

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

February 22, 2019, 2:00 – 3:30

WebEx

Welcome

Guidance Development

FDA MDUFA Performance — Actions through December 31, 2018

- Report on decision goals for 1st Quarter FY 2019.

Qualitative Update on Finances – 1st Quarter FY 2019

- User fee receipts through the 1st Quarter FY 2019.
- Number of discretionary fee waivers or reductions granted by type of submission.

CDRH Registration and Listing

- Report on registration and listing.

Independent Assessment

Universal Tracking Number (UTN)

Reminder: Set date for 2nd Quarter 2019 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 2019

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM623529	10/18/2018	Yes	No	N/A	A-List
2	Q1	Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking - Immediately in Effect Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM592340	11/05/2018	No	No	N/A	A-List
3	Q1	Recommendations for Dual 510(k) and CLIA Waiver by Application Studies - Draft Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586502	11/29/2018	No	No	N/A	A-List
4	Q1	Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices - Draft Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM586506	11/29/2018	No	Yes	Sec. 3057 of the 21st Century Cures Act	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	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Draft Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626742	11/30/2018	Yes	No	N/A	A-List
6	Q1	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use - Draft Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM626743	11/30/2018	Yes	No	N/A	A-List
7	Q1	User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications - Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM345633	12/12/2018	Yes	No	N/A	A-List
8	Q1	Manufacturing Site Change Supplements: Content and Submission - Final Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM467414	12/17/2018	Yes	No	N/A	N/A
9	Q1	Breakthrough Devices Program - Guidance for Industry and Food and Drug Administration Staff https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664	12/18/2018	Yes	Yes	Sec. 3051 of the 21st Century Cures Act (Sec. 515B(f) of the FD&C Act)	A-List

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

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Acronyms and Abbreviations

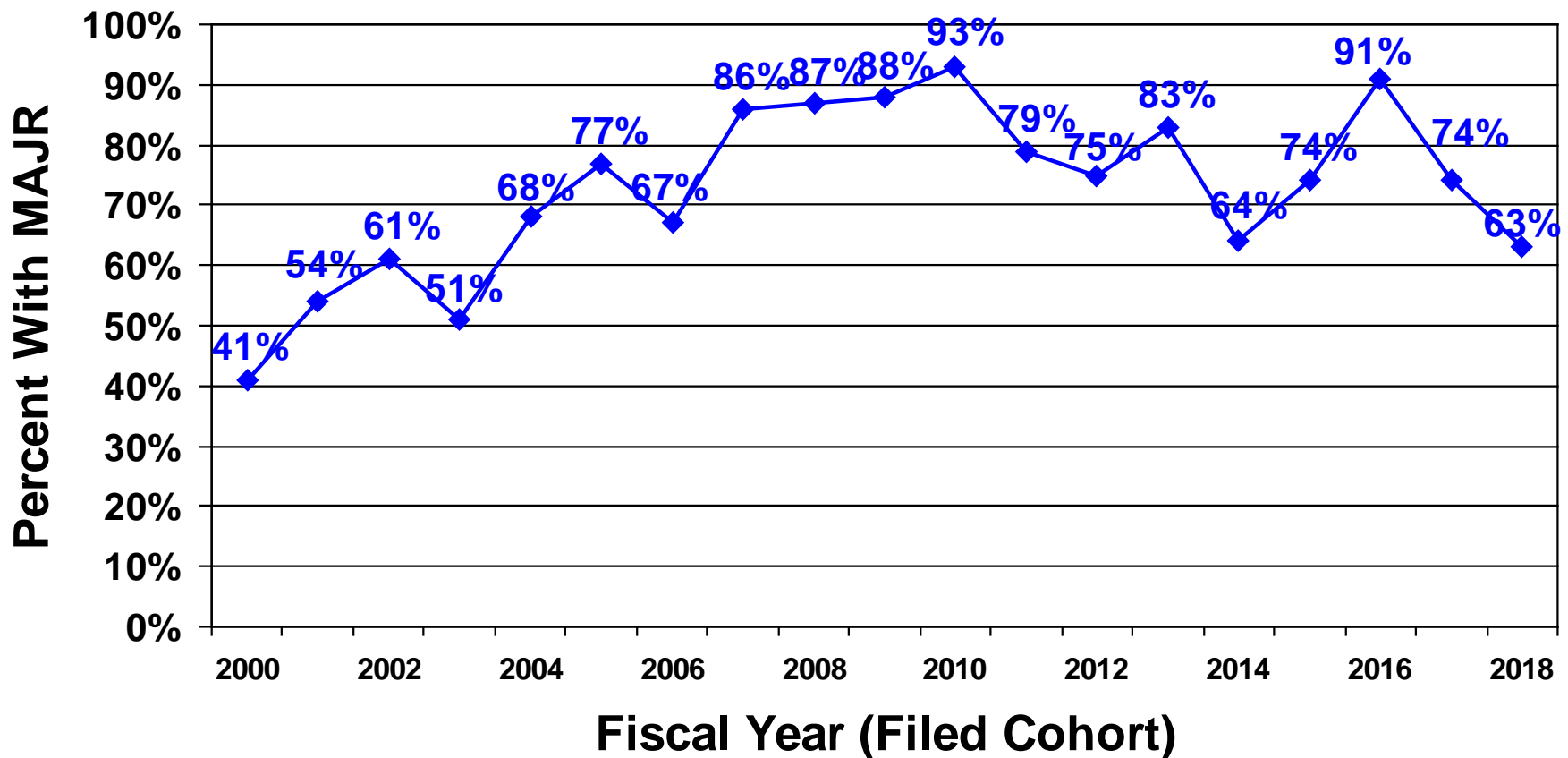
510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology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

Q1FY19

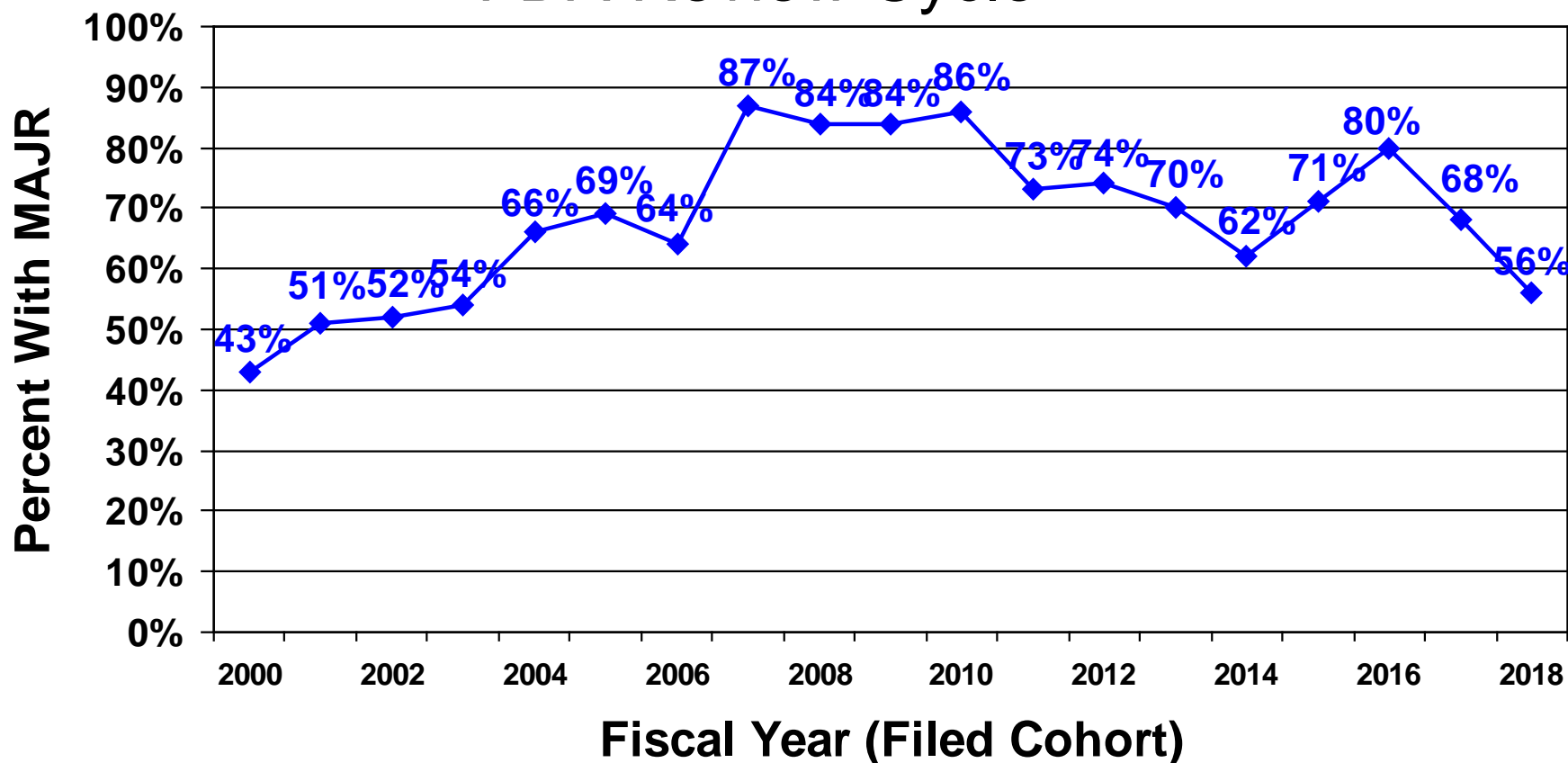
Percent of PMA Originals With Major Deficiency Letter on 1st* FDA Review Cycle*



- 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 9/30/2018. 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**

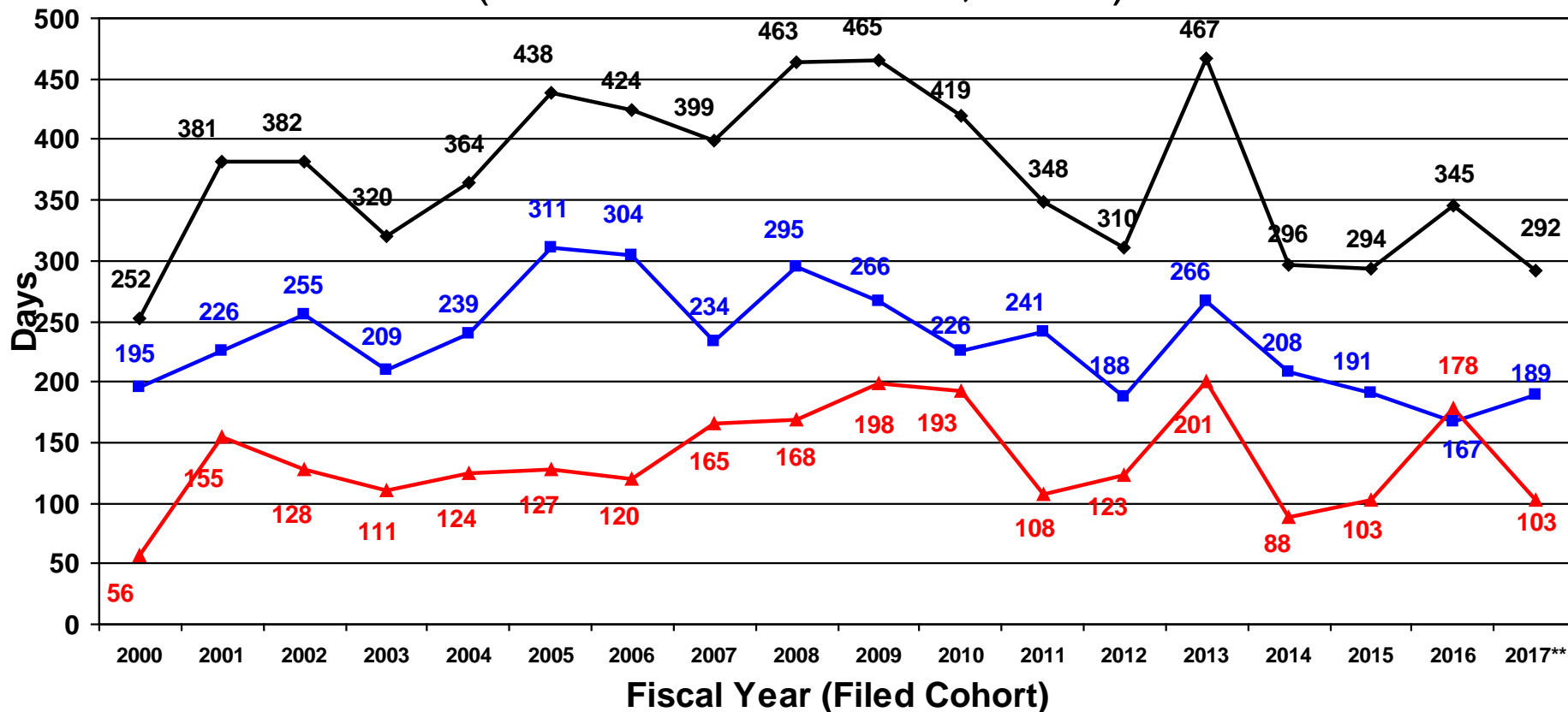


*Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle as of the date specified.

**Includes original PMAs/PTS filed as of 9/30/2018. 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 December 31, 2018)

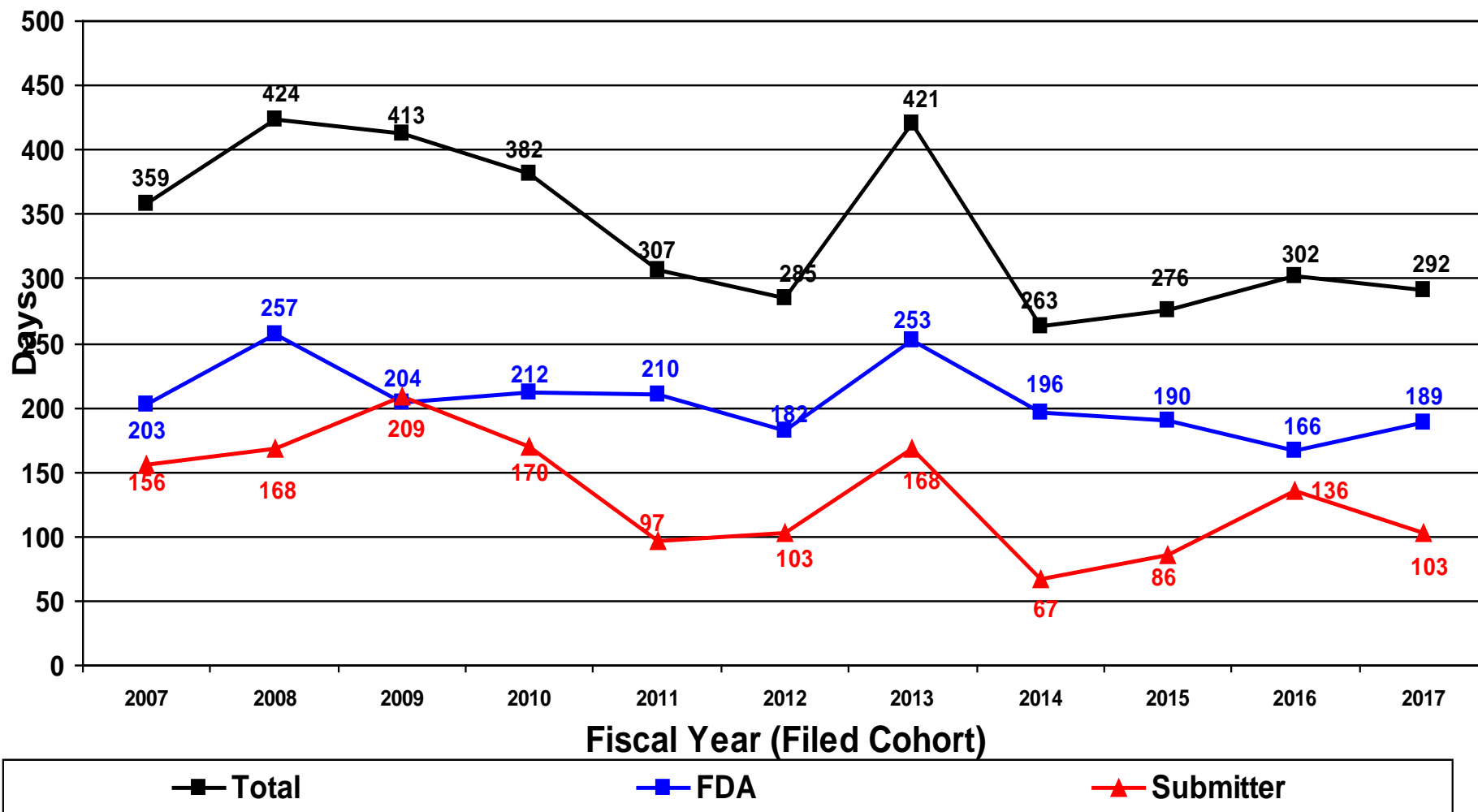


—◆— Total —■— FDA —▲— Submitter

*Includes original PMAs filed as of 12/31/2018; times may not add to total due to rounding

** Cohort still open, average times will increase. Percent of cohort with MDUFA decision: FY17 = 92% (36/39).

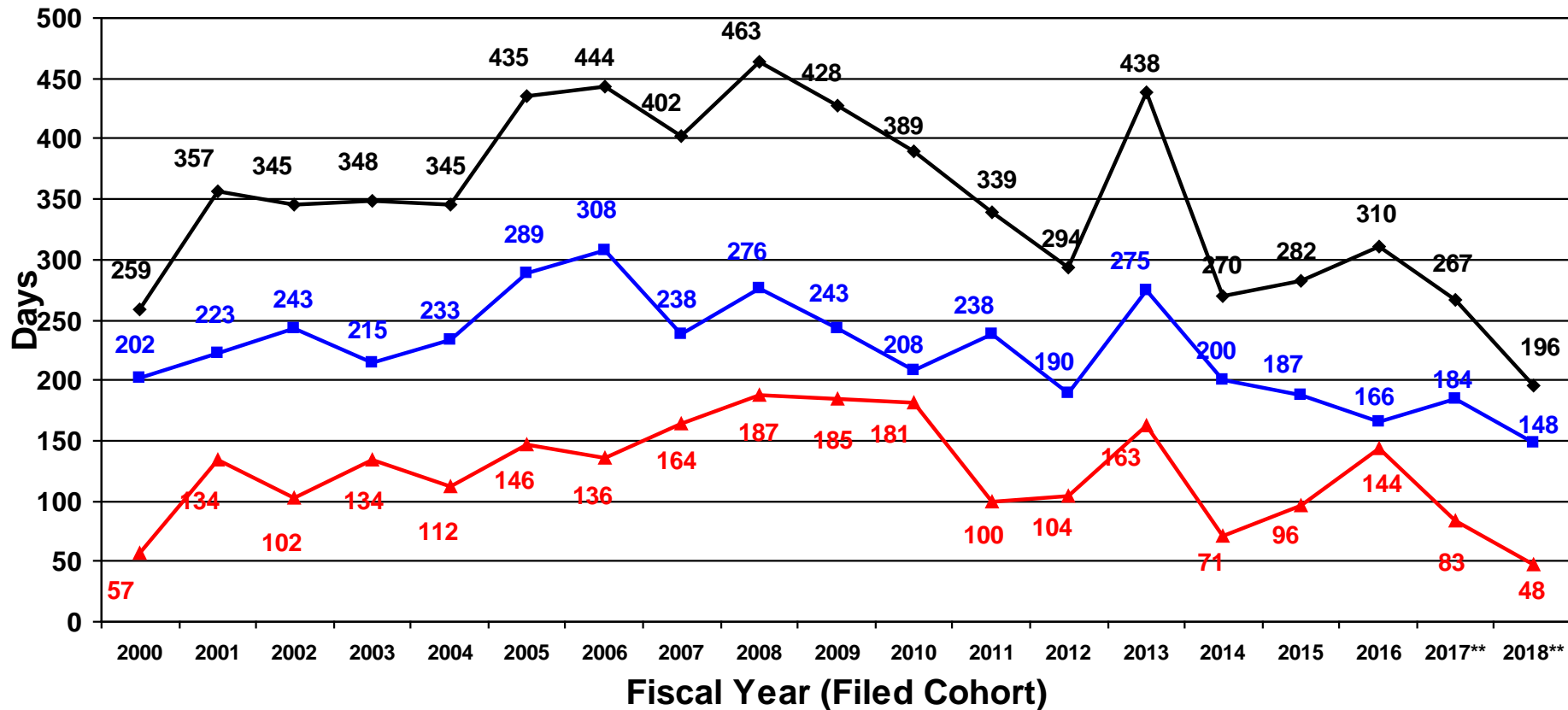
Average Time to MDUFA Decision: PMA Originals* (Comparison of Cohorts at 92% Closure)



*Includes original PMAs filed as of 9/30/2018; times may not add to total due to rounding. **Proportion of cohort closed with MDUFA decision: FY16: 50/55; FY15: 39/42; FY14: 26/28; FY13: 27/29; FY12: 22/24; FY11: 40/43; FY10: 40/43; FY09: 29/32

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

(As of December 31, 2018)



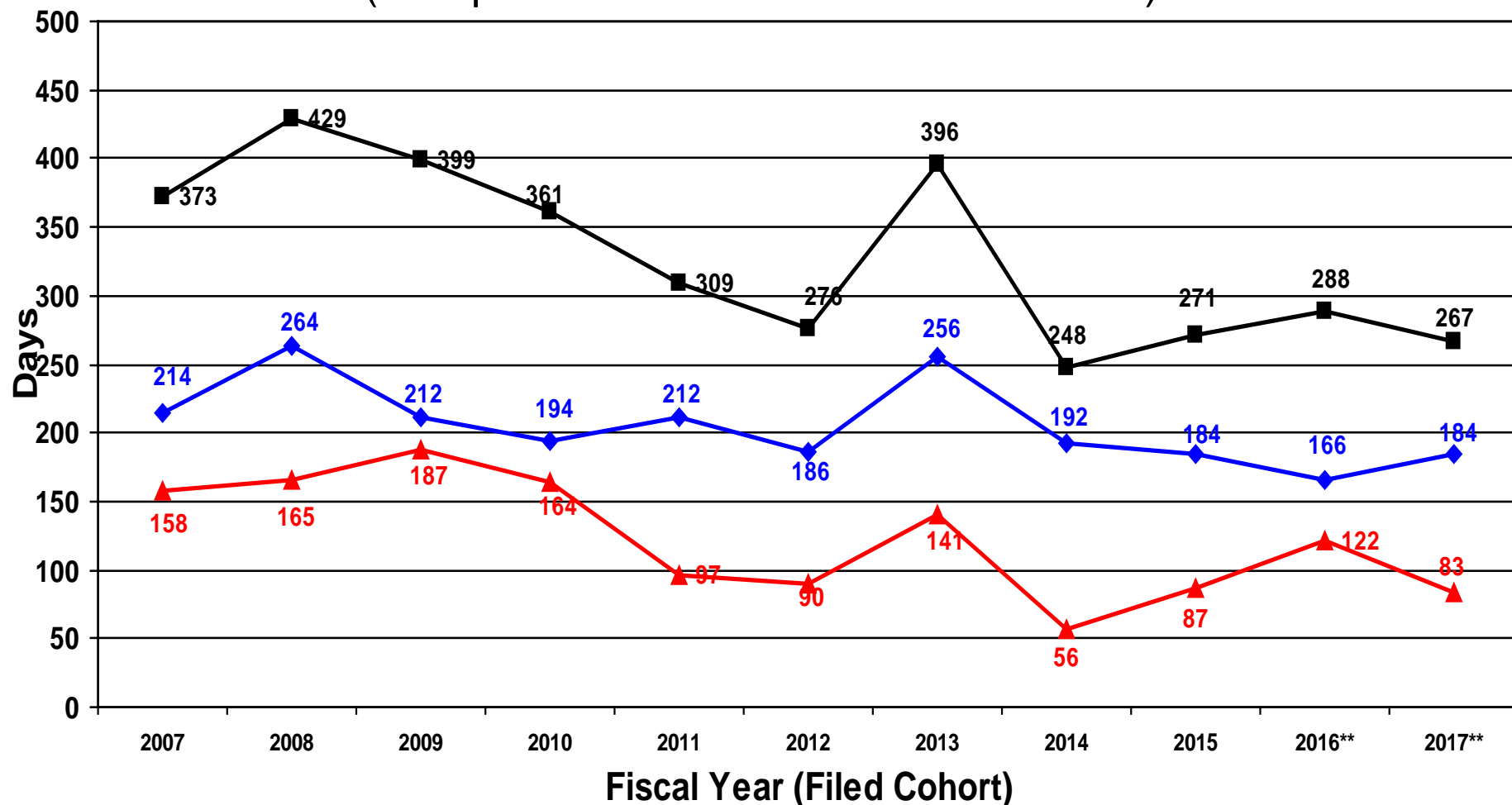
—◆— Total —■— FDA —▲— Submitter

*Includes original PMAs/PTS filed as of 12/31/2018; times may not add to total due to rounding

** Cohort still open, average times will increase. Percent of cohort closed with MDUFA decision: FY17 = 95% (62/65); FY18 = 56% (38/68)

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

(Comparison of Cohorts at 95% Closure)

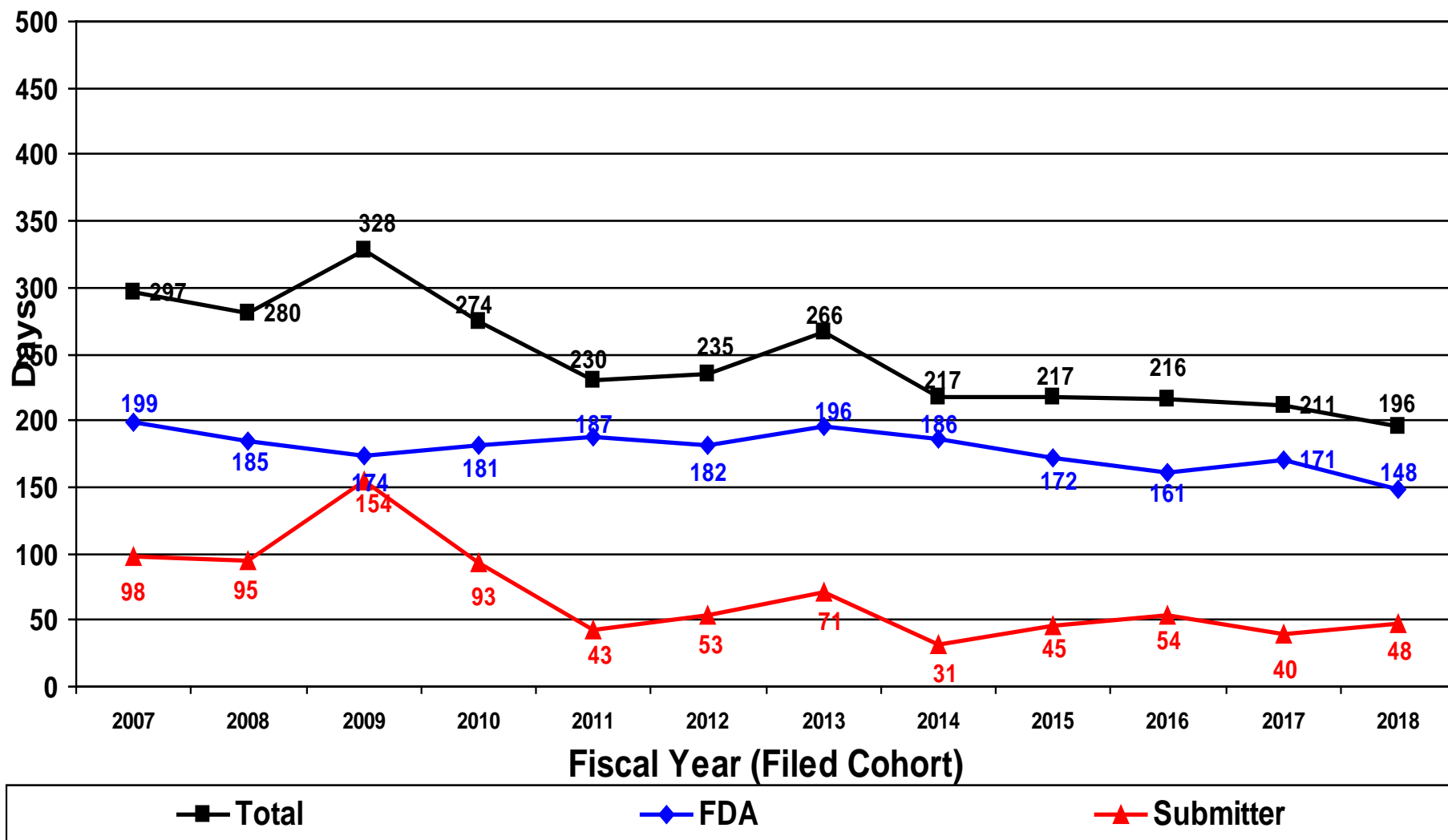


■ Total
◆ FDA
▲ Submitter

*Includes original PMAs/PTS filed as of 12/31/2018; times may not add to total due to rounding. Proportion of cohort closed with MDUFA decision in this comparison: FY16: 68/71; FY15: 65/68; FY14: 40/42; FY13: 42/44 ; FY12: 32/34; FY11: 49/51; FY10: 56/59; FY09: 41/43

