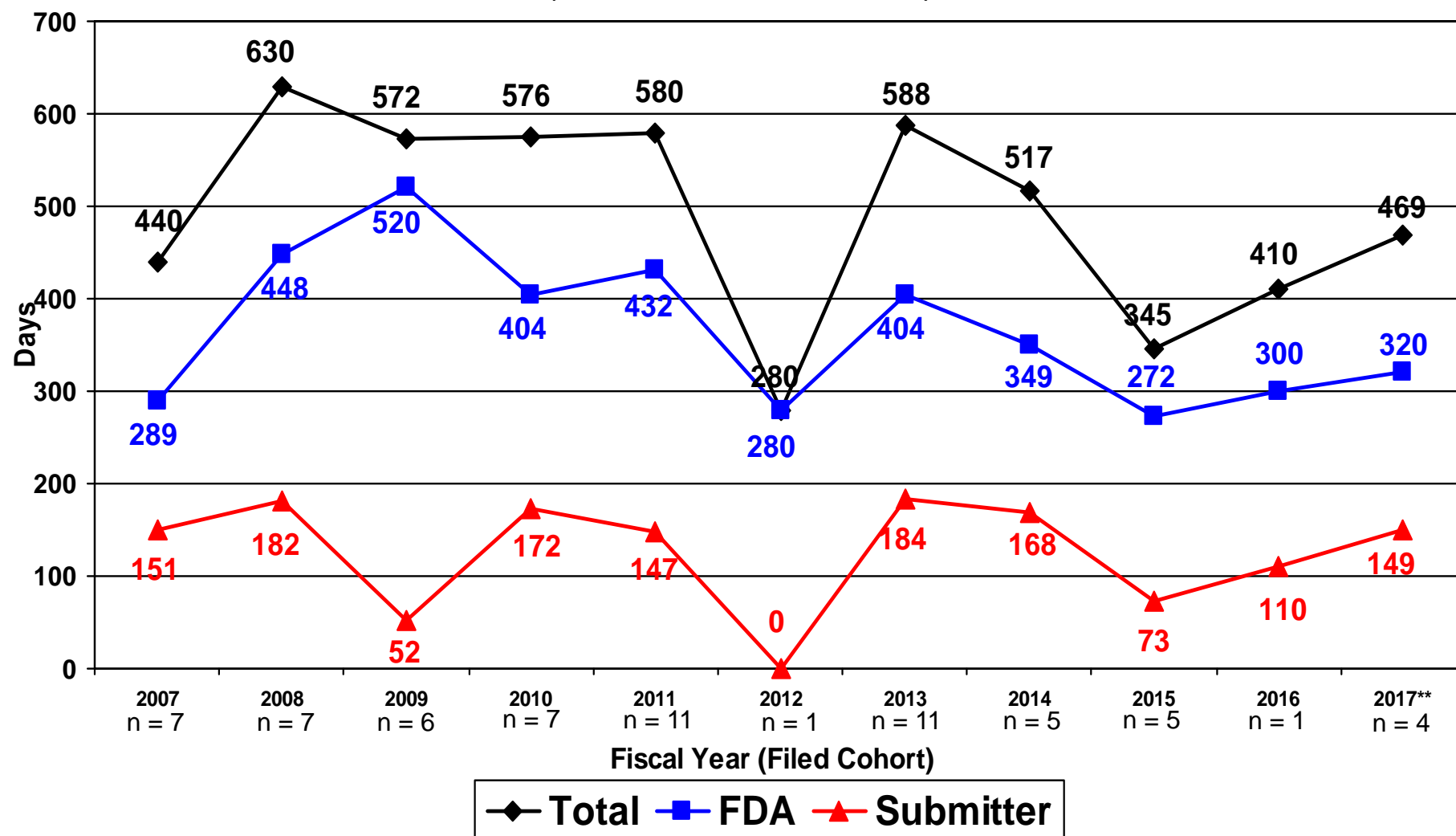


*Includes original PMAs and Panel Track Supplements; times may not add to total due to rounding

**Proportion of cohort closed with MDUFA decision in this comparison: FY17: 46/65; FY16: 50/71; FY15: 48/68; FY14: 30/42; FY13: 31/44 ; FY12: 24/34; FY11: 36/51; FY10: 42/59; FY09: 31/43; FY08: 26/37; FY07: 28/39

Average Time to MDUFA Decision: PMA Originals With Panel Review*

(As of March 31, 2018)

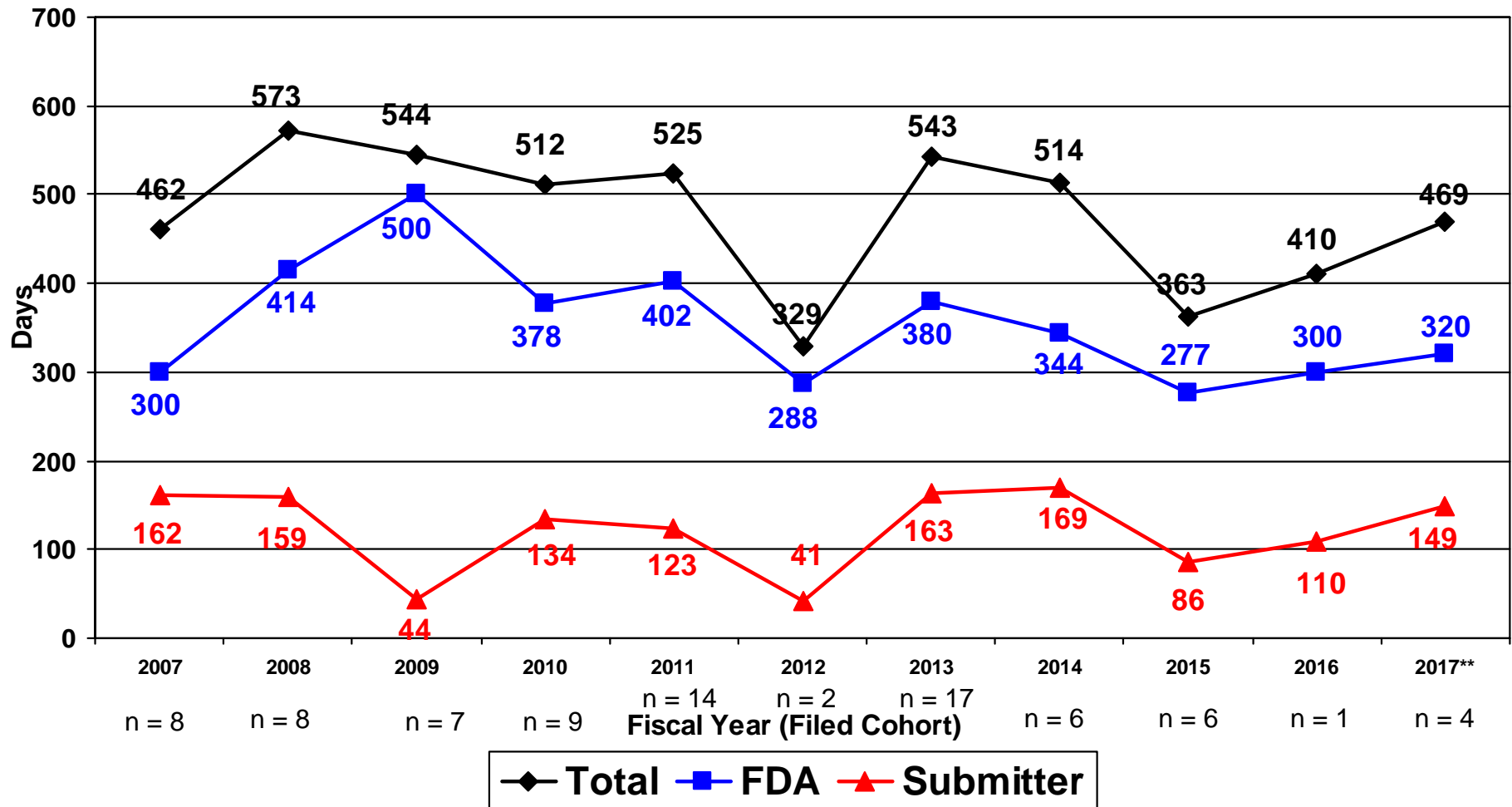


*Includes original PMAs filed as of 3/31/2018; times may not add to total due to rounding.

**Cohort still open; percent of cohort with MDUFA decision: FY17 = 25% (1/4).

Average Time to MDUFA Decision: PMA Originals & Panel Track Supplements With Panel Review*

(As of March 31, 2018)



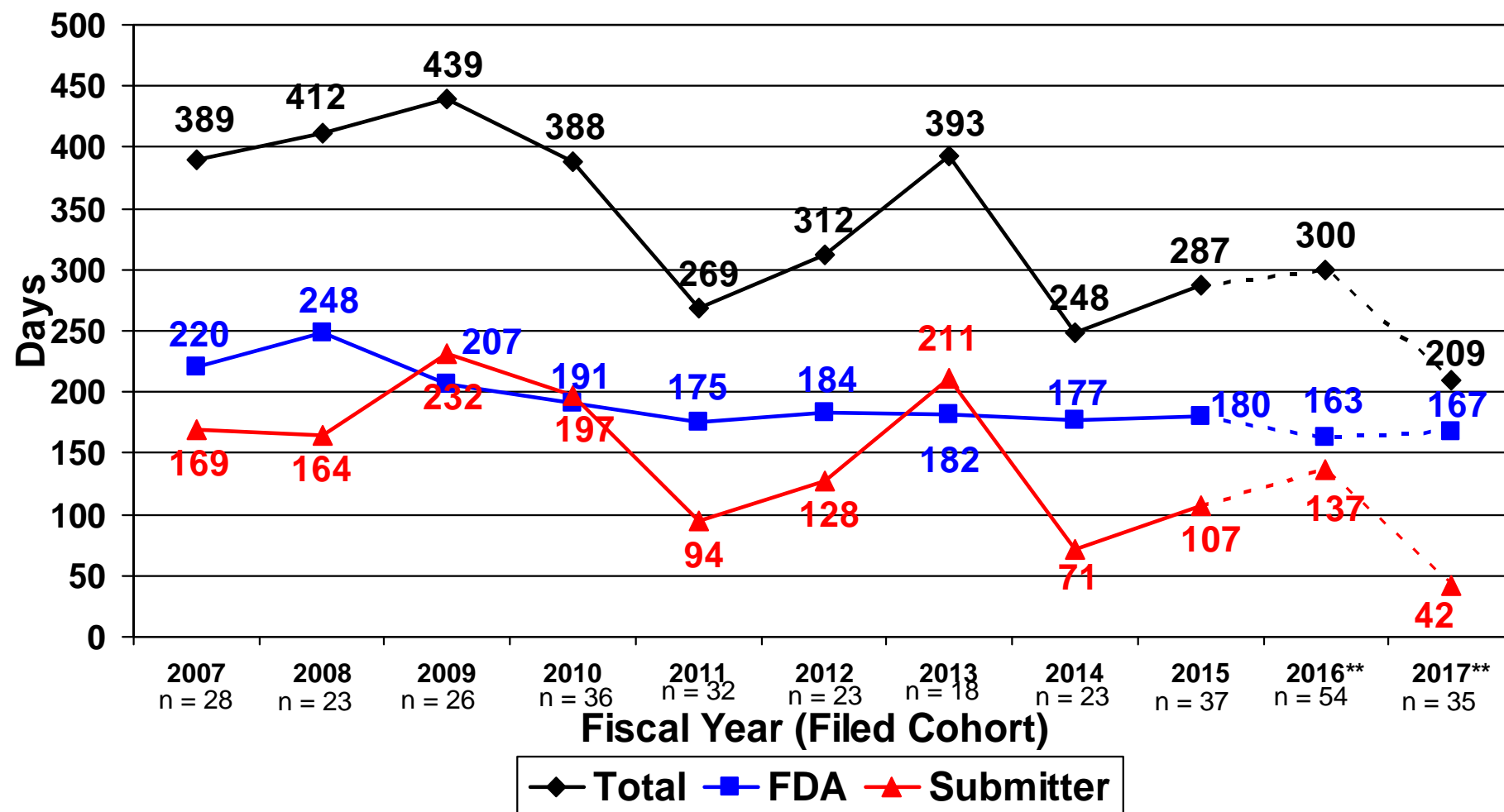
*Includes original PMAs/PTS filed as of 3/31/2018, prior cohorts are filed cohorts; times may not add to total due to rounding.

**Cohort still open; percent of cohort with MDUFA decision: FY17 = 25% (1/4).

- Performance data (from FY13 onward) map to Table 1.8 in CDRH MDUFA performance reporting. Numbers filed map to table 1.6.

Average Time to MDUFA Decision: PMA Originals Without Panel Review*

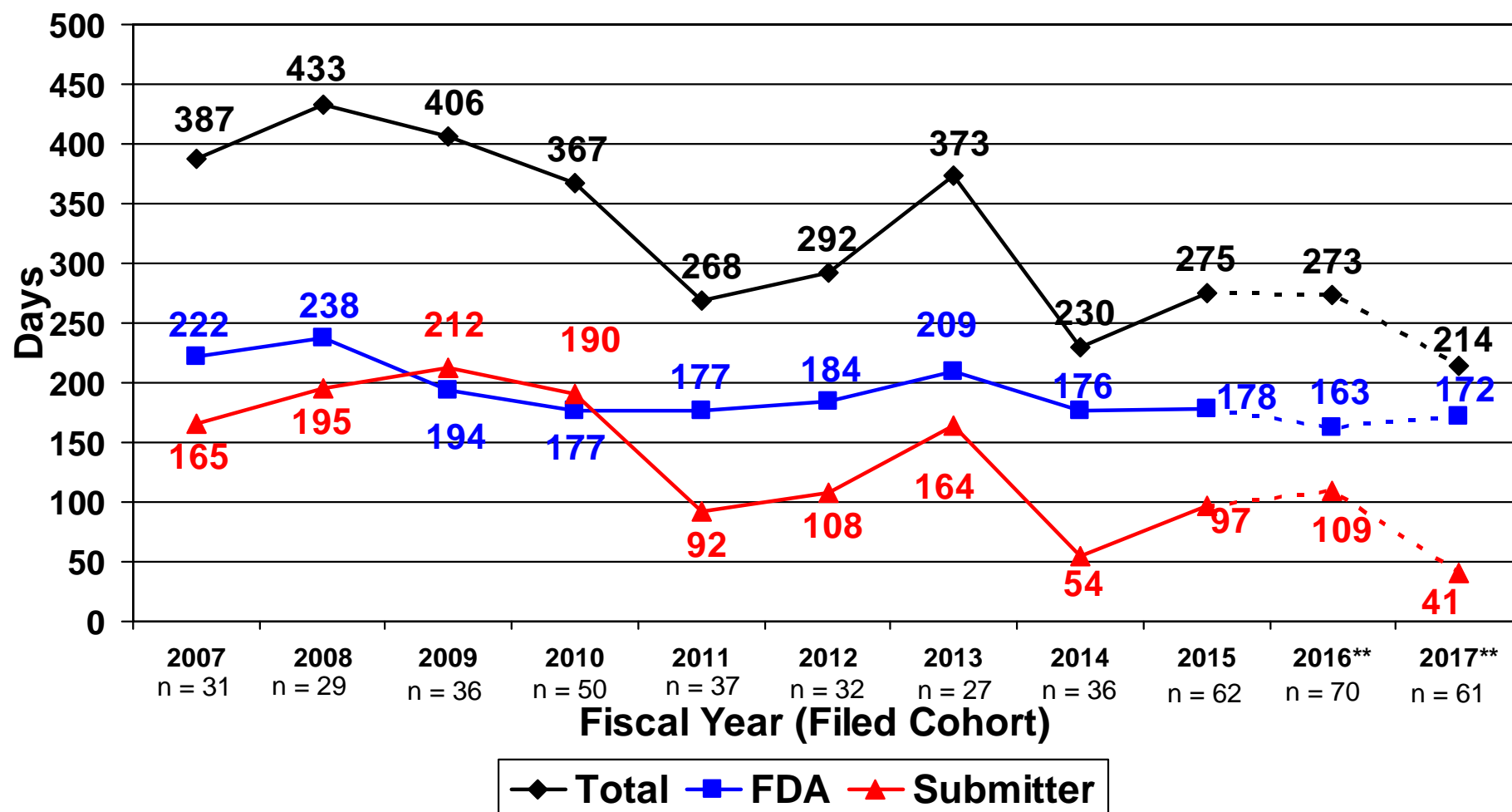
(As of March 31, 2018)



*Includes original PMAs filed as of 3/31/2018; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision:
FY16 = 91% (49/54); FY17 = 66% (23/35)

Average Time to MDUFA Decision: PMA Original & Panel Track Supplements Without Panel Review* (As of March 31, 2018)

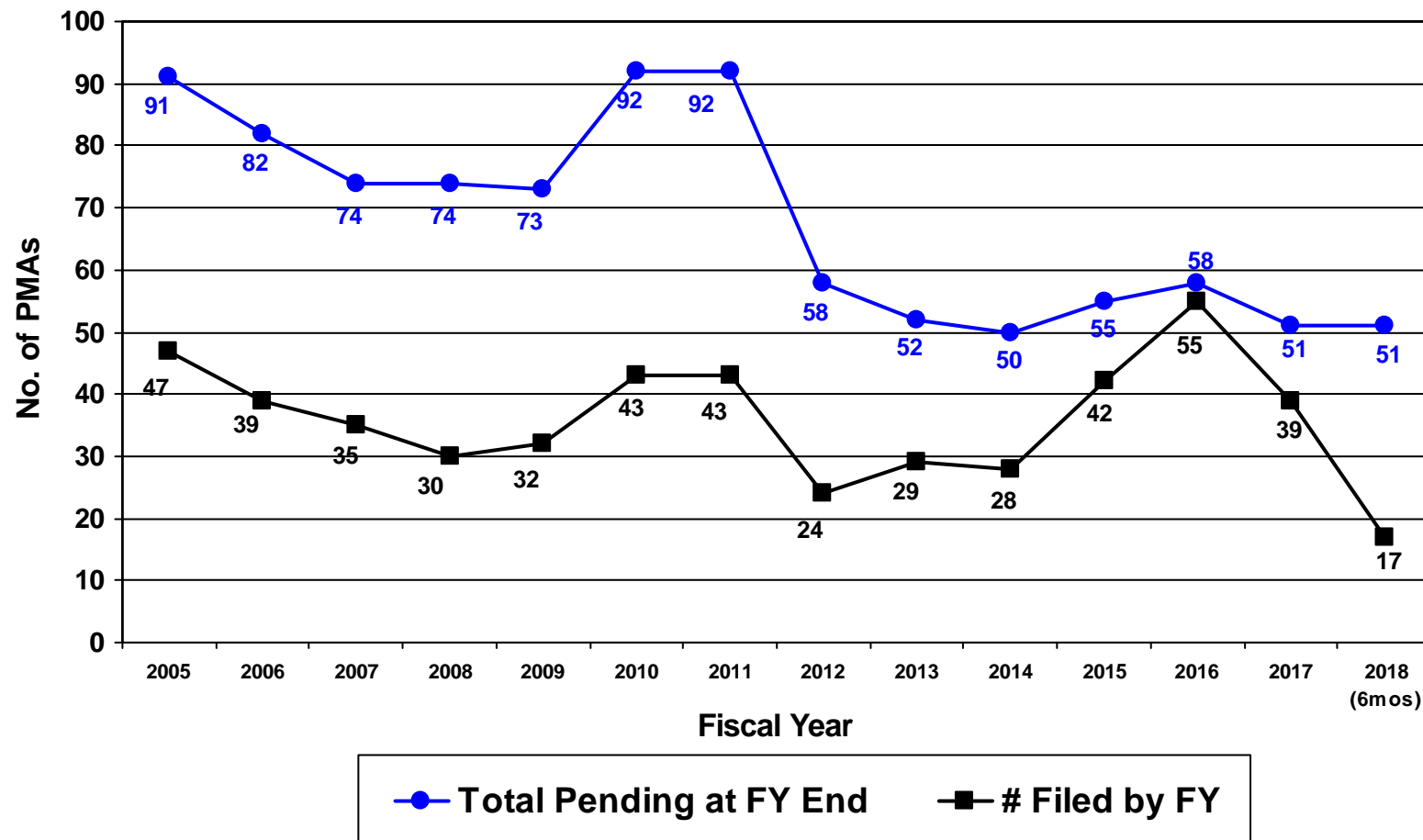


*Includes original PMAs/PTS filed as of 3/31/2018; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY16 = 93% (65/70); FY17 = 74% (45/61).

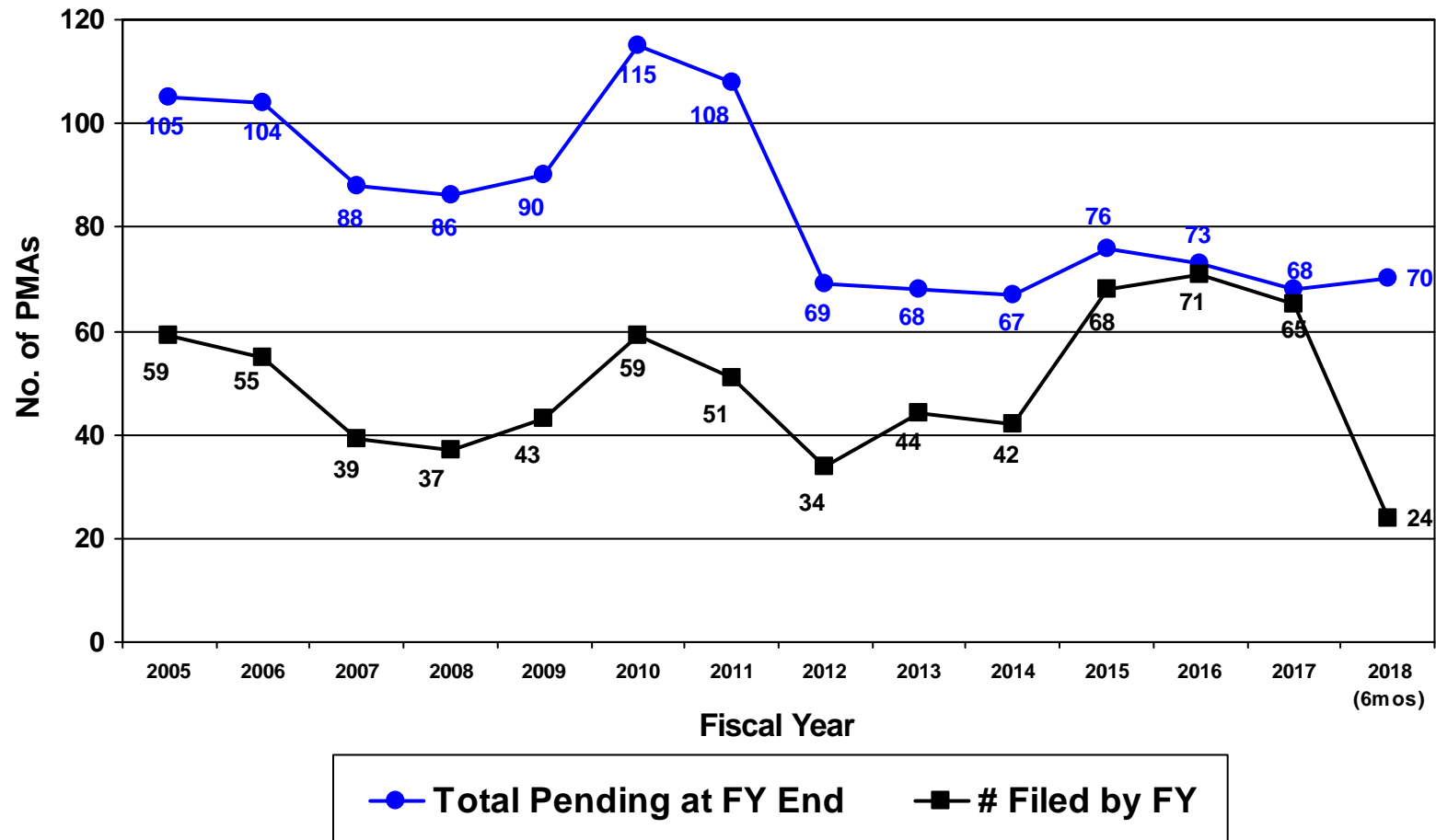
- Performance data (from FY13 onward) map to Table 1.7 in CDRH MDUFA performance reporting. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Year