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

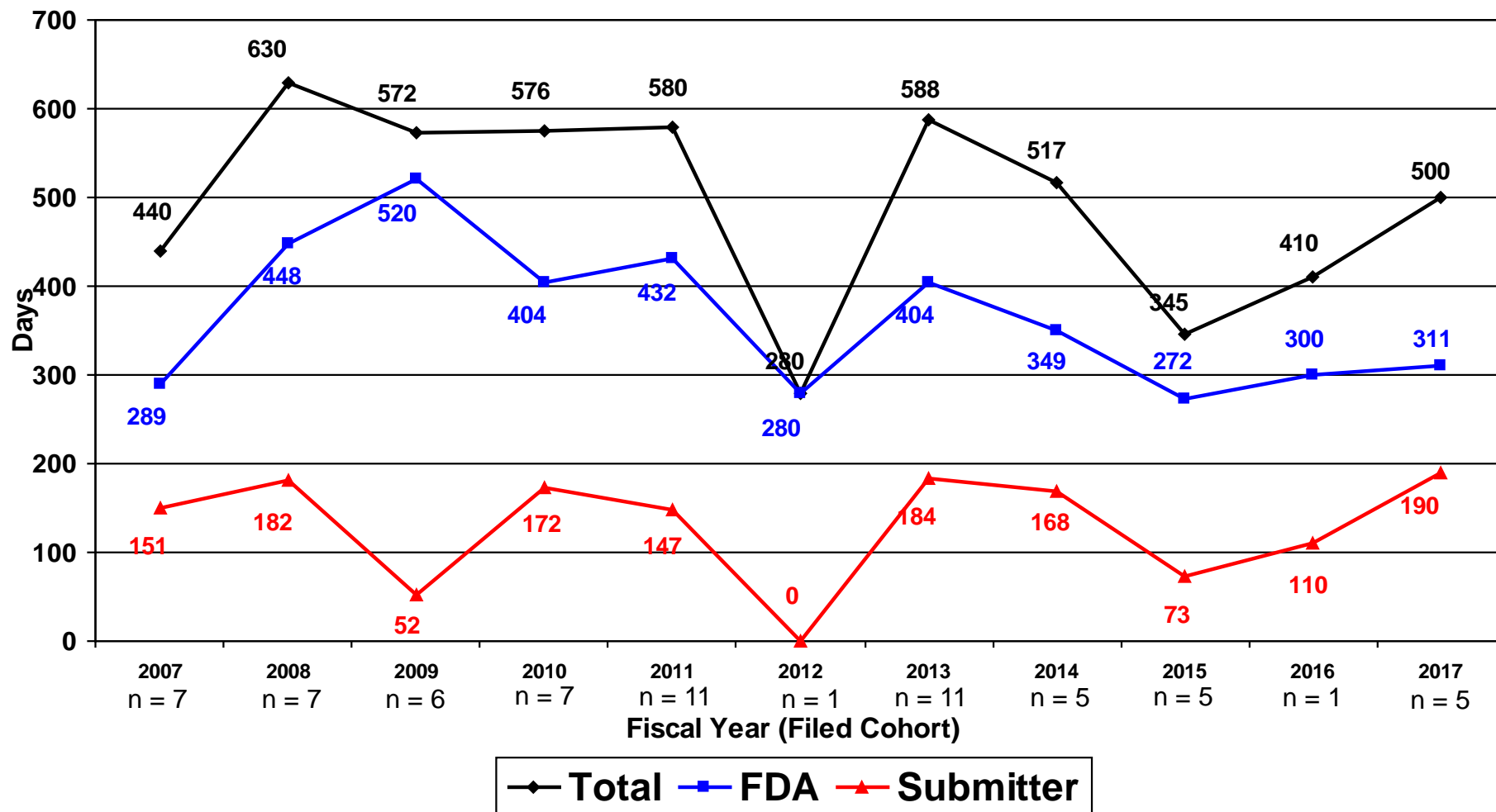
(Comparison of Cohorts at 56% Closure)



*Includes original PMAs/PTS filed as of 12/31/2018; times may not add to total due to rounding. Proportion of cohort closed with MDUFA decision in this comparison: FY18: 38/68; FY17: 39/65; FY16: 32/71; FY15: 38/68; FY14: 24/42; FY13: 25/44 ; FY12: 19/34; FY11: 29/51; FY10: 33/59; FY09: 24/43

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

(As of December 31, 2018)

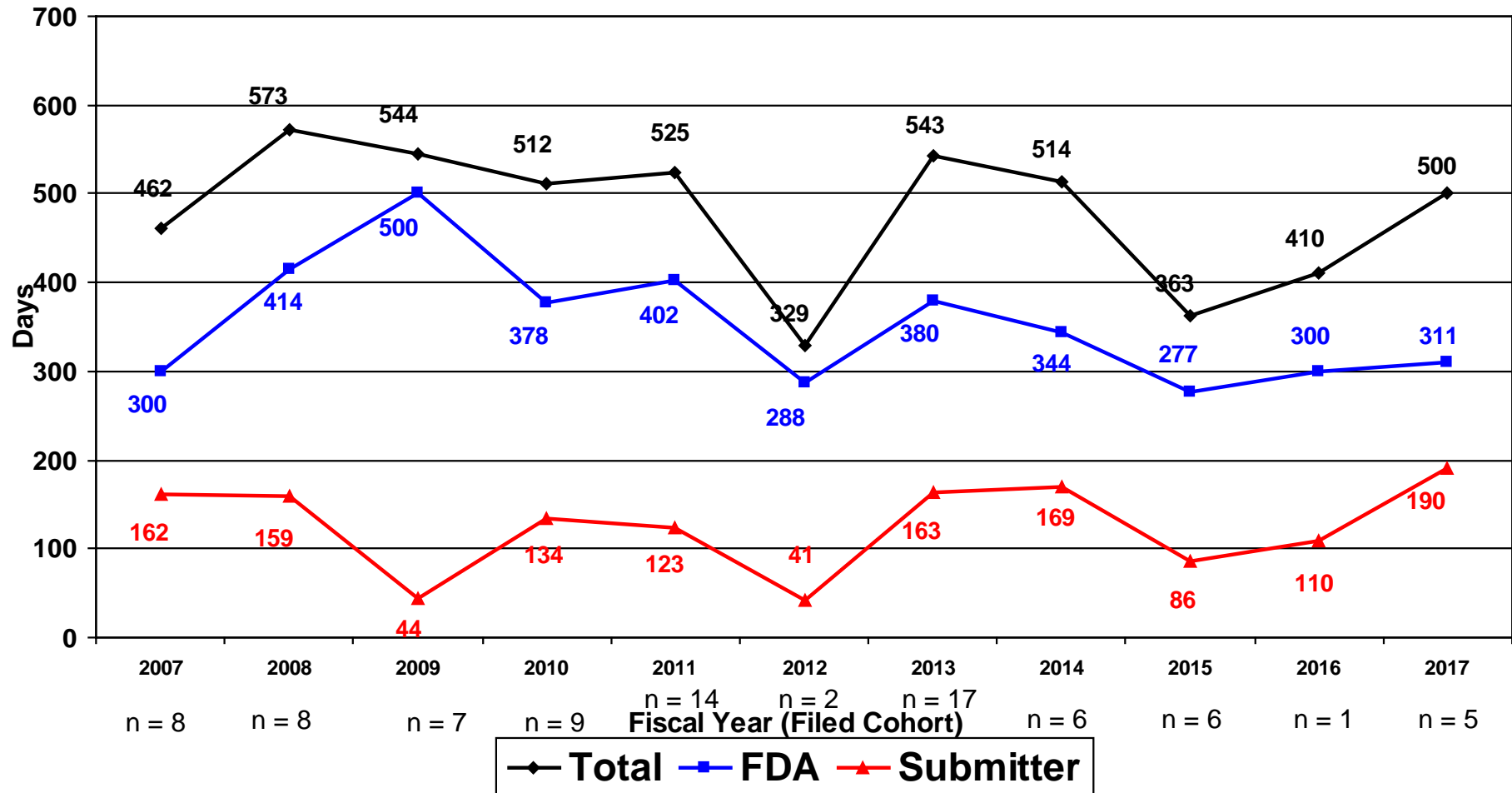


*Includes original PMAs filed as of 12/31/2018; times may not add to total due to rounding.

**Cohort still open; percent of cohort with MDUFA decision: (none as of 12/31/18)

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

(As of December 31, 2018)



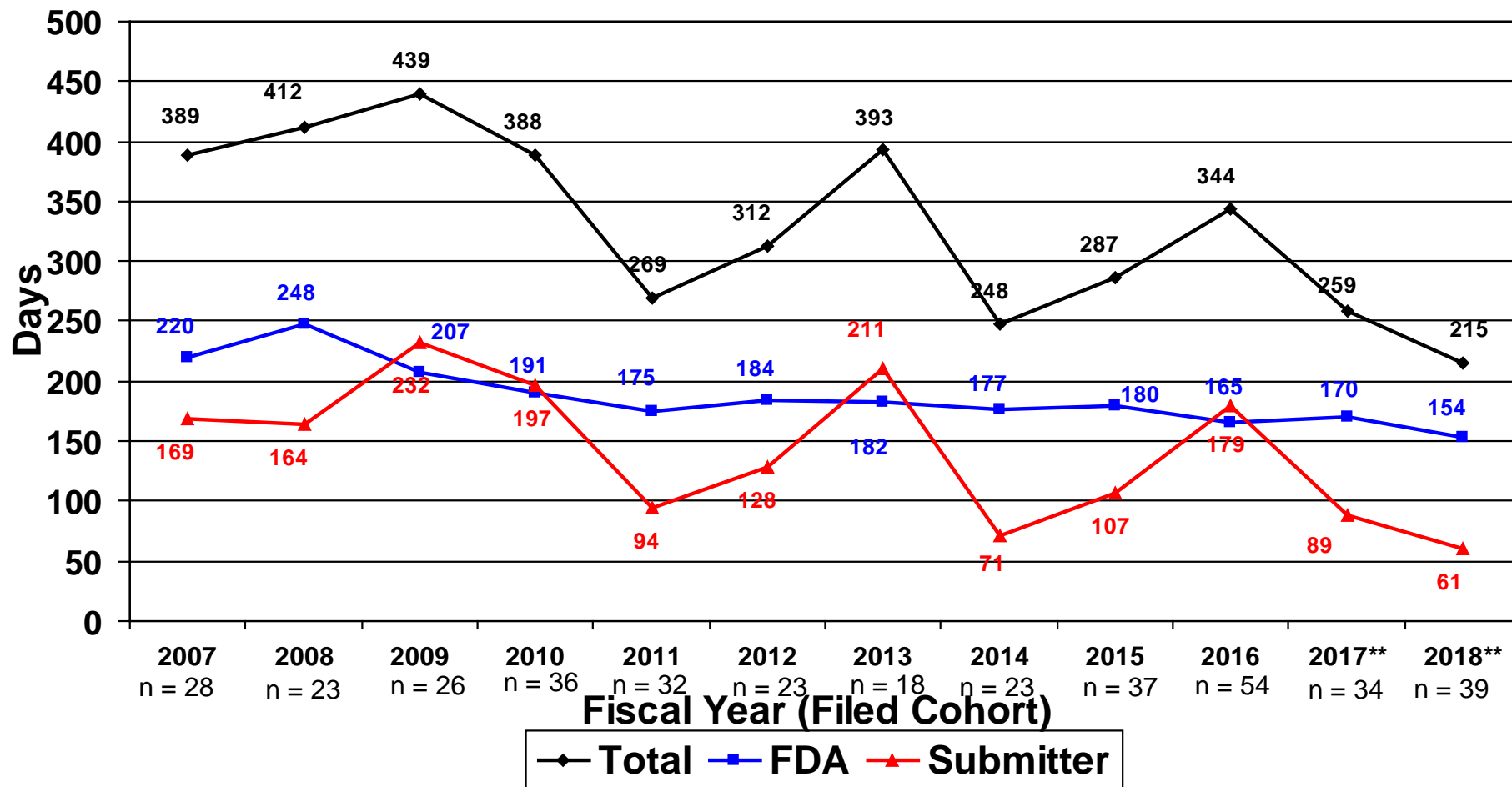
*Includes original PMAs/PTS filed as of 12/31/2018; times may not add to total due to rounding.

**Cohort still open; percent of cohort with MDUFA decision: (none as of 12/31/18)

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 December 31, 2018)

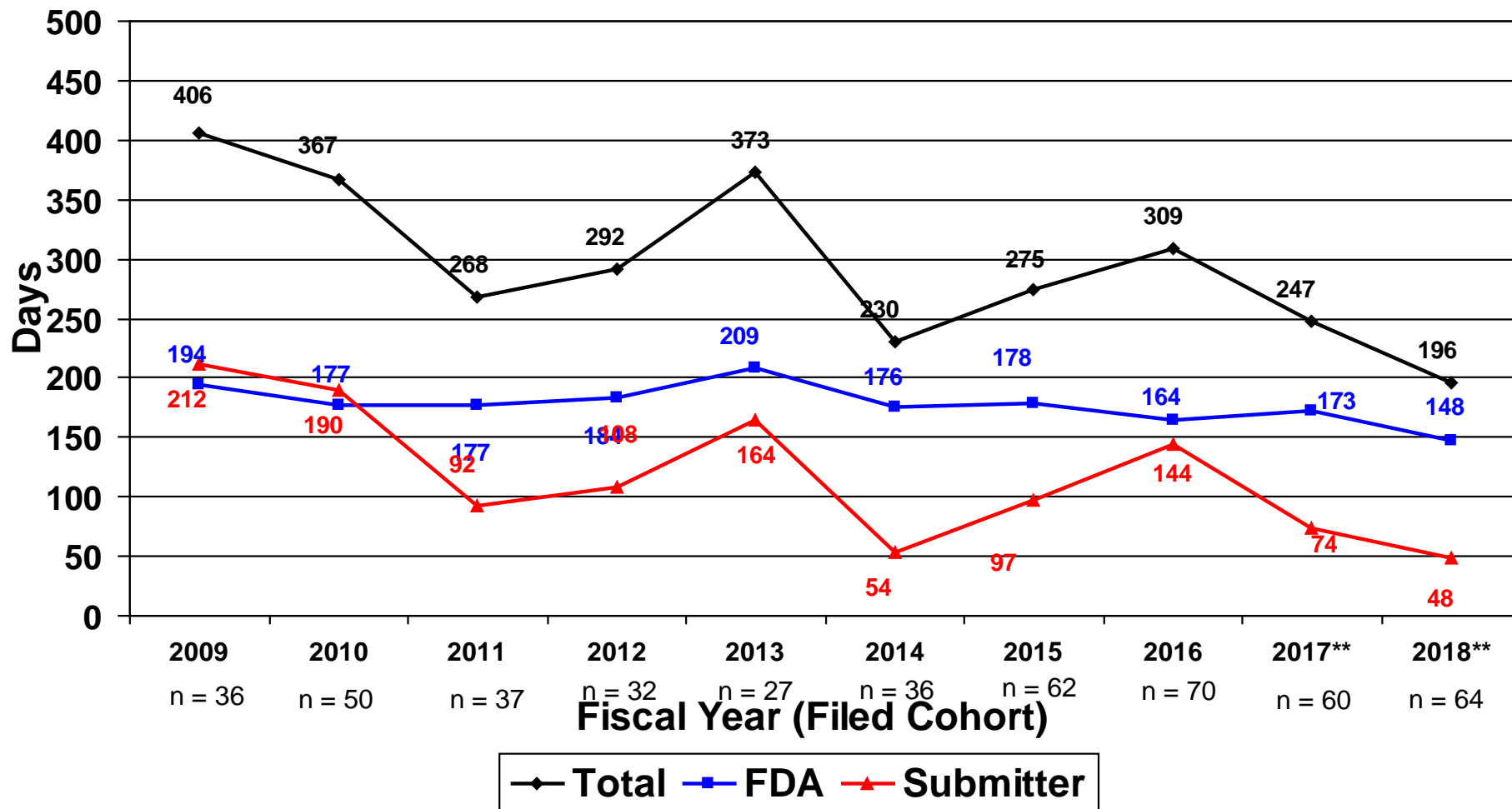


*Includes original PMAs filed as of 12/31/2018; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision:
FY18 = 51% (20/39); FY17 = 91% (31/34)

Average Time to MDUFA Decision: PMA Original & Panel Track Supplements Without Panel Review*

(As of December 31, 2018)



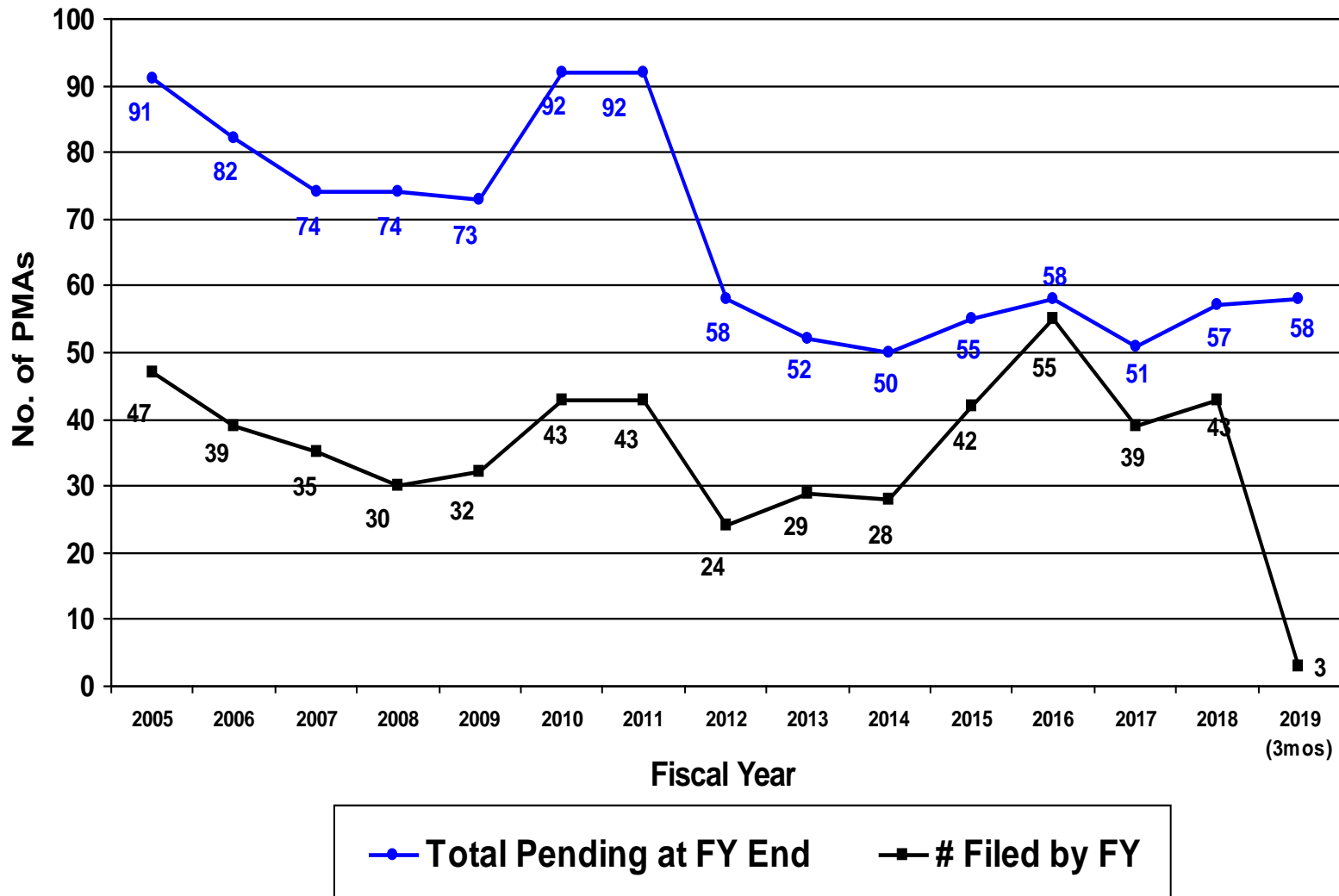
*Includes original PMAs/PTS filed as of 12/31/2018; times may not add to total due to rounding

**Cohort still open, average times will increase; percent of cohort with MDUFA decision: FY17 = 95% (57/60); FY18 59% (38/64)

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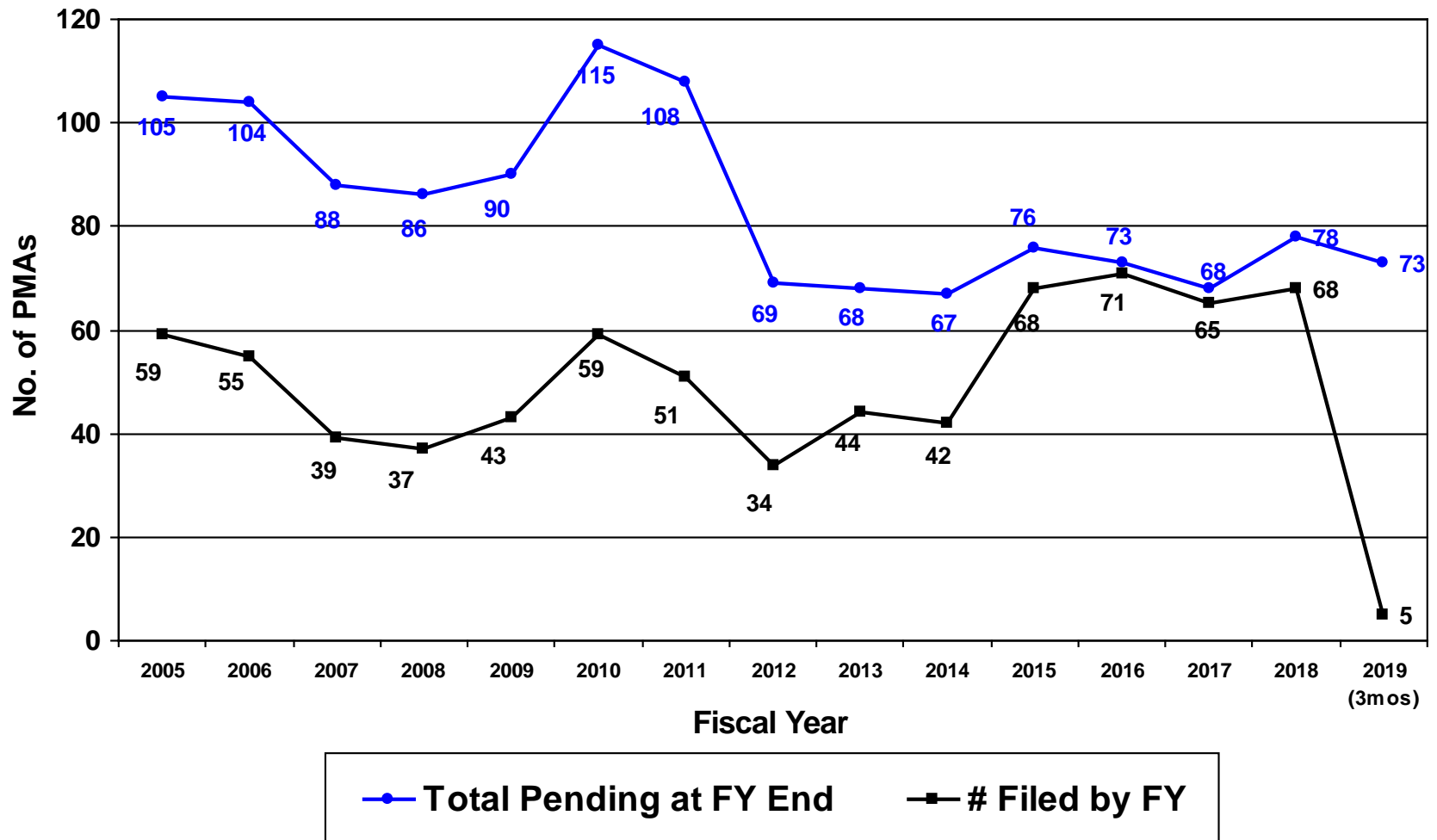
• Performance data (from FY13 onward) map to Table 1.7 in CDRH MDUFA performance reporting. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Year



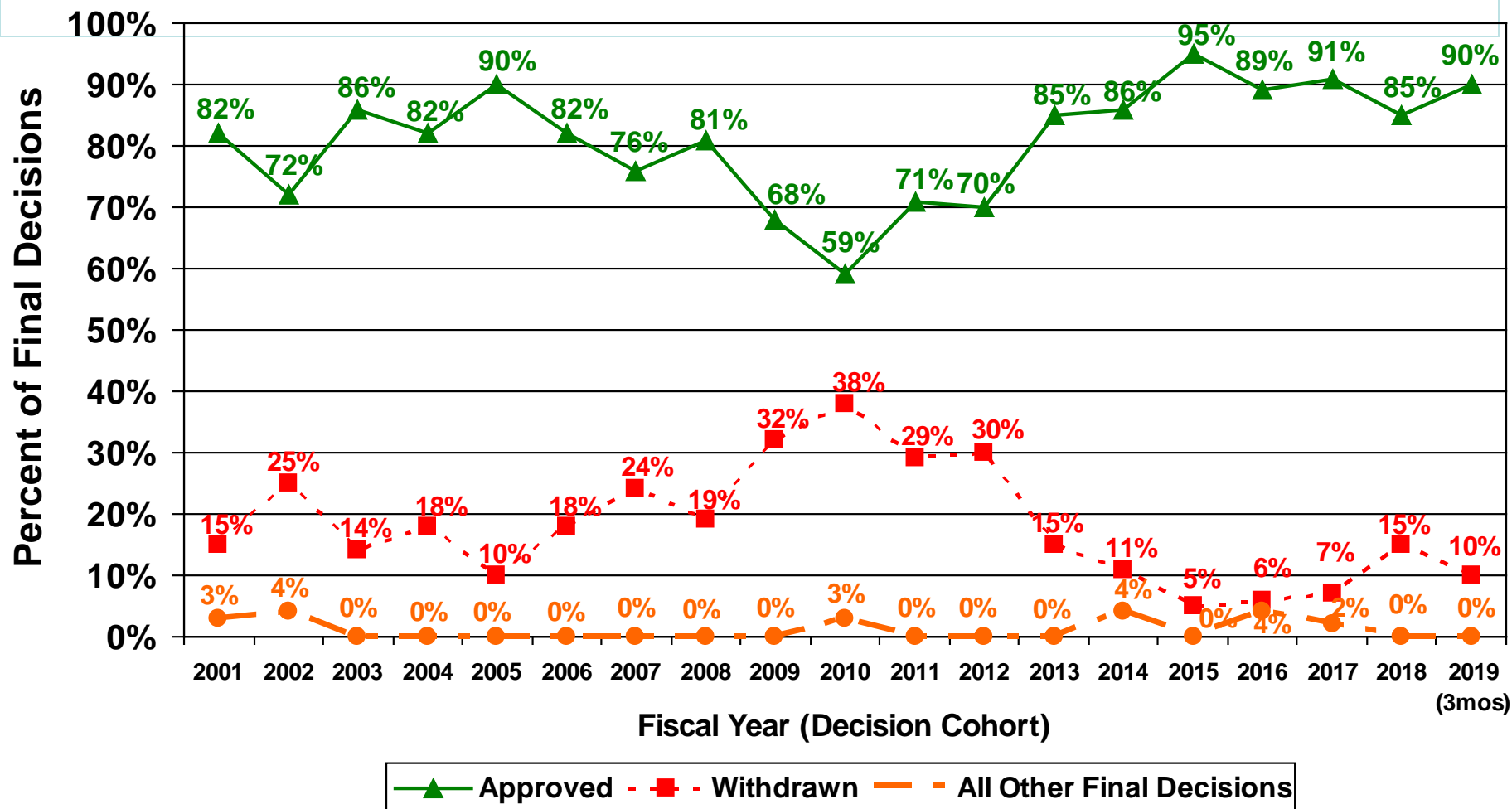
* Original PMAs under review or on hold. Numbers filed and pending include only FY 2013 - FY 2019 receipts that were accepted for review as of end of quarter/year.

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.

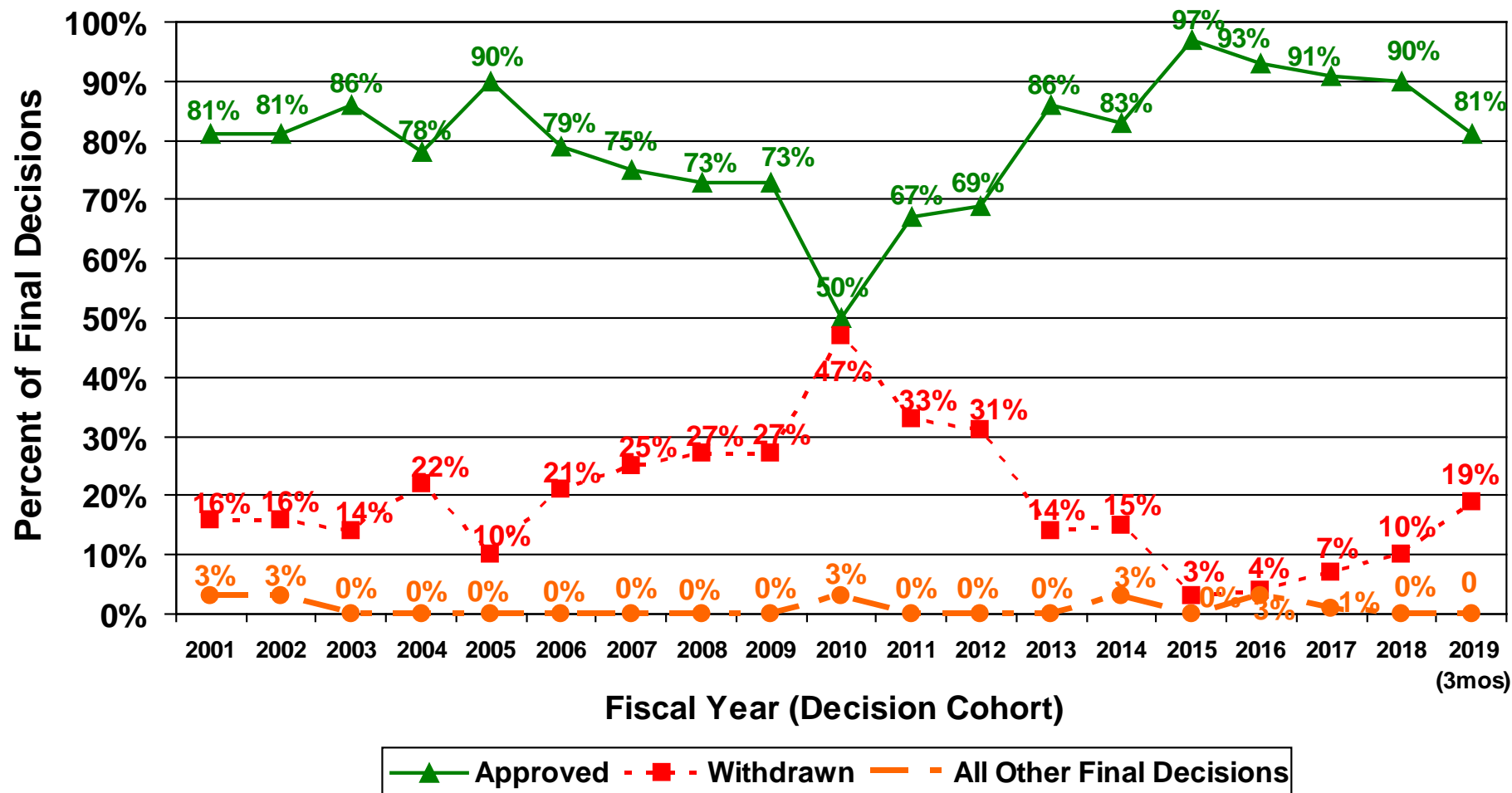
Rates* of PMA Original Approvals, Withdrawals and Other Decisions by FY of Final Decision



*Based on final decisions on original PMAs that were accepted for filing as of 12/31/2018; 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

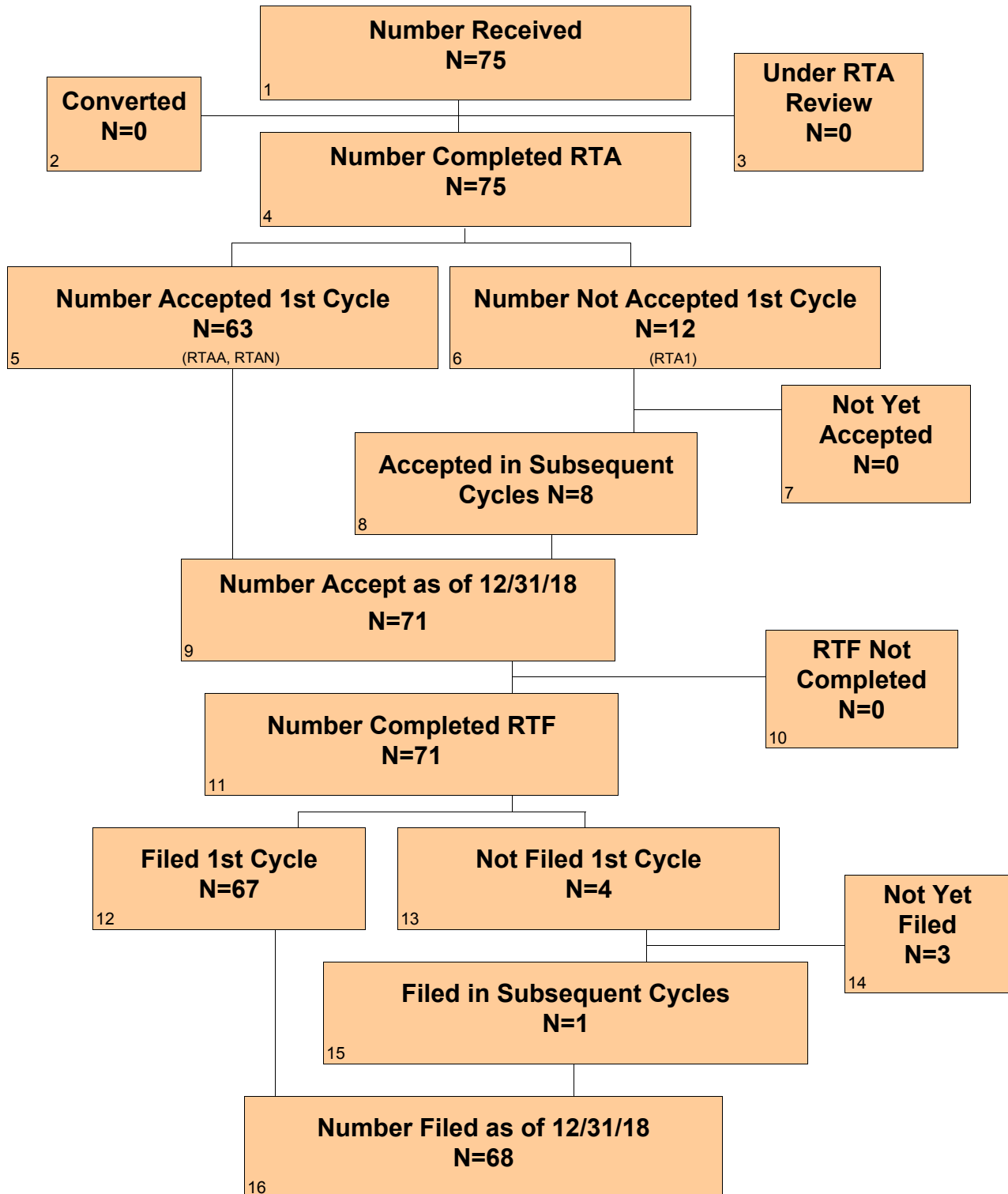
Rates* of PMA Original and Panel Track Supplement Approvals, Withdrawals and Other Decisions by FY of Final Decision



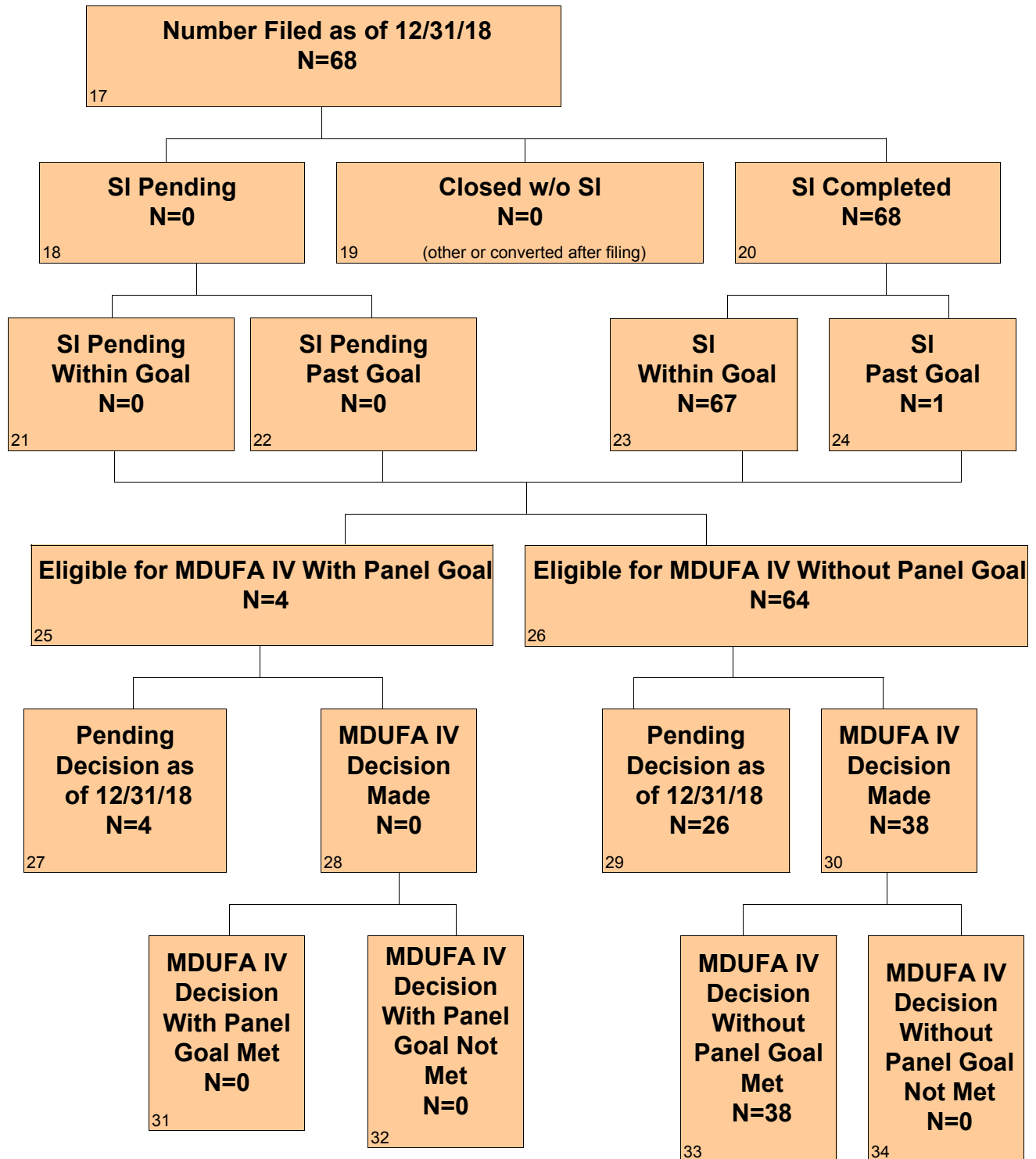
*Based on original PMAs/PTS that were accepted for filing as of 12/31/2018; percentages may not add to 100% due to rounding.

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

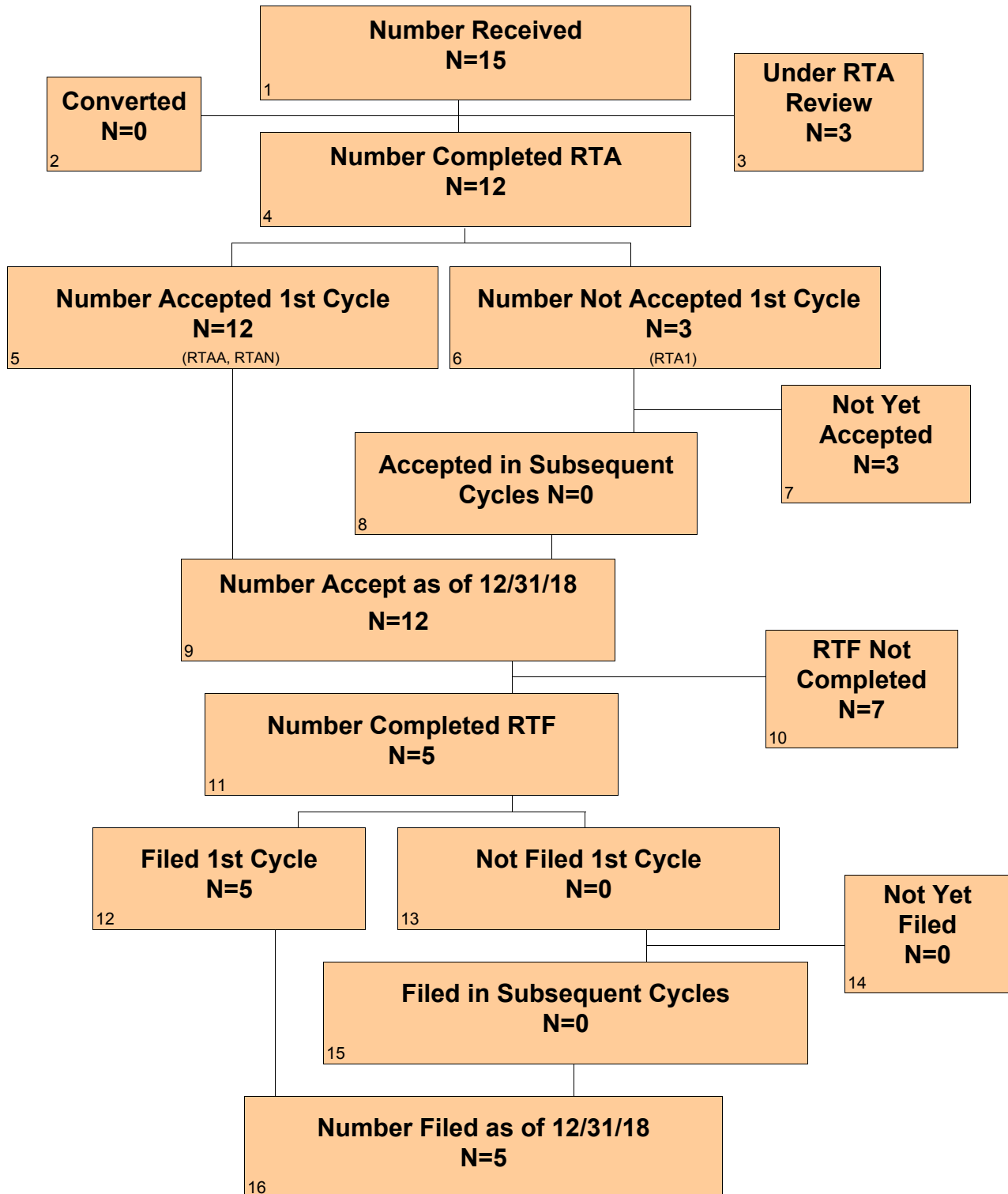
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 12/31/18



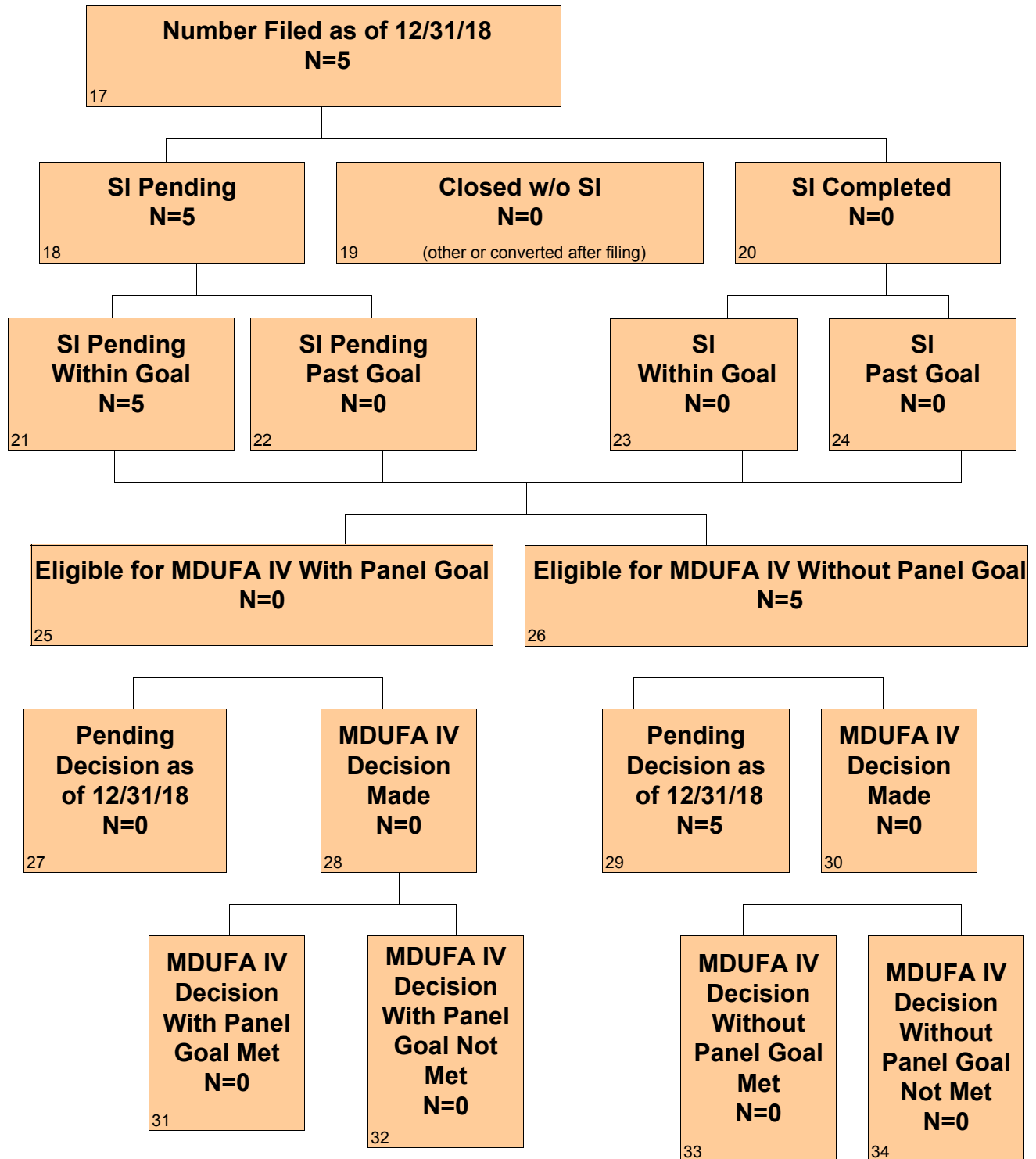
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 12/31/18 Continued



CDRH PMA Original and Panel Track Supplements - FY 2019 as of 12/31/18



CDRH PMA Original and Panel Track Supplements - FY 2019 as of 12/31/18 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	75	15			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	62	12			
Number Without a RTA Review and > 15 Days Since Date Received	1	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	3			
Number Not Accepted for Filing Review	12	0			
Rate of Submissions Not Accepted for Filing Review	16.00%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	75	15			
Number Accepted	63	12			
Completed RTF	71	5			
Number Not Filed	4	0			
Rate of Submissions Not Filed	5.63%	0%			

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	68	5			
SI Goal Met	67	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	5			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.53%	N/A			

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	68	0			
Average Number of FDA Days to Substantive Interaction	86.76	0.00			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	178	0			

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	64	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	38	0			
MDUFA IV Decision Goal Met	38	0			
PMAs Pending MDUFA IV Decision	26	5			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	4	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	4	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	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	38	0			
Average FDA Days to MDUFA IV Decision	148.05	0.00			
20th Percentile FDA Days to MDUFA IV Decision	90	0			
40th Percentile FDA Days to MDUFA IV Decision	159	0			
60th Percentile FDA Days to MDUFA IV Decision	177	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
Average Industry Days to MDUFA IV Decision	49.55	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	14	0			
80th Percentile Industry Days to MDUFA IV Decision	116	0			
Maximum Industry Days to MDUFA IV Decision	272	0			
Average Total Days to MDUFA IV Decision	197.61	0.00			
20th Percentile Total Days to MDUFA IV Decision	133	0			
40th Percentile Total Days to MDUFA IV Decision	177	0			
60th Percentile Total Days to MDUFA IV Decision	183	0			
80th Percentile Total Days to MDUFA IV Decision	262	0			
Maximum Total Days to MDUFA IV Decision	444	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

Table 1.9 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	64	5			
Number with MDUFA IV Decision	38	0			
Number of Withdrawal	5	0			
Number of Not Approvable	5	0			
Number of Deleted	0	0			
Rate of Withdrawal	13.16%	N/A			
Rate of Not Approvable	13.16%	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	4	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

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

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

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

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

*Includes submission that went to panel

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	10	0			
MDUFA IV Decision Goal Met	10	0			
PMAs Pending MDUFA IV Decision	5	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	58	7			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	45	5			
Number Without a RTA Review and > 15 Days Since Date Received	1	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted for Filing Review	12	0			
Rate of Submissions Not Accepted for Filing Review	20.69%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	58	7			
Number Accepted	46	5			
Completed RTF	54	3			
Number Not Filed	4	0			
Rate of Submissions Not Filed	7.41%	0%			

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	51	3			
SI Goal Met	50	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	98.04%	N/A			

**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	51	0			
Average Number of FDA Days to Substantive Interaction	87.59	0.00			
20th Percentile FDA Days to Substantive Interaction	86	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	178	0			

**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	47	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	27	0			
MDUFA IV Decision Goal Met	27	0			
PMAs Pending MDUFA IV Decision	20	3			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	4	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	4	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	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	27	0			
Average FDA Days to MDUFA IV Decision	167.48	0.00			
20th Percentile FDA Days to MDUFA IV Decision	162	0			
40th Percentile FDA Days to MDUFA IV Decision	177	0			
60th Percentile FDA Days to MDUFA IV Decision	178	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
Average Industry Days to MDUFA IV Decision	57.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	47	0			
80th Percentile Industry Days to MDUFA IV Decision	147	0			
Maximum Industry Days to MDUFA IV Decision	272	0			
Average Total Days to MDUFA IV Decision	224.48	0.00			
20th Percentile Total Days to MDUFA IV Decision	170	0			
40th Percentile Total Days to MDUFA IV Decision	179	0			
60th Percentile Total Days to MDUFA IV Decision	227	0			
80th Percentile Total Days to MDUFA IV Decision	293	0			
Maximum Total Days to MDUFA IV Decision	444	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

Table 1.9 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	47	3			
Number with MDUFA IV Decision	27	0			
Number of Withdrawal	1	0			
Number of Not Approvable	4	0			
Number of Deleted	0	0			
Rate of Withdrawal	3.70%	N/A			
Rate of Not Approvable	14.81%	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	4	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	17	8			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	17	7			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	8			
Number Accepted	17	7			
Completed RTF	17	2			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	17	2			
SI Goal Met	17	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	17	0			
Average Number of FDA Days to Substantive Interaction	84.29	0.00			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	87	0			
60th Percentile FDA Days to Substantive Interaction	89	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	17	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	11	0			
MDUFA IV Decision Goal Met	11	0			
PMAs Pending MDUFA IV Decision	6	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	11	0			
Average FDA Days to MDUFA IV Decision	100.36	0.00			
20th Percentile FDA Days to MDUFA IV Decision	84	0			
40th Percentile FDA Days to MDUFA IV Decision	90	0			
60th Percentile FDA Days to MDUFA IV Decision	90	0			
80th Percentile FDA Days to MDUFA IV Decision	134	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
Average Industry Days to MDUFA IV Decision	31.27	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	75	0			
Maximum Industry Days to MDUFA IV Decision	158	0			
Average Total Days to MDUFA IV Decision	131.64	0.00			
20th Percentile Total Days to MDUFA IV Decision	90	0			
40th Percentile Total Days to MDUFA IV Decision	90	0			
60th Percentile Total Days to MDUFA IV Decision	134	0			
80th Percentile Total Days to MDUFA IV Decision	195	0			
Maximum Total Days to MDUFA IV Decision	248	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	17	2			
Number with MDUFA IV Decision	11	0			
Number of Withdrawal	4	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	36.36%	N/A			
Rate of Not Approvable	9.09%	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	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

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

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

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

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

*Includes submission that went to panel

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	10	0			
MDUFA IV Decision Goal Met	10	0			
PMAs Pending MDUFA IV Decision	5	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	3	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	N/A			

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

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	0			
SI Goal Met	3	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

Table 1.4 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	3	0			
Average Number of FDA Days to Substantive Interaction	86.67	0.00			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

Table 1.5 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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	0			
MDUFA IV Decision Goal Met	3	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

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

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

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

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

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	23	4			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	20	2			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted for Filing Review	3	0			
Rate of Submissions Not Accepted for Filing Review	13.04%	0%			

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

Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	4			
Number Accepted	20	2			
Completed RTF	21	2			
Number Not Filed	1	0			
Rate of Submissions Not Filed	4.76%	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	21	2			
SI Goal Met	21	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

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	21	0			
Average Number of FDA Days to Substantive Interaction	83.05	0.00			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	87	0			
60th Percentile FDA Days to Substantive Interaction	89	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

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	20	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	14	0			
MDUFA IV Decision Goal Met	14	0			
PMAs Pending MDUFA IV Decision	6	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	1	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	1	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	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	14	0			
Average FDA Days to MDUFA IV Decision	165.43	0.00			
20th Percentile FDA Days to MDUFA IV Decision	160	0			
40th Percentile FDA Days to MDUFA IV Decision	178	0			
60th Percentile FDA Days to MDUFA IV Decision	178	0			
80th Percentile FDA Days to MDUFA IV Decision	179	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
Average Industry Days to MDUFA IV Decision	57.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	48	0			
80th Percentile Industry Days to MDUFA IV Decision	154	0			
Maximum Industry Days to MDUFA IV Decision	162	0			
Average Total Days to MDUFA IV Decision	222.43	0.00			
20th Percentile Total Days to MDUFA IV Decision	160	0			
40th Percentile Total Days to MDUFA IV Decision	179	0			
60th Percentile Total Days to MDUFA IV Decision	228	0			
80th Percentile Total Days to MDUFA IV Decision	332	0			
Maximum Total Days to MDUFA IV Decision	340	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

Table 1.9 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	20	2			
Number with MDUFA IV Decision	14	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	7.14%	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	1	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	4	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	3	1			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of Submissions Not Accepted for Filing Review	25.00%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	1			
Number Accepted	3	1			
Completed RTF	4	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	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	4	0			
SI Goal Met	3	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	75.00%	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	4	0			
Average Number of FDA Days to Substantive Interaction	90.50	0.00			
20th Percentile FDA Days to Substantive Interaction	90	0			
40th Percentile FDA Days to Substantive Interaction	90	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	91	0			
Maximum FDA Days to Substantive Interaction	92	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	4	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	3	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	0			
Average FDA Days to MDUFA IV Decision	180.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	180	0			
40th Percentile FDA Days to MDUFA IV Decision	180	0			
60th Percentile FDA Days to MDUFA IV Decision	180	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	180.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	180	0			
40th Percentile Total Days to MDUFA IV Decision	180	0			
60th Percentile Total Days to MDUFA IV Decision	180	0			
80th Percentile Total Days to MDUFA IV Decision	180	0			
Maximum Total Days to MDUFA IV Decision	180	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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

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

Interaction Performance Goal

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	0			
Average Number of FDA Days to Substantive Interaction	86.50	0.00			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	86	0			
60th Percentile FDA Days to Substantive Interaction	87	0			
80th Percentile FDA Days to Substantive Interaction	89	0			
Maximum FDA Days to Substantive Interaction	90	0			

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

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

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

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

Table 1.8 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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	13	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	5	0			
Rate of Submissions Not Accepted for Filing Review	38.46%	N/A			

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

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

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	12	0			
SI Goal Met	12	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

Table 1.4 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	12	0			
Average Number of FDA Days to Substantive Interaction	87.00	0.00			
20th Percentile FDA Days to Substantive Interaction	86	0			
40th Percentile FDA Days to Substantive Interaction	87	0			
60th Percentile FDA Days to Substantive Interaction	89	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

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	12	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	7	0			
MDUFA IV Decision Goal Met	7	0			
PMAs Pending MDUFA IV Decision	5	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	7	0			
Average FDA Days to MDUFA IV Decision	178.14	0.00			
20th Percentile FDA Days to MDUFA IV Decision	177	0			
40th Percentile FDA Days to MDUFA IV Decision	177	0			
60th Percentile FDA Days to MDUFA IV Decision	179	0			
80th Percentile FDA Days to MDUFA IV Decision	180	0			
Maximum FDA Days to MDUFA IV Decision	180	0			
Average Industry Days to MDUFA IV Decision	25.86	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	69	0			
Maximum Industry Days to MDUFA IV Decision	95	0			
Average Total Days to MDUFA IV Decision	204.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	177	0			
40th Percentile Total Days to MDUFA IV Decision	178	0			
60th Percentile Total Days to MDUFA IV Decision	180	0			
80th Percentile Total Days to MDUFA IV Decision	249	0			
Maximum Total Days to MDUFA IV Decision	271	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	12	0			
Number with MDUFA IV Decision	7	0			
Number of Withdrawal	0	0			
Number of Not Approvable	1	0			
Number of Deleted	0	0			
Rate of Withdrawal	0%	N/A			
Rate of Not Approvable	14.29%	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	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	10	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	1			
Number Without a RTA Review and > 15 Days Since Date Received	1	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of Submissions Not Accepted for Filing Review	10.00%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	10	1			
Number Accepted	9	1			
Completed RTF	10	0			
Number Not Filed	2	0			
Rate of Submissions Not Filed	20.00%	N/A			

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	8	0			
Average Number of FDA Days to Substantive Interaction	99.50	0.00			
20th Percentile FDA Days to Substantive Interaction	87	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	91	0			
Maximum FDA Days to Substantive Interaction	178	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	5	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	4	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	3	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	3	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	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	1	0			
Average FDA Days to MDUFA IV Decision	90.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	90	0			
40th Percentile FDA Days to MDUFA IV Decision	90	0			
60th Percentile FDA Days to MDUFA IV Decision	90	0			
80th Percentile FDA Days to MDUFA IV Decision	90	0			
Maximum FDA Days to MDUFA IV Decision	90	0			
Average Industry Days to MDUFA IV Decision	163.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	163	0			
40th Percentile Industry Days to MDUFA IV Decision	163	0			
60th Percentile Industry Days to MDUFA IV Decision	163	0			
80th Percentile Industry Days to MDUFA IV Decision	163	0			
Maximum Industry Days to MDUFA IV Decision	163	0			
Average Total Days to MDUFA IV Decision	253.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	253	0			
40th Percentile Total Days to MDUFA IV Decision	253	0			
60th Percentile Total Days to MDUFA IV Decision	253	0			
80th Percentile Total Days to MDUFA IV Decision	253	0			
Maximum Total Days to MDUFA IV Decision	253	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	3	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	2	0			
Rate of Submissions Not Accepted for Filing Review	66.67%	N/A			

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

Decision

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

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

Interaction Performance Goal

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

Table 1.4 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	1	0			
Average Number of FDA Days to Substantive Interaction	88.00	0.00			
20th Percentile FDA Days to Substantive Interaction	88	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	88	0			
80th Percentile FDA Days to Substantive Interaction	88	0			
Maximum FDA Days to Substantive Interaction	88	0			

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

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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	#DIV/0!			