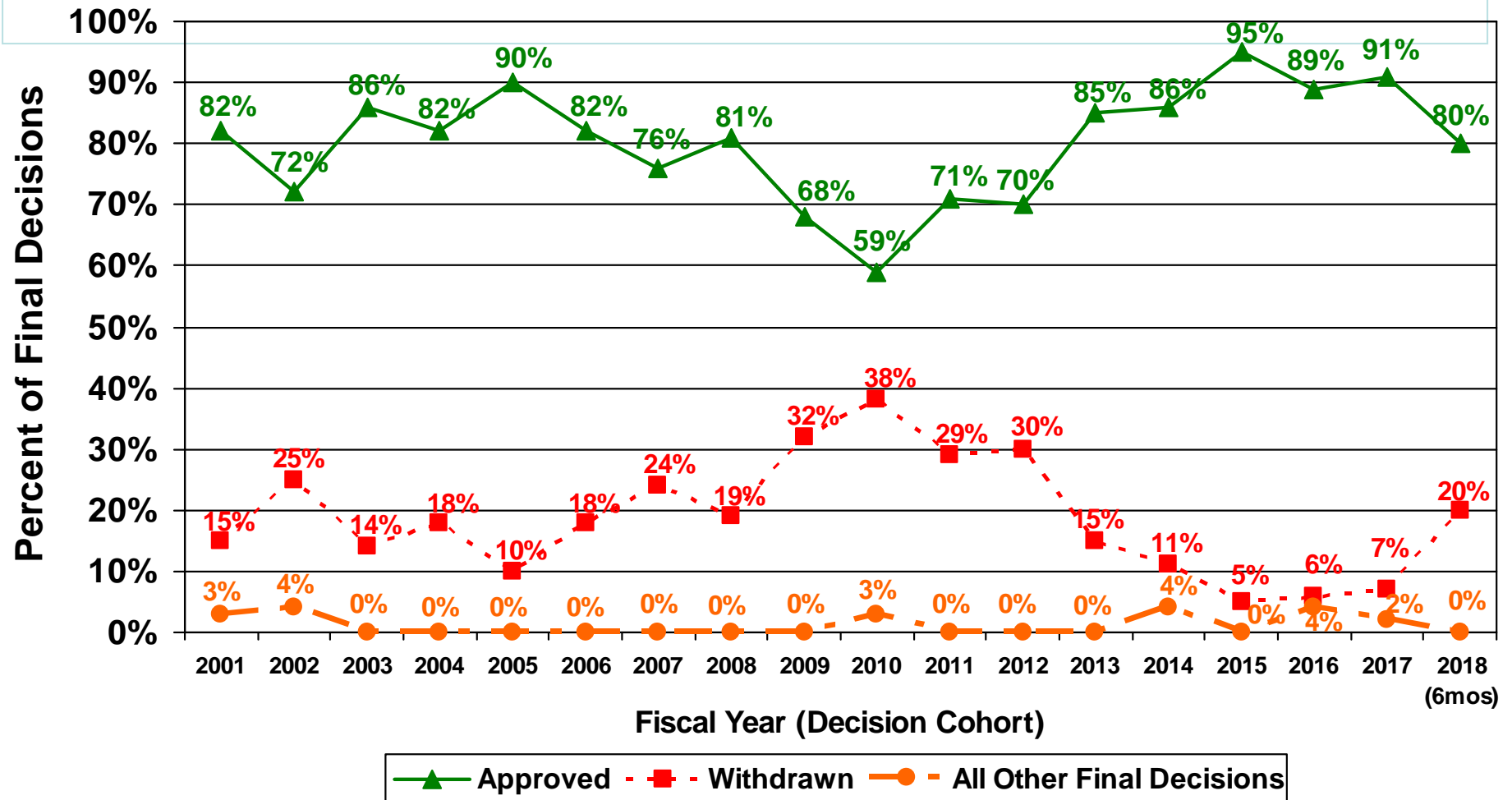
*Original PMAs under review or on hold. Excludes FY 2013 - FY 2018 receipts that were not accepted for review at quarter end

PMA Original and Panel Track Supplements Pending* at End of Year



*Original PMAs/PTS under review or on hold. Excludes FY 2013 - FY 2018 receipts that were not accepted for review at quarter end

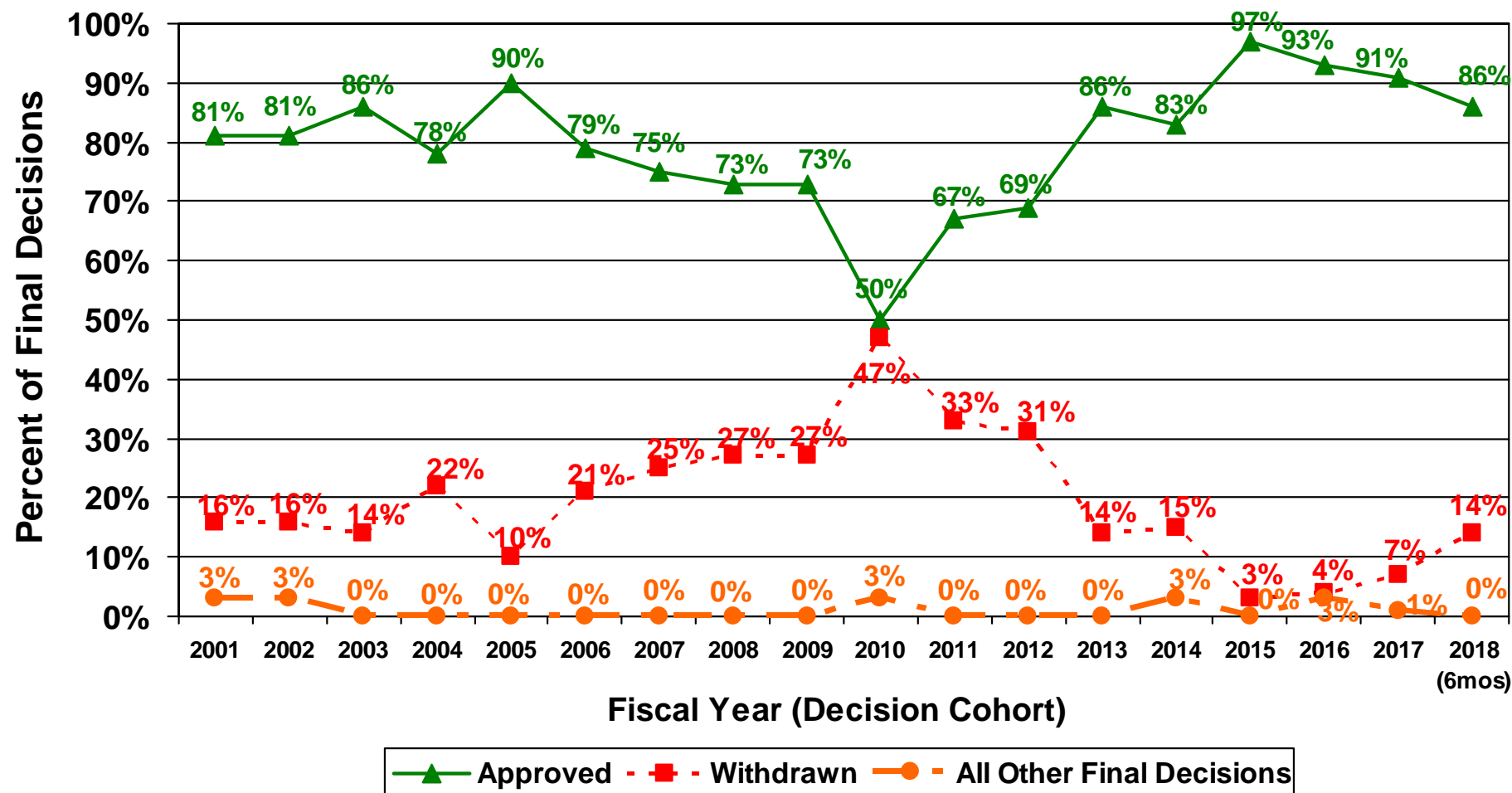
Percent of PMA Originals Approved*



*Based on final decisions on original PMAs that were accepted for filing as of 3/31/2018; percentages may not add to 100% due to rounding.

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

Percent of PMA Originals and Panel Track Supplements Approved*

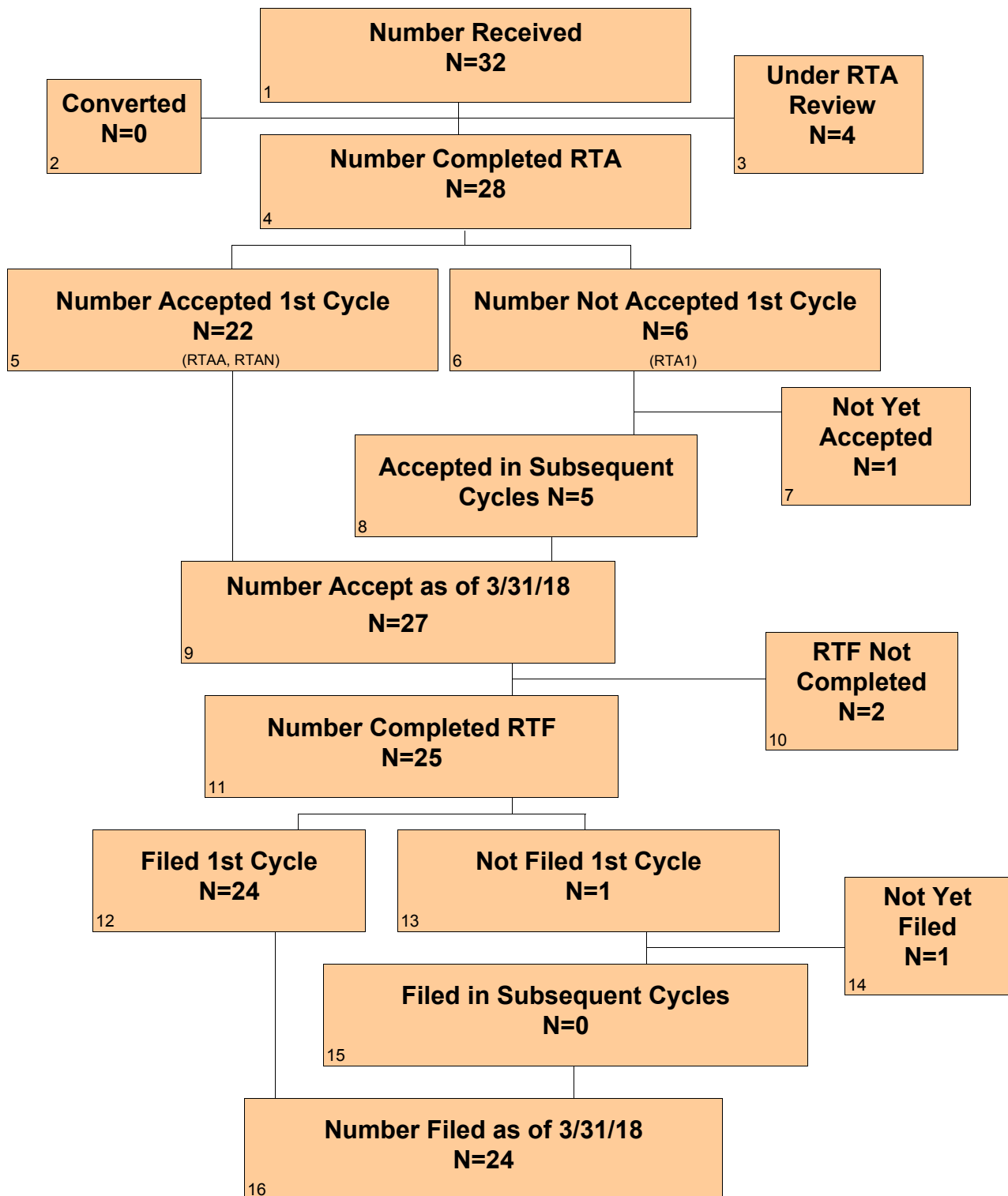


*Based on original PMAs/PTS that were accepted for filing as of 3/31/2018; percentages may not add to 100% due to rounding.

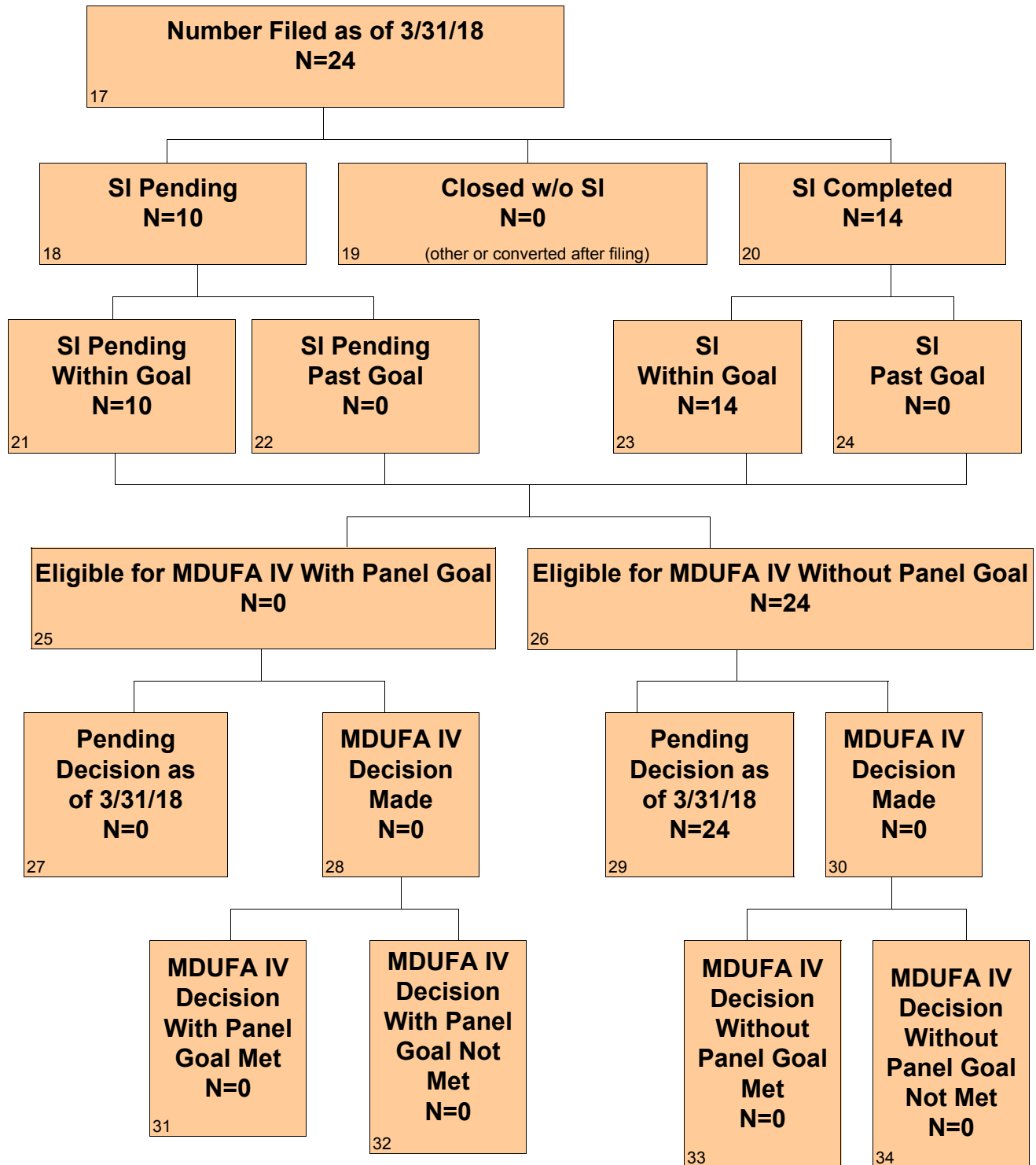
Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions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

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CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/18



CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/18 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	32				
Closed Before RTA Action	0				
Number with Accepted RTA Review	22				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	4				
Number Not Accepted for Filing Review	6				
Rate of Submissions Not Accepted for Filing Review	21.43%				

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	32				
Number Accepted	22				
Completed RTF	25				
Number Not Filed	1				
Rate of Submissions Not Filed	4.00%				

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	24				
SI Goal Met	14				
SI Goal Not Met	0				
SI Pending Within Goal	10				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

Table 1.4 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	14				
Average Number of FDA Days to Substantive Interaction	80.07				
20th Percentile FDA Days to Substantive Interaction	79				
40th Percentile FDA Days to Substantive Interaction	86				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 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	24				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	24				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	24				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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	0				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*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	5				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	5				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*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	25				
Closed Before RTA Action	0				
Number with Accepted RTA review	17				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	2				
Number Not Accepted for Filing Review	6				
Rate of Submissions Not Accepted for Filing Review	26.09%				

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	25				
Number Accepted	17				
Completed RTF	20				
Number Not Filed	1				
Rate of Submissions Not Filed	5.00%				

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	19				
SI Goal Met	12				
SI Goal Not Met	0				
SI Pending Within Goal	7				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	12				
Average Number of FDA Days to Substantive Interaction	78.42				
20th Percentile FDA Days to Substantive Interaction	78				
40th Percentile FDA Days to Substantive Interaction	86				
60th Percentile FDA Days to Substantive Interaction	88				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

**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	19				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	19				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

**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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	19				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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	0				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

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

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	7				
Closed Before RTA Action	0				
Number with Accepted RTA review	5				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	2				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	0%				

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	7				
Number Accepted	5				
Completed RTF	5				
Number Not Filed	0				
Rate of Submissions Not Filed	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	5				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	3				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	2				
Average Number of FDA Days to Substantive Interaction	90.00				
20th Percentile FDA Days to Substantive Interaction	90				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	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	5				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	5				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

**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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 OIR - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 OIR - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	5				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*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	5				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	5				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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				
Closed Before RTA Action	0				
Number with Accepted RTA review	3				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	0%				

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				
Number Accepted	3				
Completed RTF	3				
Number Not Filed	0				
Rate of Submissions Not Filed	0%				

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				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	2				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

Table 1.4 DAGRID - 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	1				
Average Number of FDA Days to Substantive Interaction	80.00				
20th Percentile FDA Days to Substantive Interaction	80				
40th Percentile FDA Days to Substantive Interaction	80				
60th Percentile FDA Days to Substantive Interaction	80				
80th Percentile FDA Days to Substantive Interaction	80				
Maximum FDA Days to Substantive Interaction	80				

Table 1.5 DAGRID - 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	3				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	3				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DAGRID - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DAGRID - ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DAGRID - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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

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	10				
Number Accepted	8				
Completed RTF	8				
Number Not Filed	0				
Rate of Submissions Not Filed	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	8				
SI Goal Met	4				
SI Goal Not Met	0				
SI Pending Within Goal	4				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

Table 1.4 DCD - 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				
Average Number of FDA Days to Substantive Interaction	64.00				
20th Percentile FDA Days to Substantive Interaction	44				
40th Percentile FDA Days to Substantive Interaction	74				
60th Percentile FDA Days to Substantive Interaction	86				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 DCD - 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	8				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	8				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DCD - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DCD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

**Table 1.8 DCD - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	8				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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	0				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	0				
Closed Before RTA Action	0				
Number with Accepted RTA review	0				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	N/A				

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	0				
Number Accepted	0				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	N/A				

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	0				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
20th Percentile FDA Days to Substantive Interaction	0				
40th Percentile FDA Days to Substantive Interaction	0				
60th Percentile FDA Days to Substantive Interaction	0				
80th Percentile FDA Days to Substantive Interaction	0				
Maximum FDA Days to Substantive Interaction	0				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DNPMD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DNPMD - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	0				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	1				
Closed Before RTA Action	0				
Number with Accepted RTA review	1				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	0%				

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	1				
Number Accepted	1				
Completed RTF	1				
Number Not Filed	0				
Rate of Submissions Not Filed	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	1				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	1				
Average Number of FDA Days to Substantive Interaction	90.00				
20th Percentile FDA Days to Substantive Interaction	90				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	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	1				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	1				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DOD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

**Table 1.8 DOD - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	1				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	8				
Closed Before RTA Action	0				
Number with Accepted RTA review	4				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	1				
Number Not Accepted for Filing Review	3				
Rate of Submissions Not Accepted for Filing Review	42.86%				

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	8				
Number Accepted	4				
Completed RTF	7				
Number Not Filed	1				
Rate of Submissions Not Filed	14.29%				

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	6				
SI Goal Met	6				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

Table 1.4 DOED - 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	6				
Average Number of FDA Days to Substantive Interaction	85.83				
20th Percentile FDA Days to Substantive Interaction	86				
40th Percentile FDA Days to Substantive Interaction	86				
60th Percentile FDA Days to Substantive Interaction	87				
80th Percentile FDA Days to Substantive Interaction	89				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 DOED - 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	6				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	6				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DOED - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DOED - ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DOED - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	6				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	1				
Closed Before RTA Action	0				
Number with Accepted RTA review	0				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of Submissions Not Accepted for Filing Review	100%				

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	1				
Number Accepted	0				
Completed RTF	1				
Number Not Filed	0				
Rate of Submissions Not Filed	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	1				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
20th Percentile FDA Days to Substantive Interaction	0				
40th Percentile FDA Days to Substantive Interaction	0				
60th Percentile FDA Days to Substantive Interaction	0				
80th Percentile FDA Days to Substantive Interaction	0				
Maximum FDA Days to Substantive Interaction	0				

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	1				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	1				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DRGUD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DRGUD - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	1				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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	0				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	2				
Closed Before RTA Action	0				
Number with Accepted RTA review	1				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of Submissions Not Accepted for Filing Review	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	2				
Number Accepted	1				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	N/A				

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	0				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

Table 1.4 DSD - 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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
20th Percentile FDA Days to Substantive Interaction	0				
40th Percentile FDA Days to Substantive Interaction	0				
60th Percentile FDA Days to Substantive Interaction	0				
80th Percentile FDA Days to Substantive Interaction	0				
Maximum FDA Days to Substantive Interaction	0				

Table 1.5 DSD - 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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DSD - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DSD - ODE - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DSD - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	0				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	N/A				
MDUFA IV Decision	N/A				
MDUFA IV Decision Goal Met	N/A				
PMAs Pending MDUFA IV Decision	N/A				
PMAs Pending MDUFA IV Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	2				
Closed Before RTA Action	0				
Number with Accepted RTA review	2				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	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	2				
Number Accepted	2				
Completed RTF	2				
Number Not Filed	0				
Rate of Submissions Not Filed	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	2				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	2				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

Table 1.4 DCTD - 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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
20th Percentile FDA Days to Substantive Interaction	0				
40th Percentile FDA Days to Substantive Interaction	0				
60th Percentile FDA Days to Substantive Interaction	0				
80th Percentile FDA Days to Substantive Interaction	0				
Maximum FDA Days to Substantive Interaction	0				

Table 1.5 DCTD - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	2				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DCTD - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DCTD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DCTD - OIR - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	2				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	2				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	2				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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				
Closed Before RTA Action	0				
Number with Accepted RTA review	1				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	0%				

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				
Number Accepted	1				
Completed RTF	1				
Number Not Filed	0				
Rate of Submissions Not Filed	0%				

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				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

Table 1.4 DIHD - 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	1				
Average Number of FDA Days to Substantive Interaction	90.00				
20th Percentile FDA Days to Substantive Interaction	90				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 DIHD - 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	1				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	1				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DIHD - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DIHD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

**Table 1.8 DIHD - OIR - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	1				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	0				
Closed Before RTA Action	0				
Number with Accepted RTA review	0				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	N/A				

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	0				
Number Accepted	0				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	N/A				

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	0				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
20th Percentile FDA Days to Substantive Interaction	0				
40th Percentile FDA Days to Substantive Interaction	0				
60th Percentile FDA Days to Substantive Interaction	0				
80th Percentile FDA Days to Substantive Interaction	0				
Maximum FDA Days to Substantive Interaction	0				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DMD - OIR - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DMD - OIR - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	0				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	4				
Closed Before RTA Action	0				
Number with Accepted RTA review	2				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	2				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	0%				

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	4				
Number Accepted	2				
Completed RTF	2				
Number Not Filed	0				
Rate of Submissions Not Filed	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	2				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

Table 1.4 DMGP - 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	1				
Average Number of FDA Days to Substantive Interaction	90.00				
20th Percentile FDA Days to Substantive Interaction	90				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 DMGP - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	2				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DMGP - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DMGP - OIR - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DMGP - OIR - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	2				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*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	2				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	2				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

Section 1 PMA Original and Panel-Track Supplements - Division Level Metric

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	0				
Closed Before RTA Action	0				
Number with Accepted RTA review	0				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	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	0				
Number Accepted	0				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	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	0				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

Table 1.4 DRH - 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	0				
Average Number of FDA Days to Substantive Interaction	0.00				
20th Percentile FDA Days to Substantive Interaction	0				
40th Percentile FDA Days to Substantive Interaction	0				
60th Percentile FDA Days to Substantive Interaction	0				
80th Percentile FDA Days to Substantive Interaction	0				
Maximum FDA Days to Substantive Interaction	0				

Table 1.5 DRH - 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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.6 DRH - 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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 DRH - OIR - CDRH - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

Table 1.8 DRH - OIR - 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	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	0				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