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

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

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

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

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

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	5	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	5	1			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	1			
Number Accepted	5	1			
Completed RTF	5	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

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

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

Table 1.4 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	5	0			
Average Number of FDA Days to Substantive Interaction	88.20	0.00			
20th Percentile FDA Days to Substantive Interaction	86	0			
40th Percentile FDA Days to Substantive Interaction	89	0			
60th Percentile FDA Days to Substantive Interaction	90	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

Table 1.5 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	5	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	5	0			
Average FDA Days to MDUFA IV Decision	105.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	89	0			
40th Percentile FDA Days to MDUFA IV Decision	90	0			
60th Percentile FDA Days to MDUFA IV Decision	100	0			
80th Percentile FDA Days to MDUFA IV Decision	121	0			
Maximum FDA Days to MDUFA IV Decision	146	0			
Average Industry Days to MDUFA IV Decision	22.20	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	22	0			
Maximum Industry Days to MDUFA IV Decision	111	0			
Average Total Days to MDUFA IV Decision	127.20	0.00			
20th Percentile Total Days to MDUFA IV Decision	90	0			
40th Percentile Total Days to MDUFA IV Decision	105	0			
60th Percentile Total Days to MDUFA IV Decision	127	0			
80th Percentile Total Days to MDUFA IV Decision	156	0			
Maximum Total Days to MDUFA IV Decision	195	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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

Table 1.2 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	0			
Number Accepted	1	0			
Completed RTF	1	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	N/A			

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

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

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

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

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

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

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

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

**Table 1.8 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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	4			
Number Accepted	2	4			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	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	2	0			
SI Goal Met	2	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	0			
Average Number of FDA Days to Substantive Interaction	84.00	0.00			
20th Percentile FDA Days to Substantive Interaction	84	0			
40th Percentile FDA Days to Substantive Interaction	84	0			
60th Percentile FDA Days to Substantive Interaction	84	0			
80th Percentile FDA Days to Substantive Interaction	84	0			
Maximum FDA Days to Substantive Interaction	84	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	2	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	2	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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	8	3			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	8	2			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	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	8	3			
Number Accepted	8	2			
Completed RTF	8	2			
Number Not Filed	0	0			
Rate of Submissions Not Filed	0%	0%			

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	8	2			
SI Goal Met	8	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

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	8	0			
Average Number of FDA Days to Substantive Interaction	83.88	0.00			
20th Percentile FDA Days to Substantive Interaction	86	0			
40th Percentile FDA Days to Substantive Interaction	88	0			
60th Percentile FDA Days to Substantive Interaction	88	0			
80th Percentile FDA Days to Substantive Interaction	90	0			
Maximum FDA Days to Substantive Interaction	90	0			

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	8	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
PMAs Pending MDUFA IV Decision	3	2			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	5	0			
Average FDA Days to MDUFA IV Decision	103.20	0.00			
20th Percentile FDA Days to MDUFA IV Decision	82	0			
40th Percentile FDA Days to MDUFA IV Decision	90	0			
60th Percentile FDA Days to MDUFA IV Decision	108	0			
80th Percentile FDA Days to MDUFA IV Decision	137	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
Average Industry Days to MDUFA IV Decision	46.60	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	30	0			
80th Percentile Industry Days to MDUFA IV Decision	92	0			
Maximum Industry Days to MDUFA IV Decision	158	0			
Average Total Days to MDUFA IV Decision	149.80	0.00			
20th Percentile Total Days to MDUFA IV Decision	82	0			
40th Percentile Total Days to MDUFA IV Decision	116	0			
60th Percentile Total Days to MDUFA IV Decision	170	0			
80th Percentile Total Days to MDUFA IV Decision	230	0			
Maximum Total Days to MDUFA IV Decision	248	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	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	8	2			
Number with MDUFA IV Decision	5	0			
Number of Withdrawal	2	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	40.00%	N/A			
Rate of Not Approvable	0%	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	0			
Number With MDUFA IV Decision	0	0			
Number of Withdrawal	0	0			
Number of Not Approvable	0	0			
Number of Deleted	0	0			
Rate of Withdrawal	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

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

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

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

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

*Includes submission that went to panel

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	7	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
PMAs Pending MDUFA IV Decision	2	1			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	1	0			
Closed Before RTA Action	0	0			
Number with Accepted RTA review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of Submissions Not Accepted for Filing Review	0%	N/A			

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

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

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

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

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

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

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

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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

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

Table 1.7 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	1	0			
Average FDA Days to MDUFA IV Decision	63.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	63	0			
40th Percentile FDA Days to MDUFA IV Decision	63	0			
60th Percentile FDA Days to MDUFA IV Decision	63	0			
80th Percentile FDA Days to MDUFA IV Decision	63	0			
Maximum FDA Days to MDUFA IV Decision	63	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	63.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	63	0			
40th Percentile Total Days to MDUFA IV Decision	63	0			
60th Percentile Total Days to MDUFA IV Decision	63	0			
80th Percentile Total Days to MDUFA IV Decision	63	0			
Maximum Total Days to MDUFA IV Decision	63	0			

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

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

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

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

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

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

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

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

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

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

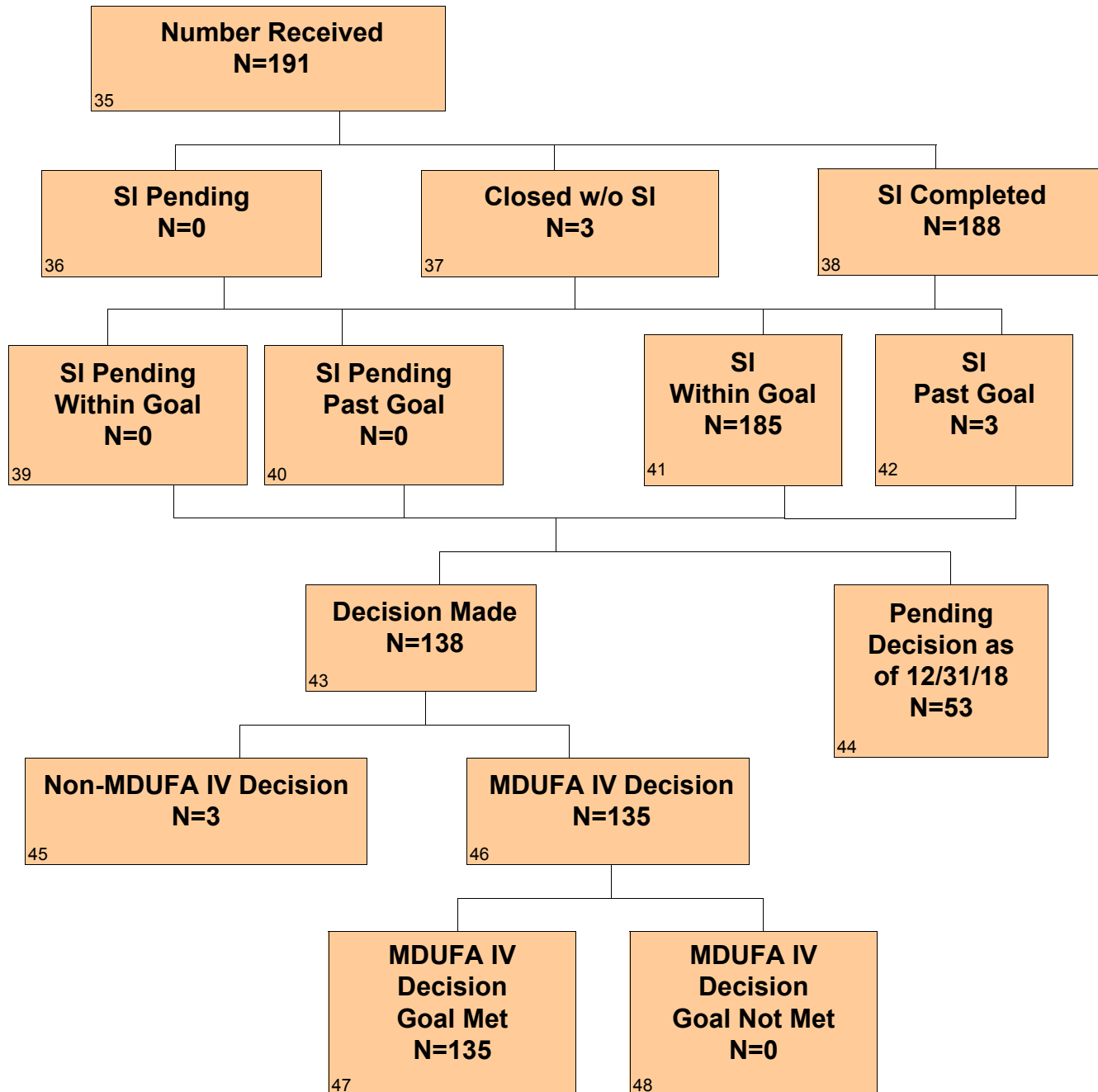
*Includes submission that went to panel

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

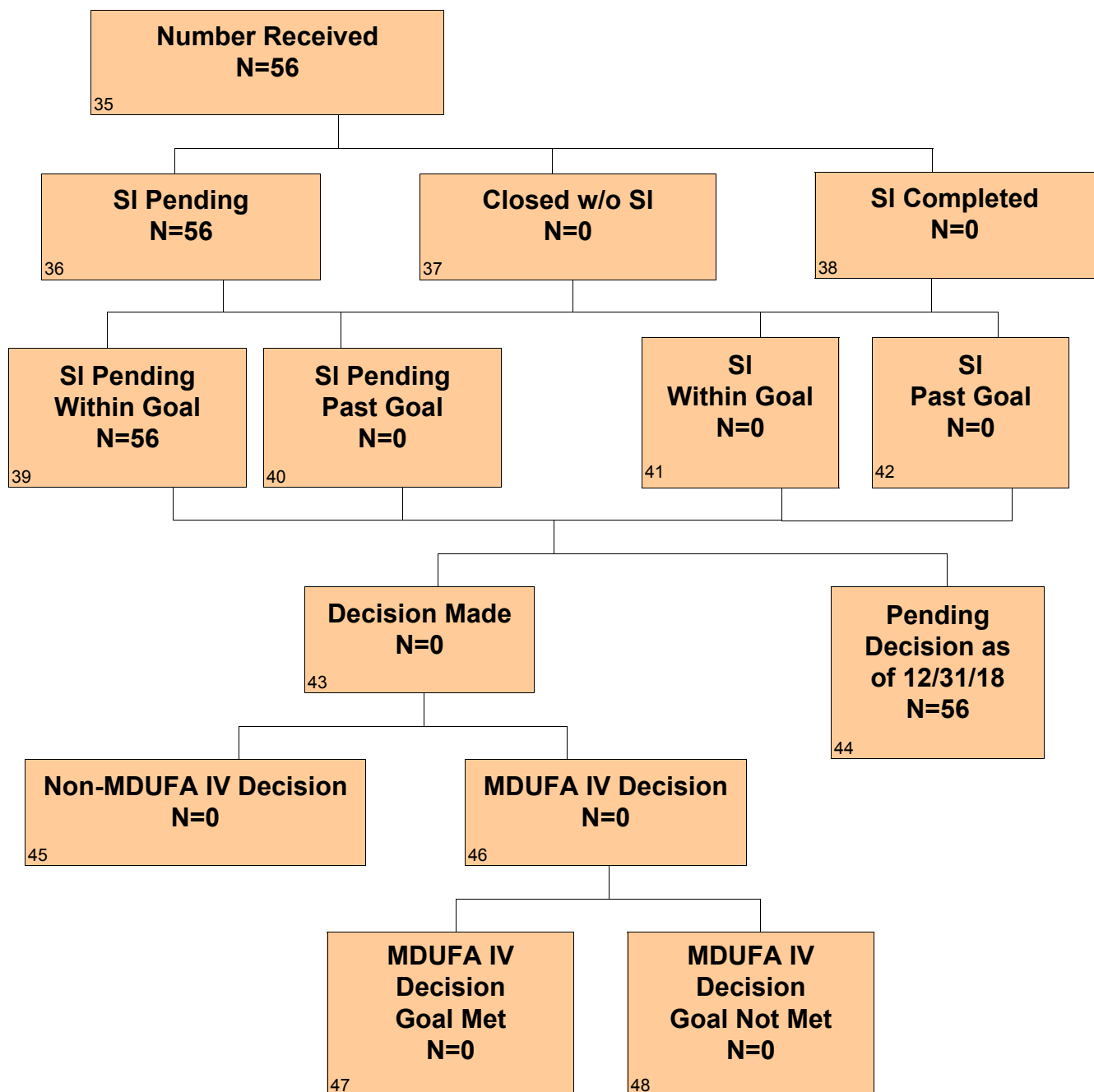
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	0	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs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

*Includes submission that went to panel

CDRH PMA 180 Day Supplements - FY 2018 as of 12/31/18



CDRH PMA 180 Day Supplements - FY 2019 as of 12/31/18



Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	191	56			
SI Goal Met	185	0			
SI Goal Not Met	3	0			
SI Pending Within Goal	0	56			
SI Pending Past Goal	0	0			
Closed Without SI	3	0			
Current SI Performance Percent Goal Met	98.40%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	191	56			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision	134	0			
MDUFA IV Decision Goal Met	134	0			
Supplements Pending MDUFA IV Decision	54	56			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	191	56			
Number with MDUFA IV Decision	134	0			
Number of Not Approvable	8	0			
Rate of Not Approvable	5.97%	N/A			

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

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	154	50			
SI Goal Met	149	0			
SI Goal Not Met	2	0			
SI Pending Within Goal	0	50			
SI Pending Past Goal	0	0			
Closed Without SI	3	0			
Current SI Performance Percent Goal Met	98.68%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	154	50			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision	111	0			
MDUFA IV Decision Goal Met	111	0			
Supplements Pending MDUFA IV Decision	40	50			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	154	50			
Number with MDUFA IV Decision	111	0			
Number of Not Approvable	7	0			
Rate of Not Approvable	6.31%	N/A			

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

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	37	6			
SI Goal Met	36	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	6			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	97.30%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days	95% Within 180 FDA Days
Supplements Received	37	6			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	23	0			
MDUFA IV Decision Goal Met	23	0			
Supplements Pending MDUFA IV Decision	14	6			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	37	6			
Number with MDUFA IV Decision	23	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	4.35%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	9	4			
SI Goal Met	8	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	88.89%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	9	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	6	0			
MDUFA IV Decision Goal Met	6	0			
Supplements Pending MDUFA IV Decision	3	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	9	4			
Number with MDUFA IV Decision	6	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	16.67%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 2 PMA 180-Day Supplements - Division Level Metric

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	94	24			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision	72	0			
MDUFA IV Decision Goal Met	72	0			
Supplements Pending MDUFA IV Decision	20	24			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	94	24			
Number with MDUFA IV Decision	72	0			
Number of Not Approvable	4	0			
Rate of Not Approvable	5.56%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	13	2			
SI Goal Met	12	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	1	0			
Current SI Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	13	2			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	10	0			
MDUFA IV Decision Goal Met	10	0			
Supplements Pending MDUFA IV Decision	2	2			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	13	2			
Number with MDUFA IV Decision	10	0			
Number of Not Approvable	2	0			
Rate of Not Approvable	20.00%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0	0			
Mean Industry Days for Submissions that Missed the Goal	0	0			

Section 2 PMA 180-Day Supplements - Division Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	1	4			
SI Goal Met	1	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	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	1	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
Supplements Pending MDUFA IV Decision	0	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	1	4			
Number with MDUFA IV Decision	1	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 2 PMA 180-Day Supplements - Division Level Metric

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	16	13			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	10	0			
MDUFA IV Decision Goal Met	10	0			
Supplements Pending MDUFA IV Decision	6	13			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	13			
Number with MDUFA IV Decision	10	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Section 2 PMA 180-Day Supplements - Division Level Metric

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

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	11	3			
SI Goal Met	11	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	11	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	0			
MDUFA IV Decision Goal Met	3	0			
Supplements Pending MDUFA IV Decision	8	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	11	3			
Number with MDUFA IV Decision	3	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 2 PMA 180-Day Supplements - Division Level Metric

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	11	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	9	0			
MDUFA IV Decision Goal Met	9	0			
Supplements Pending MDUFA IV Decision	2	2			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	11	2			
Number with MDUFA IV Decision	9	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	3	1			
SI Goal Met	3	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	3	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
Supplements Pending MDUFA IV Decision	3	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	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	3	1			
Number with MDUFA IV Decision	0	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	N/A	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 2 PMA 180-Day Supplements - Division Level Metric

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	3	0			
MDUFA IV Decision Goal Met	3	0			
Supplements Pending MDUFA IV Decision	5	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	0			
Number with MDUFA IV Decision	3	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	13	2			
SI Goal Met	12	0			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	92.31%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	13	2			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	10	0			
MDUFA IV Decision Goal Met	10	0			
Supplements Pending MDUFA IV Decision	3	2			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	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	13	2			
Number with MDUFA IV Decision	10	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	10.00%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 2 PMA 180-Day Supplements - Division Level Metric

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

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

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

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

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

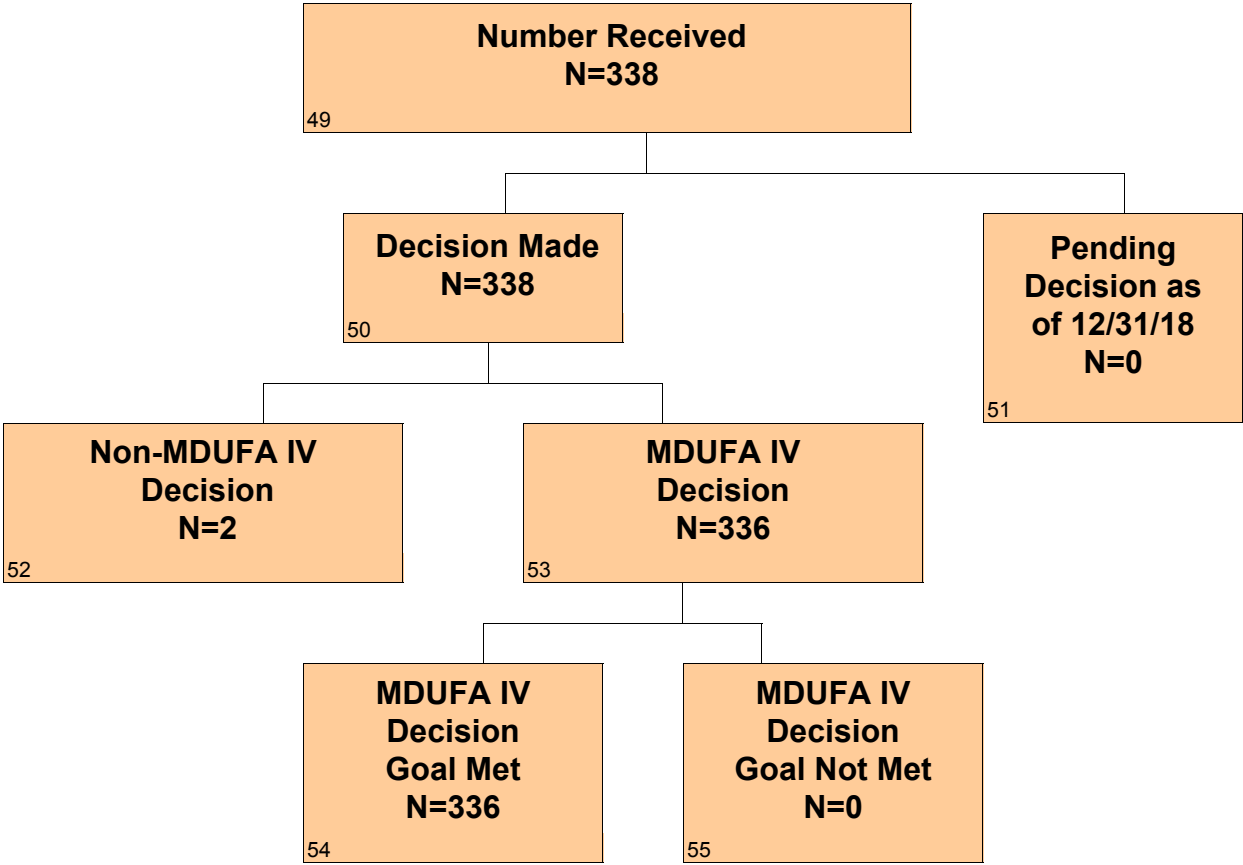
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	1			
Number with MDUFA IV Decision	1	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

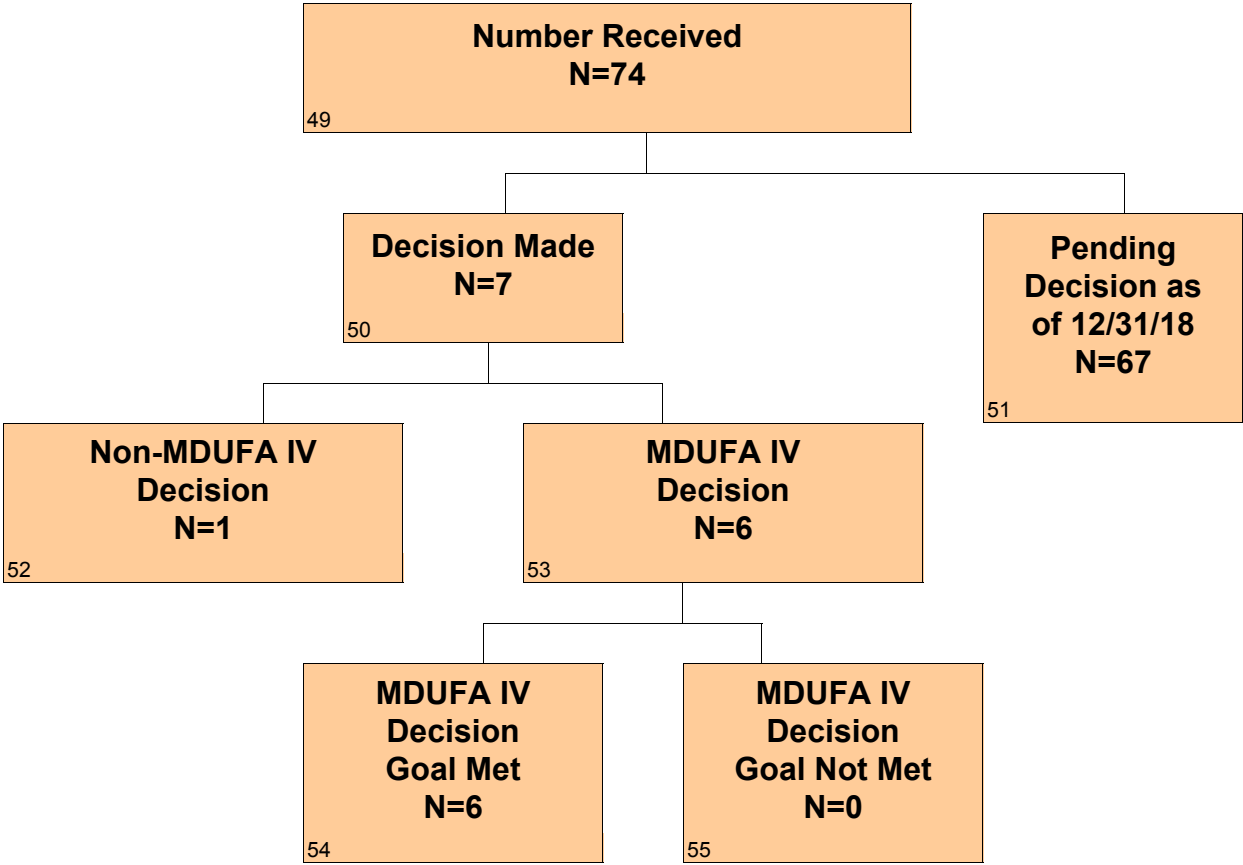
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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CDRH PMA Real Time Supplements - FY 2018 as of 12/31/18



CDRH PMA Real Time Supplements - FY 2019 as of 12/31/18



Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	338	74			
Non-MDUFA IV Decision	2	1			
MDUFA IV Decision	336	6			
MDUFA IV Decision Goal Met	336	6			
Supplements Pending MDUFA IV Decision	0	67			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	338	74			
Number With MDUFA IV Decision	336	6			
Number of Not Approvable	20	0			
Rate of Not Approvable	5.95%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	243	64			
Non-MDUFA IV Decision	1	1			
MDUFA IV Decision	242	5			
MDUFA IV Decision Goal Met	242	5			
Supplements Pending MDUFA IV Decision	0	58			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	243	64			
Number With MDUFA IV Decision	242	5			
Number of Not Approvable	20	0			
Rate of Not Approvable	8.26%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	95	10			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	94	1			
MDUFA IV Decision Goal Met	94	1			
Supplements Pending MDUFA IV Decision	0	9			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	95	10			
Number With MDUFA IV Decision	94	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 3 PMA Real-Time Supplements - Division Level Metric

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

Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	9	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	9	0			
MDUFA IV Decision Goal Met	9	0			
Supplements Pending MDUFA IV Decision	0	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	3			
Number with MDUFA IV Decision	9	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	154	44			
Non-MDUFA IV Decision	0	1			
MDUFA IV Decision	154	5			
MDUFA IV Decision Goal Met	154	5			
Supplements Pending MDUFA IV Decision	0	38			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	154	44			
Number with MDUFA IV Decision	154	5			
Number of Not Approvable	12	0			
Rate of Not Approvable	7.79%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	16	5			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	16	0			
MDUFA IV Decision Goal Met	16	0			
Supplements Pending MDUFA IV Decision	0	5			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	5			
Number with MDUFA IV Decision	16	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	17	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	17	0			
MDUFA IV Decision Goal Met	17	0			
Supplements Pending MDUFA IV Decision	0	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	4			
Number with MDUFA IV Decision	17	0			
Number of Not Approvable	2	0			
Rate of Not Approvable	11.76%	N/A			

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

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

Section 3 PMA Real-Time Supplements - Division Level Metric

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	19	2			
Number with MDUFA IV Decision	19	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	5.26%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	15	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	15	0			
MDUFA IV Decision Goal Met	15	0			
Supplements Pending MDUFA IV Decision	0	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	15	3			
Number with MDUFA IV Decision	15	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	6.67%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	13	3			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	12	0			
MDUFA IV Decision Goal Met	12	0			
Supplements Pending MDUFA IV Decision	0	3			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	3			
Number with MDUFA IV Decision	12	0			
Number of Not Approvable	4	0			
Rate of Not Approvable	33.33%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	28	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	28	0			
MDUFA IV Decision Goal Met	28	0			
Supplements Pending MDUFA IV Decision	0	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	28	4			
Number with MDUFA IV Decision	28	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	18	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	18	0			
MDUFA IV Decision Goal Met	18	0			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	18	0			
Number with MDUFA IV Decision	18	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	38	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	38	0			
MDUFA IV Decision Goal Met	38	0			
Supplements Pending MDUFA IV Decision	0	4			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	38	4			
Number with MDUFA IV Decision	38	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	9	2			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision	8	1			
MDUFA IV Decision Goal Met	8	1			
Supplements Pending MDUFA IV Decision	0	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	9	2			
Number with MDUFA IV Decision	8	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	2	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	2	0			
MDUFA IV Decision Goal Met	2	0			
Supplements Pending MDUFA IV Decision	0	0			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

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

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

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

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

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Section 4 Pre-Market Report Submissions

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

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Section 5 PMA Annual Metrics and Goals

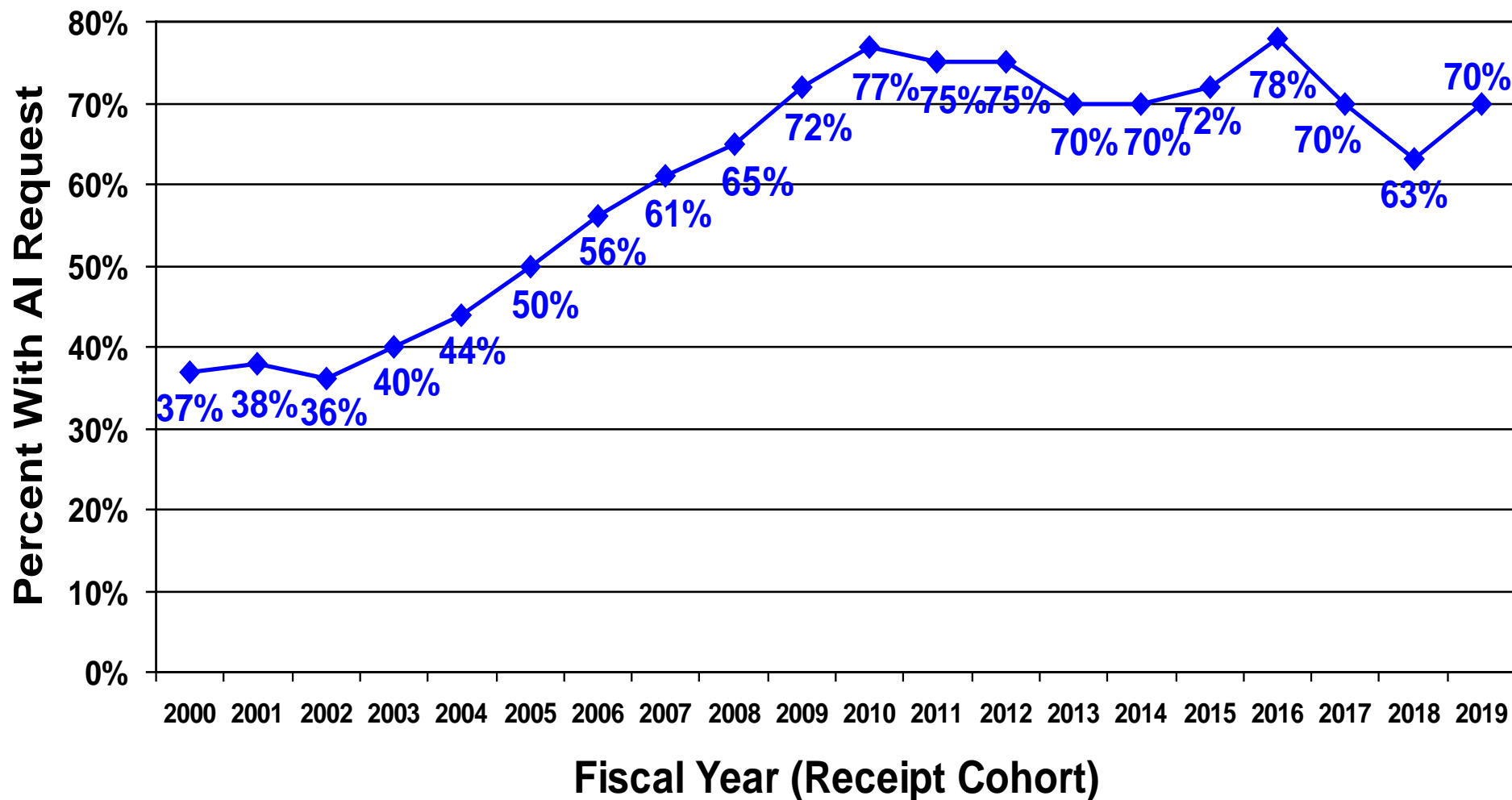
PMA Annual Metrics and Goals will be reported in the Annual Report.

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510(k)s

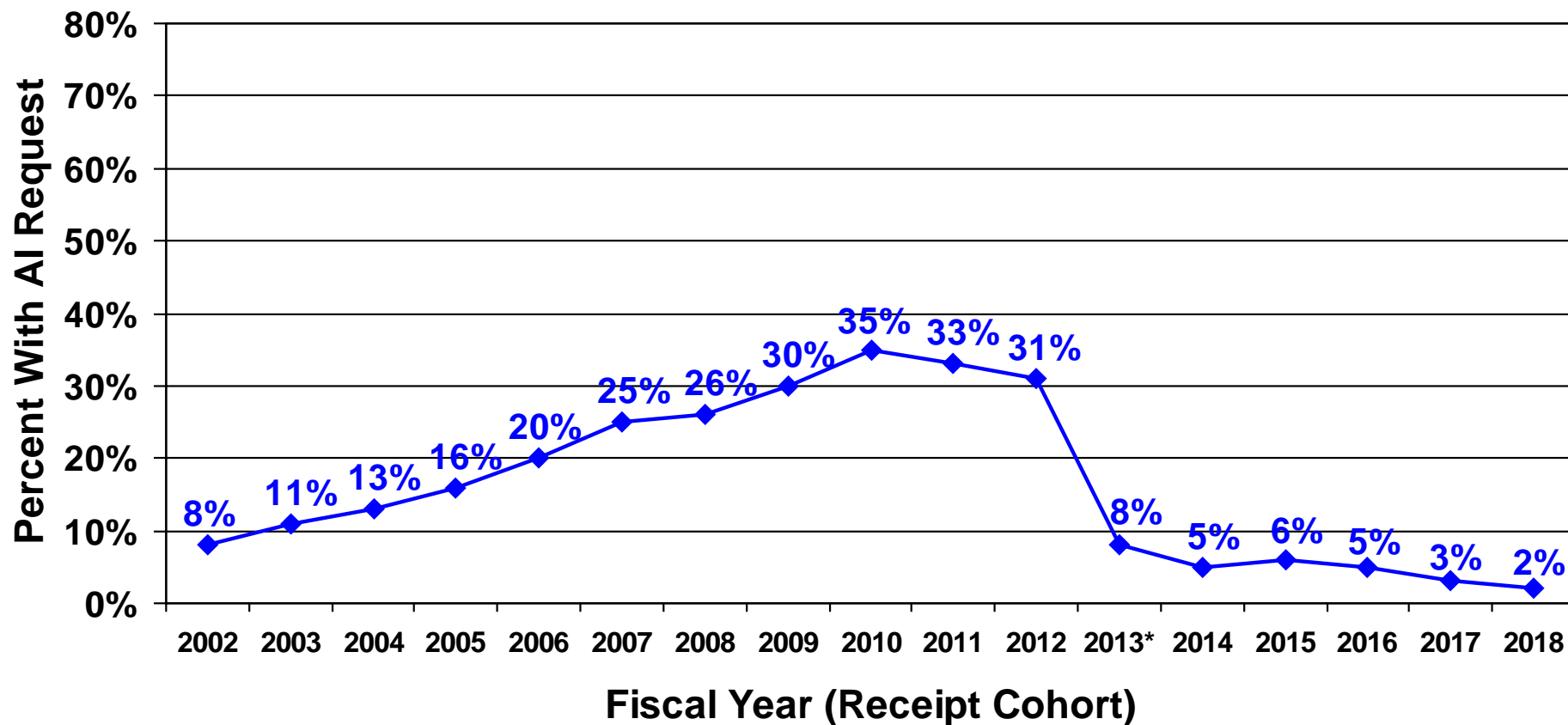
Q1FY19

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



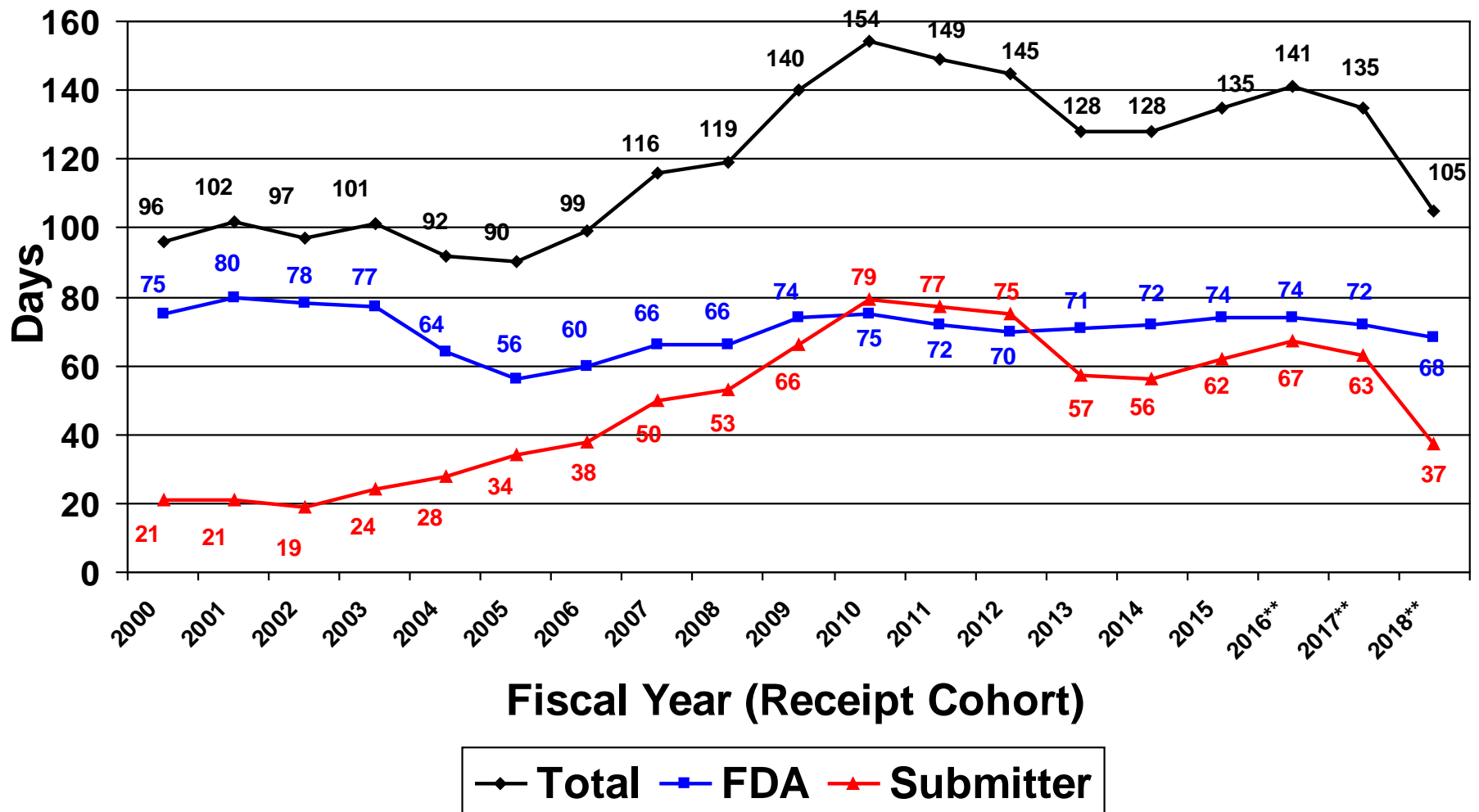
*FY 2013 - FY 2018 data are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 10/31/2018.

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



*FY 2013 – FY 2018 data are for 510(k)s accepted as of 5/31/2018. FY 2017 and FY2018 2nd cycles are still open as of 12/31/2018; data may change.

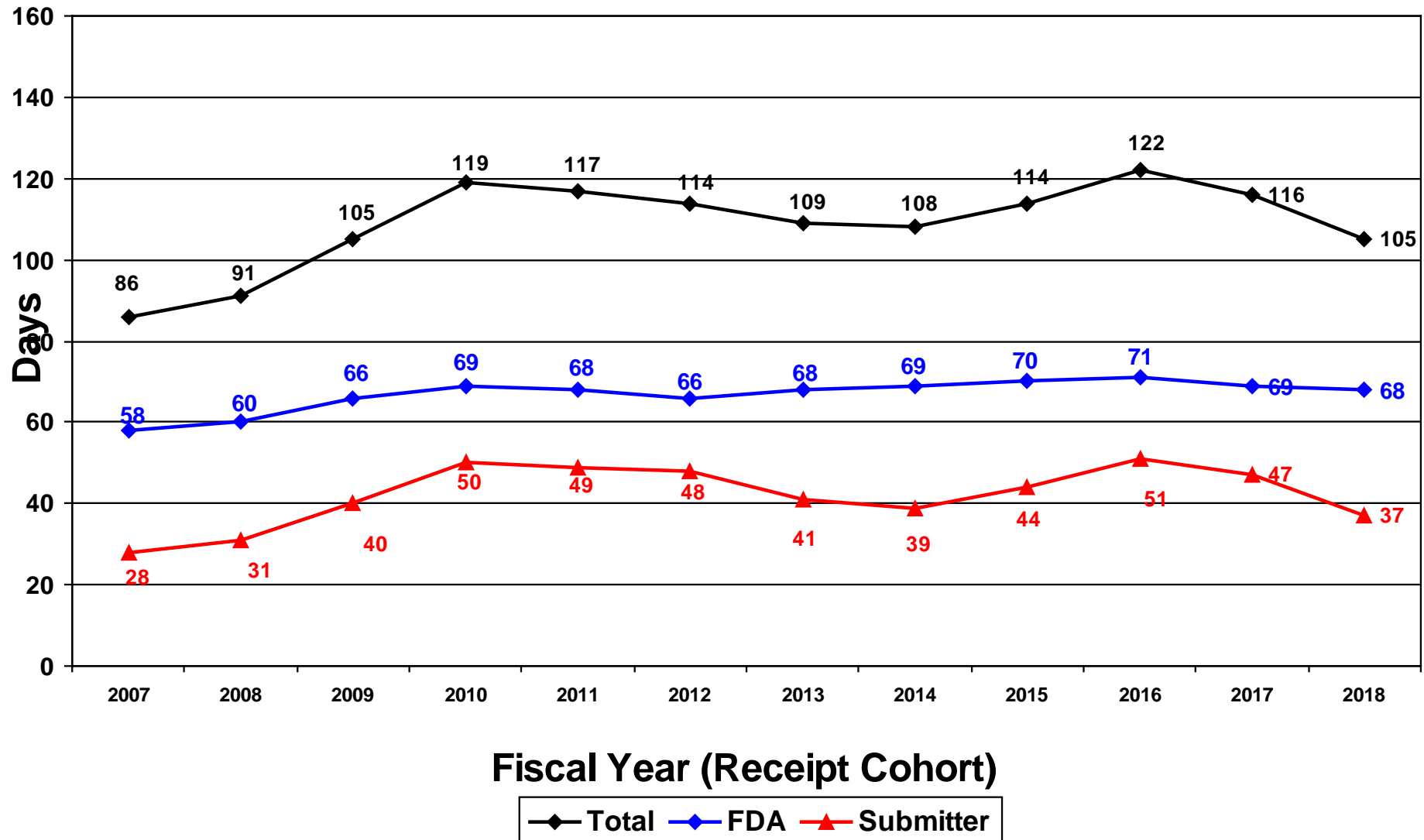
Average Time to MDUFA Decision: 510(k)s* (Receipt Cohorts as of December 31, 2018)



*SE and NSE decisions only; times may not add to total due to rounding.

**Cohorts still open; percentage of cohort closed: FY2016 = 99.8%, FY 2017 = 99.6%, FY2018 = 78.9% => avg times for FY2016, FY2017 & FY2018 will increase.

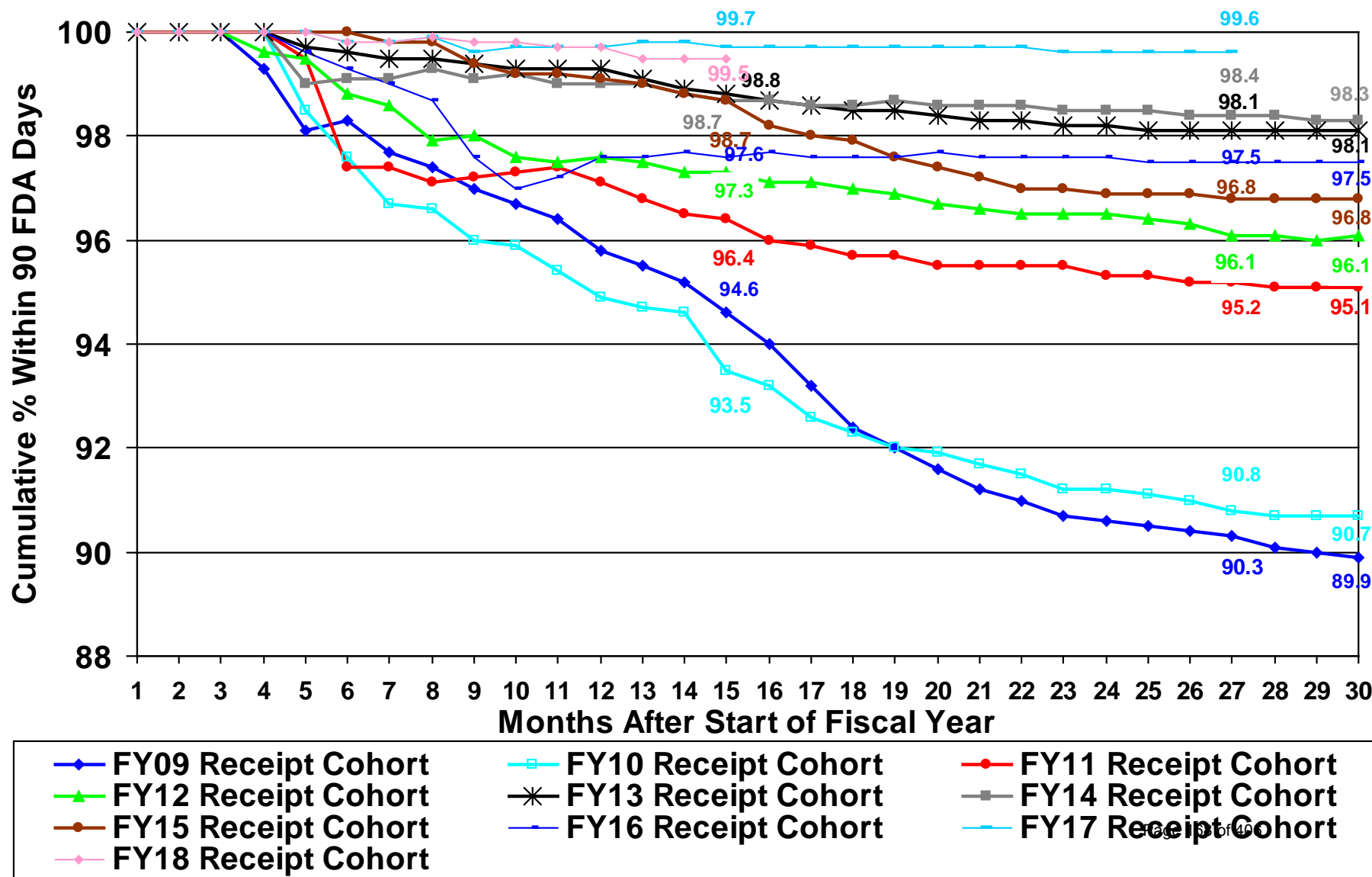
Average Time to MDUFA Decision: 510(k)s* (Comparison of Cohorts 78.9% Closure)



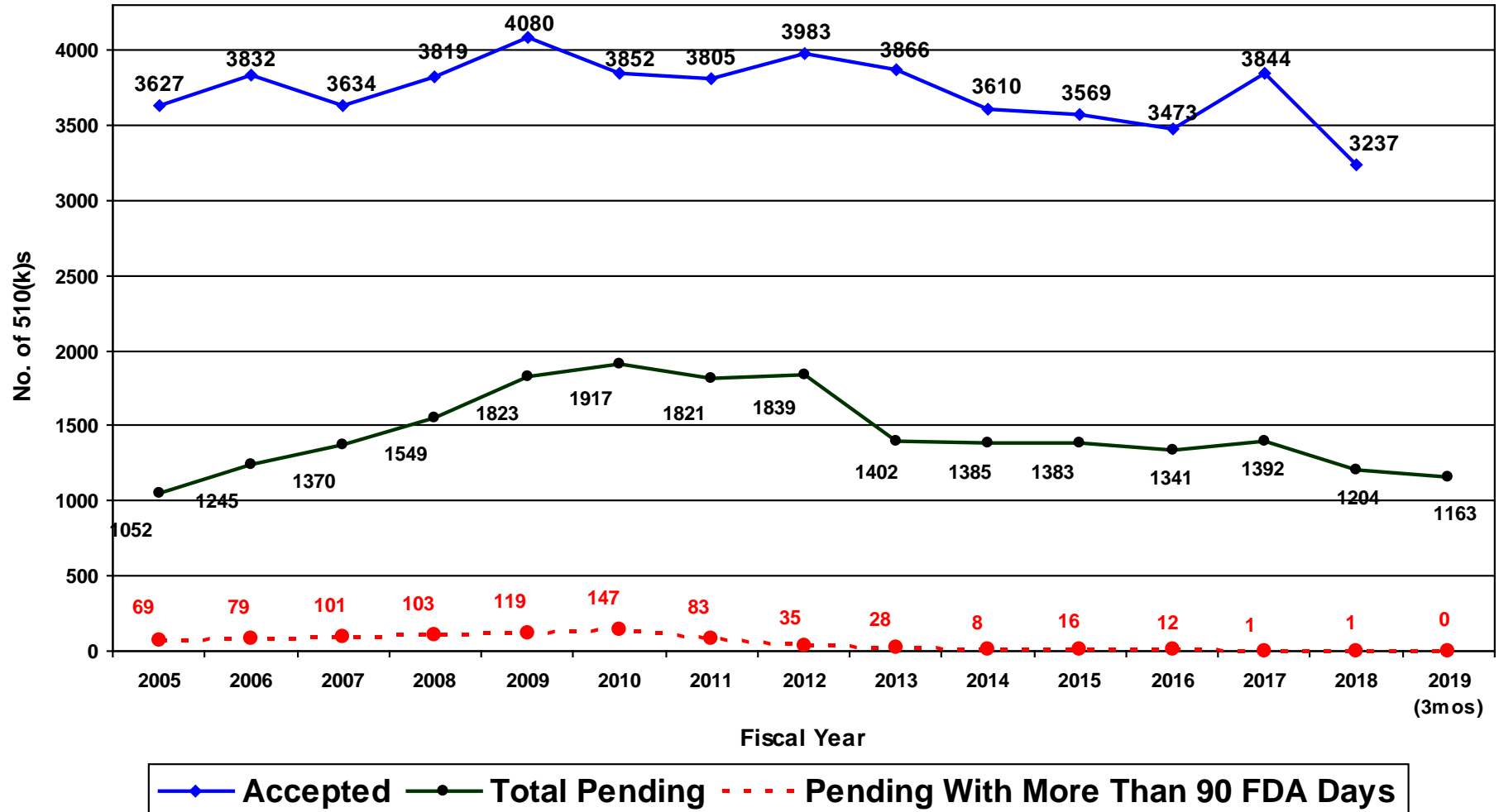
*SE and NSE decisions only; times may not add to total due to rounding.

Trend in 510(k) MDUFA Decision Goal Performance

Comparison of FY09 - FY18 Receipt Cohorts

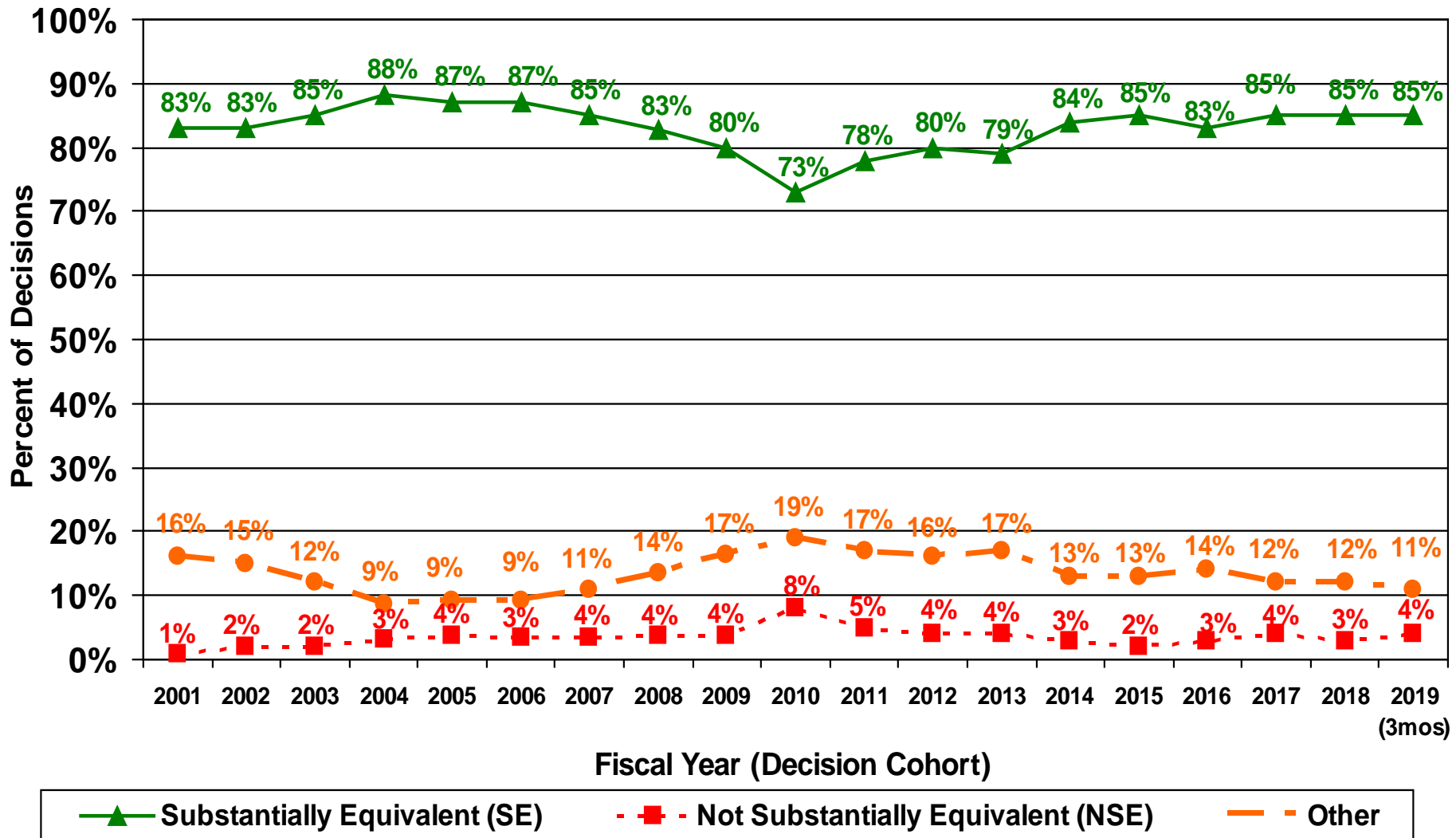


510(k)s Pending* at End of Year



*Under review or on hold. Numbers accepted and pending include only FY 2013 - FY 2019 receipts that were accepted for review as of end of year. FY19 number accepted will be updated later in FY19.

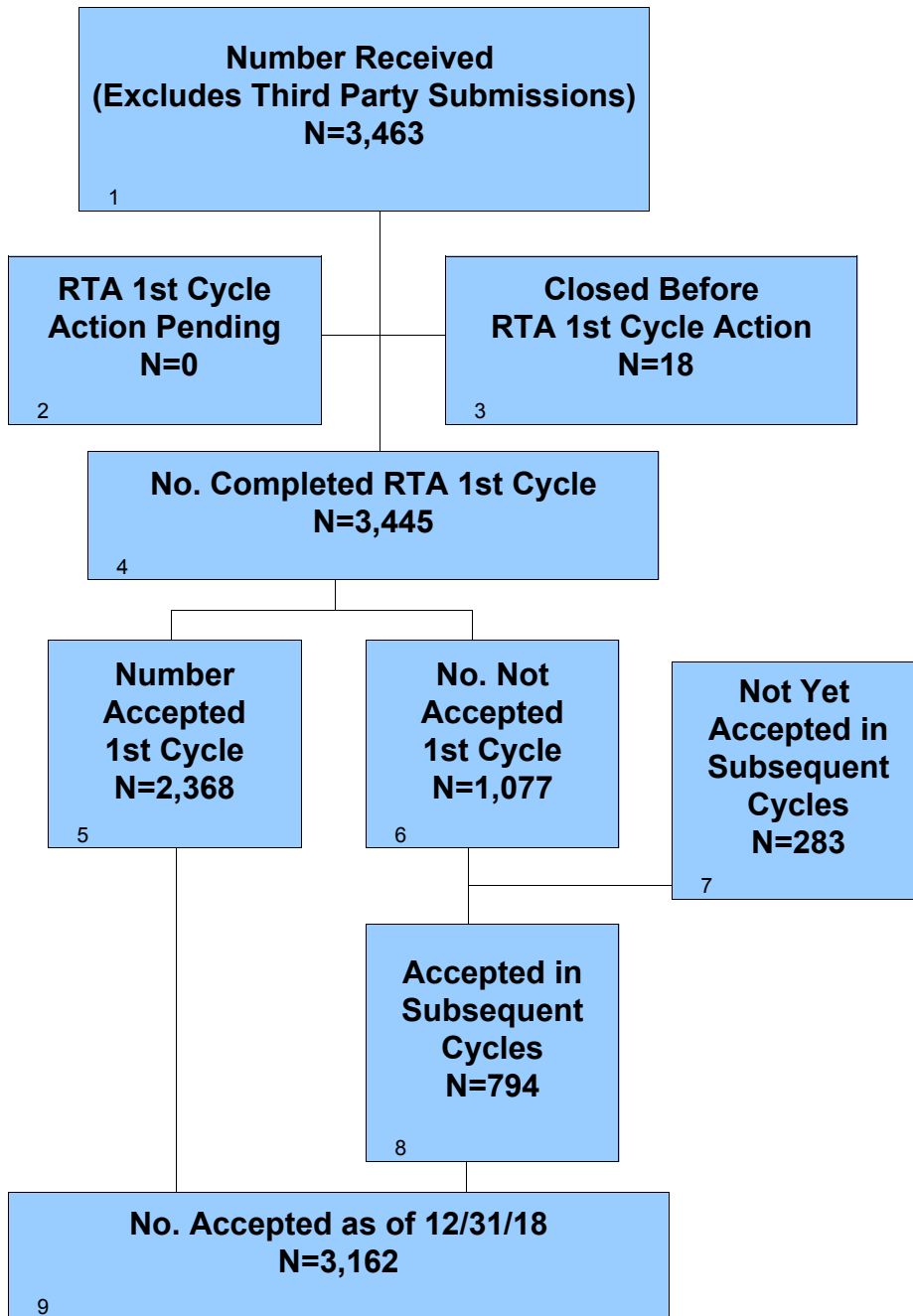
Rates* of SE, NSE and Other Decisions by FY of Decision



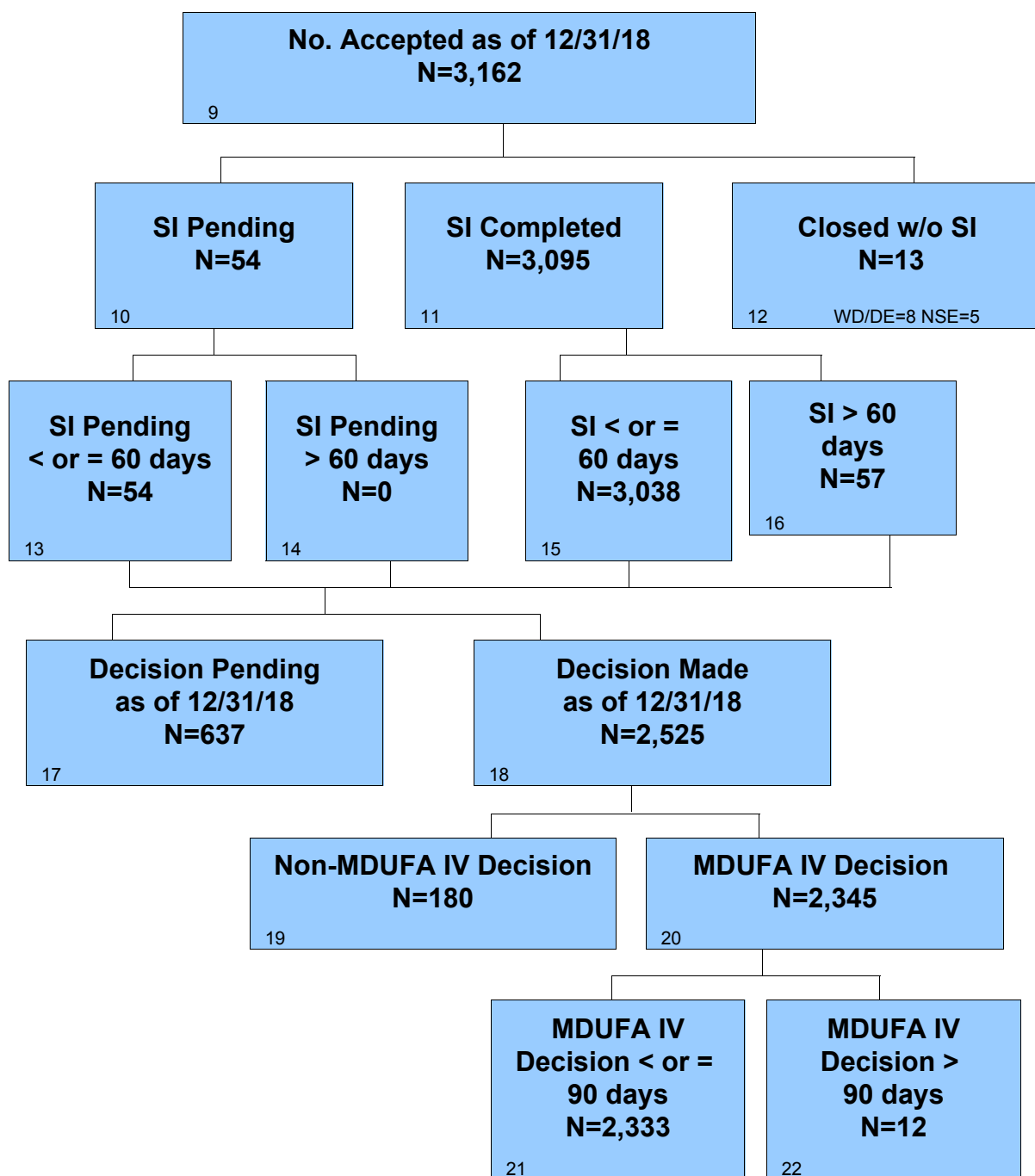
*Percentages may not add to 100% due to rounding. Includes final decisions made on FY 2013 - FY 2019 receipts that were accepted for review as of 12/31/2018.