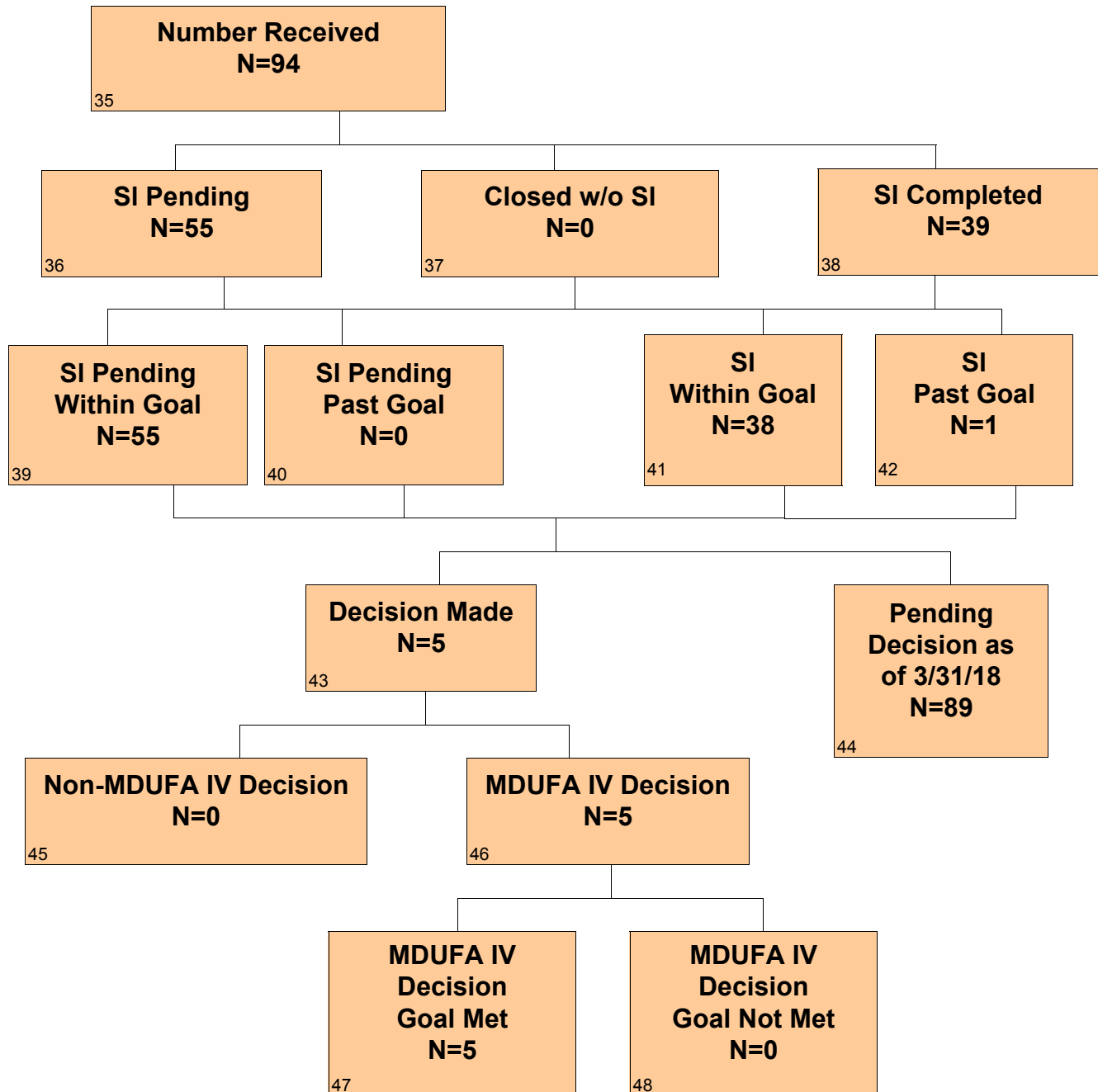
*Includes submission that went to panel

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*Includes submission that went to panel

CDRH PMA 180 Day Supplements - FY 2018 as of 3/31/18



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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	94				
SI Goal Met	38				
SI Goal Not Met	1				
SI Pending Within Goal	55				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	97.44%				

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	94				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	5				
MDUFA IV Decision Goal Met	5				
Supplements Pending MDUFA IV Decision	89				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	100%				

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	94				
Number with MDUFA IV Decision	5				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	75				
SI Goal Met	29				
SI Goal Not Met	1				
SI Pending Within Goal	45				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	96.67%				

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	75				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	4				
MDUFA IV Decision Goal Met	4				
Supplements Pending MDUFA IV Decision	71				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	100%				

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	75				
Number with MDUFA IV Decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	19				
SI Goal Met	9				
SI Goal Not Met	0				
SI Pending Within Goal	10				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	19				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	18				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	19				
Number with MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	5				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	2				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

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	5				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	5				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	5				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	41				
SI Goal Met	14				
SI Goal Not Met	1				
SI Pending Within Goal	26				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	93.33%				

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	41				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	2				
MDUFA IV Decision Goal Met	2				
Supplements Pending MDUFA IV Decision	39				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	41				
Number with MDUFA IV Decision	2				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	10				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	7				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	10				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	10				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	10				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	0				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	0				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	9				
SI Goal Met	5				
SI Goal Not Met	0				
SI Pending Within Goal	4				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	9				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	8				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	100%				

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	9				
Number with MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	6				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	3				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	6				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	5				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	6				
Number with MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	4				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	3				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100%				

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	4				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	4				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	4				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	5				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	4				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	5				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	4				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	5				
Number with MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	2				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	2				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	2				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	2				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	5				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	2				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	5				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	5				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	5				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	6				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	4				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	6				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	6				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	6				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	1				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	1				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	1				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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

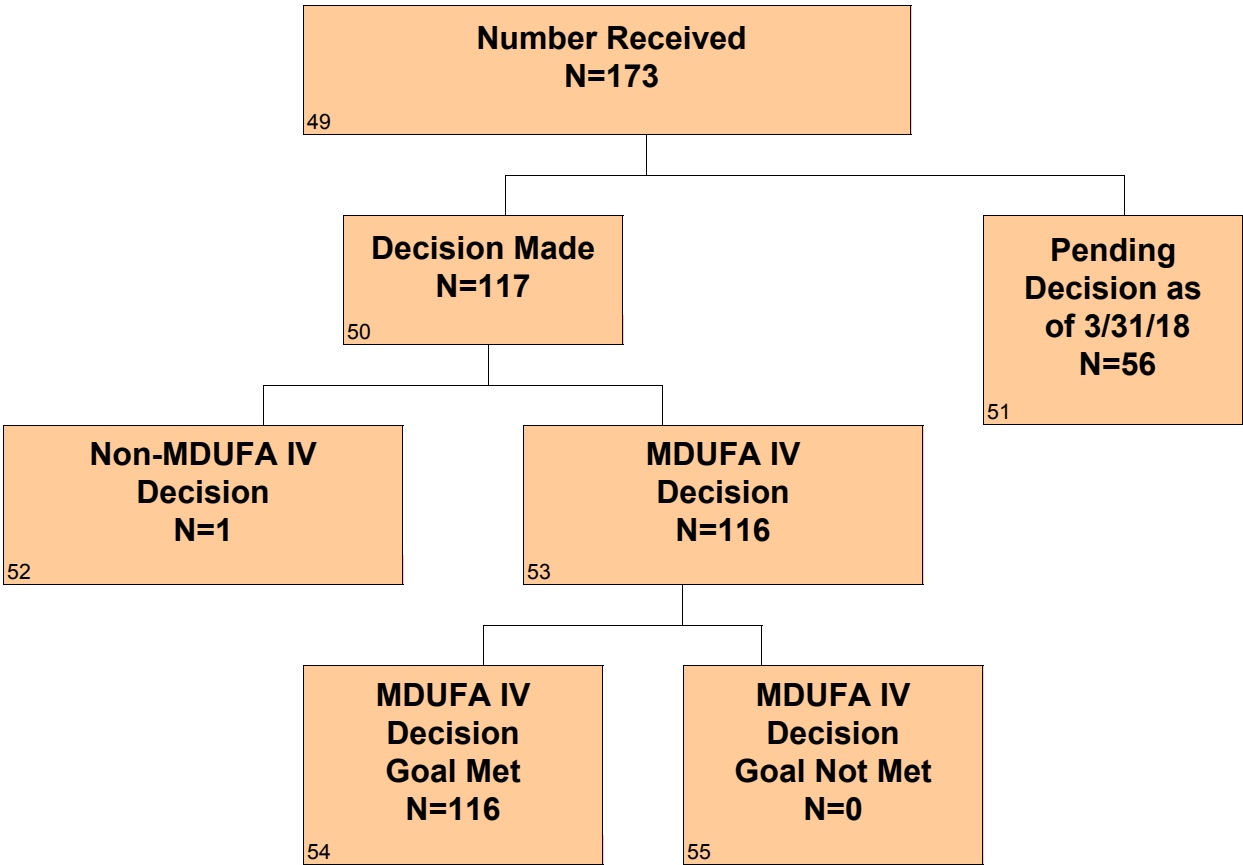
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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CDRH PMA Real Time Supplements - FY 2018 as of 3/31/18



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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	173				
Non-MDUFA IV Decision	1				
MDUFA IV Decision	116				
MDUFA IV Decision Goal Met	116				
Supplements Pending MDUFA IV Decision	56				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	173				
Number With MDUFA IV Decision	116				
Number of Not Approvable	8				
Rate of Not Approvable	6.90%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	133				
Non-MDUFA IV Decision	1				
MDUFA IV Decision	87				
MDUFA IV Decision Goal Met	87				
Supplements Pending MDUFA IV Decision	45				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	133				
Number With MDUFA IV Decision	87				
Number of Not Approvable	8				
Rate of Not Approvable	9.20%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	40				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	29				
MDUFA IV Decision Goal Met	29				
Supplements Pending MDUFA IV Decision	11				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	40				
Number With MDUFA IV Decision	29				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	5				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	4				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	5				
Number with MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	94				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	70				
MDUFA IV Decision Goal Met	70				
Supplements Pending MDUFA IV Decision	24				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	94				
Number with MDUFA IV Decision	70				
Number of Not Approvable	8				
Rate of Not Approvable	11.43%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	9				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	6				
MDUFA IV Decision Goal Met	6				
Supplements Pending MDUFA IV Decision	3				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	9				
Number with MDUFA IV Decision	6				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	6				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	3				
MDUFA IV Decision Goal Met	3				
Supplements Pending MDUFA IV Decision	3				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	6				
Number with MDUFA IV Decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	10				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	3				
MDUFA IV Decision Goal Met	3				
Supplements Pending MDUFA IV Decision	7				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	10				
Number with MDUFA IV Decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	6				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	3				
MDUFA IV Decision Goal Met	3				
Supplements Pending MDUFA IV Decision	3				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	6				
Number with MDUFA IV Decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	3				
Non-MDUFA IV Decision	1				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	1				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	3				
Number with MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	14				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	12				
MDUFA IV Decision Goal Met	12				
Supplements Pending MDUFA IV Decision	2				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	14				
Number with MDUFA IV Decision	12				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	4				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	2				
MDUFA IV Decision Goal Met	2				
Supplements Pending MDUFA IV Decision	2				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	4				
Number with MDUFA IV Decision	2				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	21				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	14				
MDUFA IV Decision Goal Met	14				
Supplements Pending MDUFA IV Decision	7				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	21				
Number with MDUFA IV Decision	14				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	0				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	0				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	1				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	0				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	100%				

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	1				
Number with MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2017 and March 31, 2018.

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Section 5 PMA Annual Metrics and Goals

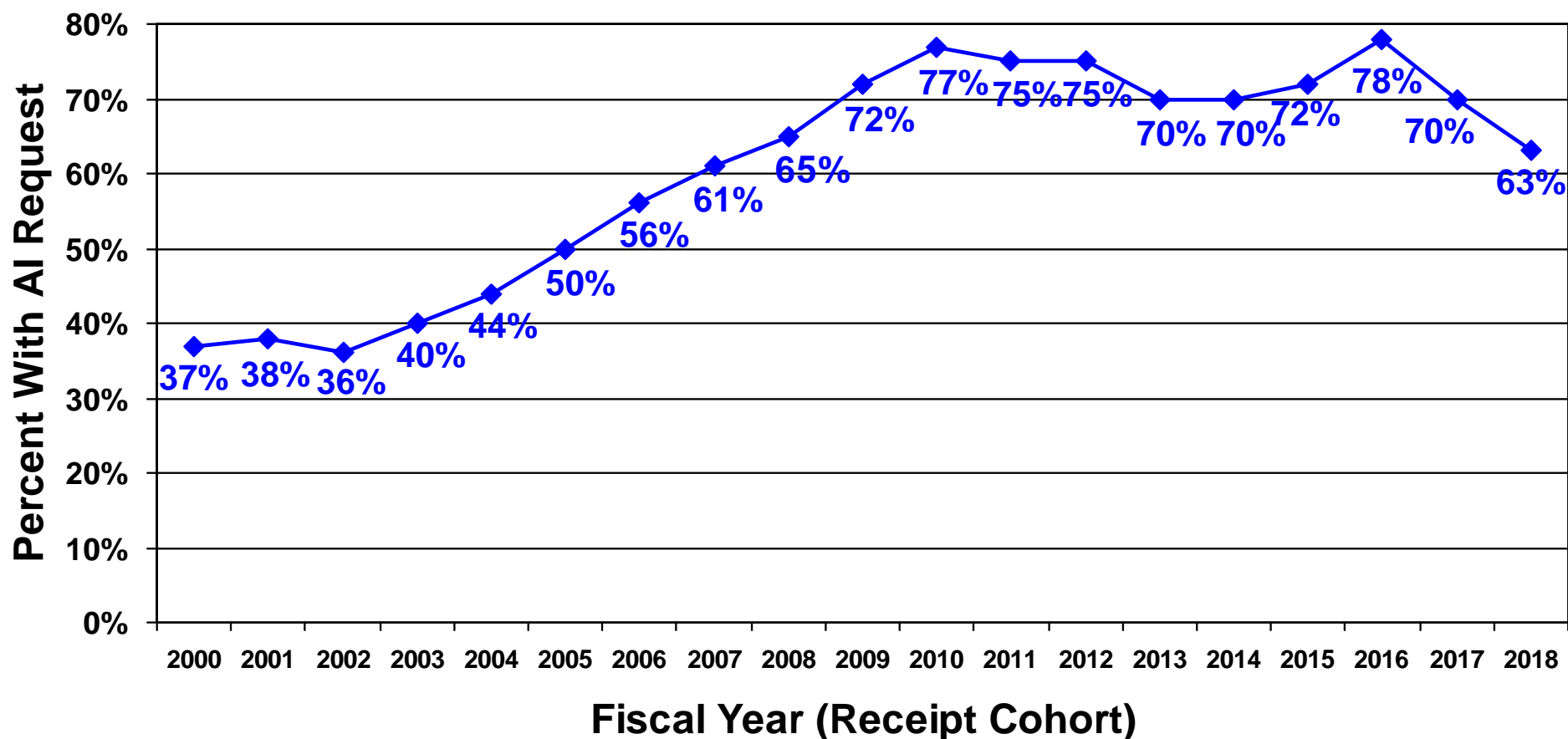
PMA Annual Metrics and Goals will be reported in the Annual Report.

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510(k)s

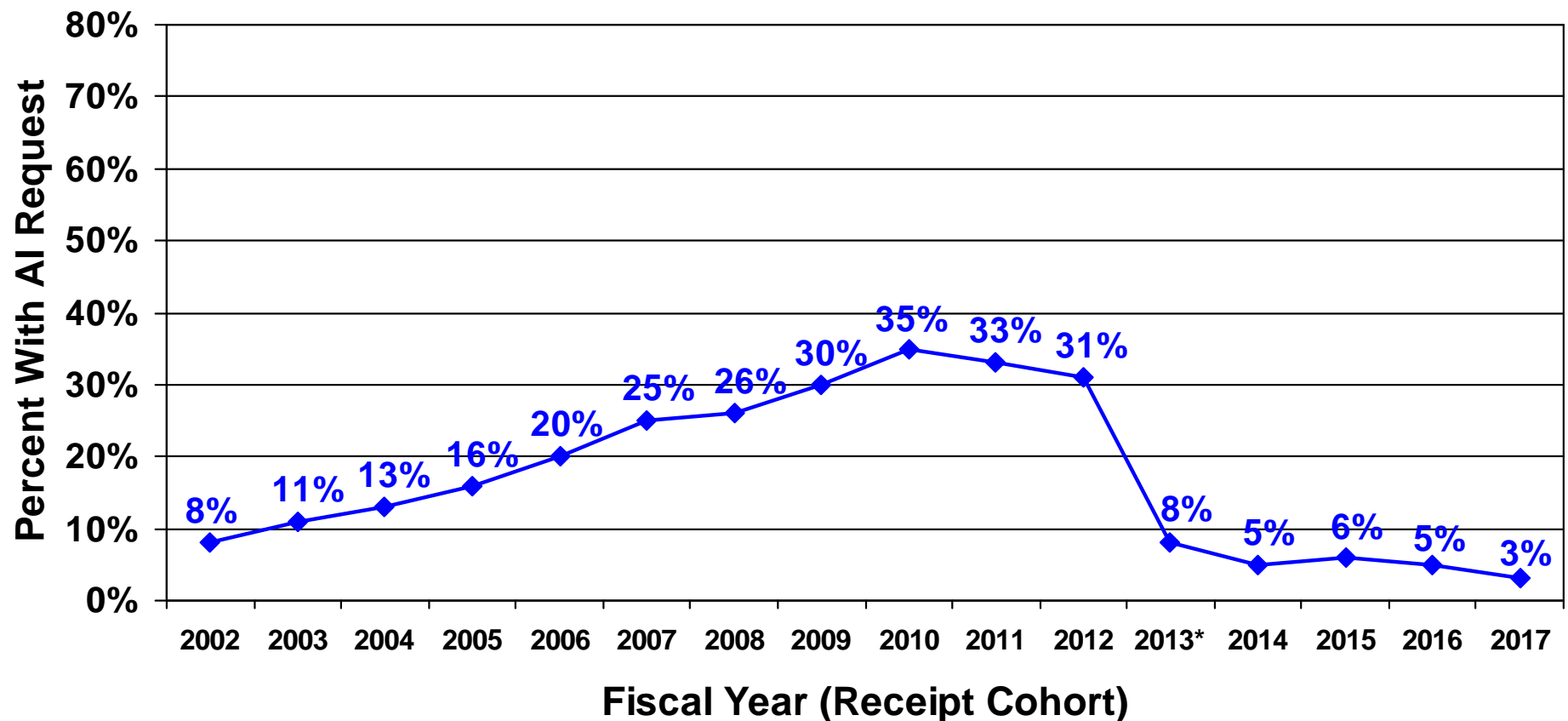
Q2FY18

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



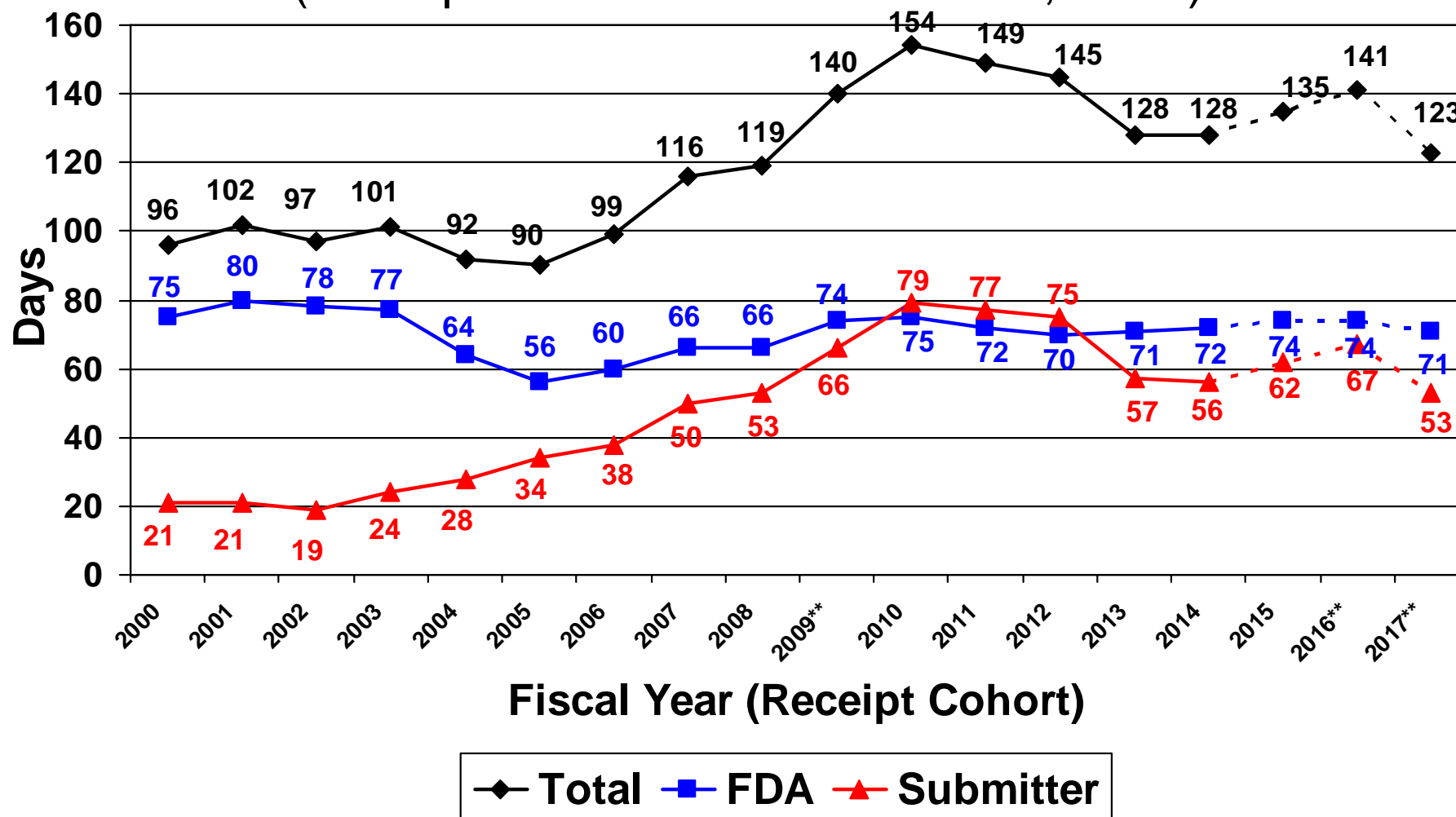
*FY 2013 - FY 2018 data are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 12/31/2017. Includes Third Party 510(k)s.

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



*FY 2013 – FY 2017 data are for 510(k)s accepted as of 8/31/2017. FY 2017 2nd cycle is still open as of 3/31/2018; data may change

Average Time to MDUFA Decision: 510(k)s* (Receipt Cohorts as of March 31, 2018)

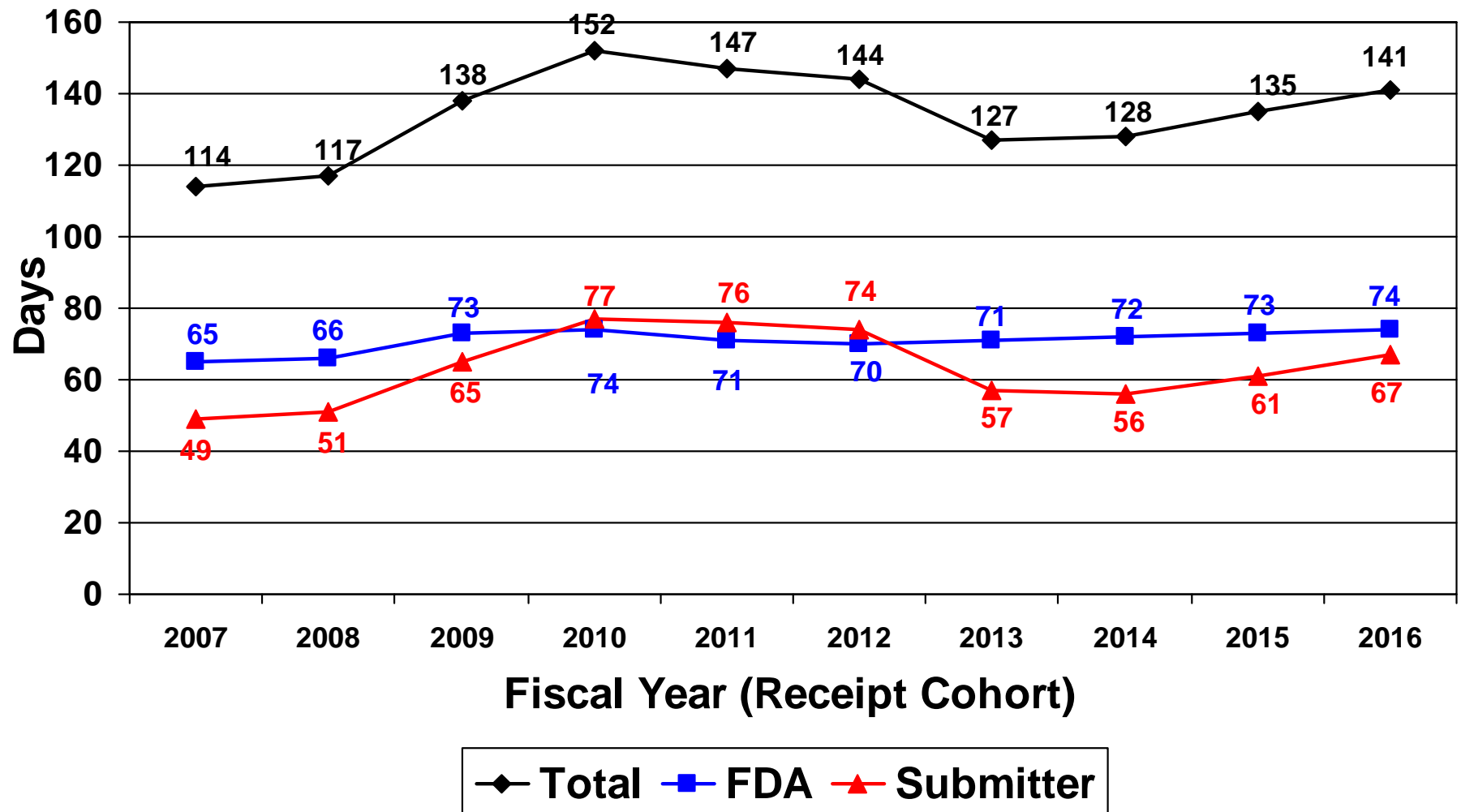


*SE and NSE decisions only; times may not add to total due to rounding. Analysis includes Third Party 510ks.