CDRH 510(k)s - FY 2018

as of 12/31/18

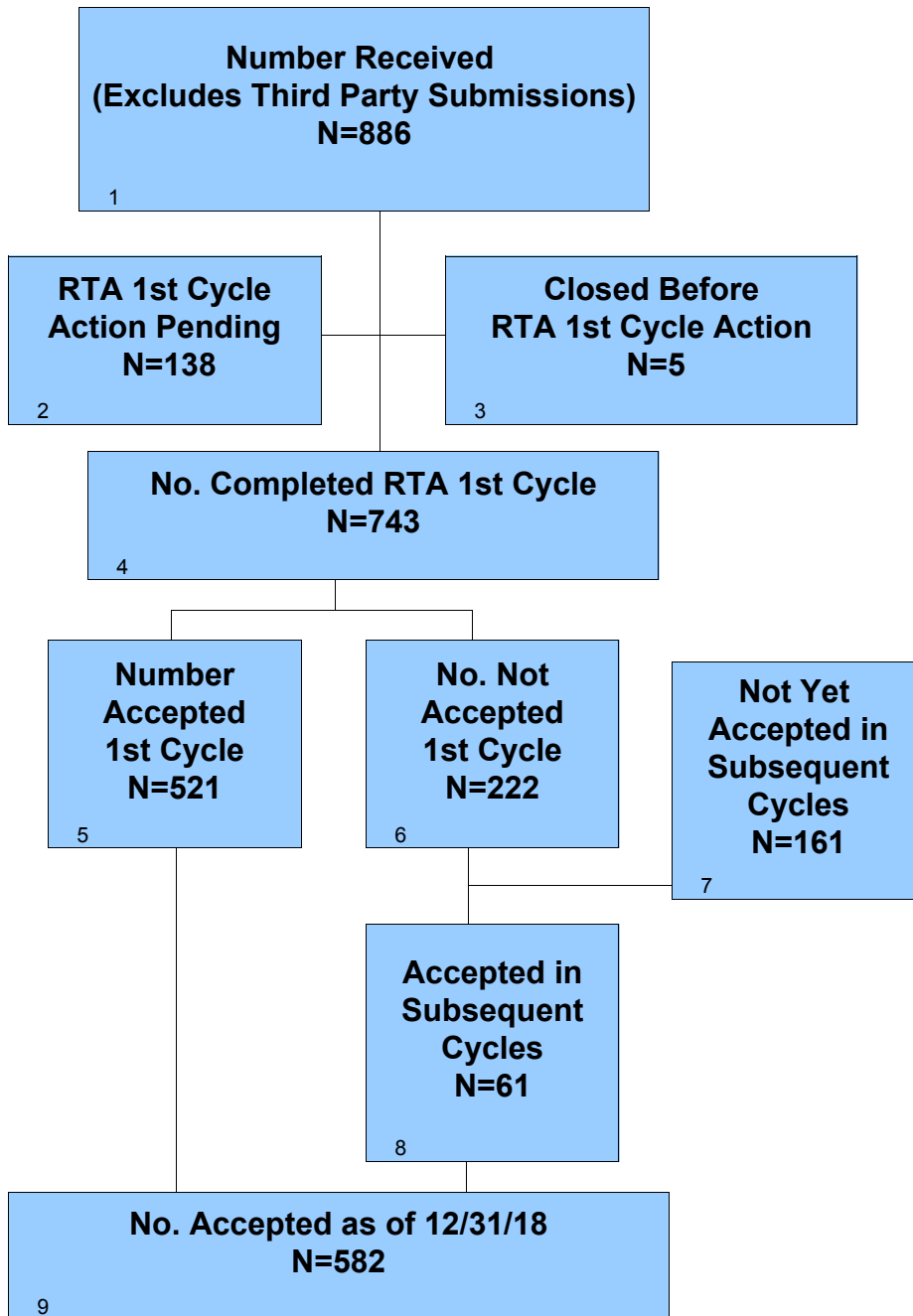


CDRH 510(k)s - FY 2018 as of 12/31/18 Continued

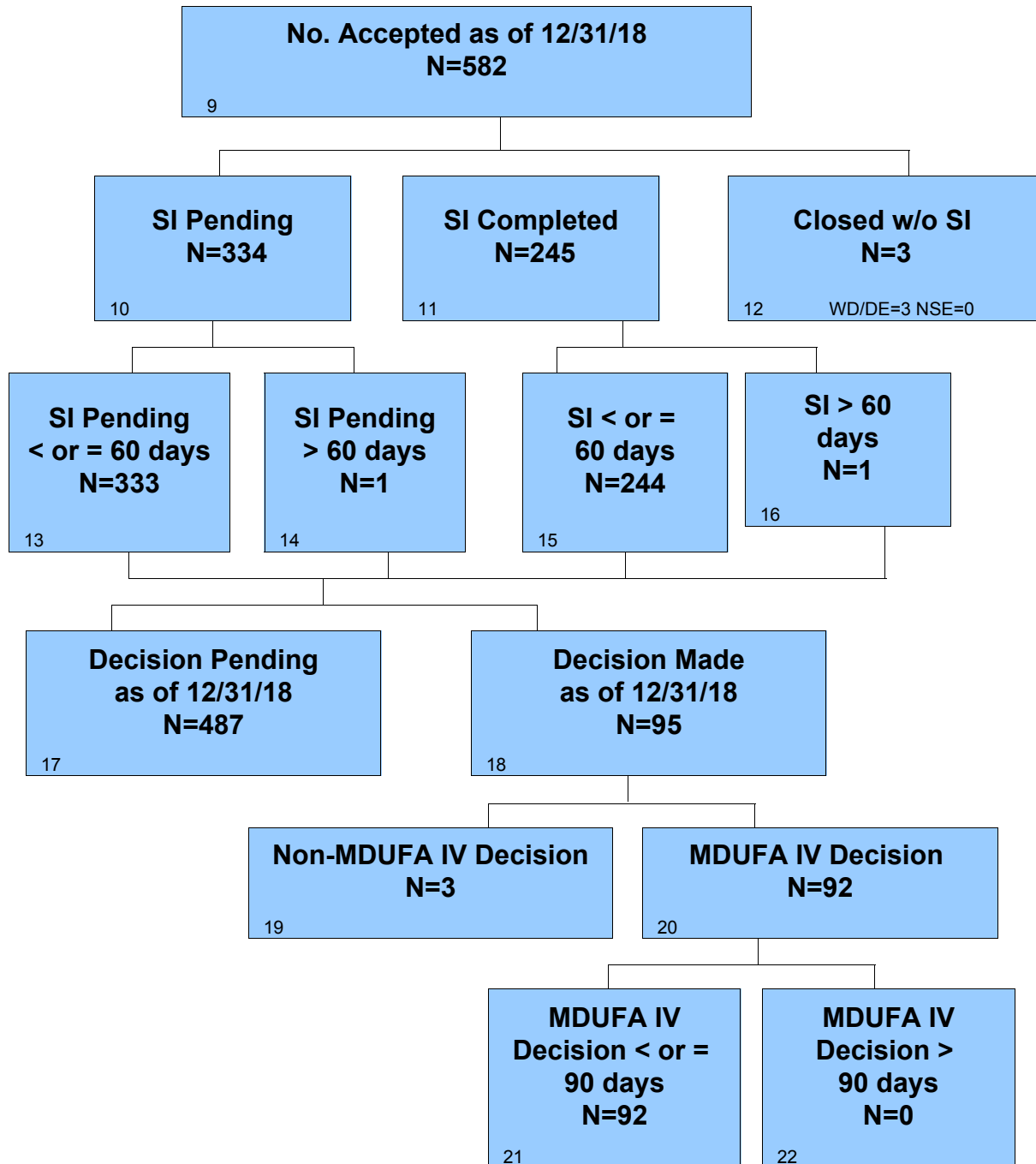


CDRH 510(k)s - FY 2019

as of 12/31/18



CDRH 510(k)s - FY 2019 as of 12/31/18 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	3463	886			
Closed Before RTA Action	18	5			
Number Accepted	2353	505			
Number Without a RTA Review and > 15 Days Since Date Received	15	16			
Number Without a RTA Review and <= 15 Days Since Date Received	0	138			
Number Not Accepted	1077	222			
Rate of Submissions Not Accepted for Review	31.26%	29.88%			

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	3162	582			
Deleted or Withdrawn Prior to SI	8	3			
SI Within 60 FDA Days	3038	244			
SI Over 60 FDA Days	57	1			
SI Pending Within 60 FDA Days	54	333			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	5	0			
Current SI Performance Percent Within 60 FDA Days	98.00%	99.19%			

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	3095	245			
Average Number of FDA Days to Substantive Interaction	50.69	43.71			
20th Percentile FDA Days to Substantive Interaction	41	28			
40th Percentile FDA Days to Substantive Interaction	55	43			
60th Percentile FDA Days to Substantive Interaction	58	53			
80th Percentile FDA Days to Substantive Interaction	60	58			
Maximum FDA Days to Substantive Interaction	86	66			

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	3162	582			
Non-MDUFA IV Decision	180	3			
MDUFA IV Decision (SE/NSE)	2345	92			
MDUFA IV Decision Within 90 FDA Days	2333	92			
510(k)s Pending MDUFA IV Decision	637	487			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.49%	100%			

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	1.54	1.10			
Number With MDUFA IV Decision	2345	92			
Average Number of FDA Days to MDUFA IV Decision	69.17	35.22			
20th Percentile FDA Days to MDUFA IV Decision	48	25			
40th Percentile FDA Days to MDUFA IV Decision	71	29			
60th Percentile FDA Days to MDUFA IV Decision	86	33			
80th Percentile FDA Days to MDUFA IV Decision	89	50			
Maximum FDA Days to MDUFA IV Decision	170	81			
Average Number of Industry Days to MDUFA IV Decision	37.67	1.20			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	23	0			
80th Percentile Industry Days to MDUFA IV Decision	72	0			
Maximum Industry Days to MDUFA IV Decision	245	20			
Average Number of Total Days to MDUFA IV Decision	106.84	36.41			
20th Percentile Total Days to MDUFA IV Decision	51	26			
40th Percentile Total Days to MDUFA IV Decision	83	29			
60th Percentile Total Days to MDUFA IV Decision	106	33			
80th Percentile Total Days to MDUFA IV Decision	157	54			
Maximum Total Days to MDUFA IV Decision	346	81			

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	3162	582			
Number With MDUFA IV Decision	2345	92			
Number of SE Decision	2274	92			
Number of NSE Decision	71	0			
Number of Withdrawal	109	3			
Number of Deleted	63	0			
Rate of SE Decision	96.97%	100%			
Rate of NSE Decision	3.03%	0%			
Rate of Withdrawal	3.45%	0.52%			
Rate of Deleted	1.99%	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	12	0			
Mean FDA Days for Submissions that Missed the Goal	112.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	88	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	1			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	1	0			
MDUFA IV Decision Within 90 FDA Days	1	0			
510(k)s Pending MDUFA IV Decision	0	1			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	267	57			
Non-MDUFA IV Decision	24	0			
MDUFA IV Decision (SE/NSE)	193	13			
MDUFA IV Decision Within 90 FDA Days	193	13			
510(k)s Pending MDUFA IV Decision	50	44			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2782	690			
Closed Before RTA Action	15	4			
Number Accepted	1761	367			
Number Without a RTA and > 15 Days Since Date Received	13	13			
Number Without a RTA and <= 15 Days Since Date Received	0	110			
Number Not Accepted	993	196			
Rate of Submissions Not Accepted For Review	35.89%	34.03%			

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	2508	435			
Deleted or Withdrawn Prior to SI	6	3			
SI Within 60 FDA Days	2392	181			
SI Over 60 FDA Days	56	1			
SI Pending Within 60 FDA Days	50	249			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	4	0			
Current SI Performance Percent Within 60 FDA Days	97.55%	98.91%			

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	2448	182			
Average Number of FDA Days to Substantive Interaction	51.81	44.66			
20th Percentile FDA Days to Substantive Interaction	46	29			
40th Percentile FDA Days to Substantive Interaction	56	46			
60th Percentile FDA Days to Substantive Interaction	58	55			
80th Percentile FDA Days to Substantive Interaction	60	58			
Maximum FDA Days to Substantive Interaction	86	66			

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	2508	435			
Non-MDUFA IV Decision	145	3			
MDUFA IV Decision (SE/NSE)	1809	60			
MDUFA IV Decision Within 90 FDA Days	1797	60			
510(k)s Pending MDUFA IV Decision	554	372			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.34%	100%			

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	1.56	1.10			
Number With MDUFA IV Decision	1809	60			
Average Number of FDA Days to MDUFA IV Decision	71.34	35.17			
20th Percentile FDA Days to MDUFA IV Decision	52	26			
40th Percentile FDA Days to MDUFA IV Decision	77	29			
60th Percentile FDA Days to MDUFA IV Decision	87	31			
80th Percentile FDA Days to MDUFA IV Decision	89	49			
Maximum FDA Days to MDUFA IV Decision	170	81			
Average Number of Industry Days to MDUFA IV Decision	39.24	1.08			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	27	0			
80th Percentile Industry Days to MDUFA IV Decision	75	0			
Maximum Industry Days to MDUFA IV Decision	245	16			
Average Number of Total Days to MDUFA IV Decision	110.57	36.25			
20th Percentile Total Days to MDUFA IV Decision	56	27			
40th Percentile Total Days to MDUFA IV Decision	85	29			
60th Percentile Total Days to MDUFA IV Decision	109	34			
80th Percentile Total Days to MDUFA IV Decision	160	51			
Maximum Total Days to MDUFA IV Decision	346	81			

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	2508	435			
Number With MDUFA IV Decision	1809	60			
Number of SE Decision	1752	60			
Number of NSE Decision	57	0			
Number of Withdrawal	87	3			
Number of Deleted	52	0			
Rate of SE Decision	96.85%	100%			
Rate of NSE Decision	3.15%	0%			
Rate of Withdrawal	3.47%	0.69%			
Rate of Deleted	2.07%	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	12	0			
Mean FDA Days for Submissions that Missed the Goal	112.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	87.58	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	681	196			
Closed Before RTA Action	3	1			
Number Accepted	592	138			
Number Without a RTA and > 15 Days Since Date Received	2	3			
Number Without a RTA and <= 15 Days Since Date Received	0	28			
Number Not Accepted	84	26			
Rate of Submissions Not Accepted For Review	12.39%	15.57%			

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	654	147			
Deleted or Withdrawn Prior to SI	2	0			
SI Within 60 FDA Days	646	63			
SI Over 60 FDA Days	1	0			
SI Pending Within 60 FDA Days	4	84			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	100%	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	647	63			
Average Number of FDA Days to Substantive Interaction	46.45	40.97			
20th Percentile FDA Days to Substantive Interaction	30	28			
40th Percentile FDA Days to Substantive Interaction	48	35			
60th Percentile FDA Days to Substantive Interaction	56	49			
80th Percentile FDA Days to Substantive Interaction	58	56			
Maximum FDA Days to Substantive Interaction	61	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	654	147			
Non-MDUFA IV Decision	35	0			
MDUFA IV Decision (SE/NSE)	536	32			
MDUFA IV Decision Within 90 FDA Days	536	32			
510(k)s Pending MDUFA IV Decision	83	115			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.44	1.09			
Number With MDUFA IV Decision	536	32			
Average Number of FDA Days to MDUFA IV Decision	61.83	35.31			
20th Percentile FDA Days to MDUFA IV Decision	30	23			
40th Percentile FDA Days to MDUFA IV Decision	57	28			
60th Percentile FDA Days to MDUFA IV Decision	77	33			
80th Percentile FDA Days to MDUFA IV Decision	87	54			
Maximum FDA Days to MDUFA IV Decision	90	81			
Average Number of Industry Days to MDUFA IV Decision	32.39	1.41			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	11	0			
80th Percentile Industry Days to MDUFA IV Decision	56	0			
Maximum Industry Days to MDUFA IV Decision	231	20			
Average Number of Total Days to MDUFA IV Decision	94.22	36.72			
20th Percentile Total Days to MDUFA IV Decision	30	23			
40th Percentile Total Days to MDUFA IV Decision	60	28			
60th Percentile Total Days to MDUFA IV Decision	89	33			
80th Percentile Total Days to MDUFA IV Decision	137	54			
Maximum Total Days to MDUFA IV Decision	321	81			

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	654	147			
Number With MDUFA IV Decision	536	32			
Number of SE Decision	522	32			
Number of NSE Decision	14	0			
Number of Withdrawal	22	0			
Number of Deleted	11	0			
Rate of SE Decision	97.39%	100%			
Rate of NSE Decision	2.61%	0%			
Rate of Withdrawal	3.36%	0%			
Rate of Deleted	1.68%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	267	57			
Non-MDUFA IV Decision	24	0			
MDUFA IV Decision (SE/NSE)	193	13			
MDUFA IV Decision Within 90 FDA Days	193	13			
510(k)s Pending MDUFA IV Decision	50	44			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	694	156			
Closed Before RTA Action	3	0			
Number Accepted	262	44			
Number Without a RTA and > 15 Days Since Date Received	3	2			
Number Without a RTA and <= 15 Days Since Date Received	0	21			
Number Not Accepted	426	89			
Rate of Submissions Not Accepted for Review	61.65%	65.93%			

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	559	62			
Deleted or Withdrawn Prior to SI	0	1			
SI Within 60 FDA Days	527	19			
SI Over 60 FDA Days	13	0			
SI Pending Within 60 FDA Days	19	41			
SI Pending Over 60 FDA Days	0	1			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.59%	95.00%			

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	540	19			
Average Number of FDA Days to Substantive Interaction	55.24	47.32			
20th Percentile FDA Days to Substantive Interaction	53	29			
40th Percentile FDA Days to Substantive Interaction	57	51			
60th Percentile FDA Days to Substantive Interaction	59	58			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	78	60			

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	559	62			
Non-MDUFA IV Decision	40	1			
MDUFA IV Decision (SE/NSE)	339	5			
MDUFA IV Decision Within 90 FDA Days	338	5			
510(k)s Pending MDUFA IV Decision	180	56			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.71%	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	1.69	1.20			
Number With MDUFA IV Decision	339	5			
Average Number of FDA Days to MDUFA IV Decision	80.24	34.60			
20th Percentile FDA Days to MDUFA IV Decision	75	28			
40th Percentile FDA Days to MDUFA IV Decision	85	29			
60th Percentile FDA Days to MDUFA IV Decision	88	35			
80th Percentile FDA Days to MDUFA IV Decision	90	44			
Maximum FDA Days to MDUFA IV Decision	92	46			
Average Number of Industry Days to MDUFA IV Decision	52.31	2.60			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	18	0			
60th Percentile Industry Days to MDUFA IV Decision	48	0			
80th Percentile Industry Days to MDUFA IV Decision	101	3			
Maximum Industry Days to MDUFA IV Decision	214	13			
Average Number of Total Days to MDUFA IV Decision	132.55	37.20			
20th Percentile Total Days to MDUFA IV Decision	82	28			
40th Percentile Total Days to MDUFA IV Decision	102	29			
60th Percentile Total Days to MDUFA IV Decision	133	36			
80th Percentile Total Days to MDUFA IV Decision	187	48			
Maximum Total Days to MDUFA IV Decision	304	56			

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	559	62			
Number With MDUFA IV Decision	339	5			
Number of SE Decision	327	5			
Number of NSE Decision	12	0			
Number of Withdrawal	24	1			
Number of Deleted	16	0			
Rate of SE Decision	96.46%	100%			
Rate of NSE Decision	3.54%	0%			
Rate of Withdrawal	4.29%	1.61%			
Rate of Deleted	2.86%	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	1	0			
Mean FDA Days for Submissions that Missed the Goal	92.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	95.00	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	357	103			
Closed Before RTA Action	4	0			
Number Accepted	237	55			
Number Without a RTA and > 15 Days Since Date Received	2	4			
Number Without a RTA and <= 15 Days Since Date Received	0	23			
Number Not Accepted	114	21			
Rate of Submissions Not Accepted for Review	32.29%	26.25%			

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	335	70			
Deleted or Withdrawn Prior to SI	4	0			
SI Within 60 FDA Days	312	29			
SI Over 60 FDA Days	13	1			
SI Pending Within 60 FDA Days	6	40			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.00%	96.67%			

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	325	30			
Average Number of FDA Days to Substantive Interaction	49.43	40.27			
20th Percentile FDA Days to Substantive Interaction	30	27			
40th Percentile FDA Days to Substantive Interaction	53	29			
60th Percentile FDA Days to Substantive Interaction	58	49			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	83	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	335	70			
Non-MDUFA IV Decision	19	0			
MDUFA IV Decision (SE/NSE)	242	16			
MDUFA IV Decision Within 90 FDA Days	238	16			
510(k)s Pending MDUFA IV Decision	74	54			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	98.35%	100%			

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	1.61	1.06			
Number With MDUFA IV Decision	242	16			
Average Number of FDA Days to MDUFA IV Decision	67.49	33.19			
20th Percentile FDA Days to MDUFA IV Decision	30	23			
40th Percentile FDA Days to MDUFA IV Decision	61	28			
60th Percentile FDA Days to MDUFA IV Decision	86	29			
80th Percentile FDA Days to MDUFA IV Decision	89	49			
Maximum FDA Days to MDUFA IV Decision	159	60			
Average Number of Industry Days to MDUFA IV Decision	46.42	0.94			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	38	0			
80th Percentile Industry Days to MDUFA IV Decision	101	0			
Maximum Industry Days to MDUFA IV Decision	245	15			
Average Number of Total Days to MDUFA IV Decision	113.91	34.13			
20th Percentile Total Days to MDUFA IV Decision	30	23			
40th Percentile Total Days to MDUFA IV Decision	81	28			
60th Percentile Total Days to MDUFA IV Decision	121	29			
80th Percentile Total Days to MDUFA IV Decision	187	55			
Maximum Total Days to MDUFA IV Decision	332	60			

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	335	70			
Number With MDUFA IV Decision	242	16			
Number of SE Decision	233	16			
Number of NSE Decision	9	0			
Number of Withdrawal	12	0			
Number of Deleted	5	0			
Rate of SE Decision	96.28%	100%			
Rate of NSE Decision	3.72%	0%			
Rate of Withdrawal	3.58%	0%			
Rate of Deleted	1.49%	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	4	0			
Mean FDA Days for Submissions that Missed the Goal	112.75	0.00			
Mean Industry Days for Submissions that Missed the Goal	114.50	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	259	65			
Closed Before RTA Action	3	0			
Number Accepted	146	32			
Number Without a RTA and > 15 Days Since Date Received	3	0			
Number Without a RTA and <= 15 Days Since Date Received	0	12			
Number Not Accepted	107	21			
Rate of Submissions Not Accepted for Review	41.80%	39.62%			

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	218	43			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	202	12			
SI Over 60 FDA Days	4	0			
SI Pending Within 60 FDA Days	12	31			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	98.06%	100%			

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	206	12			
Average Number of FDA Days to Substantive Interaction	53.49	41.92			
20th Percentile FDA Days to Substantive Interaction	52	28			
40th Percentile FDA Days to Substantive Interaction	58	30			
60th Percentile FDA Days to Substantive Interaction	60	50			
80th Percentile FDA Days to Substantive Interaction	60	57			
Maximum FDA Days to Substantive Interaction	86	60			

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	218	43			
Non-MDUFA IV Decision	14	0			
MDUFA IV Decision (SE/NSE)	153	4			
MDUFA IV Decision Within 90 FDA Days	149	4			
510(k)s Pending MDUFA IV Decision	51	39			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	97.39%	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	1.46	1.00			
Number With MDUFA IV Decision	153	4			
Average Number of FDA Days to MDUFA IV Decision	73.71	28.75			
20th Percentile FDA Days to MDUFA IV Decision	56	28			
40th Percentile FDA Days to MDUFA IV Decision	83	28			
60th Percentile FDA Days to MDUFA IV Decision	88	29			
80th Percentile FDA Days to MDUFA IV Decision	90	29			
Maximum FDA Days to MDUFA IV Decision	170	30			
Average Number of Industry Days to MDUFA IV Decision	27.86	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	19	0			
80th Percentile Industry Days to MDUFA IV Decision	53	0			
Maximum Industry Days to MDUFA IV Decision	180	0			
Average Number of Total Days to MDUFA IV Decision	101.57	28.75			
20th Percentile Total Days to MDUFA IV Decision	57	28			
40th Percentile Total Days to MDUFA IV Decision	87	28			
60th Percentile Total Days to MDUFA IV Decision	106	29			
80th Percentile Total Days to MDUFA IV Decision	140	29			
Maximum Total Days to MDUFA IV Decision	346	30			

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	218	43			
Number With MDUFA IV Decision	153	4			
Number of SE Decision	146	4			
Number of NSE Decision	7	0			
Number of Withdrawal	8	0			
Number of Deleted	3	0			
Rate of SE Decision	95.42%	100%			
Rate of NSE Decision	4.58%	0%			
Rate of Withdrawal	3.67%	0%			
Rate of Deleted	1.38%	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	4	0			
Mean FDA Days for Submissions that Missed the Goal	113.75	0.00			
Mean Industry Days for Submissions that Missed the Goal	100.75	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	606	149			
Closed Before RTA Action	2	2			
Number Accepted	466	107			
Number Without a RTA and > 15 Days Since Date Received	0	3			
Number Without a RTA and <= 15 Days Since Date Received	0	14			
Number Not Accepted	138	23			
Rate of Submissions Not Accepted for Review	22.85%	17.29%			

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	587	115			
Deleted or Withdrawn Prior to SI	0	1			
SI Within 60 FDA Days	564	57			
SI Over 60 FDA Days	19	0			
SI Pending Within 60 FDA Days	4	57			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	96.74%	100%			

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	583	57			
Average Number of FDA Days to Substantive Interaction	50.27	43.12			
20th Percentile FDA Days to Substantive Interaction	38	29			
40th Percentile FDA Days to Substantive Interaction	55	42			
60th Percentile FDA Days to Substantive Interaction	57	54			
80th Percentile FDA Days to Substantive Interaction	59	57			
Maximum FDA Days to Substantive Interaction	78	60			