**Cohorts still open; percentage of cohort closed: FY 2009 = 99.97%, FY 2016 = 99.6% and FY2017 = 88.3% => avg times for FY2016 & FY2017 will increase.

Average Time to Decision: 510(k)s*

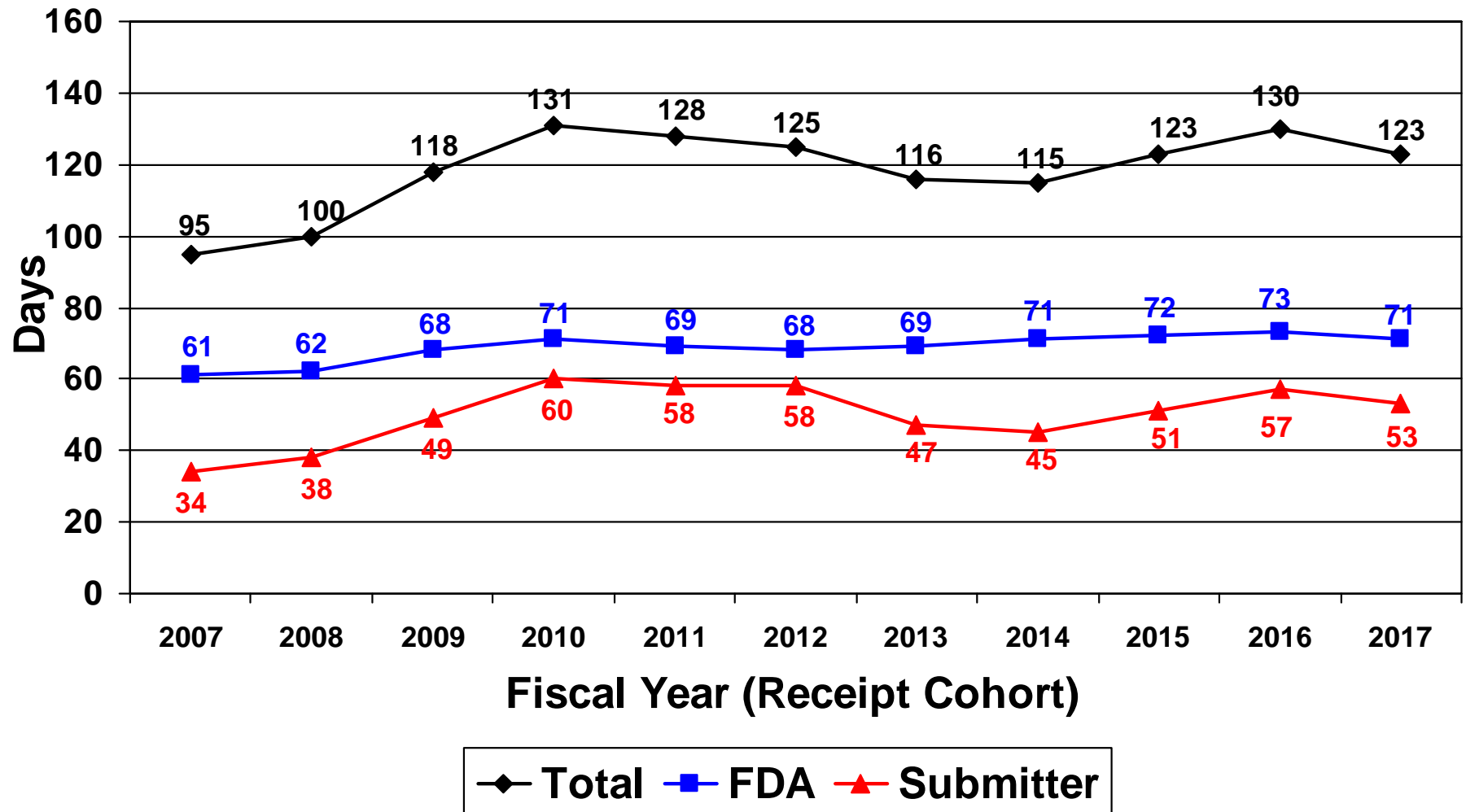
- Comparison of Receipt Cohorts When 99.6% Closed -



*SE and NSE decisions only; times may not add to total due to rounding.
Analysis includes Third Party 510ks.

Average Time to Decision: 510(k)s*

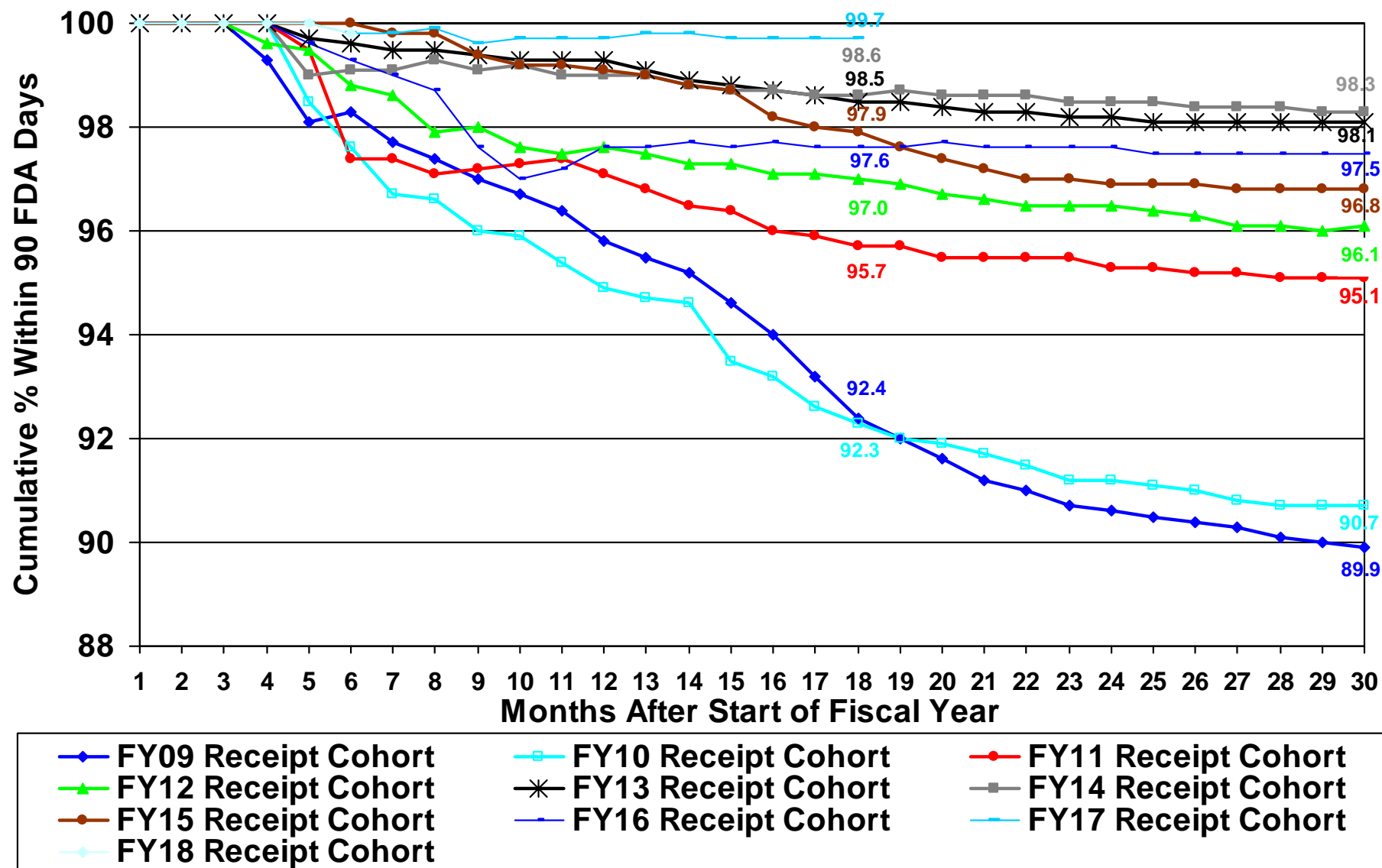
- Comparison of Receipt Cohorts When 88.3% Closed -



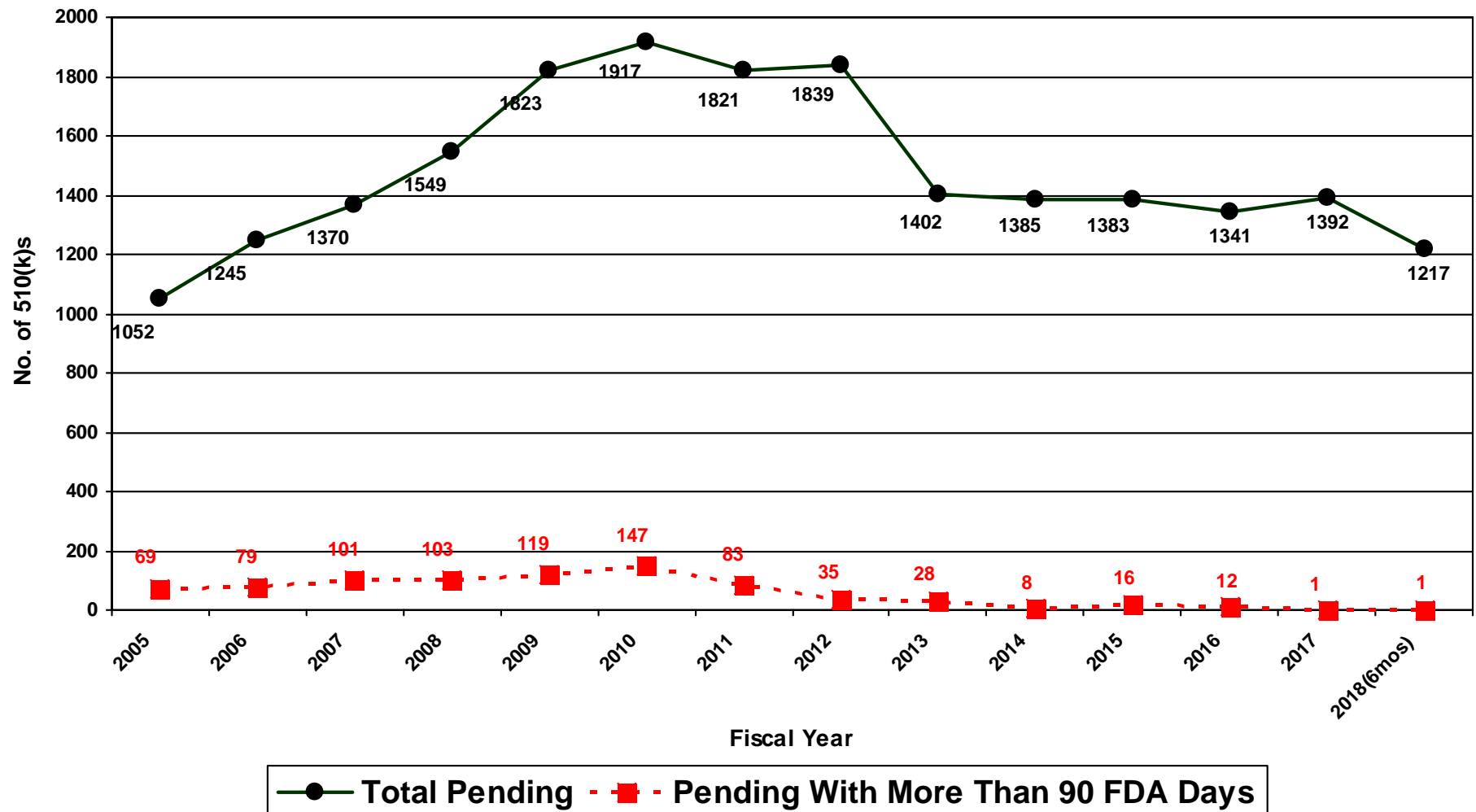
*SE and NSE decisions only; times may not add to total due to rounding.
Analysis includes Third Party 510ks.

Trend in 510(k) MDUFA Decision Goal Performance

Comparison of FY09 - FY17 Receipt Cohorts (Includes 3rd Party 510(k)s)

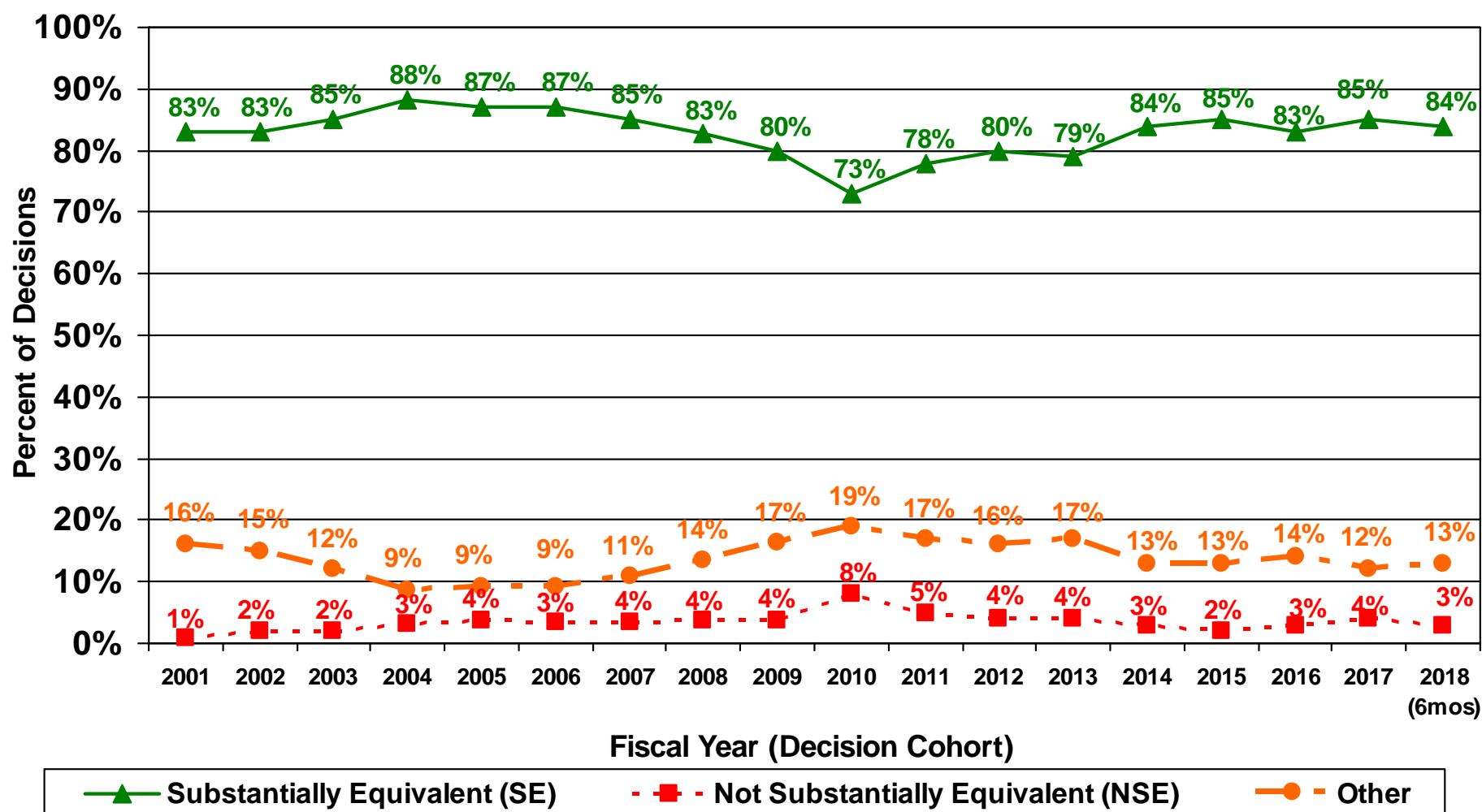


510(k)s Pending* at End of Year



*Under review or on hold, including Third Party 510ks. Excludes FY 2013 - FY 2018 receipts that were not accepted for review as of end of year.

Percent of 510(k)s Determined to be Substantially Equivalent (SE)*

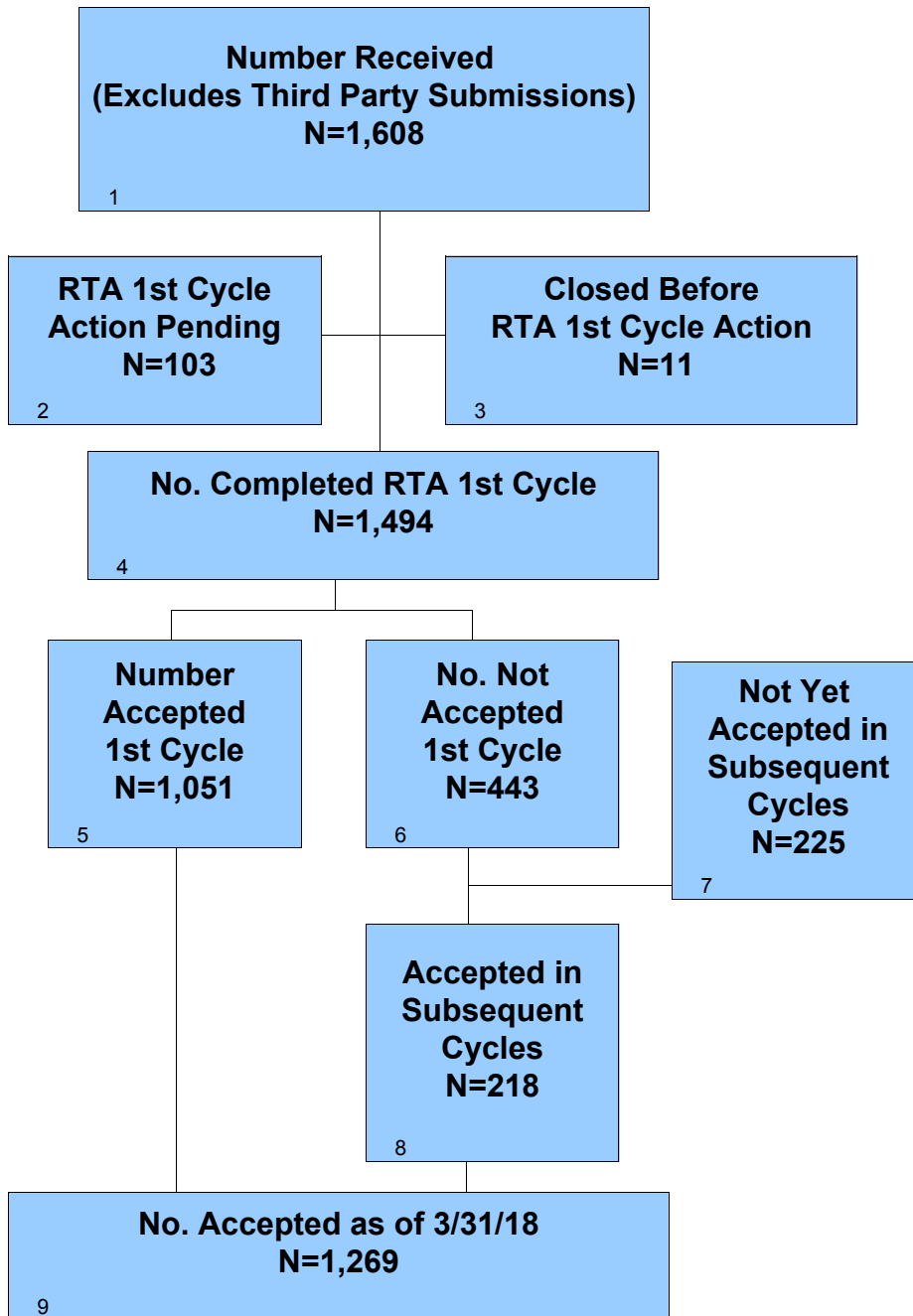


*Percentages may not add to 100% due to rounding. Excludes final decisions made on FY 2013 - FY 2018 receipts that were not accepted for review as of 3/31/2018. Includes Third Party 510ks.

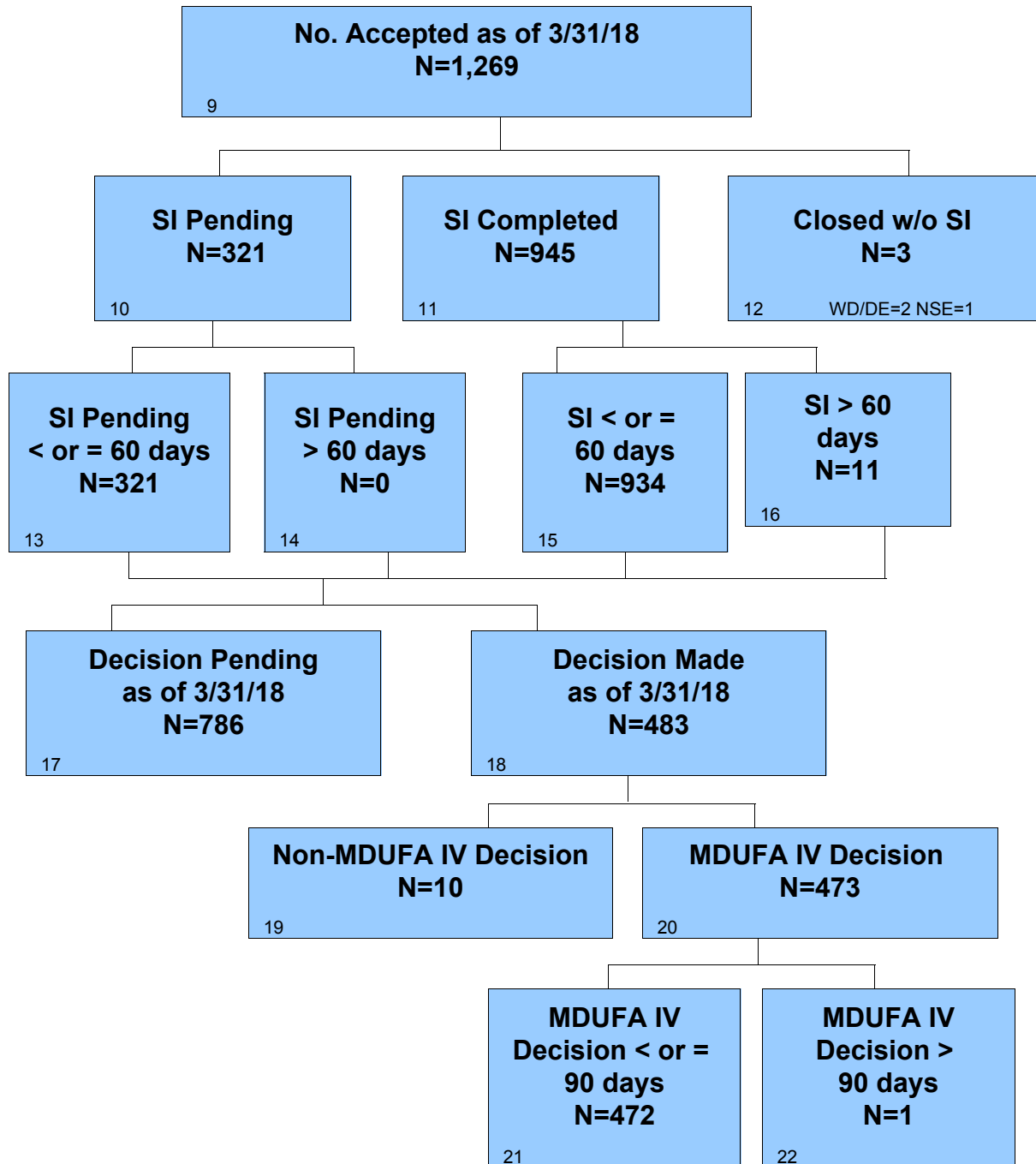
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CDRH 510(k)s - FY 2018

as of 3/31/18



CDRH 510(k)s - FY 2018 as of 3/31/18 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	1,608				
Closed Before RTA Action	11				
Number Accepted	1,046				
Number Without a RTA Review and > 15 Days Since Date Received	5				
Number Without a RTA Review and <= 15 Days Since Date Received	103				
Number Not Accepted	443				
Rate of Submissions Not Accepted for Review	29.65%				

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	1,269				
Deleted or Withdrawn Prior to SI	2				
SI Within 60 FDA Days	934				
SI Over 60 FDA Days	11				
SI Pending Within 60 FDA Days	321				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	1				
Current SI Performance Percent Within 60 FDA Days	98.73%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	945				
Average Number of FDA Days to Substantive Interaction	48.97				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	52				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	86				

Table 6.4 CDRH - 510(k) 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
510(k)s Accepted	1,269				
Non-MDUFA IV Decision	10				
MDUFA IV Decision (SE/NSE)	473				
MDUFA IV Decision Within 90 FDA Days	472				
510(k)s Pending MDUFA IV Decision	786				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	99.79%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.30				
Number With MDUFA IV Decision	473				
Average Number of FDA Days to MDUFA IV Decision	58.52				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	51				
60th Percentile FDA Days to MDUFA IV Decision	73				
80th Percentile FDA Days to MDUFA IV Decision	87				
Maximum FDA Days to MDUFA IV Decision	92				
Average Number of Industry Days to MDUFA IV Decision	8.96				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	20				
Maximum Industry Days to MDUFA IV Decision	82				
Average Number of Total Days to MDUFA IV Decision	67.48				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	55				
60th Percentile Total Days to MDUFA IV Decision	79				
80th Percentile Total Days to MDUFA IV Decision	98				
Maximum Total Days to MDUFA IV Decision	170				

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	1,269				
Number With MDUFA IV Decision	473				
Number of SE Decision	469				
Number of NSE Decision	4				
Number of Withdrawal	6				
Number of Deleted	0				
Rate of SE Decision	99.15%				
Rate of NSE Decision	0.85%				
Rate of Withdrawal	0.47%				
Rate of Deleted	0%				

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	1				
Mean FDA Days for Submissions that Missed the Goal	92				
Mean Industry Days for Submissions that Missed the Goal	0				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	1				
MDUFA IV Decision Within 90 FDA Days	1				
510(k)s Pending MDUFA IV Decision	1				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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	102				
Non-MDUFA IV Decision	1				
MDUFA IV Decision (SE/NSE)	40				
MDUFA IV Decision Within 90 FDA Days	40				
510(k)s Pending MDUFA IV Decision	61				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1,297				
Closed Before RTA Action	10				
Number Accepted	787				
Number Without a RTA and > 15 Days Since Date Received	4				
Number Without a RTA and <= 15 Days Since Date Received	93				
Number Not Accepted	403				
Rate of Submissions Not Accepted For Review	33.75%				

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	992				
Deleted or Withdrawn Prior to SI	1				
SI Within 60 FDA Days	709				
SI Over 60 FDA Days	11				
SI Pending Within 60 FDA Days	270				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	1				
Current SI Performance Percent Within 60 FDA Days	98.34%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	720				
Average Number of FDA Days to Substantive Interaction	49.70				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	54				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	86				

Table 6.4 ODE - CDRH - 510(k) 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
510(k)s Accepted	992				
Non-MDUFA IV Decision	8				
MDUFA IV Decision (SE/NSE)	334				
MDUFA IV Decision Within 90 FDA Days	333				
510(k)s Pending MDUFA IV Decision	650				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	99.70%				

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	1.31				
Number With MDUFA IV Decision	334				
Average Number of FDA Days to MDUFA IV Decision	59.31				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	52				
60th Percentile FDA Days to MDUFA IV Decision	76				
80th Percentile FDA Days to MDUFA IV Decision	87				
Maximum FDA Days to MDUFA IV Decision	92				
Average Number of Industry Days to MDUFA IV Decision	9.02				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	19				
Maximum Industry Days to MDUFA IV Decision	82				
Average Number of Total Days to MDUFA IV Decision	68.33				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	56				
60th Percentile Total Days to MDUFA IV Decision	79				
80th Percentile Total Days to MDUFA IV Decision	98				
Maximum Total Days to MDUFA IV Decision	170				

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	992				
Number With MDUFA IV Decision	334				
Number of SE Decision	330				
Number of NSE Decision	4				
Number of Withdrawal	5				
Number of Deleted	0				
Rate of SE Decision	98.80%				
Rate of NSE Decision	1.20%				
Rate of Withdrawal	0.50%				
Rate of Deleted	0%				

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	1				
Mean FDA Days for Submissions that Missed the Goal	92				
Mean Industry Days for Submissions that Missed the Goal	0				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	311				
Closed Before RTA Action	1				
Number Accepted	259				
Number Without a RTA and > 15 Days Since Date Received	1				
Number Without a RTA and <= 15 Days Since Date Received	10				
Number Not Accepted	40				
Rate of Submissions Not Accepted For Review	13.33%				

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	277				
Deleted or Withdrawn Prior to SI	1				
SI Within 60 FDA Days	225				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	51				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	225				
Average Number of FDA Days to Substantive Interaction	46.64				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	49				
60th Percentile FDA Days to Substantive Interaction	56				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 OIR - CDRH - 510(k) 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
510(k)s Accepted	277				
Non-MDUFA IV Decision	2				
MDUFA IV Decision (SE/NSE)	139				
MDUFA IV Decision Within 90 FDA Days	139				
510(k)s Pending MDUFA IV Decision	136				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.29				
Number With MDUFA IV Decision	139				
Average Number of FDA Days to MDUFA IV Decision	56.63				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	49				
60th Percentile FDA Days to MDUFA IV Decision	71				
80th Percentile FDA Days to MDUFA IV Decision	86				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	8.82				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	21				
Maximum Industry Days to MDUFA IV Decision	66				
Average Number of Total Days to MDUFA IV Decision	65.45				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	53				
60th Percentile Total Days to MDUFA IV Decision	75				
80th Percentile Total Days to MDUFA IV Decision	93				
Maximum Total Days to MDUFA IV Decision	141				

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	277				
Number With MDUFA IV Decision	139				
Number of SE Decision	139				
Number of NSE Decision	0				
Number of Withdrawal	1				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0.36%				
Rate of Deleted	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	1				
MDUFA IV Decision Within 90 FDA Days	1				
510(k)s Pending MDUFA IV Decision	1				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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	102				
Non-MDUFA IV Decision	1				
MDUFA IV Decision (SE/NSE)	40				
MDUFA IV Decision Within 90 FDA Days	40				
510(k)s Pending MDUFA IV Decision	61				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	325				
Closed Before RTA Action	3				
Number Accepted	128				
Number Without a RTA and > 15 Days Since Date Received	2				
Number Without a RTA and <= 15 Days Since Date Received	19				
Number Not Accepted	173				
Rate of Submissions Not Accepted for Review	57.10%				

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	206				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	132				
SI Over 60 FDA Days	2				
SI Pending Within 60 FDA Days	72				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	98.51%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	134				
Average Number of FDA Days to Substantive Interaction	53.97				
20th Percentile FDA Days to Substantive Interaction	52				
40th Percentile FDA Days to Substantive Interaction	57				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	67				

Table 6.4 DAGRID - ODE - CDRH - 510(k) 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
510(k)s Accepted	206				
Non-MDUFA IV Decision	2				
MDUFA IV Decision (SE/NSE)	49				
MDUFA IV Decision Within 90 FDA Days	49				
510(k)s Pending MDUFA IV Decision	155				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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	1.53				
Number With MDUFA IV Decision	49				
Average Number of FDA Days to MDUFA IV Decision	78.57				
20th Percentile FDA Days to MDUFA IV Decision	72				
40th Percentile FDA Days to MDUFA IV Decision	87				
60th Percentile FDA Days to MDUFA IV Decision	88				
80th Percentile FDA Days to MDUFA IV Decision	89				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	14.02				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	12				
80th Percentile Industry Days to MDUFA IV Decision	31				
Maximum Industry Days to MDUFA IV Decision	69				
Average Number of Total Days to MDUFA IV Decision	92.59				
20th Percentile Total Days to MDUFA IV Decision	72				
40th Percentile Total Days to MDUFA IV Decision	89				
60th Percentile Total Days to MDUFA IV Decision	100				
80th Percentile Total Days to MDUFA IV Decision	120				
Maximum Total Days to MDUFA IV Decision	159				

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	206				
Number With MDUFA IV Decision	49				
Number of SE Decision	48				
Number of NSE Decision	1				
Number of Withdrawal	2				
Number of Deleted	0				
Rate of SE Decision	97.96%				
Rate of NSE Decision	2.04%				
Rate of Withdrawal	0.97%				
Rate of Deleted	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	178				
Closed Before RTA Action	3				
Number Accepted	108				
Number Without a RTA and > 15 Days Since Date Received	1				
Number Without a RTA and <= 15 Days Since Date Received	12				
Number Not Accepted	54				
Rate of Submissions Not Accepted for Review	33.13%				

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	137				
Deleted or Withdrawn Prior to SI	1				
SI Within 60 FDA Days	104				
SI Over 60 FDA Days	4				
SI Pending Within 60 FDA Days	28				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	96.30%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	108				
Average Number of FDA Days to Substantive Interaction	45.95				
20th Percentile FDA Days to Substantive Interaction	29				
40th Percentile FDA Days to Substantive Interaction	48				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	66				

Table 6.4 DCD - ODE - CDRH - 510(k) 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
510(k)s Accepted	137				
Non-MDUFA IV Decision	2				
MDUFA IV Decision (SE/NSE)	55				
MDUFA IV Decision Within 90 FDA Days	54				
510(k)s Pending MDUFA IV Decision	80				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	98.18%				

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	1.25				
Number With MDUFA IV Decision	55				
Average Number of FDA Days to MDUFA IV Decision	48.45				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	30				
60th Percentile FDA Days to MDUFA IV Decision	51				
80th Percentile FDA Days to MDUFA IV Decision	82				
Maximum FDA Days to MDUFA IV Decision	92				
Average Number of Industry Days to MDUFA IV Decision	8.96				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	13				
Maximum Industry Days to MDUFA IV Decision	68				
Average Number of Total Days to MDUFA IV Decision	57.42				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	30				
60th Percentile Total Days to MDUFA IV Decision	55				
80th Percentile Total Days to MDUFA IV Decision	90				
Maximum Total Days to MDUFA IV Decision	146				

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	137				
Number With MDUFA IV Decision	55				
Number of SE Decision	54				
Number of NSE Decision	1				
Number of Withdrawal	2				
Number of Deleted	0				
Rate of SE Decision	98.18%				
Rate of NSE Decision	1.82%				
Rate of Withdrawal	1.46%				
Rate of Deleted	0%				

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	1				
Mean FDA Days for Submissions that Missed the Goal	92				
Mean Industry Days for Submissions that Missed the Goal	0				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	105				
Closed Before RTA Action	2				
Number Accepted	56				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	12				
Number Not Accepted	35				
Rate of Submissions Not Accepted for Review	38.46%				

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	75				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	58				
SI Over 60 FDA Days	1				
SI Pending Within 60 FDA Days	16				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	98.31%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	59				
Average Number of FDA Days to Substantive Interaction	51.15				
20th Percentile FDA Days to Substantive Interaction	31				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	86				

Table 6.4 DNPMD - ODE - CDRH - 510(k) 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
510(k)s Accepted	75				
Non-MDUFA IV Decision	2				
MDUFA IV Decision (SE/NSE)	26				
MDUFA IV Decision Within 90 FDA Days	26				
510(k)s Pending MDUFA IV Decision	47				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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	1.27				
Number With MDUFA IV Decision	26				
Average Number of FDA Days to MDUFA IV Decision	53.77				
20th Percentile FDA Days to MDUFA IV Decision	30				
40th Percentile FDA Days to MDUFA IV Decision	38				
60th Percentile FDA Days to MDUFA IV Decision	57				
80th Percentile FDA Days to MDUFA IV Decision	79				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	8.73				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	13				
Maximum Industry Days to MDUFA IV Decision	54				
Average Number of Total Days to MDUFA IV Decision	62.50				
20th Percentile Total Days to MDUFA IV Decision	30				
40th Percentile Total Days to MDUFA IV Decision	38				
60th Percentile Total Days to MDUFA IV Decision	77				
80th Percentile Total Days to MDUFA IV Decision	90				
Maximum Total Days to MDUFA IV Decision	139				

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	75				
Number With MDUFA IV Decision	26				
Number of SE Decision	26				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0%				
Rate of Deleted	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	0				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	275				
Closed Before RTA Action	0				
Number Accepted	194				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	23				
Number Not Accepted	58				
Rate of Submissions Not Accepted for Review	23.02%				

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	234				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	169				
SI Over 60 FDA Days	3				
SI Pending Within 60 FDA Days	62				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	98.26%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	172				
Average Number of FDA Days to Substantive Interaction	48.57				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	51				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	64				

Table 6.4 DOD - ODE - CDRH - 510(k) 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
510(k)s Accepted	234				
Non-MDUFA IV Decision	1				
MDUFA IV Decision (SE/NSE)	87				
MDUFA IV Decision Within 90 FDA Days	87				
510(k)s Pending MDUFA IV Decision	146				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.31				
Number With MDUFA IV Decision	87				
Average Number of FDA Days to MDUFA IV Decision	57.74				
20th Percentile FDA Days to MDUFA IV Decision	30				
40th Percentile FDA Days to MDUFA IV Decision	50				
60th Percentile FDA Days to MDUFA IV Decision	62				
80th Percentile FDA Days to MDUFA IV Decision	84				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	9.51				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	19				
Maximum Industry Days to MDUFA IV Decision	82				
Average Number of Total Days to MDUFA IV Decision	67.24				
20th Percentile Total Days to MDUFA IV Decision	30				
40th Percentile Total Days to MDUFA IV Decision	55				
60th Percentile Total Days to MDUFA IV Decision	78				
80th Percentile Total Days to MDUFA IV Decision	93				
Maximum Total Days to MDUFA IV Decision	170				

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	234				
Number With MDUFA IV Decision	87				
Number of SE Decision	87				
Number of NSE Decision	0				
Number of Withdrawal	1				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0.43%				
Rate of Deleted	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	55				
Closed Before RTA Action	0				
Number Accepted	43				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	2				
Number Not Accepted	10				
Rate of Submissions Not Accepted for Review	18.87%				

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	47				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	33				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	14				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	33				
Average Number of FDA Days to Substantive Interaction	47.52				
20th Percentile FDA Days to Substantive Interaction	33				
40th Percentile FDA Days to Substantive Interaction	49				
60th Percentile FDA Days to Substantive Interaction	53				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 DOED - ODE - CDRH - 510(k) 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
510(k)s Accepted	47				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	23				
MDUFA IV Decision Within 90 FDA Days	23				
510(k)s Pending MDUFA IV Decision	24				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.26				
Number With MDUFA IV Decision	23				
Average Number of FDA Days to MDUFA IV Decision	59.04				
20th Percentile FDA Days to MDUFA IV Decision	48				
40th Percentile FDA Days to MDUFA IV Decision	53				
60th Percentile FDA Days to MDUFA IV Decision	59				
80th Percentile FDA Days to MDUFA IV Decision	82				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	6.39				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	14				
Maximum Industry Days to MDUFA IV Decision	49				
Average Number of Total Days to MDUFA IV Decision	65.43				
20th Percentile Total Days to MDUFA IV Decision	48				
40th Percentile Total Days to MDUFA IV Decision	53				
60th Percentile Total Days to MDUFA IV Decision	75				
80th Percentile Total Days to MDUFA IV Decision	95				
Maximum Total Days to MDUFA IV Decision	118				

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	47				
Number With MDUFA IV Decision	23				
Number of SE Decision	23				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0%				
Rate of Deleted	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	155				
Closed Before RTA Action	0				
Number Accepted	125				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	9				
Number Not Accepted	21				
Rate of Submissions Not Accepted for Review	14.38%				

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	134				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	104				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	29				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	1				
Current SI Performance Percent Within 60 FDA Days	99.05%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	104				
Average Number of FDA Days to Substantive Interaction	49.22				
20th Percentile FDA Days to Substantive Interaction	42				
40th Percentile FDA Days to Substantive Interaction	49				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 DRGUD - ODE - CDRH - 510(k) 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
510(k)s Accepted	134				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	34				
MDUFA IV Decision Within 90 FDA Days	34				
510(k)s Pending MDUFA IV Decision	100				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.21				
Number With MDUFA IV Decision	34				
Average Number of FDA Days to MDUFA IV Decision	57.85				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	55				
60th Percentile FDA Days to MDUFA IV Decision	61				
80th Percentile FDA Days to MDUFA IV Decision	85				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	4.85				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	2				
Maximum Industry Days to MDUFA IV Decision	47				
Average Number of Total Days to MDUFA IV Decision	62.71				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	55				
60th Percentile Total Days to MDUFA IV Decision	62				
80th Percentile Total Days to MDUFA IV Decision	89				
Maximum Total Days to MDUFA IV Decision	135				

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	134				
Number With MDUFA IV Decision	34				
Number of SE Decision	33				
Number of NSE Decision	1				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	97.06%				
Rate of NSE Decision	2.94%				
Rate of Withdrawal	0%				
Rate of Deleted	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	204				
Closed Before RTA Action	2				
Number Accepted	133				
Number Without a RTA and > 15 Days Since Date Received	1				
Number Without a RTA and <= 15 Days Since Date Received	16				
Number Not Accepted	52				
Rate of Submissions Not Accepted for Review	27.96%				

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	159				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	109				
SI Over 60 FDA Days	1				
SI Pending Within 60 FDA Days	49				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	99.09%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	110				
Average Number of FDA Days to Substantive Interaction	50.27				
20th Percentile FDA Days to Substantive Interaction	32				
40th Percentile FDA Days to Substantive Interaction	55				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	61				

Table 6.4 DSD - ODE - CDRH - 510(k) 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
510(k)s Accepted	159				
Non-MDUFA IV Decision	1				
MDUFA IV Decision (SE/NSE)	60				
MDUFA IV Decision Within 90 FDA Days	60				
510(k)s Pending MDUFA IV Decision	98				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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	1.27				
Number With MDUFA IV Decision	60				
Average Number of FDA Days to MDUFA IV Decision	59.15				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	56				
60th Percentile FDA Days to MDUFA IV Decision	75				
80th Percentile FDA Days to MDUFA IV Decision	86				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	7.78				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	16				
Maximum Industry Days to MDUFA IV Decision	63				
Average Number of Total Days to MDUFA IV Decision	66.93				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	57				
60th Percentile Total Days to MDUFA IV Decision	85				
80th Percentile Total Days to MDUFA IV Decision	92				
Maximum Total Days to MDUFA IV Decision	137				

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	159				
Number With MDUFA IV Decision	60				
Number of SE Decision	59				
Number of NSE Decision	1				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	98.33%				
Rate of NSE Decision	1.67%				
Rate of Withdrawal	0%				
Rate of Deleted	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	59				
Closed Before RTA Action	1				
Number Accepted	46				
Number Without a RTA and > 15 Days Since Date Received	1				
Number Without a RTA and <= 15 Days Since Date Received	1				
Number Not Accepted	10				
Rate of Submissions Not Accepted for Review	17.54%				

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	52				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	41				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	11				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	41				
Average Number of FDA Days to Substantive Interaction	51.61				
20th Percentile FDA Days to Substantive Interaction	47				
40th Percentile FDA Days to Substantive Interaction	53				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 DCTD - OIR - CDRH - 510(k) 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
510(k)s Accepted	52				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	10				
MDUFA IV Decision Within 90 FDA Days	10				
510(k)s Pending MDUFA IV Decision	42				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.30				
Number With MDUFA IV Decision	10				
Average Number of FDA Days to MDUFA IV Decision	56.50				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	45				
60th Percentile FDA Days to MDUFA IV Decision	64				
80th Percentile FDA Days to MDUFA IV Decision	87				
Maximum FDA Days to MDUFA IV Decision	89				
Average Number of Industry Days to MDUFA IV Decision	10.70				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	27				
Maximum Industry Days to MDUFA IV Decision	45				
Average Number of Total Days to MDUFA IV Decision	67.20				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	45				
60th Percentile Total Days to MDUFA IV Decision	64				
80th Percentile Total Days to MDUFA IV Decision	115				
Maximum Total Days to MDUFA IV Decision	132				

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	52				
Number With MDUFA IV Decision	10				
Number of SE Decision	10				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0%				
Rate of Deleted	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	52				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	10				
MDUFA IV Decision Within 90 FDA Days	10				
510(k)s Pending MDUFA IV Decision	42				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	17				
Closed Before RTA Action	0				
Number Accepted	11				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	2				
Number Not Accepted	4				
Rate of Submissions Not Accepted for Review	26.67%				

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	12				
Deleted or Withdrawn Prior to SI	1				
SI Within 60 FDA Days	9				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	2				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	9				
Average Number of FDA Days to Substantive Interaction	54.33				
20th Percentile FDA Days to Substantive Interaction	55				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 DIHD - OIR - CDRH - 510(k) 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
510(k)s Accepted	12				
Non-MDUFA IV Decision	1				
MDUFA IV Decision (SE/NSE)	4				
MDUFA IV Decision Within 90 FDA Days	4				
510(k)s Pending MDUFA IV Decision	7				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.25				
Number With MDUFA IV Decision	4				
Average Number of FDA Days to MDUFA IV Decision	73.50				
20th Percentile FDA Days to MDUFA IV Decision	64				
40th Percentile FDA Days to MDUFA IV Decision	88				
60th Percentile FDA Days to MDUFA IV Decision	89				
80th Percentile FDA Days to MDUFA IV Decision	89				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	7.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	11				
Maximum Industry Days to MDUFA IV Decision	28				
Average Number of Total Days to MDUFA IV Decision	80.50				
20th Percentile Total Days to MDUFA IV Decision	64				
40th Percentile Total Days to MDUFA IV Decision	88				
60th Percentile Total Days to MDUFA IV Decision	89				
80th Percentile Total Days to MDUFA IV Decision	101				
Maximum Total Days to MDUFA IV Decision	118				

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	12				
Number With MDUFA IV Decision	4				
Number of SE Decision	4				
Number of NSE Decision	0				
Number of Withdrawal	1				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	8.33%				
Rate of Deleted	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	12				
Non-MDUFA IV Decision	1				
MDUFA IV Decision (SE/NSE)	4				
MDUFA IV Decision Within 90 FDA Days	4				
510(k)s Pending MDUFA IV Decision	7				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	41				
Closed Before RTA Action	0				
Number Accepted	37				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	1				
Number Not Accepted	3				
Rate of Submissions Not Accepted for Review	7.50%				

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	37				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	33				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	4				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	33				
Average Number of FDA Days to Substantive Interaction	51.61				
20th Percentile FDA Days to Substantive Interaction	48				
40th Percentile FDA Days to Substantive Interaction	57				
60th Percentile FDA Days to Substantive Interaction	58				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 DMD - OIR - CDRH - 510(k) 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
510(k)s Accepted	37				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	25				
MDUFA IV Decision Within 90 FDA Days	25				
510(k)s Pending MDUFA IV Decision	12				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.00				
Number With MDUFA IV Decision	25				
Average Number of FDA Days to MDUFA IV Decision	68.96				
20th Percentile FDA Days to MDUFA IV Decision	36				
40th Percentile FDA Days to MDUFA IV Decision	75				
60th Percentile FDA Days to MDUFA IV Decision	86				
80th Percentile FDA Days to MDUFA IV Decision	89				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Number of Total Days to MDUFA IV Decision	68.96				
20th Percentile Total Days to MDUFA IV Decision	36				
40th Percentile Total Days to MDUFA IV Decision	75				
60th Percentile Total Days to MDUFA IV Decision	86				
80th Percentile Total Days to MDUFA IV Decision	89				
Maximum Total Days to MDUFA IV Decision	90				