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	587	115			
Non-MDUFA IV Decision	20	1			
MDUFA IV Decision (SE/NSE)	465	17			
MDUFA IV Decision Within 90 FDA Days	465	17			
510(k)s Pending MDUFA IV Decision	102	97			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 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	1.59	1.24			
Number With MDUFA IV Decision	465	17			
Average Number of FDA Days to MDUFA IV Decision	68.39	33.00			
20th Percentile FDA Days to MDUFA IV Decision	49	26			
40th Percentile FDA Days to MDUFA IV Decision	63	29			
60th Percentile FDA Days to MDUFA IV Decision	85	31			
80th Percentile FDA Days to MDUFA IV Decision	88	46			
Maximum FDA Days to MDUFA IV Decision	90	72			
Average Number of Industry Days to MDUFA IV Decision	32.87	2.18			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	21	0			
80th Percentile Industry Days to MDUFA IV Decision	58	2			
Maximum Industry Days to MDUFA IV Decision	182	16			
Average Number of Total Days to MDUFA IV Decision	101.26	35.18			
20th Percentile Total Days to MDUFA IV Decision	53	28			
40th Percentile Total Days to MDUFA IV Decision	81	29			
60th Percentile Total Days to MDUFA IV Decision	98	36			
80th Percentile Total Days to MDUFA IV Decision	140	48			
Maximum Total Days to MDUFA IV Decision	272	72			

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	587	115			
Number With MDUFA IV Decision	465	17			
Number of SE Decision	460	17			
Number of NSE Decision	5	0			
Number of Withdrawal	14	1			
Number of Deleted	6	0			
Rate of SE Decision	98.92%	100%			
Rate of NSE Decision	1.08%	0%			
Rate of Withdrawal	2.39%	0.87%			
Rate of Deleted	1.02%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	140	31			
Closed Before RTA Action	0	0			
Number Accepted	112	23			
Number Without a RTA and > 15 Days Since Date Received	0	1			
Number Without a RTA and <= 15 Days Since Date Received	0	4			
Number Not Accepted	28	3			
Rate of Submissions Not Accepted for Review	20.00%	11.11%			

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	136	24			
Deleted or Withdrawn Prior to SI	2	1			
SI Within 60 FDA Days	132	13			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	1	10			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	99.25%	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	132	13			
Average Number of FDA Days to Substantive Interaction	51.77	45.85			
20th Percentile FDA Days to Substantive Interaction	48	38			
40th Percentile FDA Days to Substantive Interaction	53	50			
60th Percentile FDA Days to Substantive Interaction	57	52			
80th Percentile FDA Days to Substantive Interaction	59	56			
Maximum FDA Days to Substantive Interaction	60	58			

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	136	24			
Non-MDUFA IV Decision	7	1			
MDUFA IV Decision (SE/NSE)	103	3			
MDUFA IV Decision Within 90 FDA Days	103	3			
510(k)s Pending MDUFA IV Decision	26	20			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.36	1.00			
Number With MDUFA IV Decision	103	3			
Average Number of FDA Days to MDUFA IV Decision	68.05	62.00			
20th Percentile FDA Days to MDUFA IV Decision	50	52			
40th Percentile FDA Days to MDUFA IV Decision	59	55			
60th Percentile FDA Days to MDUFA IV Decision	83	61			
80th Percentile FDA Days to MDUFA IV Decision	88	71			
Maximum FDA Days to MDUFA IV Decision	90	81			
Average Number of Industry Days to MDUFA IV Decision	24.12	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	48	0			
Maximum Industry Days to MDUFA IV Decision	179	0			
Average Number of Total Days to MDUFA IV Decision	92.17	62.00			
20th Percentile Total Days to MDUFA IV Decision	50	52			
40th Percentile Total Days to MDUFA IV Decision	60	55			
60th Percentile Total Days to MDUFA IV Decision	88	61			
80th Percentile Total Days to MDUFA IV Decision	133	71			
Maximum Total Days to MDUFA IV Decision	266	81			

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	136	24			
Number With MDUFA IV Decision	103	3			
Number of SE Decision	101	3			
Number of NSE Decision	2	0			
Number of Withdrawal	6	1			
Number of Deleted	1	0			
Rate of SE Decision	98.06%	100%			
Rate of NSE Decision	1.94%	0%			
Rate of Withdrawal	4.41%	4.17%			
Rate of Deleted	0.74%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	309	83			
Closed Before RTA Action	1	2			
Number Accepted	250	49			
Number Without a RTA and > 15 Days Since Date Received	0	2			
Number Without a RTA and <= 15 Days Since Date Received	0	15			
Number Not Accepted	58	15			
Rate of Submissions Not Accepted for Review	18.83%	22.73%			

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	295	56			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	287	27			
SI Over 60 FDA Days	3	0			
SI Pending Within 60 FDA Days	2	29			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	3	0			
Current SI Performance Percent Within 60 FDA Days	97.95%	100%			

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	290	27			
Average Number of FDA Days to Substantive Interaction	49.76	48.59			
20th Percentile FDA Days to Substantive Interaction	42	43			
40th Percentile FDA Days to Substantive Interaction	51	49			
60th Percentile FDA Days to Substantive Interaction	58	55			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	64	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	295	56			
Non-MDUFA IV Decision	18	0			
MDUFA IV Decision (SE/NSE)	224	3			
MDUFA IV Decision Within 90 FDA Days	223	3			
510(k)s Pending MDUFA IV Decision	53	53			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.55%	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	1.61	1.00			
Number With MDUFA IV Decision	224	3			
Average Number of FDA Days to MDUFA IV Decision	70.50	22.00			
20th Percentile FDA Days to MDUFA IV Decision	54	19			
40th Percentile FDA Days to MDUFA IV Decision	73	20			
60th Percentile FDA Days to MDUFA IV Decision	87	22			
80th Percentile FDA Days to MDUFA IV Decision	89	25			
Maximum FDA Days to MDUFA IV Decision	92	27			
Average Number of Industry Days to MDUFA IV Decision	53.16	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	6	0			
60th Percentile Industry Days to MDUFA IV Decision	42	0			
80th Percentile Industry Days to MDUFA IV Decision	122	0			
Maximum Industry Days to MDUFA IV Decision	182	0			
Average Number of Total Days to MDUFA IV Decision	123.66	22.00			
20th Percentile Total Days to MDUFA IV Decision	57	19			
40th Percentile Total Days to MDUFA IV Decision	90	20			
60th Percentile Total Days to MDUFA IV Decision	128	22			
80th Percentile Total Days to MDUFA IV Decision	209	25			
Maximum Total Days to MDUFA IV Decision	271	27			

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	295	56			
Number With MDUFA IV Decision	224	3			
Number of SE Decision	209	3			
Number of NSE Decision	15	0			
Number of Withdrawal	9	0			
Number of Deleted	9	0			
Rate of SE Decision	93.30%	100%			
Rate of NSE Decision	6.70%	0%			
Rate of Withdrawal	3.05%	0%			
Rate of Deleted	3.05%	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	1	0			
Mean FDA Days for Submissions that Missed the Goal	92.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	35.00	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	417	103			
Closed Before RTA Action	2	0			
Number Accepted	288	57			
Number Without a RTA and > 15 Days Since Date Received	5	1			
Number Without a RTA and <= 15 Days Since Date Received	0	21			
Number Not Accepted	122	24			
Rate of Submissions Not Accepted for Review	29.40%	29.27%			

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	378	65			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	368	24			
SI Over 60 FDA Days	4	0			
SI Pending Within 60 FDA Days	6	41			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	98.92%	100%			

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	372	24			
Average Number of FDA Days to Substantive Interaction	52.01	48.04			
20th Percentile FDA Days to Substantive Interaction	48	32			
40th Percentile FDA Days to Substantive Interaction	57	50			
60th Percentile FDA Days to Substantive Interaction	58	58			
80th Percentile FDA Days to Substantive Interaction	60	58			
Maximum FDA Days to Substantive Interaction	69	60			

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	378	65			
Non-MDUFA IV Decision	27	0			
MDUFA IV Decision (SE/NSE)	283	12			
MDUFA IV Decision Within 90 FDA Days	281	12			
510(k)s Pending MDUFA IV Decision	68	53			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	99.29%	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	1.42	1.00			
Number With MDUFA IV Decision	283	12			
Average Number of FDA Days to MDUFA IV Decision	69.39	39.83			
20th Percentile FDA Days to MDUFA IV Decision	46	28			
40th Percentile FDA Days to MDUFA IV Decision	72	31			
60th Percentile FDA Days to MDUFA IV Decision	86	43			
80th Percentile FDA Days to MDUFA IV Decision	89	55			
Maximum FDA Days to MDUFA IV Decision	163	65			
Average Number of Industry Days to MDUFA IV Decision	28.53	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	7	0			
80th Percentile Industry Days to MDUFA IV Decision	52	0			
Maximum Industry Days to MDUFA IV Decision	200	0			
Average Number of Total Days to MDUFA IV Decision	97.91	39.83			
20th Percentile Total Days to MDUFA IV Decision	51	28			
40th Percentile Total Days to MDUFA IV Decision	78	31			
60th Percentile Total Days to MDUFA IV Decision	90	43			
80th Percentile Total Days to MDUFA IV Decision	137	55			
Maximum Total Days to MDUFA IV Decision	290	65			

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	378	65			
Number With MDUFA IV Decision	283	12			
Number of SE Decision	276	12			
Number of NSE Decision	7	0			
Number of Withdrawal	14	0			
Number of Deleted	12	0			
Rate of SE Decision	97.53%	100%			
Rate of NSE Decision	2.47%	0%			
Rate of Withdrawal	3.70%	0%			
Rate of Deleted	3.17%	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	2	0			
Mean FDA Days for Submissions that Missed the Goal	127.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	30.00	0.00			

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	142	31			
Closed Before RTA Action	3	0			
Number Accepted	109	16			
Number Without a RTA and > 15 Days Since Date Received	1	1			
Number Without a RTA and <= 15 Days Since Date Received	0	10			
Number Not Accepted	29	4			
Rate of Submissions Not Accepted for Review	20.86%	19.05%			

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	129	19			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	128	8			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	11			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	1	0			
Current SI Performance Percent Within 60 FDA Days	99.22%	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	128	8			
Average Number of FDA Days to Substantive Interaction	49.82	45.00			
20th Percentile FDA Days to Substantive Interaction	44	29			
40th Percentile FDA Days to Substantive Interaction	51	43			
60th Percentile FDA Days to Substantive Interaction	56	51			
80th Percentile FDA Days to Substantive Interaction	59	60			
Maximum FDA Days to Substantive Interaction	60	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	129	19			
Non-MDUFA IV Decision	19	0			
MDUFA IV Decision (SE/NSE)	82	4			
MDUFA IV Decision Within 90 FDA Days	82	4			
510(k)s Pending MDUFA IV Decision	28	15			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.61	1.00			
Number With MDUFA IV Decision	82	4			
Average Number of FDA Days to MDUFA IV Decision	71.10	41.50			
20th Percentile FDA Days to MDUFA IV Decision	55	28			
40th Percentile FDA Days to MDUFA IV Decision	79	29			
60th Percentile FDA Days to MDUFA IV Decision	88	30			
80th Percentile FDA Days to MDUFA IV Decision	90	50			
Maximum FDA Days to MDUFA IV Decision	90	81			
Average Number of Industry Days to MDUFA IV Decision	61.99	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	50	0			
80th Percentile Industry Days to MDUFA IV Decision	151	0			
Maximum Industry Days to MDUFA IV Decision	231	0			
Average Number of Total Days to MDUFA IV Decision	133.09	41.50			
20th Percentile Total Days to MDUFA IV Decision	55	28			
40th Percentile Total Days to MDUFA IV Decision	90	29			
60th Percentile Total Days to MDUFA IV Decision	137	30			
80th Percentile Total Days to MDUFA IV Decision	236	50			
Maximum Total Days to MDUFA IV Decision	321	81			

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	129	19			
Number With MDUFA IV Decision	82	4			
Number of SE Decision	79	4			
Number of NSE Decision	3	0			
Number of Withdrawal	14	0			
Number of Deleted	4	0			
Rate of SE Decision	96.34%	100%			
Rate of NSE Decision	3.66%	0%			
Rate of Withdrawal	10.85%	0%			
Rate of Deleted	3.10%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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

Table 6.9 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	129	18			
Non-MDUFA IV Decision	19	0			
MDUFA IV Decision (SE/NSE)	82	4			
MDUFA IV Decision Within 90 FDA Days	82	4			
510(k)s Pending MDUFA IV Decision	28	14			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	50	18			
Closed Before RTA Action	0	0			
Number Accepted	43	10			
Number Without a RTA and > 15 Days Since Date Received	0	1			
Number Without a RTA and <= 15 Days Since Date Received	0	4			
Number Not Accepted	7	3			
Rate of Submissions Not Accepted for Review	14.00%	21.43%			

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	46	12			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	44	3			
SI Over 60 FDA Days	1	0			
SI Pending Within 60 FDA Days	0	9			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	97.78%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	45	3			
Average Number of FDA Days to Substantive Interaction	52.67	42.67			
20th Percentile FDA Days to Substantive Interaction	48	33			
40th Percentile FDA Days to Substantive Interaction	57	38			
60th Percentile FDA Days to Substantive Interaction	59	44			
80th Percentile FDA Days to Substantive Interaction	60	52			
Maximum FDA Days to Substantive Interaction	61	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	46	12			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	32	1			
MDUFA IV Decision Within 90 FDA Days	32	1			
510(k)s Pending MDUFA IV Decision	13	11			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

Table 6.5 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	1.38	1.00			
Number With MDUFA IV Decision	32	1			
Average Number of FDA Days to MDUFA IV Decision	73.22	52.00			
20th Percentile FDA Days to MDUFA IV Decision	40	52			
40th Percentile FDA Days to MDUFA IV Decision	84	52			
60th Percentile FDA Days to MDUFA IV Decision	90	52			
80th Percentile FDA Days to MDUFA IV Decision	90	52			
Maximum FDA Days to MDUFA IV Decision	90	52			
Average Number of Industry Days to MDUFA IV Decision	44.75	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	99	0			
Maximum Industry Days to MDUFA IV Decision	179	0			
Average Number of Total Days to MDUFA IV Decision	117.97	52.00			
20th Percentile Total Days to MDUFA IV Decision	40	52			
40th Percentile Total Days to MDUFA IV Decision	88	52			
60th Percentile Total Days to MDUFA IV Decision	90	52			
80th Percentile Total Days to MDUFA IV Decision	188	52			
Maximum Total Days to MDUFA IV Decision	269	52			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	46	12			
Number With MDUFA IV Decision	32	1			
Number of SE Decision	31	1			
Number of NSE Decision	1	0			
Number of Withdrawal	1	0			
Number of Deleted	0	0			
Rate of SE Decision	96.88%	100%			
Rate of NSE Decision	3.13%	0%			
Rate of Withdrawal	2.17%	0%			
Rate of Deleted	0%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	46	12			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	32	1			
MDUFA IV Decision Within 90 FDA Days	32	1			
510(k)s Pending MDUFA IV Decision	13	11			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	89	25			
Closed Before RTA Action	0	0			
Number Accepted	86	22			
Number Without a RTA and > 15 Days Since Date Received	0	1			
Number Without a RTA and <= 15 Days Since Date Received	0	2			
Number Not Accepted	3	0			
Rate of Submissions Not Accepted for Review	3.37%	0%			

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	87	23			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	87	8			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	15			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	87	8			
Average Number of FDA Days to Substantive Interaction	50.67	39.00			
20th Percentile FDA Days to Substantive Interaction	41	28			
40th Percentile FDA Days to Substantive Interaction	57	29			
60th Percentile FDA Days to Substantive Interaction	58	44			
80th Percentile FDA Days to Substantive Interaction	59	56			
Maximum FDA Days to Substantive Interaction	60	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	87	23			
Non-MDUFA IV Decision	4	0			
MDUFA IV Decision (SE/NSE)	77	6			
MDUFA IV Decision Within 90 FDA Days	77	6			
510(k)s Pending MDUFA IV Decision	6	17			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.19	1.00			
Number With MDUFA IV Decision	77	6			
Average Number of FDA Days to MDUFA IV Decision	68.57	40.33			
20th Percentile FDA Days to MDUFA IV Decision	37	28			
40th Percentile FDA Days to MDUFA IV Decision	73	29			
60th Percentile FDA Days to MDUFA IV Decision	87	41			
80th Percentile FDA Days to MDUFA IV Decision	89	56			
Maximum FDA Days to MDUFA IV Decision	90	60			
Average Number of Industry Days to MDUFA IV Decision	19.47	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	180	0			
Average Number of Total Days to MDUFA IV Decision	88.04	40.33			
20th Percentile Total Days to MDUFA IV Decision	41	28			
40th Percentile Total Days to MDUFA IV Decision	74	29			
60th Percentile Total Days to MDUFA IV Decision	88	41			
80th Percentile Total Days to MDUFA IV Decision	90	56			
Maximum Total Days to MDUFA IV Decision	270	60			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	87	23			
Number With MDUFA IV Decision	77	6			
Number of SE Decision	77	6			
Number of NSE Decision	0	0			
Number of Withdrawal	2	0			
Number of Deleted	2	0			
Rate of SE Decision	100%	100%			
Rate of NSE Decision	0%	0%			
Rate of Withdrawal	2.30%	0%			
Rate of Deleted	2.30%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	86	23			
Non-MDUFA IV Decision	4	0			
MDUFA IV Decision (SE/NSE)	76	6			
MDUFA IV Decision Within 90 FDA Days	76	6			
510(k)s Pending MDUFA IV Decision	6	17			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	4			
Closed Before RTA Action	0	0			
Number Accepted	6	4			
Number Without a RTA and > 15 Days Since Date Received	0	0			
Number Without a RTA and <= 15 Days Since Date Received	0	0			
Number Not Accepted	2	0			
Rate of Submissions Not Accepted for Review	25.00%	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	7	4			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	7	3			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	0	1			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

Table 6.3 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	7	3			
Average Number of FDA Days to Substantive Interaction	50.00	38.67			
20th Percentile FDA Days to Substantive Interaction	42	29			
40th Percentile FDA Days to Substantive Interaction	55	30			
60th Percentile FDA Days to Substantive Interaction	58	36			
80th Percentile FDA Days to Substantive Interaction	59	47			
Maximum FDA Days to Substantive Interaction	59	58			

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	7	4			
Non-MDUFA IV Decision	1	0			
MDUFA IV Decision (SE/NSE)	3	2			
MDUFA IV Decision Within 90 FDA Days	3	2			
510(k)s Pending MDUFA IV Decision	3	2			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.67	1.00			
Number With MDUFA IV Decision	3	2			
Average Number of FDA Days to MDUFA IV Decision	49.33	29.00			
20th Percentile FDA Days to MDUFA IV Decision	42	28			
40th Percentile FDA Days to MDUFA IV Decision	45	29			
60th Percentile FDA Days to MDUFA IV Decision	50	29			
80th Percentile FDA Days to MDUFA IV Decision	56	30			
Maximum FDA Days to MDUFA IV Decision	62	30			
Average Number of Industry Days to MDUFA IV Decision	16.33	0.00			
20th Percentile Industry Days to MDUFA IV Decision	4	0			
40th Percentile Industry Days to MDUFA IV Decision	7	0			
60th Percentile Industry Days to MDUFA IV Decision	15	0			
80th Percentile Industry Days to MDUFA IV Decision	28	0			
Maximum Industry Days to MDUFA IV Decision	40	0			
Average Number of Total Days to MDUFA IV Decision	65.67	29.00			
20th Percentile Total Days to MDUFA IV Decision	52	28			
40th Percentile Total Days to MDUFA IV Decision	65	29			
60th Percentile Total Days to MDUFA IV Decision	74	29			
80th Percentile Total Days to MDUFA IV Decision	81	30			
Maximum Total Days to MDUFA IV Decision	87	30			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	7	4			
Number With MDUFA IV Decision	3	2			
Number of SE Decision	2	2			
Number of NSE Decision	1	0			
Number of Withdrawal	0	0			
Number of Deleted	1	0			
Rate of SE Decision	66.67%	100%			
Rate of NSE Decision	33.33%	0%			
Rate of Withdrawal	0%	0%			
Rate of Deleted	14.29%	0%			

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	6	4			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	3	2			
MDUFA IV Decision Within 90 FDA Days	3	2			
510(k)s Pending MDUFA IV Decision	3	2			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	392	118			
Closed Before RTA Action	0	1			
Number Accepted	348	86			
Number Without a RTA and > 15 Days Since Date Received	1	0			
Number Without a RTA and <= 15 Days Since Date Received	0	12			
Number Not Accepted	43	19			
Rate of Submissions Not Accepted for Review	10.97%	18.10%			

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible For SI	385	89			
Deleted or Withdrawn Prior to SI	1	0			
SI Within 60 FDA Days	380	41			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	4	48			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	380	41			
Average Number of FDA Days to Substantive Interaction	43.55	40.61			
20th Percentile FDA Days to Substantive Interaction	29	26			
40th Percentile FDA Days to Substantive Interaction	42	35			
60th Percentile FDA Days to Substantive Interaction	52	50			
80th Percentile FDA Days to Substantive Interaction	57	55			
Maximum FDA Days to Substantive Interaction	60	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	385	89			
Non-MDUFA IV Decision	10	0			
MDUFA IV Decision (SE/NSE)	342	19			
MDUFA IV Decision Within 90 FDA Days	342	19			
510(k)s Pending MDUFA IV Decision	33	70			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.46	1.16			
Number With MDUFA IV Decision	342	19			
Average Number of FDA Days to MDUFA IV Decision	57.14	32.21			
20th Percentile FDA Days to MDUFA IV Decision	29	16			
40th Percentile FDA Days to MDUFA IV Decision	53	25			
60th Percentile FDA Days to MDUFA IV Decision	71	33			
80th Percentile FDA Days to MDUFA IV Decision	84	52			
Maximum FDA Days to MDUFA IV Decision	90	67			
Average Number of Industry Days to MDUFA IV Decision	27.18	2.37			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	13	0			
80th Percentile Industry Days to MDUFA IV Decision	49	0			
Maximum Industry Days to MDUFA IV Decision	181	20			
Average Number of Total Days to MDUFA IV Decision	84.32	34.58			
20th Percentile Total Days to MDUFA IV Decision	29	16			
40th Percentile Total Days to MDUFA IV Decision	56	25			
60th Percentile Total Days to MDUFA IV Decision	85	33			
80th Percentile Total Days to MDUFA IV Decision	130	52			
Maximum Total Days to MDUFA IV Decision	267	79			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	385	89			
Number With MDUFA IV Decision	342	19			
Number of SE Decision	333	19			
Number of NSE Decision	9	0			
Number of Withdrawal	5	0			
Number of Deleted	4	0			
Rate of SE Decision	97.37%	100%			
Rate of NSE Decision	2.63%	0%			
Rate of Withdrawal	1.30%	0%			
Rate of Deleted	1.04%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

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

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

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

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

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

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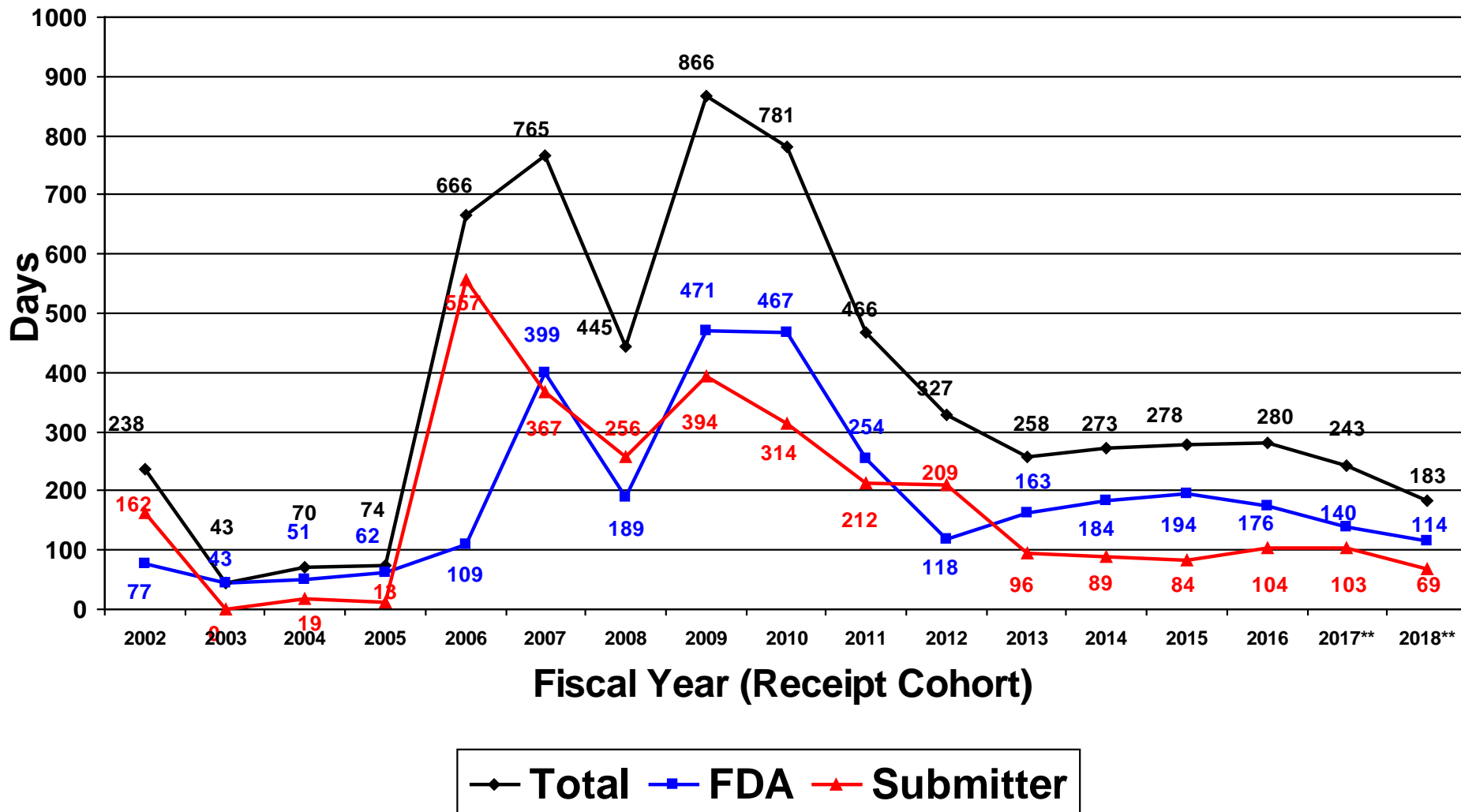
De Novos

Q1FY19

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Average Time to MDUFA Decision: De Novos*

(Receipt Cohorts as of 12/31/2018)

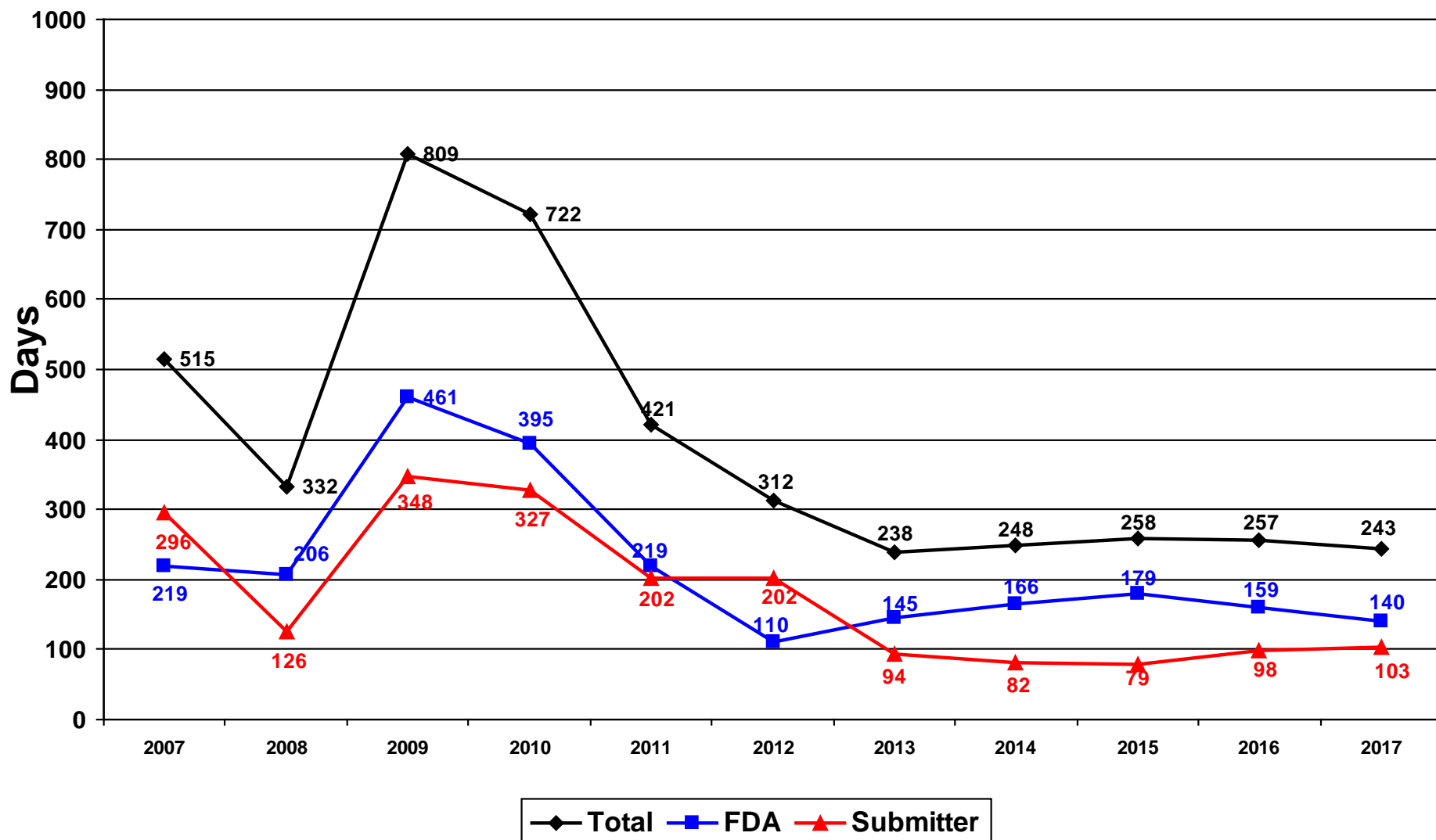


* MDUFA (Grant/Decline/Withdrawal/Deletion) decisions only; times may not add to total due to rounding