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	37				
Number With MDUFA IV Decision	25				
Number of SE Decision	25				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0%				
Rate of Deleted	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	1				
MDUFA IV Decision Within 90 FDA Days	1				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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	36				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	24				
MDUFA IV Decision Within 90 FDA Days	24				
510(k)s Pending MDUFA IV Decision	12				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	3				
Closed Before RTA Action	0				
Number Accepted	3				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	0				
Number Not Accepted	0				
Rate of Submissions Not Accepted for Review	0%				

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	3				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	3				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	0				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	3				
Average Number of FDA Days to Substantive Interaction	41.00				
20th Percentile FDA Days to Substantive Interaction	31				
40th Percentile FDA Days to Substantive Interaction	36				
60th Percentile FDA Days to Substantive Interaction	43				
80th Percentile FDA Days to Substantive Interaction	51				
Maximum FDA Days to Substantive Interaction	59				

Table 6.4 DMGP - OIR - CDRH - 510(k) 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
510(k)s Accepted	3				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	2				
MDUFA IV Decision Within 90 FDA Days	2				
510(k)s Pending MDUFA IV Decision	1				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.50				
Number With MDUFA IV Decision	2				
Average Number of FDA Days to MDUFA IV Decision	43.00				
20th Percentile FDA Days to MDUFA IV Decision	41				
40th Percentile FDA Days to MDUFA IV Decision	42				
60th Percentile FDA Days to MDUFA IV Decision	44				
80th Percentile FDA Days to MDUFA IV Decision	45				
Maximum FDA Days to MDUFA IV Decision	47				
Average Number of Industry Days to MDUFA IV Decision	20.00				
20th Percentile Industry Days to MDUFA IV Decision	8				
40th Percentile Industry Days to MDUFA IV Decision	16				
60th Percentile Industry Days to MDUFA IV Decision	24				
80th Percentile Industry Days to MDUFA IV Decision	32				
Maximum Industry Days to MDUFA IV Decision	40				
Average Number of Total Days to MDUFA IV Decision	63.00				
20th Percentile Total Days to MDUFA IV Decision	49				
40th Percentile Total Days to MDUFA IV Decision	58				
60th Percentile Total Days to MDUFA IV Decision	68				
80th Percentile Total Days to MDUFA IV Decision	77				
Maximum Total Days to MDUFA IV Decision	87				

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	3				
Number With MDUFA IV Decision	2				
Number of SE Decision	2				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0%				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	1				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	2				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	2				
MDUFA IV Decision Within 90 FDA Days	2				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	191				
Closed Before RTA Action	0				
Number Accepted	162				
Number Without a RTA and > 15 Days Since Date Received	0				
Number Without a RTA and <= 15 Days Since Date Received	6				
Number Not Accepted	23				
Rate of Submissions Not Accepted for Review	12.43%				

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	173				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	139				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	34				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	139				
Average Number of FDA Days to Substantive Interaction	43.63				
20th Percentile FDA Days to Substantive Interaction	29				
40th Percentile FDA Days to Substantive Interaction	41				
60th Percentile FDA Days to Substantive Interaction	52				
80th Percentile FDA Days to Substantive Interaction	57				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 DRH - OIR - CDRH - 510(k) 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
510(k)s Accepted	173				
Non-MDUFA IV Decision	1				
MDUFA IV Decision (SE/NSE)	98				
MDUFA IV Decision Within 90 FDA Days	98				
510(k)s Pending MDUFA IV Decision	74				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.37				
Number With MDUFA IV Decision	98				
Average Number of FDA Days to MDUFA IV Decision	53.08				
20th Percentile FDA Days to MDUFA IV Decision	29				
40th Percentile FDA Days to MDUFA IV Decision	47				
60th Percentile FDA Days to MDUFA IV Decision	58				
80th Percentile FDA Days to MDUFA IV Decision	80				
Maximum FDA Days to MDUFA IV Decision	89				
Average Number of Industry Days to MDUFA IV Decision	10.72				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	25				
Maximum Industry Days to MDUFA IV Decision	66				
Average Number of Total Days to MDUFA IV Decision	63.81				
20th Percentile Total Days to MDUFA IV Decision	29				
40th Percentile Total Days to MDUFA IV Decision	51				
60th Percentile Total Days to MDUFA IV Decision	66				
80th Percentile Total Days to MDUFA IV Decision	103				
Maximum Total Days to MDUFA IV Decision	141				

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	173				
Number With MDUFA IV Decision	98				
Number of SE Decision	98				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0%				
Rate of Deleted	0%				

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				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	N/A				

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Section 7 510(k) Annual General Metrics - Annual Metrics and Goals will be reported in the Annual Report.

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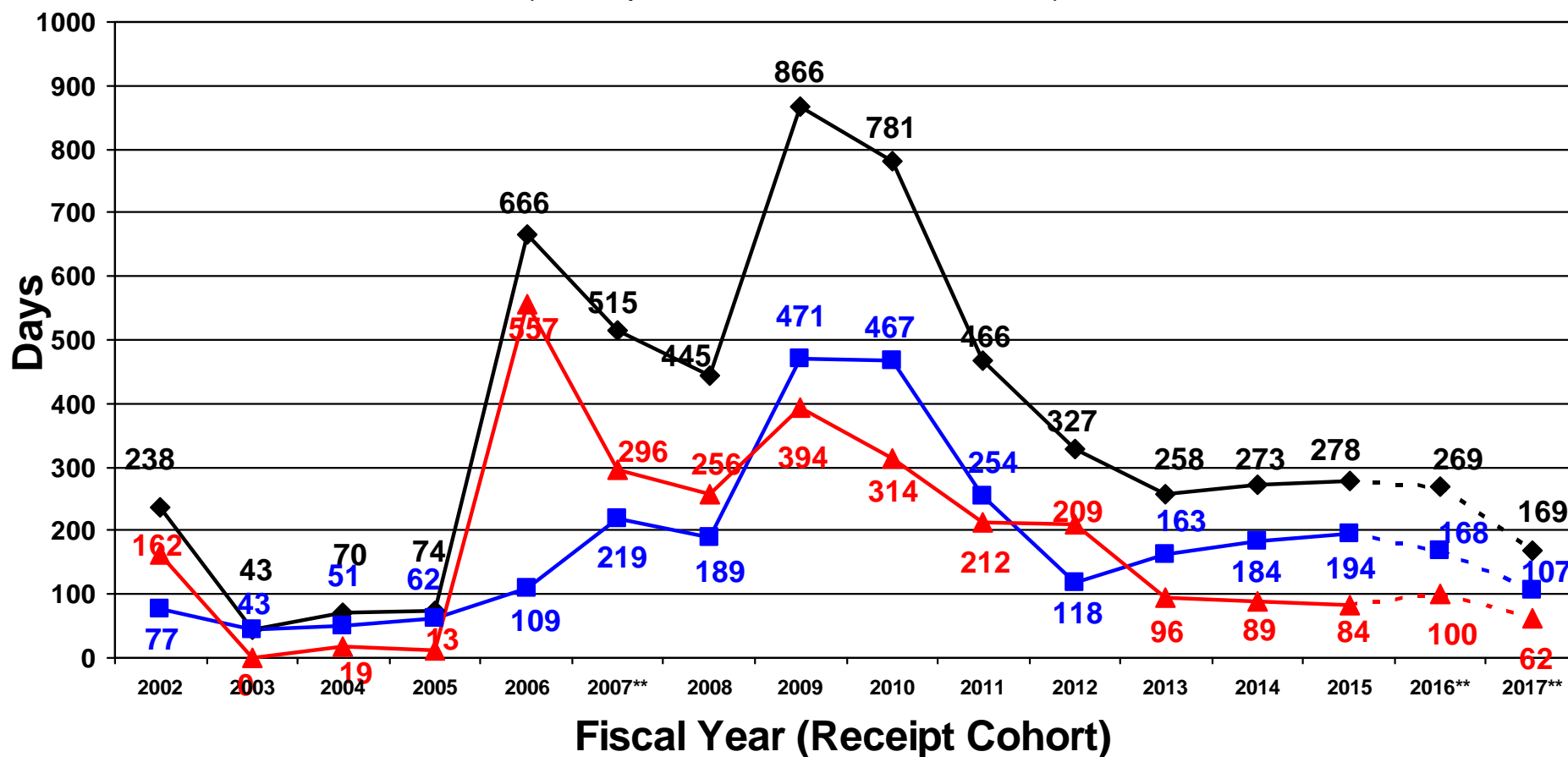
De Novos

Q2FY18

Average Time to Grant/Decline/Withdrawal/Deletion

Decision: De Novos*

(Receipt Cohorts as of 3/31/2018)



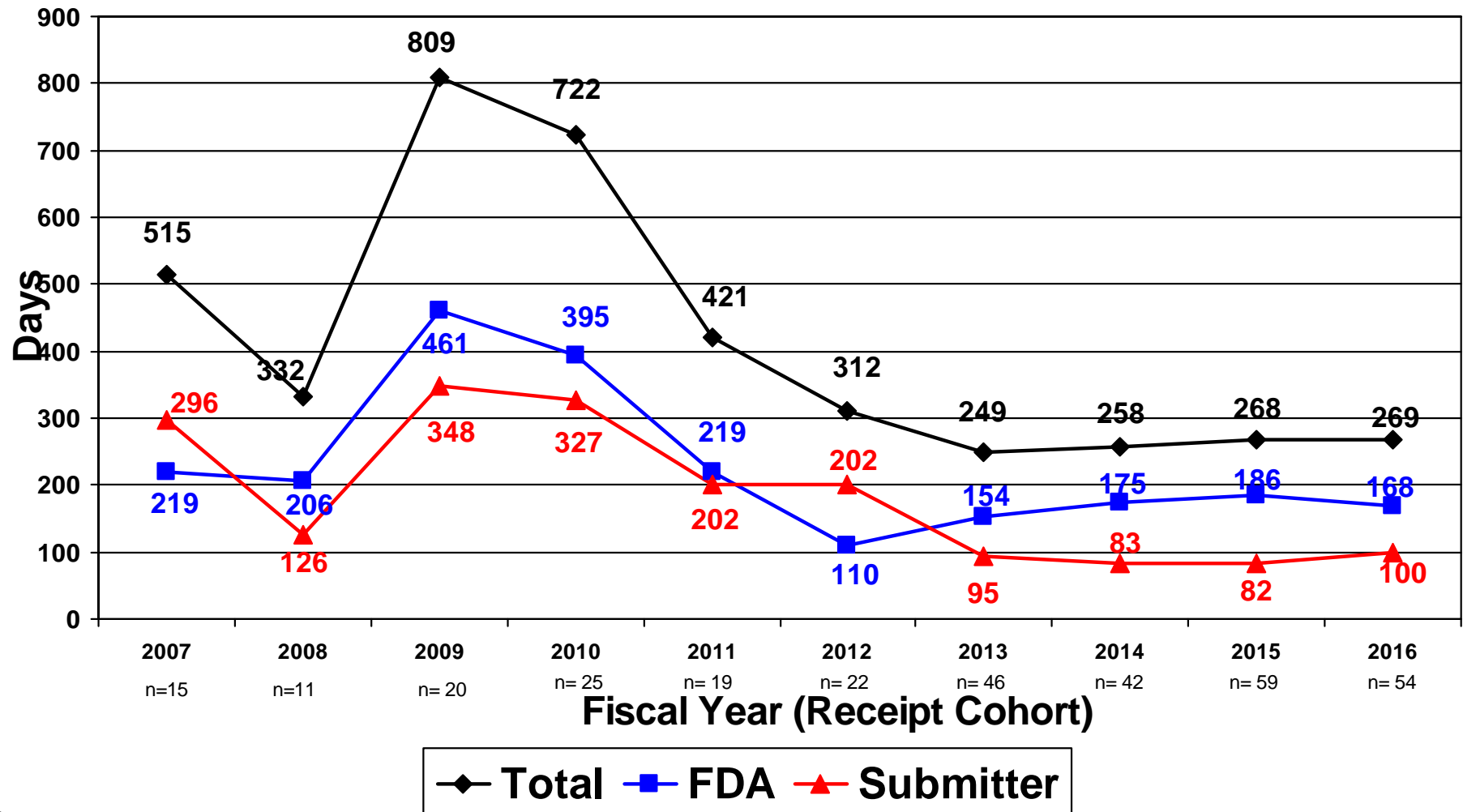
◆ Total ■ FDA ▲ Submitter

* Grant/Decline/Withdrawal/Deletion decisions only; times may not add to total due to rounding

** Cohorts still open; percentage of cohort closed: FY 2007 = 93.3%, FY2016 = 98%, FY2017 = 61% => avg times for FY2007, FY2016 & FY2017 will increase

Average Time to Grant/Decline/Withdrawal/Deletion Decision: De Novos*

- Comparison of Receipt Cohorts When 98% Closed -

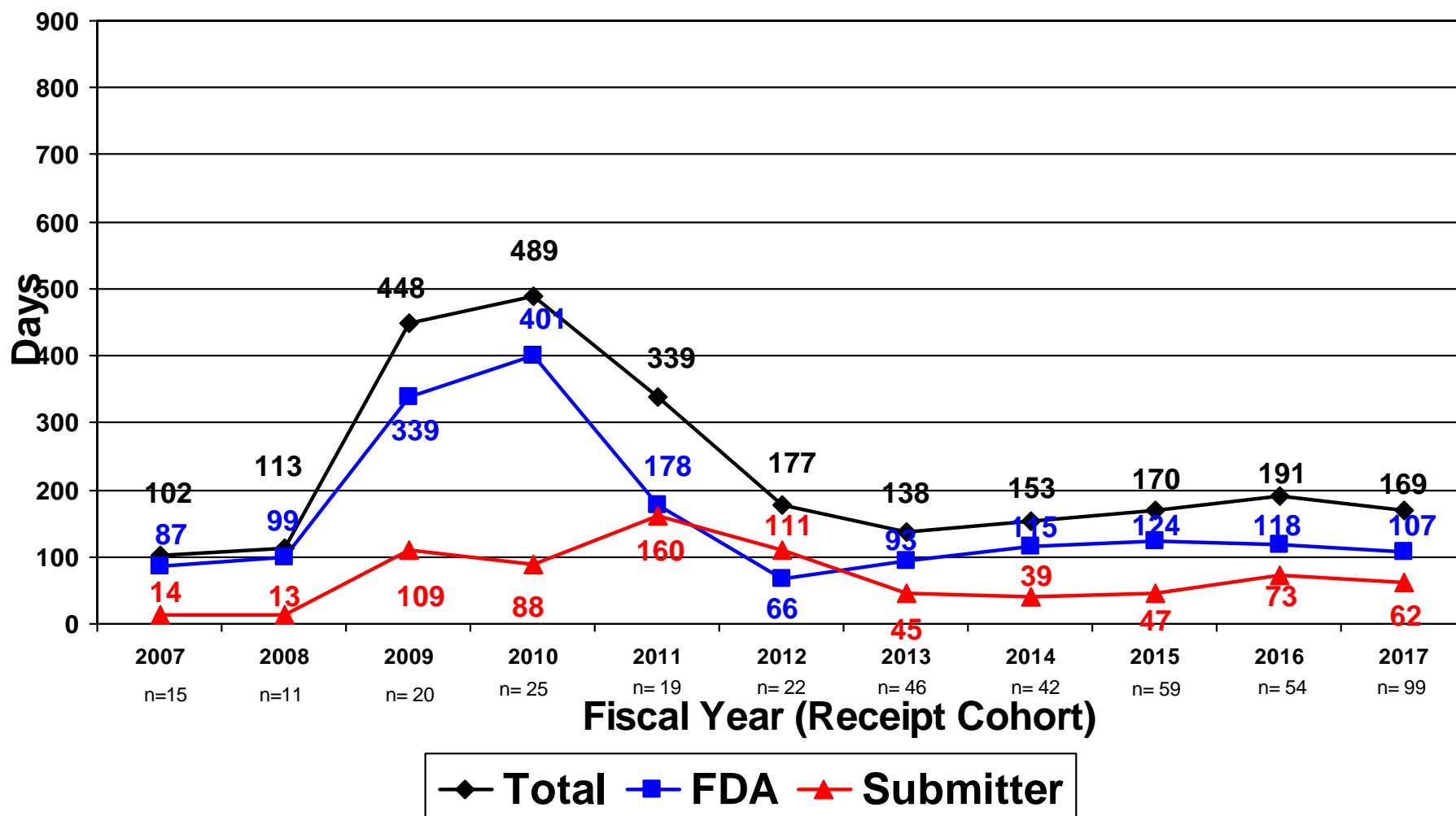


* Grant/Decline/Withdrawal decisions only; times may not add to total due to rounding

Note: "n=x" signifies the number of De Novos in each FY receipt cohort. Some De Novos ultimately dropped out of the average days calculation because they received a decision other than a Grant/Decline/Withdrawal/Deletion decision.

Average Time to Grant/Decline/Withdrawal/Deletion Decision: De Novos*

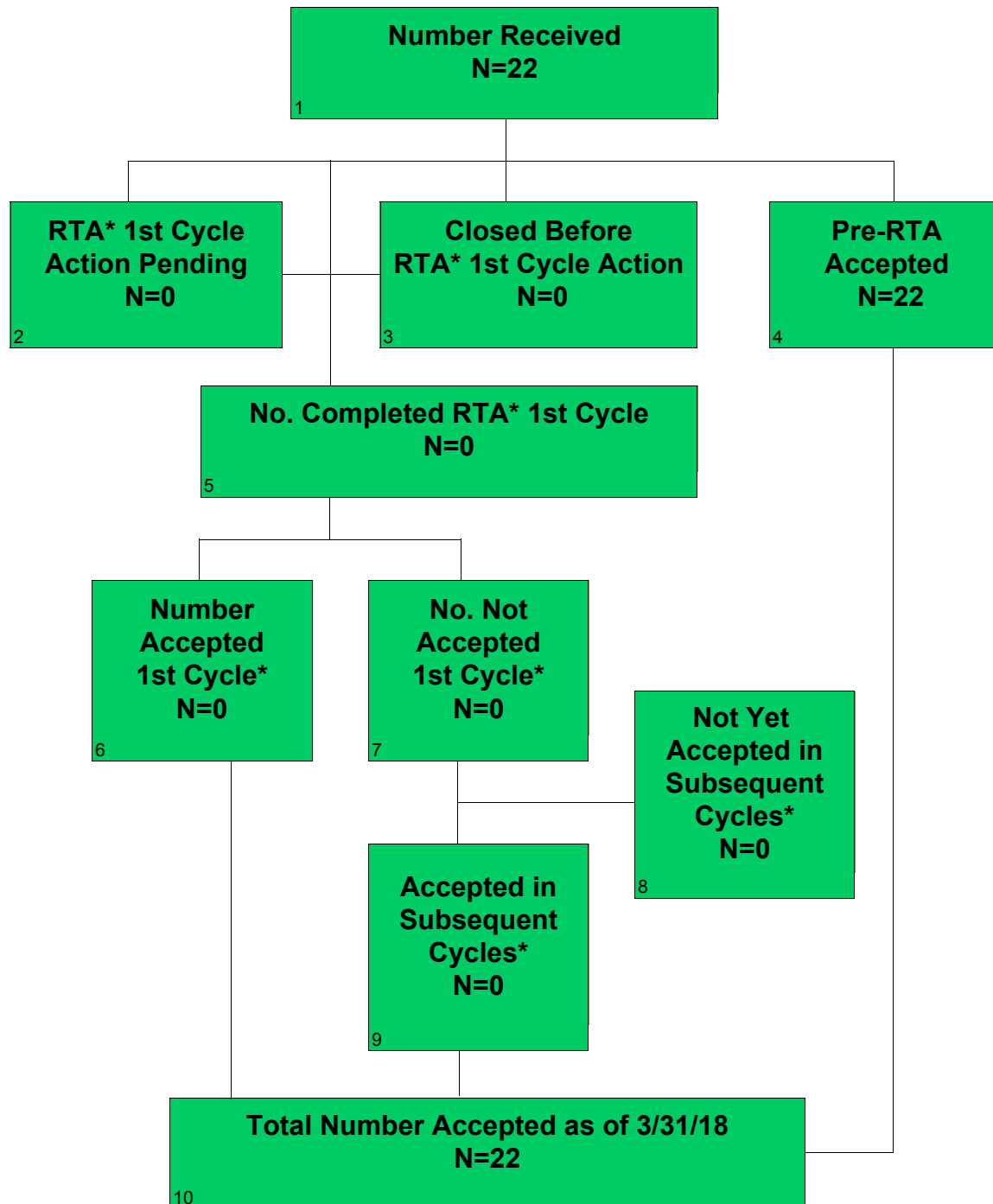
- Comparison of Receipt Cohorts When 61% Closed -



* Grant/Decline/Withdrawal decisions only; times may not add to total due to rounding

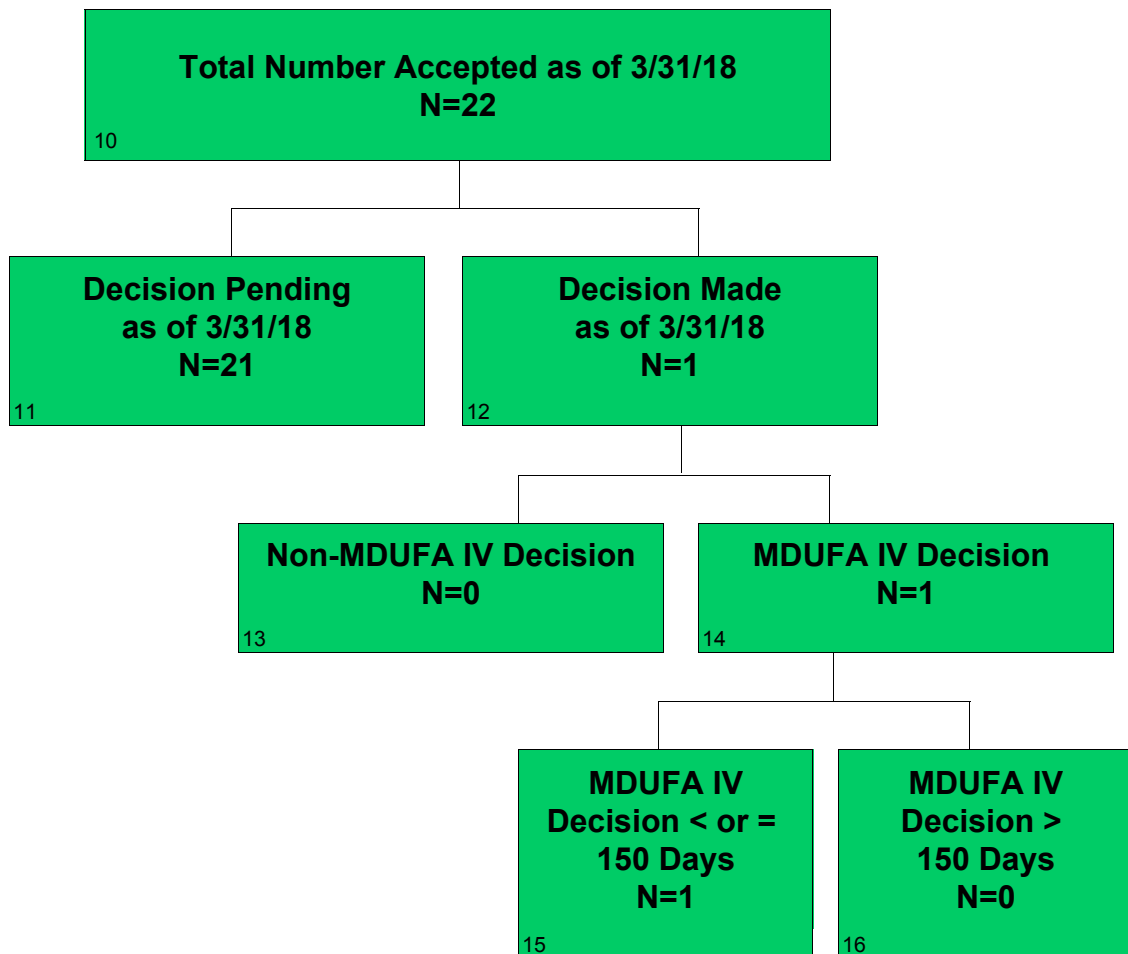
Note: "n=x" signifies the number of De Novos in each FY receipt cohort. Some De Novos ultimately dropped out of the average days calculation because they received a decision other than a Grant/Decline/Withdrawal/Deletion decision.

CDRH De Novo - FY 2018 as of 3/31/18



* RTA will be implemented when the guidance, including the submission checklist, is finalized.

CDRH De Novo - FY 2018 as of 3/31/18 Continued



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	22				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	22				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	1				
MDUFA IV Decisions Within 150 FDA Days	1				
De Novos Pending MDUFA IV Decision	21				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100%				

Table 8.3 CDRH - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.00				
Number With MDUFA IV Decision	1				
Average FDA Days to MDUFA IV Decision	109.00				
20th Percentile FDA Days to MDUFA IV Decision	109				
40th Percentile FDA Days to MDUFA IV Decision	109				
60th Percentile FDA Days to MDUFA IV Decision	109				
80th Percentile FDA Days to MDUFA IV Decision	109				
Maximum FDA Days to MDUFA IV Decision	109				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	109.00				
20th Percentile Total Days to MDUFA IV Decision	109				
40th Percentile Total Days to MDUFA IV Decision	109				
60th Percentile Total Days to MDUFA IV Decision	109				
80th Percentile Total Days to MDUFA IV Decision	109				
Maximum Total Days to MDUFA IV Decision	109				

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	22				
Number With MDUFA IV Decisions	1				
Number With Granted Decisions	1				
Number With Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	100%				
Rate of Declined Decisions	0%				
Rate of Withdrawals	0%				
Rate of Deleted	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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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	5				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	1				
MDUFA IV Decisions Within 150 FDA Days	1				
De Novos Pending MDUFA IV Decision	4				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	16				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	16				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	16				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 ODE - CDRH - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	0.00				
Number With MDUFA IV Decision	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

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	16				
Number With MDUFA IV Decisions	0				
Number With Granted Decisions	0				
Number With Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	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	0				
Mean FDA Days for Submissions That Missed the Goal	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	6				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	6				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	1				
MDUFA IV Decisions Within 150 FDA Days	1				
De Novos Pending MDUFA IV Decision	5				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100%				

Table 8.3 OIR - CDRH - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.00				
Number With MDUFA IV Decision	1				
Average FDA Days to MDUFA IV Decision	109.00				
20th Percentile FDA Days to MDUFA IV Decision	109				
40th Percentile FDA Days to MDUFA IV Decision	109				
60th Percentile FDA Days to MDUFA IV Decision	109				
80th Percentile FDA Days to MDUFA IV Decision	109				
Maximum FDA Days to MDUFA IV Decision	109				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	109.00				
20th Percentile Total Days to MDUFA IV Decision	109				
40th Percentile Total Days to MDUFA IV Decision	109				
60th Percentile Total Days to MDUFA IV Decision	109				
80th Percentile Total Days to MDUFA IV Decision	109				
Maximum Total Days to MDUFA IV Decision	109				

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	6				
Number With MDUFA IV Decisions	1				
Number With Granted Decisions	1				
Number With Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	100%				
Rate of Declined Decisions	0%				
Rate of Withdrawals	0%				
Rate of Deleted	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				
Mean FDA Days for Submissions That Missed the Goal	0.00				
Mean Industry Days for Submissions That Missed the Goal	0.00				

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	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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	5				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	1				
MDUFA IV Decisions Within 150 FDA Days	1				
De Novos Pending MDUFA IV Decision	4				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	3				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DAGRID - ODE - CDRH - De Novo Time to MDUFA IV Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	0.00				
Number with MDUFA IV Decision	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	0				

Table 8.5 DAGRID - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performa

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.7 DAGRID - 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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	1				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	1				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	1				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DCD - ODE - CDRH - De Novo Time to MDUFA IV Decisions

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

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	1				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	3				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	3				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	3				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DNPMD - ODE - CDRH - De Novo Time to MDUFA IV Decisions

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

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	3				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.7 DNPMD - 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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	1				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	1				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	1				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DOD - ODE - CDRH - De Novo Time to MDUFA IV Decisions

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

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	1				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	2				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	2				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	2				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DOED - ODE - CDRH - De Novo Time to MDUFA IV Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	0.00				
Number with MDUFA IV Decision	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	2				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	0				

Table 8.5 DOED - 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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.7 DOED - ODE - 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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	2				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	2				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	2				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DRGUD - ODE - CDRH - De Novo Time to MDUFA IV Decisions

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

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	2				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.7 DRGUD - 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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	4				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	4				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	4				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DSD - ODE - CDRH - De Novo Time to MDUFA IV Decisions

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

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	4				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	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	0				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	4				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	4				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	1				
MDUFA IV Decisions Within 150 FDA Days	1				
De Novos Pending MDUFA IV Decision	3				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100%				

Table 8.3 DCTD - OIR - CDRH - De Novo Time to MDUFA IV Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.00				
Number with MDUFA IV Decision	1				
Average FDA Days to MDUFA IV Decision	109.00				
20th Percentile FDA Days to MDUFA IV Decision	109				
40th Percentile FDA Days to MDUFA IV Decision	109				
60th Percentile FDA Days to MDUFA IV Decision	109				
80th Percentile FDA Days to MDUFA IV Decision	109				
Maximum FDA Days to MDUFA IV Decision	109				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	109.00				
20th Percentile Total Days to MDUFA IV Decision	109				
40th Percentile Total Days to MDUFA IV Decision	109				
60th Percentile Total Days to MDUFA IV Decision	109				
80th Percentile Total Days to MDUFA IV Decision	109				
Maximum Total Days to MDUFA IV Decision	109				

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	4				
Number with MDUFA IV Decision	1				
Number with Granted Decisions	1				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	100%				
Rate of Declined Decisions	0%				
Rate of Withdrawals	0%				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.7 DCTD - 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	4				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	1				
MDUFA IV Decisions Within 150 FDA Days	1				
De Novos Pending MDUFA IV Decision	3				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	0				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DIHD - OIR - CDRH - De Novo Time to MDUFA IV Decisions

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

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	0				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	N/A				
Rate of Deleted	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	1				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	1				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	1				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DMD - OIR - CDRH - De Novo Time to MDUFA IV Decisions

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

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	1				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	1				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	1				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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	0				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DMGP - OIR - CDRH - De Novo Time to MDUFA IV Decisions

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

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	0				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	N/A				
Rate of Deleted	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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				
Closed Before RTA Action	N/A				
Number Accepted First RTA Cycle	N/A				
Number Without a RTA Review and > 15 Days Since Date Received	N/A				
Number Without a RTA Review and <= 15 Days Since Date Received	N/A				
Number Not Accepted	N/A				
Rate of Submissions Not Accepted for Review	N/A				

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	1				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 DRH - OIR - CDRH - De Novo Time to MDUFA IV Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	0.00				
Number with MDUFA IV Decision	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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				
Number with MDUFA IV Decision	0				
Number with Granted Decisions	0				
Number with Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	0				
Rate of Deleted	0				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

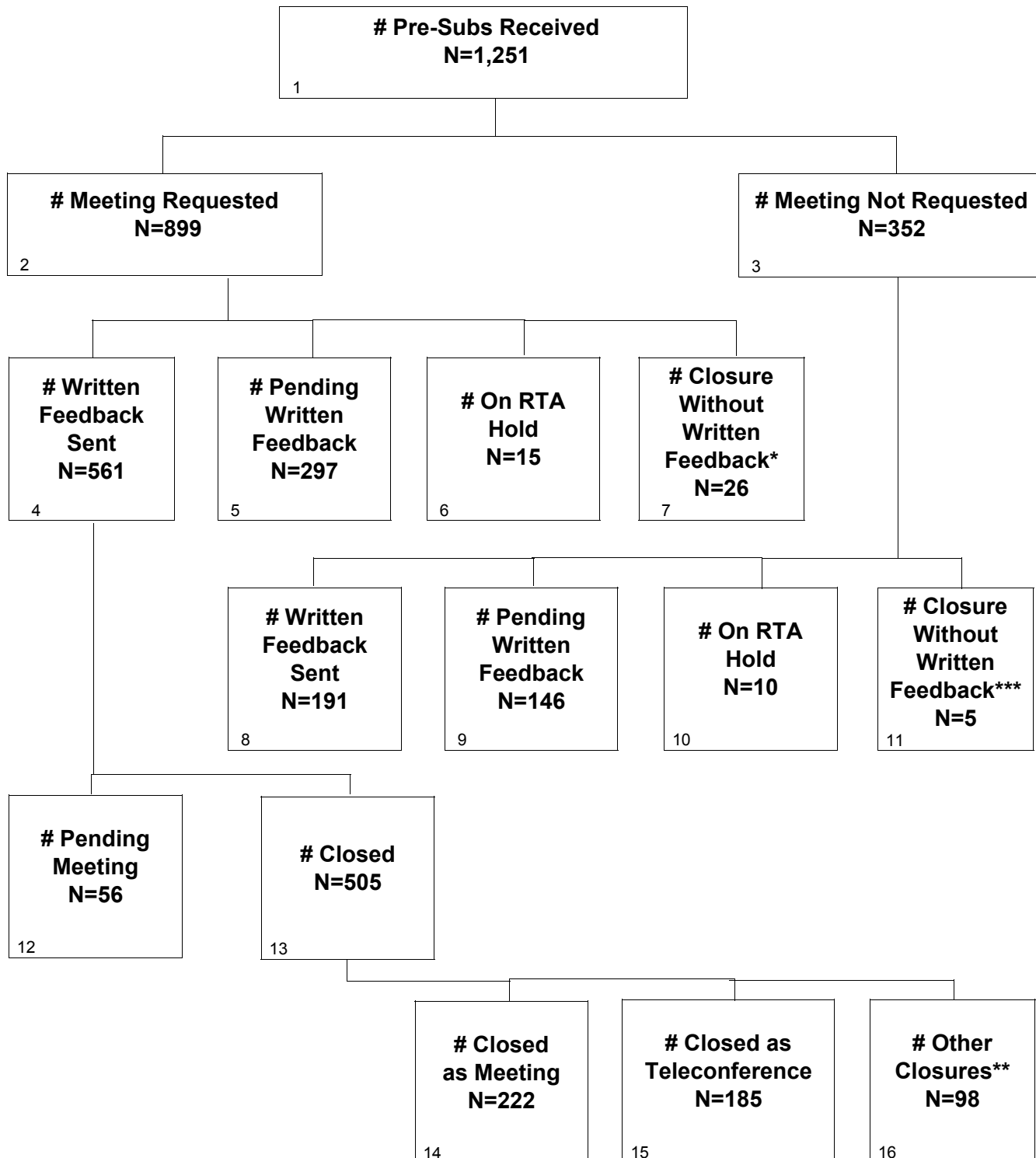
Table 8.7 DRH - OIR - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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CDRH Pre-Sub - FY 2018

as of 3/31/18



* Closures include Cancelled by Requestor (CNLR, n=7), Cancelled by FDA (CNLF, n=2), Product Jurisdiction Pending (JPND, n=3), Product Jurisdiction Transferred (JTRX, n=8) & Withdrawn (WTDR, n=6)

** Closures include Cancelled by Requestor (CNLR)

*** Closures include Product Jurisdiction Transferred (JTRX, n=1) & Withdrawn (WTDR, n=4)

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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	1,251				
Closed Before RTA Action	14				
Number Accepted First RTA Cycle	1,103				
Number Without a RTA Review and > 15 Days Since Date Received	23				
Number Without a RTA Review and <= 15 Days Since Date Received	78				
Number Not Accepted	33				
Rate of Submissions Not Accepted for Review	2.85%				

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	752				
Written Feedback Provided Within MDUFA IV Goal	703				

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	752				
Average FDA Days to Written Feedback	57.34				
20th Percentile FDA Days to Written Feedback	48				
40th Percentile FDA Days to Written Feedback	57				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	69				
Maximum FDA Days to Written Feedback	94				

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	8				
Average Days to Scheduling for Meetings Scheduled After Day 30	39.38				

Table 9.5 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	407				
Meeting Minutes Submitted Within 15 Days of Meeting	248				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	26				
Meeting Minutes Past 15 Days of Meeting	102				
Meeting Minutes Not Submitted and >15 Days Since Meeting	31				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	65.09%				

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	839				
Closed Before RTA Action	9				
Number Accepted First RTA Cycle	720				
Number Without a RTA Review and > 15 Days Since Date Received	23				
Number Without a RTA Review and <= 15 Days Since Date Received	58				
Number Not Accepted	29				
Rate of Submissions Not Accepted for Review	3.76%				

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	497				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	450				

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	497				
Average FDA Days to Written Feedback	57.85				
20th Percentile FDA Days to Written Feedback	48				
40th Percentile FDA Days to Written Feedback	57				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	69				
Maximum FDA Days to Written Feedback	94				

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	7				
Average Days to Scheduling for Meetings Scheduled After Day 30	39.57				

Table 9.5 ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	269				
Meeting Minutes Submitted Within 15 Days of Meeting	167				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	16				
Meeting Minutes Past 15 Days of Meeting	69				
Meeting Minutes Not Submitted and >15 Days Since Meeting	17				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	66.01%				

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	412				
Closed Before RTA Action	5				
Number Accepted First RTA Cycle	383				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	20				
Number Not Accepted	4				
Rate of Submissions Not Accepted for Review	1.03%				

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	255				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	253				

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	255				
Average FDA Days to Written Feedback	56.34				
20th Percentile FDA Days to Written Feedback	48				
40th Percentile FDA Days to Written Feedback	57				
60th Percentile FDA Days to Written Feedback	63				
80th Percentile FDA Days to Written Feedback	67				
Maximum FDA Days to Written Feedback	71				

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	1				
Average Days to Scheduling for Meetings Scheduled After Day 30	38.00				

Table 9.5 OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	138				
Meeting Minutes Submitted Within 15 Days of Meeting	81				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	10				
Meeting Minutes Past 15 Days of Meeting	33				
Meeting Minutes Not Submitted and >15 Days Since Meeting	14				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.28%				

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	150				
Closed Before RTA Action	2				
Number Accepted First RTA Cycle	119				
Number Without a RTA Review and > 15 Days Since Date Received	3				
Number Without a RTA Review and <= 15 Days Since Date Received	10				
Number Not Accepted	16				
Rate of Submissions Not Accepted for Review	11.59%				

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	77				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	61				

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	77				
Average FDA Days to Written Feedback	60.32				
20th Percentile FDA Days to Written Feedback	50				
40th Percentile FDA Days to Written Feedback	60				
60th Percentile FDA Days to Written Feedback	66				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	81				

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	4				
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75				

Table 9.5 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	41				
Meeting Minutes Submitted Within 15 Days of Meeting	26				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	9				
Meeting Minutes Not Submitted and >15 Days Since Meeting	4				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	66.67%				

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	236				
Closed Before RTA Action	1				
Number Accepted First RTA Cycle	203				
Number Without a RTA Review and > 15 Days Since Date Received	8				
Number Without a RTA Review and <= 15 Days Since Date Received	20				
Number Not Accepted	4				
Rate of Submissions Not Accepted for Review	1.86%				

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	143				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	133				

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	143				
Average FDA Days to Written Feedback	51.24				
20th Percentile FDA Days to Written Feedback	38				
40th Percentile FDA Days to Written Feedback	49				
60th Percentile FDA Days to Written Feedback	56				
80th Percentile FDA Days to Written Feedback	66				
Maximum FDA Days to Written Feedback	76				

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	2				
Average Days to Scheduling for Meetings Scheduled After Day 30	31.00				

Table 9.5 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	85				
Meeting Minutes Submitted Within 15 Days of Meeting	51				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	4				
Meeting Minutes Past 15 Days of Meeting	23				
Meeting Minutes Not Submitted and >15 Days Since Meeting	7				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.96%				

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	109				
Closed Before RTA Action	2				
Number Accepted First RTA Cycle	98				
Number Without a RTA Review and > 15 Days Since Date Received	3				
Number Without a RTA Review and <= 15 Days Since Date Received	6				
Number Not Accepted	0				
Rate of Submissions Not Accepted for Review	0%				

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	72				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	65				

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	72				
Average FDA Days to Written Feedback	63.15				
20th Percentile FDA Days to Written Feedback	55				
40th Percentile FDA Days to Written Feedback	64				
60th Percentile FDA Days to Written Feedback	69				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	80				

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	1				
Average Days to Scheduling for Meetings Scheduled After Day 30	36.00				

Table 9.5 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	36				
Meeting Minutes Submitted Within 15 Days of Meeting	21				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	3				
Meeting Minutes Past 15 Days of Meeting	10				
Meeting Minutes Not Submitted and >15 Days Since Meeting	2				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.64%				

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	56				
Closed Before RTA Action	0				
Number Accepted First RTA Cycle	52				
Number Without a RTA Review and > 15 Days Since Date Received	2				
Number Without a RTA Review and <= 15 Days Since Date Received	2				
Number Not Accepted	0				
Rate of Submissions Not Accepted for Review	0%				

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	35				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	30				

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	35				
Average FDA Days to Written Feedback	61.29				
20th Percentile FDA Days to Written Feedback	47				
40th Percentile FDA Days to Written Feedback	61				
60th Percentile FDA Days to Written Feedback	66				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	94				

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	0				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	14				
Meeting Minutes Submitted Within 15 Days of Meeting	8				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	3				
Meeting Minutes Past 15 Days of Meeting	3				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	72.73%				

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	73				
Closed Before RTA Action	0				
Number Accepted First RTA Cycle	64				
Number Without a RTA Review and > 15 Days Since Date Received	2				
Number Without a RTA Review and <= 15 Days Since Date Received	4				
Number Not Accepted	3				
Rate of Submissions Not Accepted for Review	4.35%				

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	41				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	40				

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	41				
Average FDA Days to Written Feedback	61.90				
20th Percentile FDA Days to Written Feedback	54				
40th Percentile FDA Days to Written Feedback	61				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	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	0				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	26				
Meeting Minutes Submitted Within 15 Days of Meeting	20				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	5				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.00%				

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	108				
Closed Before RTA Action	1				
Number Accepted First RTA Cycle	94				
Number Without a RTA Review and > 15 Days Since Date Received	2				
Number Without a RTA Review and <= 15 Days Since Date Received	9				
Number Not Accepted	2				
Rate of Submissions Not Accepted for Review	2.04%				

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	64				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	63				

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	64				
Average FDA Days to Written Feedback	57.19				
20th Percentile FDA Days to Written Feedback	51				
40th Percentile FDA Days to Written Feedback	56				
60th Percentile FDA Days to Written Feedback	63				
80th Percentile FDA Days to Written Feedback	67				
Maximum FDA Days to Written Feedback	70				

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	0				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	35				
Meeting Minutes Submitted Within 15 Days of Meeting	20				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	13				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	60.61%				

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	107				
Closed Before RTA Action	3				
Number Accepted First RTA Cycle	90				
Number Without a RTA Review and > 15 Days Since Date Received	3				
Number Without a RTA Review and <= 15 Days Since Date Received	7				
Number Not Accepted	4				
Rate of Submissions Not Accepted for Review	4.12%				

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	65				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	58				

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	65				
Average FDA Days to Written Feedback	59.80				
20th Percentile FDA Days to Written Feedback	52				
40th Percentile FDA Days to Written Feedback	58				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	69				
Maximum FDA Days to Written Feedback	84				

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	0				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	32				
Meeting Minutes Submitted Within 15 Days of Meeting	21				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	6				
Meeting Minutes Not Submitted and >15 Days Since Meeting	4				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	67.74%				

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	114				
Closed Before RTA Action	3				
Number Accepted First RTA Cycle	100				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	10				
Number Not Accepted	1				
Rate of Submissions Not Accepted for Review	0.99%				

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	67				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	66				

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	67				
Average FDA Days to Written Feedback	57.94				
20th Percentile FDA Days to Written Feedback	47				
40th Percentile FDA Days to Written Feedback	59				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	71				

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	1				
Average Days to Scheduling for Meetings Scheduled After Day 30	38.00				

Table 9.5 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	39				
Meeting Minutes Submitted Within 15 Days of Meeting	23				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	9				
Meeting Minutes Not Submitted and >15 Days Since Meeting	5				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.16%				

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	60				
Closed Before RTA Action	2				
Number Accepted First RTA Cycle	57				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	1				
Number Not Accepted	0				
Rate of Submissions Not Accepted for Review	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	39				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	38				

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	39				
Average FDA Days to Written Feedback	59.51				
20th Percentile FDA Days to Written Feedback	52				
40th Percentile FDA Days to Written Feedback	57				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	68				
Maximum FDA Days to Written Feedback	71				

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	0				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	19				
Meeting Minutes Submitted Within 15 Days of Meeting	11				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	3				
Meeting Minutes Not Submitted and >15 Days Since Meeting	3				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.71%				

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	98				
Closed Before RTA Action	0				
Number Accepted First RTA Cycle	94				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	3				
Number Not Accepted	1				
Rate of Submissions Not Accepted for Review	1.05%				

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	60				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	60				

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	60				
Average FDA Days to Written Feedback	57.92				
20th Percentile FDA Days to Written Feedback	53				
40th Percentile FDA Days to Written Feedback	60				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	69				
Maximum FDA Days to Written Feedback	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				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	26				
Meeting Minutes Submitted Within 15 Days of Meeting	12				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0				
Meeting Minutes Past 15 Days of Meeting	9				
Meeting Minutes Not Submitted and >15 Days Since Meeting	5				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	46.15%				

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	88				
Closed Before RTA Action	0				
Number Accepted First RTA Cycle	86				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	2				
Number Not Accepted	0				
Rate of Submissions Not Accepted for Review	0%				

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	59				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	59				

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	59				
Average FDA Days to Written Feedback	56.24				
20th Percentile FDA Days to Written Feedback	47				
40th Percentile FDA Days to Written Feedback	53				
60th Percentile FDA Days to Written Feedback	62				
80th Percentile FDA Days to Written Feedback	66				
Maximum FDA Days to Written Feedback	70				

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				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	35				
Meeting Minutes Submitted Within 15 Days of Meeting	20				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	5				
Meeting Minutes Past 15 Days of Meeting	9				
Meeting Minutes Not Submitted and >15 Days Since Meeting	1				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	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	52				
Closed Before RTA Action	0				
Number Accepted First RTA Cycle	46				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	4				
Number Not Accepted	2				
Rate of Submissions Not Accepted for Review	4.17%				

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	30				
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	30				

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	30				
Average FDA Days to Written Feedback	45.67				
20th Percentile FDA Days to Written Feedback	34				
40th Percentile FDA Days to Written Feedback	48				
60th Percentile FDA Days to Written Feedback	51				
80th Percentile FDA Days to Written Feedback	57				
Maximum FDA Days to Written Feedback	63				

Table 9.4 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

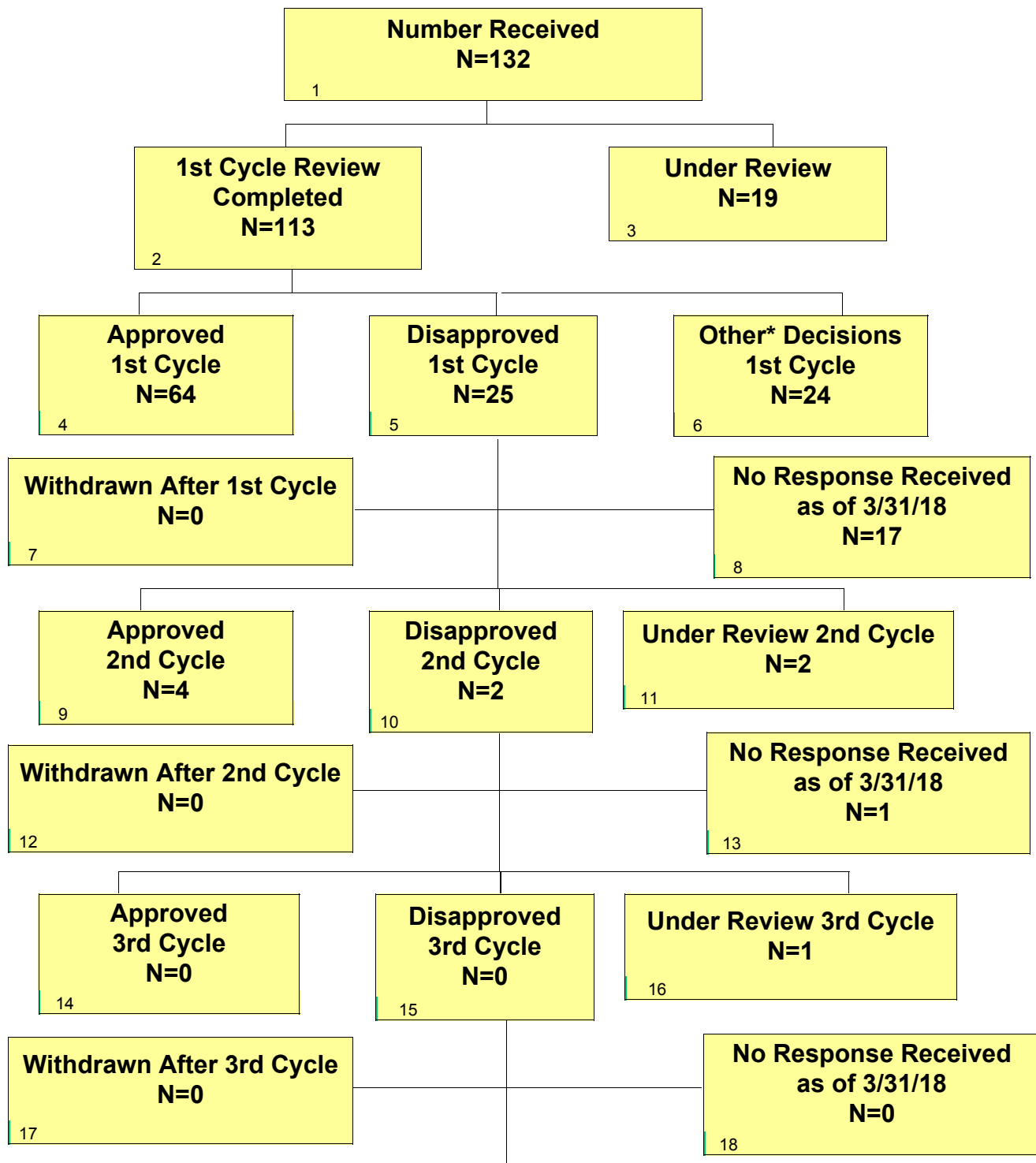
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0				
Average Days to Scheduling for Meetings Scheduled After Day 30	N/A				

Table 9.5 DRH - OIR - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	19				
Meeting Minutes Submitted Within 15 Days of Meeting	15				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	3				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	83.33%				

CDRH IDEs - FY 2018

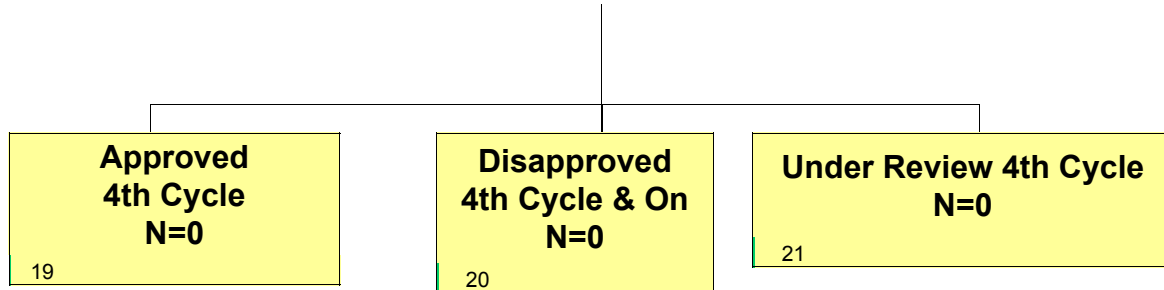
as of 3/31/18



* Other decisions include withdrawn (N=3), withdrawn and converted (N=15), RTA (N=0), nonsignificant risk device (N=4), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).

CDRH IDEs - FY 2018

as of 3/31/18



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	132				
Average Number of Cycles to IDE Approval or Conditional Approval	1.06				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.06				

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	111				
Average Number of Cycles to IDE Approval or Conditional Approval	1.08				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.08				

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	21				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	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	8				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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	22				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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	27				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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	8				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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	19				
Average Number of Cycles to IDE Approval or Conditional Approval	1.20				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.20				

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	17				
Average Number of Cycles to IDE Approval or Conditional Approval	1.25				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25				

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	10				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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	14				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	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	0				
Average Number of Cycles to IDE Approval or Conditional Approval	N/A				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	N/A				

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				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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	4				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	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	1				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

Section 11 CLIA Waiver Annual Metrics

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.

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Section 12 Dual (510(k) and CLIA Waiver) Annual Metrics

Dual (510(k) and CLIA Waiver) Annual Metrics and Goals will be reported in the Annual Report.

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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).

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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 [#]	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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 submission 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 submission 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 th 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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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
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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 include 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 th Percentile FDA Days to MDUFA IV Decision	The 90 th percentile of FDA days to MDUFA IV decision on 3 rd 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 PercentWithin 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 th Percentile FDA Days to Written Feedback	20 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
4	40 th Percentile FDA Days to Written Feedback	40 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
5	60 th Percentile FDA Days to Written Feedback	60 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
6	80 th Percentile FDA Days to Written Feedback	80 th 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 th 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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th 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 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

**Quarterly Update on
Medical Device Performance Goals
----MDUFA IV CBER Performance Data ----
Action through 31 Mar 2018**

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	2				
Closed Before RTA Action	0				
Number with Accepted RTA Review	1				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of Submissions Not Accepted for Filing Review	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	2				
Number Accepted	1				
Completed RTF	1				
Number Not Filed	0				
Rate of Submissions Not Filed	N/A				

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	1				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

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	1				
Average Number of FDA Days to Substantive Interaction	50.00				
20th Percentile FDA Days to Substantive Interaction	50.00				
40th Percentile FDA Days to Substantive Interaction	50.00				
60th Percentile FDA Days to Substantive Interaction	50.00				
80th Percentile FDA Days to Substantive Interaction	50.00				
Maximum FDA Days to Substantive Interaction	50.00				

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	1				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	1				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

Table 1.7 CBER - PMA Original and Panel-Track Supplements (Without 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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	0				

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				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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	1				
Number with MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Number With MDUFA IV Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
PMAs Pending MDUFA IV Decision	0				
PMAs Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

*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	4				
SI Goal Met	3				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	4				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	0				
MDUFA IV Decision Goal Met	0				
Supplements Pending MDUFA IV Decision	4				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

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	4				
Number with MDUFA IV Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	N/A				

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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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	1				
Non-MDUFA IV Decision	0				
MDUFA IV Decision	1				
MDUFA IV Decision Goal Met	1				
Supplements Pending MDUFA IV Decision	0				
Supplements Pending MDUFA IV Decision Past Goal	0				
Current Performance Percent Goal Met	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	1				
Number With MDUFA IV Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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	25				
Closed Before RTA Action	0				
Number Accepted	17				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	1				
Number Not Accepted	6				
Rate of Submissions Not Accepted for Review	26.09%				

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	19				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	14				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	5				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	14				
Average Number of FDA Days to Substantive Interaction	44.71				
20th Percentile FDA Days to Substantive Interaction	21				
40th Percentile FDA Days to Substantive Interaction	49				
60th Percentile FDA Days to Substantive Interaction	53				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 CBER - 510(k) 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
510(k)s Accepted	19				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	7				
MDUFA IV Decision Within 90 FDA Days	7				
510(k)s Pending MDUFA IV Decision	12				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100%				

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.14				
Number With MDUFA IV Decision	7				
Average Number of FDA Days to MDUFA IV Decision	52.43				
20th Percentile FDA Days to MDUFA IV Decision	28				
40th Percentile FDA Days to MDUFA IV Decision	29				
60th Percentile FDA Days to MDUFA IV Decision	78				
80th Percentile FDA Days to MDUFA IV Decision	87				
Maximum FDA Days to MDUFA IV Decision	90				
Average Number of Industry Days to MDUFA IV Decision	39.00				
20th Percentile Industry Days to MDUFA IV Decision	39.00				
40th Percentile Industry Days to MDUFA IV Decision	39.00				
60th Percentile Industry Days to MDUFA IV Decision	39.00				
80th Percentile Industry Days to MDUFA IV Decision	39.00				
Maximum Industry Days to MDUFA IV Decision	39.00				
Average Number of Total Days to MDUFA IV Decision	58.00				
20th Percentile Total Days to MDUFA IV Decision	28				
40th Percentile Total Days to MDUFA IV Decision	29				
60th Percentile Total Days to MDUFA IV Decision	78				
80th Percentile Total Days to MDUFA IV Decision	87				
Maximum Total Days to MDUFA IV Decision	90				

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	19				
Number With MDUFA IV Decision	7				
Number of SE Decision	7				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100%				
Rate of NSE Decision	0%				
Rate of Withdrawal	0%				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	0				
Non-MDUFA IV Decision	0				
MDUFA IV Decision (SE/NSE)	0				
MDUFA IV Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA IV Decision	0				
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	N/A				

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				
Closed Before RTA Action	0				
Number Accepted First RTA Cycle	0				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted	0				
Rate of Submissions Not Accepted for Review	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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

Table 8.3 CBER - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	0.00				
Number With MDUFA IV Decision	0				
Average FDA Days to MDUFA IV Decision	0.00				
20th Percentile FDA Days to MDUFA IV Decision	0				
40th Percentile FDA Days to MDUFA IV Decision	0				
60th Percentile FDA Days to MDUFA IV Decision	0				
80th Percentile FDA Days to MDUFA IV Decision	0				
Maximum FDA Days to MDUFA IV Decision	0				
Average Industry Days to MDUFA IV Decision	0.00				
20th Percentile Industry Days to MDUFA IV Decision	0				
40th Percentile Industry Days to MDUFA IV Decision	0				
60th Percentile Industry Days to MDUFA IV Decision	0				
80th Percentile Industry Days to MDUFA IV Decision	0				
Maximum Industry Days to MDUFA IV Decision	0				
Average Total Days to MDUFA IV Decision	0.00				
20th Percentile Total Days to MDUFA IV Decision	0				
40th Percentile Total Days to MDUFA IV Decision	0				
60th Percentile Total Days to MDUFA IV Decision	0				
80th Percentile Total Days to MDUFA IV Decision	0				
Maximum Total Days to MDUFA IV Decision	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				
Number With MDUFA IV Decisions	0				
Number With Granted Decisions	0				
Number With Declined Decisions	0				
Number of Withdrawals	0				
Number Deleted	0				
Rate of Granted Decisions	N/A				
Rate of Declined Decisions	N/A				
Rate of Withdrawals	N/A				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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				
Non-MDUFA IV Decisions	0				
MDUFA IV Decisions	0				
MDUFA IV Decisions Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	0				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	37				
Closed Before RTA Action	1				
Number Accepted First RTA Cycle	33				
Number Without a RTA Review and > 15 Days Since Date Received	1				
Number Without a RTA Review and <= 15 Days Since Date Received	1				
Number Not Accepted	1				
Rate of Submissions Not Accepted for Review	2.86%				

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	23				
Written Feedback Provided Within MDUFA IV Goal	23				

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	23				
Average FDA Days to Written Feedback	56.87				
20th Percentile FDA Days to Written Feedback	49				
40th Percentile FDA Days to Written Feedback	57				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	67				
Maximum FDA Days to Written Feedback	72				

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				
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00				

Table 9.5 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	10				
Meeting Minutes Submitted Within 15 Days of Meeting	6				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0				
Meeting Minutes Past 15 Days of Meeting	4				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	60.00%				

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	10				
Average Number of Cycles to IDE Approval or Conditional Approval	1.20				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.20				

BLA

CBER – Annual General Metric Report for BLAs

****Annual Metrics and Goals will be reported in the Annual Report****

BLA Efficacy Supplements

CBER – Annual General Metric Report for BLA Efficacy Supplements

****Annual Metrics and Goals will be reported in the Annual Report****

BLA Prior Approval Manufacturing Supplements

CBER – Annual General Metric Report for BLA PAS Supplements

****Annual Metrics and Goals will be reported in the Annual Report****

BLA/BLA Resubmissions

CBER – Annual General Metric Report for BLA/BLA Resubmissions

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FY 2018 Medical Device User Fee Collections
as of March 31th, 2018
Excludes Unearned Fees

	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$117,917,100	\$132,041	\$117,785,059		
Application Fees	\$31,716,989	\$181,621	\$31,535,368		
Total	\$149,634,089	\$313,662	\$149,320,427	\$193,291,000	77%

Medical Device User Fee Collection History
Excludes Unearned Fees, Includes Refunds

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
MD I	\$21,620,549	\$26,281,779	\$31,728,269	\$34,413,918	\$27,818,706
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
MD II	\$47,709,640	\$57,556,012	\$63,932,631	\$70,131,130	\$65,811,376
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
MD III	\$101,247,043	\$121,102,422	\$134,505,872	\$146,226,300	\$136,963,855
	FY 2018				
MD IV	\$149,320,427				

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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^{1/}**

CDRH Data 1st Quarter FY 2018 by Submission type	# Waived	# Reduced
Full Fee applications^{2/}		
PMA	3	2
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	2
De Novo Classification	3	12
180-Day Supplements	0	7
Real-Time Supplements	1	8
510(k)s	16	560
30-day Notices	1	22
513(g)s	0	9
PMA Annual Report	0	13
Total	24	635

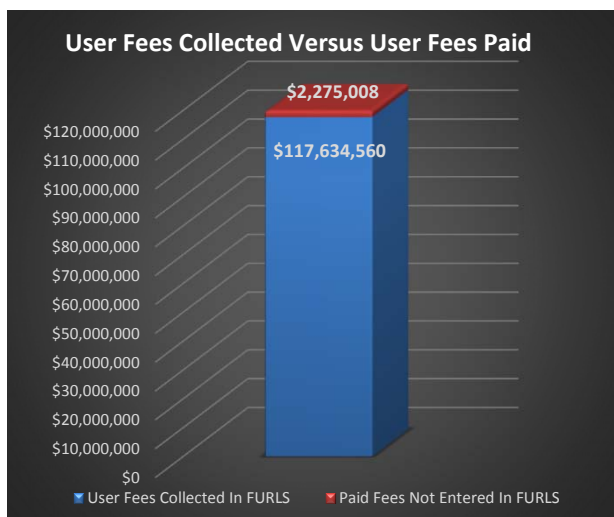
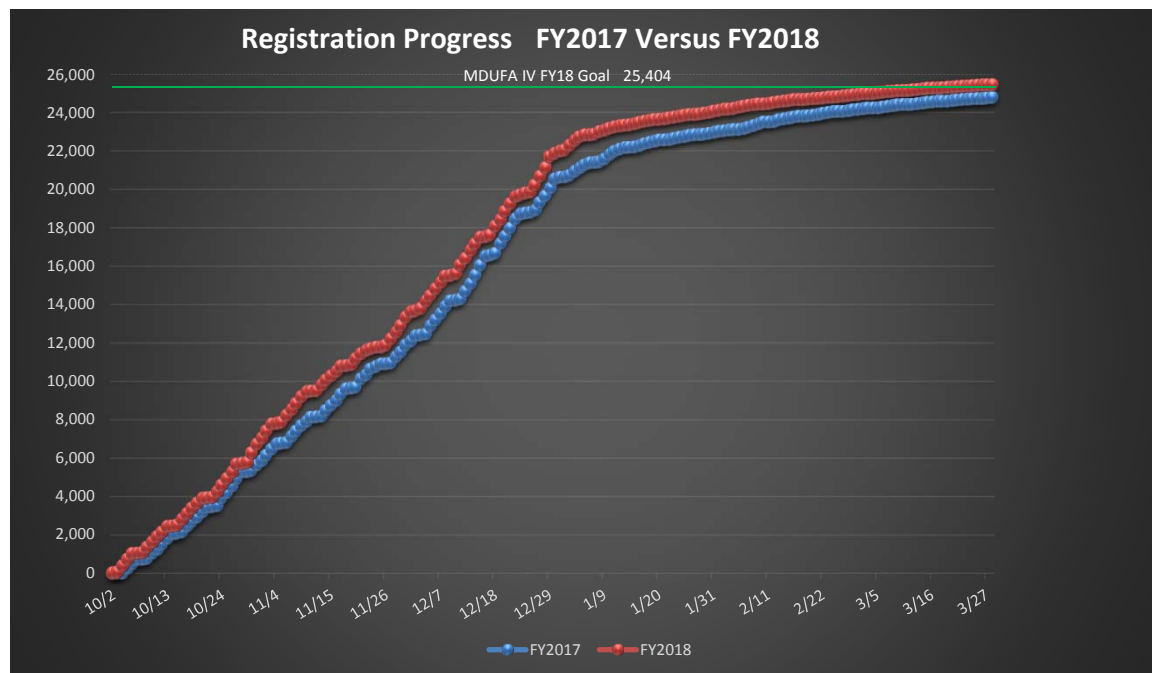
^{1/} User fees may be waived for several reasons, including but not limited to: the submitter is a State or Federal Government entity who does not intend to distribute the device commercially; the proposed conditions of use for the device involved are solely for a pediatric population; and, the submitter 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.

^{2/} As specified in the MDUFA 4 Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually.

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MDUFA IV Registrations - Second Quarter Summary FY2018

Active Registrations by Type	FY18 End 2nd Quarter			FY17 Year End Active Totals			FY18 vs End FY17
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,933	9,357	15,290	6,135	9,611	15,746	97.10%
Contract Manufacturer	1,054	1,401	2,455	1,074	1,441	2,515	97.61%
Contract Sterilizer	74	135	209	71	132	203	102.96%
Specification Developer	1,601	490	2,091	1,737	518	2,255	92.73%
Reprocessor of Single Use Devices	21	3	24	29	1	30	80.00%
U.S. Manufacturer of Export Only Devices	126	0	126	128	0	128	98.44%
Repackager/Relabeler	1,065	173	1,238	1,159	202	1,361	90.96%
Remanufacturer	18	12	30	23	10	33	90.91%
Foreign Exporter/Private Label Distributor	0	871	871	0	921	921	94.57%
Initial Importer	2,985	0	2,985	3,327	0	3,327	89.72%
Unknown	9	9	18	16	12	28	64.29%
Total:	12,886	12,451	25,337	13,699	12,848	26,547	95.44%



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Center for Devices and Radiological Health Internal Training Summary Report

Q2 FY18

October 2017 – March 2018

Prepared by: The Division of Employee Training and Development (DETD)

As of: 4/20/2018

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, 2017 and March 31, 2018. DETD offered 439 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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Science (SCI) Training:	12
Center-Specific IT (CIT) Training	12

Table X – FY18 CDRH Internal Training Conducted by DETD:*October 1, 2017 – March 31, 2018*

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA IV	5	1071	810
	ELP	42	593	9294
	Least Burdensome	27	2163	2677
	Other LAW	199	5737	7579
<i>LAW Subtotal:</i>		<i>273</i>	<i>9564</i>	<i>20360</i>
Leadership Development Training (LED)	LEAD: Leadership for Managers	49	484	1579
	Leadership for Non-Managers	15	200	1430
	Other LED	4	96	96
<i>LED Subtotal:</i>		<i>68</i>	<i>780</i>	<i>3105</i>
Professional Development (PRO) Training	New Employee Orientation (NEO)	2	46	322
	Other PRO	26	328	1962
<i>PRO Subtotal:</i>		<i>28</i>	<i>374</i>	<i>2284</i>
Center-Specific Information Technology (CIT) Training	Premarket IT	2	781	773
	Other CIT	10	16	16
<i>CIT Subtotal:</i>		<i>12</i>	<i>797</i>	<i>789</i>
Science (SCI) Training	All SCI	<i>58</i>	<i>2065</i>	<i>4538</i>
Grand Total:		439	13580	31076

CDRH Informal Training

CDRH Informal Training:

In 2015, DETD implemented a process for tracking the Informal training conducted in the Center. Unlike Formal Center-wide training managed by DETD, Informal training addresses specialized topics for a targeted audience. Examples of informal training content include:

- Additional instruction provided following formal training (e.g. Pre-market reviewer specific training)
- Policy change updates (e.g. Technology updates, MDUFA updates, new guidance being issued)
- Best practices used in a specific product area.

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 and management. Tracking both formal and informal training allows for an accounting of all training activities occurring in the Center and provides training participants with a comprehensive training transcript.

CDRH Informal Training: *October 1, 2015 – March 31, 2018*

Year	# of Learning Events	Total # of Participants	Total Contact Hours
FY'15	34	1249	3350
FY'16	42	978	2122
FY'17	105	2649	7421
FY'18	25	455	1043
Total:	206	5331	13936

Premarket Reviewer Training - RCP

Reviewer Certification Program (RCP) Refresh:

The RCP curriculum is a 27-hour program consisting of both online and classroom courses that are essential to new reviewers in their first 60 days of hire. While the goals and missions are consistent with the earlier version of RCP, the condensed course design results in reviewers receiving the most salient core knowledge in a timely fashion. After completion of the Program, reviewers will enroll in advanced courses designed to further enhance their knowledge and skills. The current curriculum consists of the following components:

- 15 classroom courses, including a program Orientation and Capstone, totaling 22.5 hours of training
- 5 online courses, totaling 4.5 hours
- 7 Advanced courses, to be taken within a year of employment
- Practical activities and hands-on exercises
- Knowledge assessments

RCP Refresh Training by Cohort: *October 1, 2017 – March 31, 2018*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 1 2017 Cohort	10	10	OC	3	21	25
			OCE	1	7	9
			ODE	1	2	2
			OIR	6	113	136
			OSEL	3	47	58
			Subtotal:	14	190	230
Fall 2 2017 Cohort	11	10	OCD	3	20	24
			OCE	3	23	29
			ODE	12	133	155
			OIR	3	32	38
			OSEL	2	17	21
			Subtotal:	23	225	267
Spring 1 2018 Cohort	11	10	OC	1	16	21
			ODE	10	171	217
			OIR	5	89	110
			OSEL	3	43	55
			Subtotal:	19	319	403
Total:	32	30	-	56	734	900

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 premarket review of the resulting medical devices. The Program fosters the premarket reviewers' understanding of how medical devices are developed, clinically tested, manufactured, and utilized by visiting sites identified by training need and a formalized submission process.

ELP Training Completed: *October 1, 2017 – March 31, 2018*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
42	593	9294	<ul style="list-style-type: none">• Innovation – Medical Device Innovation and Development• Stents, Flow Diverters, Mesh Balls, Coils, and other related devices; Observation of Surgical Procedures; understanding clinical decision making for relevant patient populations• Digital Health-Agile software development practice and methodology• Biocompatibility• Medical device usability testing and how it relates to documents in the device's design history file, e.g. risk analysis.

ELP Training Completed, by Office: *October 1, 2017 – March 31, 2018*

Office	Total # of Attendees	Total Training Hours
OC	51	736
OCD	23	384
OCE	1	16
ODE	327	5250
OIR	93	1322
OSB	72	1186
OSEL	26	400
Total:	593	9294

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, 2017 – March 31, 2018*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	49	484	1579	<ul style="list-style-type: none">• Diversity, Unconscious Bias• Effective Performance Management• CDRH Manager Orientation Program• Leading Through Change• Leading with Personal Integrity and Ethics• Managing Up, Communicating with your Boss

LEAD Training for ODE and OIR Completed: *October 1, 2017 – March 31, 2018*

Office	Total # of Managers/Supervisors	# of Training Participants	Training Hours Required*	% of Required Training Hours Completed
ODE	74	52	1184	27%
OIR	40	26	640	18%
Total:	114	78	1824	23%

*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. The total number of managers/supervisors onboard and their required training hours was calculated as a baseline on October 1, 2017. To increase training participation, CDRH has implemented a process for providing Center management with monthly LEAD training completion reports.

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 Program facilitates learning in the areas of mentoring, self-study, classroom-based courses, and other practical activities. The target audience for the Program 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
2006 – 2007	OIVD	3	3
	ODE	13	12
2008 – 2009	OIVD	3	3
	ODE	10	10
	Other	17	16
2010 – 2011	OIVD	3	3
	ODE	9	8
	Other	8	8
2012 – 2013	OIR	3	3
	ODE	6	6
	Other	11	11
2014 – 2015	OIR	2	2
	ODE	6	6
	Other	12	12
2016-2017	OIR	3	3
	ODE	9	9
	Other	8	8
Total:		126	123

CDRH Training Courses by Category:

The following section contains a sampling of DETD courses provided during FY18.

Regulatory and Law (LAW) Training:

Benefit-Risk Guidance – Online	This online course outlines the factors to consider when making benefit-risk determinations in medical device Premarket Approval (PMA) applications and De novo petitions.
Master Four-Part Harmony	This class provides instruction to improve the ability for writing deficiencies that are clear, concise, and in the appropriate format.
Master Technical Writing	This class teaches the basic elements of plain writing and how to use them to write succinct, well-written technical documents.
Pre-Submission Program, Meetings with FDA, IDEs, and Clinical Trials	This class provides practical knowledge and insights 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 class addresses Real-world communication strategies for those serving in scientific and technical capacities.
Introduction to Premarket Review	This class describes the essential elements in premarket review.
Premarket programs: 510k and 513g	This class provides an understanding of the device classifications.
Conducting 510k Reviews	This class provides an overview of the 510(k) flowchart.
Basics of Writing Consult Requests and Reviews	This class examples the essential elements of a written pre-market consulting review.
Premarket Programs: IDEs	This class 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.
Conducting a PMA Annual Report	This training provides an understanding of the various components of a post market application including benefit-risk and least burdensome.
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 types and aspects 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 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 to CDRH.
RCP: Basics of Standards in Premarket Review	This training provides participants with instruction on locating recognized standards, standards guidance's, and accessing standards library resources.
Overview of FOIA	This training provides an overview of FOIA's applications and discusses the impact of OPEN Government amendments to FOIA.
SMART Template	This class provides instruction for using the programmed 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 class provides participants with a big-picture mentality regarding their work and a blueprint for productivity. Participants also learn techniques for empowering their team and making each team member 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 class provides organizations with an understanding of unconscious bias, the tools to confront and combat its negative effects and the ability to recognize when it impacts decision making.
LEAD: Managing Up, Communicating with Your Boss	This class 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 class 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 class provides participants will 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 class is designed to provide ODE Reviewers 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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