** Cohort still open; percentage of cohort closed: FY2017: 95%; FY2018: 50%

Average Time to MDUFA Decision: De Novos*

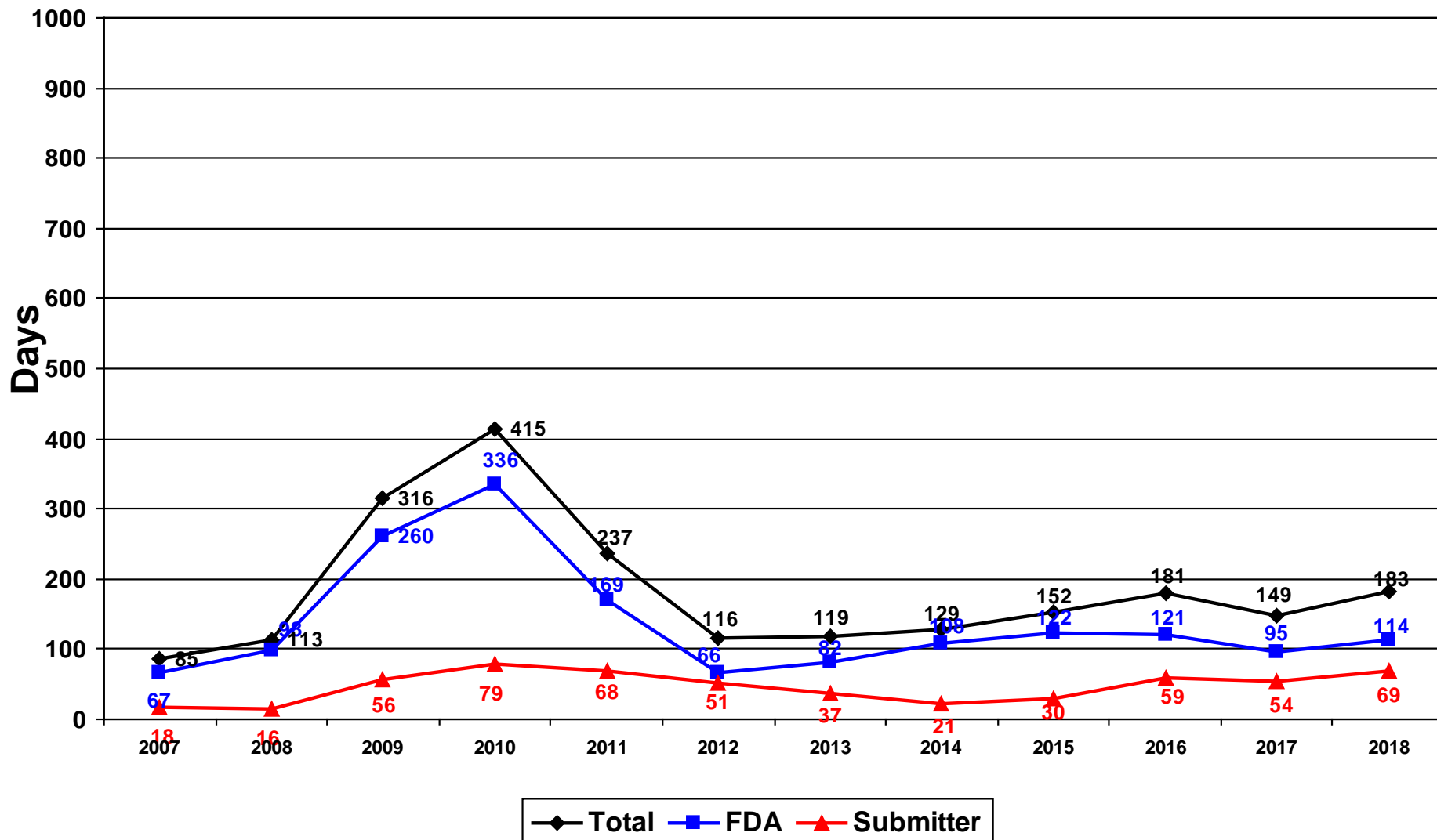
(Comparison of Cohorts at 95% Closure)



* MDUFA (Grant/Decline/Withdrawal/Deletion) decisions only; times may not add to total due to rounding. Some De Novos ultimately dropped out of the average days calculation because they received a non-MDUFA decision.

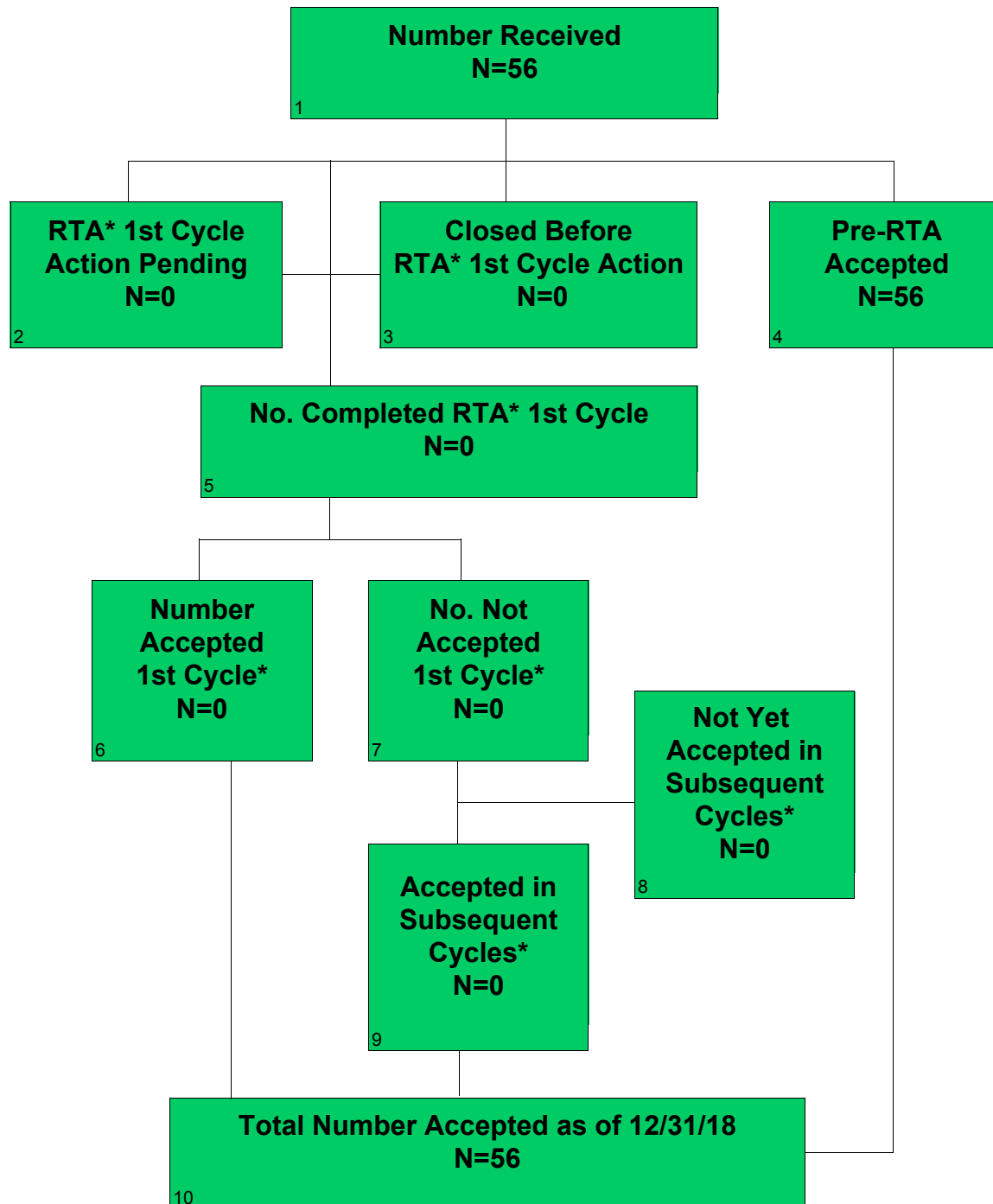
Average Time to MDUFA Decision: De Novos*

(Comparison of Cohorts at 50% Closure)



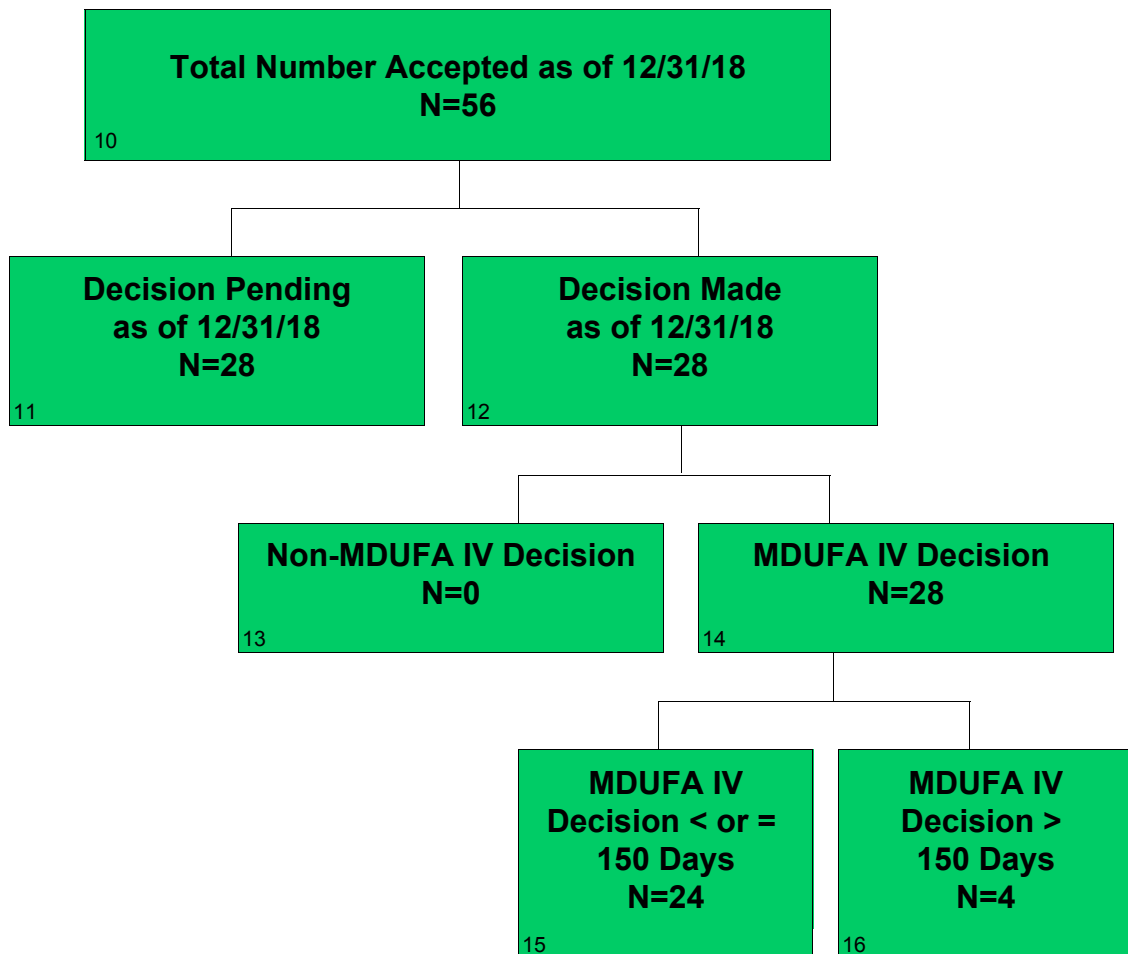
* MDUFA (Grant/Decline/Withdrawal/Deletion) decisions only; times may not add to total due to rounding. Some De Novos ultimately dropped out of the average days calculation because they received a non-MDUFA decision.

CDRH De Novo - FY 2018 as of 12/31/18

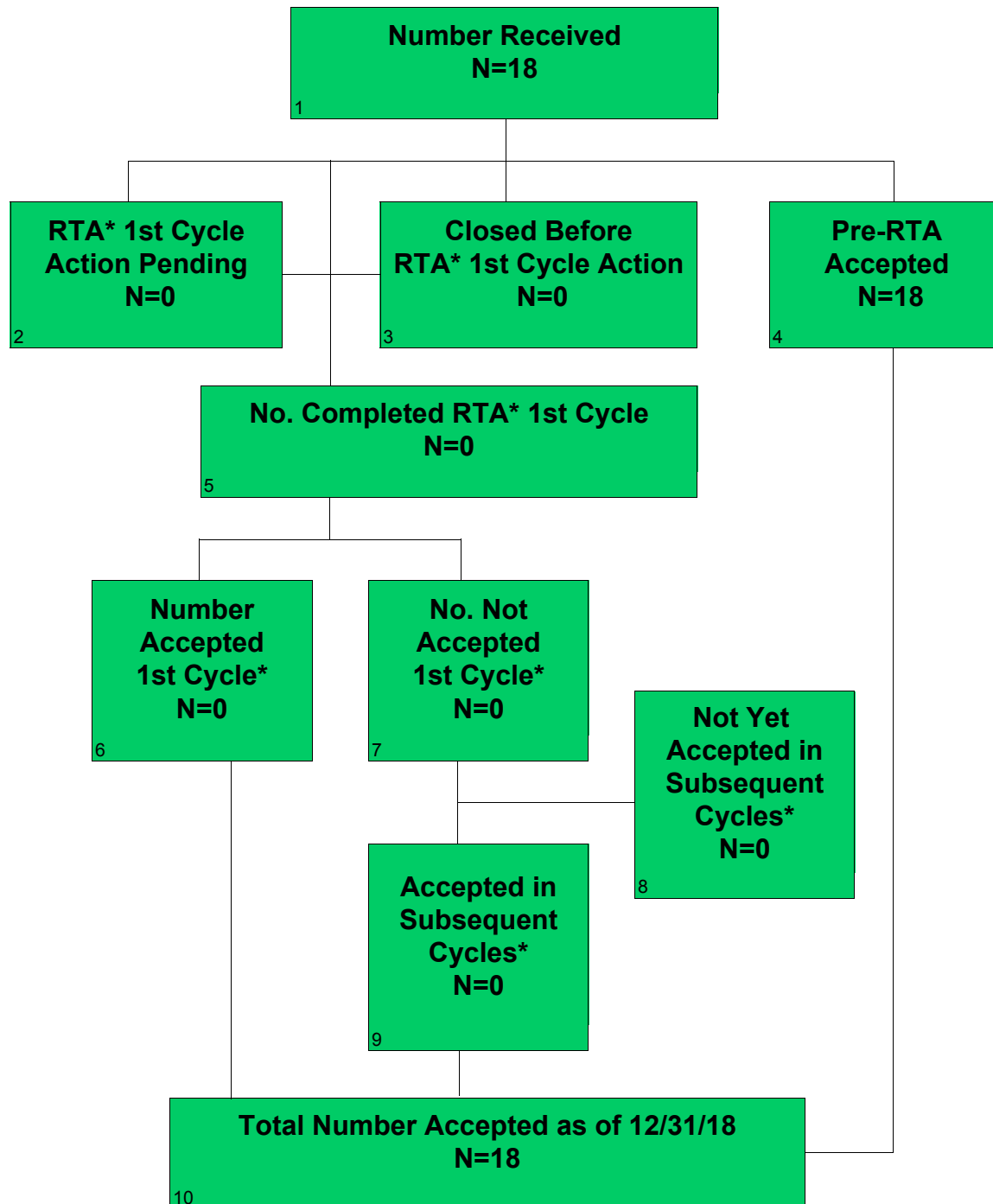


* RTA will be implemented when the guidance, including the submission checklist, is finalized.

CDRH De Novo - FY 2018 as of 12/31/18 Continued

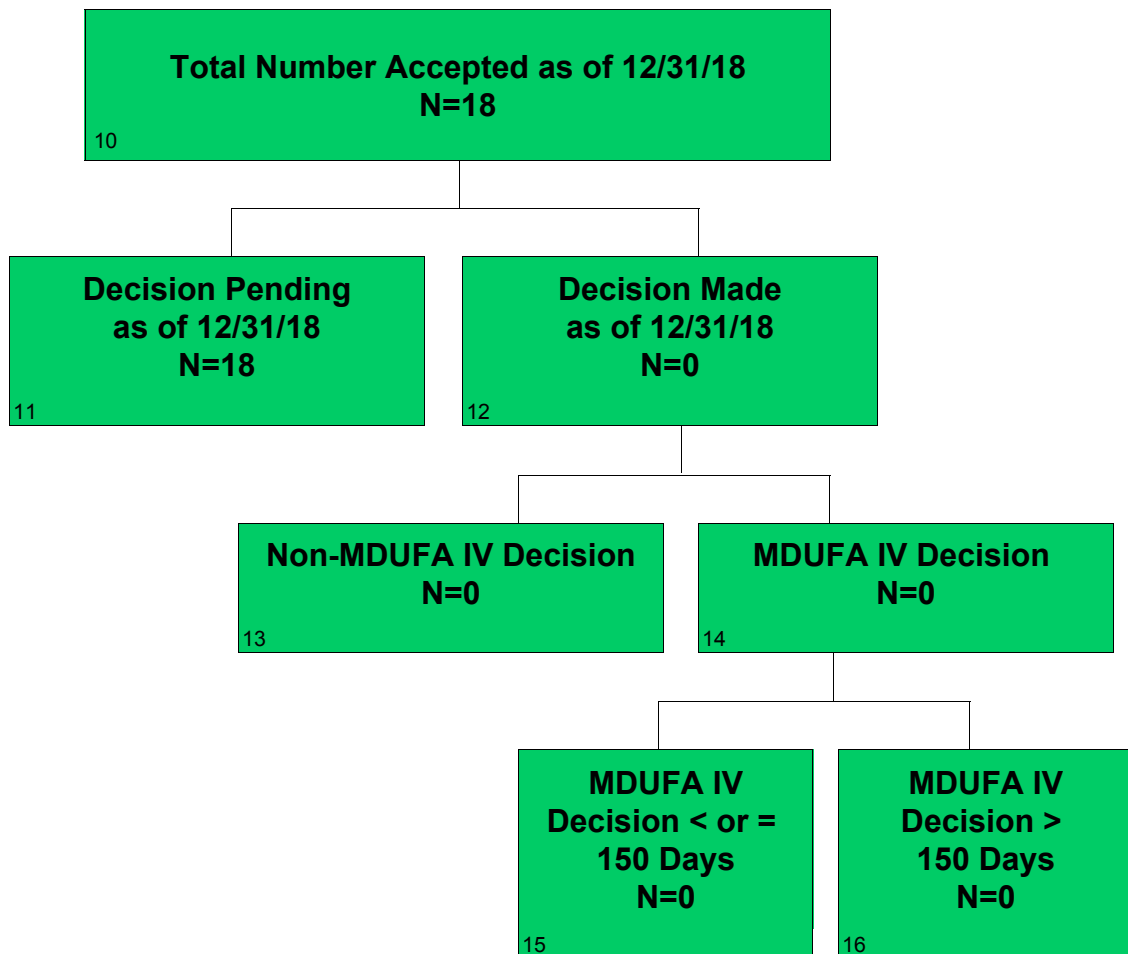


CDRH De Novo - FY 2019 as of 12/31/18



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

CDRH De Novo - FY 2019 as of 12/31/18 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	56	18			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	56	18			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	28	0			
MDUFA IV Decisions Within 150 FDA Days	24	0			
De Novos Pending MDUFA IV Decision	28	18			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	3	0			
Current Performance Percent Within 150 FDA Days	77.42%	N/A			

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	1.43	0.00			
Number With MDUFA IV Decision	28	0			
Average FDA Days to MDUFA IV Decision	114.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	62	0			
40th Percentile FDA Days to MDUFA IV Decision	109	0			
60th Percentile FDA Days to MDUFA IV Decision	147	0			
80th Percentile FDA Days to MDUFA IV Decision	150	0			
Maximum FDA Days to MDUFA IV Decision	208	0			
Average Industry Days to MDUFA IV Decision	68.75	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	64	0			
80th Percentile Industry Days to MDUFA IV Decision	165	0			
Maximum Industry Days to MDUFA IV Decision	189	0			
Average Total Days to MDUFA IV Decision	182.75	0.00			
20th Percentile Total Days to MDUFA IV Decision	72	0			
40th Percentile Total Days to MDUFA IV Decision	147	0			
60th Percentile Total Days to MDUFA IV Decision	238	0			
80th Percentile Total Days to MDUFA IV Decision	290	0			
Maximum Total Days to MDUFA IV Decision	371	0			

Table 8.4 CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	56	18			
Number With MDUFA IV Decisions	28	0			
Number With Granted Decisions	17	0			
Number With Declined Decisions	4	0			
Number of Withdrawals	5	0			
Number Deleted	2	0			
Rate of Granted Decisions	60.71%	N/A			
Rate of Declined Decisions	14.29%	N/A			
Rate of Withdrawals	17.86%	N/A			
Rate of Deleted	3.57%	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	4	0			
Mean FDA Days for Submissions that Missed the Goal	176.50	0.00			
Mean Industry Days for Submissions that Missed the Goal	135.75	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	1	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	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	15	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	8	0			
MDUFA IV Decisions Within 150 FDA Days	8	0			
De Novos Pending MDUFA IV Decision	7	5			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Section 8 - De Novo Office Level Metrics

Table 8.1 ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	39	13			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	39	13			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	18	0			
MDUFA IV Decisions Within 150 FDA Days	14	0			
De Novos Pending MDUFA IV Decision	21	13			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	3	0			
Current Performance Percent Within 150 FDA Days	66.67%	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	1.50	0.00			
Number With MDUFA IV Decision	18	0			
Average FDA Days to MDUFA IV Decision	112.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	51	0			
40th Percentile FDA Days to MDUFA IV Decision	86	0			
60th Percentile FDA Days to MDUFA IV Decision	150	0			
80th Percentile FDA Days to MDUFA IV Decision	151	0			
Maximum FDA Days to MDUFA IV Decision	208	0			
Average Industry Days to MDUFA IV Decision	60.72	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	52	0			
80th Percentile Industry Days to MDUFA IV Decision	163	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
Average Total Days to MDUFA IV Decision	172.72	0.00			
20th Percentile Total Days to MDUFA IV Decision	51	0			
40th Percentile Total Days to MDUFA IV Decision	135	0			
60th Percentile Total Days to MDUFA IV Decision	214	0			
80th Percentile Total Days to MDUFA IV Decision	296	0			
Maximum Total Days to MDUFA IV Decision	371	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	39	13			
Number With MDUFA IV Decisions	18	0			
Number With Granted Decisions	10	0			
Number With Declined Decisions	4	0			
Number of Withdrawals	3	0			
Number Deleted	1	0			
Rate of Granted Decisions	55.56%	N/A			
Rate of Declined Decisions	22.22%	N/A			
Rate of Withdrawals	16.67%	N/A			
Rate of Deleted	2.56%	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	4	0			
Mean FDA Days for Submissions That Missed the Goal	176.50	0.00			
Mean Industry Days for Submissions That Missed the Goal	135.75	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 ODE - CDRH - Conventional IV (non-LDT) De Novo MDUFA IV Decision Metrics

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

Section 8 - De Novo Office Level Metrics

Table 8.1 OIR - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	5			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

* RTA 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	17	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	10	0			
MDUFA IV Decisions Within 150 FDA Days	10	0			
De Novos Pending MDUFA IV Decision	7	5			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.30	0.00			
Number With MDUFA IV Decision	10	0			
Average FDA Days to MDUFA IV Decision	117.60	0.00			
20th Percentile FDA Days to MDUFA IV Decision	101	0			
40th Percentile FDA Days to MDUFA IV Decision	117	0			
60th Percentile FDA Days to MDUFA IV Decision	127	0			
80th Percentile FDA Days to MDUFA IV Decision	147	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
Average Industry Days to MDUFA IV Decision	83.20	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	137	0			
80th Percentile Industry Days to MDUFA IV Decision	180	0			
Maximum Industry Days to MDUFA IV Decision	189	0			
Average Total Days to MDUFA IV Decision	200.80	0.00			
20th Percentile Total Days to MDUFA IV Decision	120	0			
40th Percentile Total Days to MDUFA IV Decision	148	0			
60th Percentile Total Days to MDUFA IV Decision	242	0			
80th Percentile Total Days to MDUFA IV Decision	277	0			
Maximum Total Days to MDUFA IV Decision	312	0			

Table 8.4 OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	17	5			
Number With MDUFA IV Decisions	10	0			
Number With Granted Decisions	7	0			
Number With Declined Decisions	0	0			
Number of Withdrawals	2	0			
Number Deleted	1	0			
Rate of Granted Decisions	70.00%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	20.00%	N/A			
Rate of Deleted	5.88%	0%			

Table 8.5 OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions That Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions That Missed the Goal	0.00	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	1	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	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	15	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	8	0			
MDUFA IV Decisions Within 150 FDA Days	8	0			
De Novos Pending MDUFA IV Decision	7	5			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Section 8 - De Novo Division Level Metrics

Table 8.1 DAGRID - ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	0			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	2	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	1	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	50.00%	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	2.00	0.00			
Number with MDUFA IV Decision	2	0			
Average FDA Days to MDUFA IV Decision	172.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	159	0			
40th Percentile FDA Days to MDUFA IV Decision	168	0			
60th Percentile FDA Days to MDUFA IV Decision	176	0			
80th Percentile FDA Days to MDUFA IV Decision	185	0			
Maximum FDA Days to MDUFA IV Decision	194	0			
Average Industry Days to MDUFA IV Decision	37.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	28.6	0			
40th Percentile Industry Days to MDUFA IV Decision	34.2	0			
60th Percentile Industry Days to MDUFA IV Decision	39.8	0			
80th Percentile Industry Days to MDUFA IV Decision	45	0			
Maximum Industry Days to MDUFA IV Decision	51	0			
Average Total Days to MDUFA IV Decision	209.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	187	0			
40th Percentile Total Days to MDUFA IV Decision	202	0			
60th Percentile Total Days to MDUFA IV Decision	216	0			
80th Percentile Total Days to MDUFA IV Decision	231	0			
Maximum Total Days to MDUFA IV Decision	245	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	0			
Number with MDUFA IV Decision	2	0			
Number with Granted Decisions	2	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	100%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	194.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	51.00	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.7 DAGRID - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Met

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

Section 8 - De Novo Division Level Metrics

Table 8.1 DCD - ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	2			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

* RTA 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	5	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	3	0			
De Novos Pending MDUFA IV Decision	2	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Table 8.3 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	1.00	0.00			
Number with MDUFA IV Decision	3	0			
Average FDA Days to MDUFA IV Decision	49.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	30	0			
40th Percentile FDA Days to MDUFA IV Decision	32	0			
60th Percentile FDA Days to MDUFA IV Decision	44	0			
80th Percentile FDA Days to MDUFA IV Decision	65	0			
Maximum FDA Days to MDUFA IV Decision	86	0			
Average Industry Days to MDUFA IV Decision	60.33	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	36	0			
80th Percentile Industry Days to MDUFA IV Decision	109	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
Average Total Days to MDUFA IV Decision	109.33	0.00			
20th Percentile Total Days to MDUFA IV Decision	30	0			
40th Percentile Total Days to MDUFA IV Decision	32	0			
60th Percentile Total Days to MDUFA IV Decision	80	0			
80th Percentile Total Days to MDUFA IV Decision	173	0			
Maximum Total Days to MDUFA IV Decision	267	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	5	2			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	2	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	1	0			
Rate of Granted Decisions	66.67%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	20.00%	0%			

Table 8.5 DCD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

Section 8 - De Novo Division Level Metrics

Table 8.1 DNPMD - ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	3			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 DNPMD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	13	3			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	2	0			
De Novos Pending MDUFA IV Decision	10	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	2	0			
Current Performance Percent Within 150 FDA Days	40.00%	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	1.33	0.00			
Number with MDUFA IV Decision	3	0			
Average FDA Days to MDUFA IV Decision	103.67	0.00			
20th Percentile FDA Days to MDUFA IV Decision	51	0			
40th Percentile FDA Days to MDUFA IV Decision	52	0			
60th Percentile FDA Days to MDUFA IV Decision	84	0			
80th Percentile FDA Days to MDUFA IV Decision	146	0			
Maximum FDA Days to MDUFA IV Decision	208	0			
Average Industry Days to MDUFA IV Decision	54.33	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	33	0			
80th Percentile Industry Days to MDUFA IV Decision	98	0			
Maximum Industry Days to MDUFA IV Decision	163	0			
Average Total Days to MDUFA IV Decision	158.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	51	0			
40th Percentile Total Days to MDUFA IV Decision	52	0			
60th Percentile Total Days to MDUFA IV Decision	117	0			
80th Percentile Total Days to MDUFA IV Decision	244	0			
Maximum Total Days to MDUFA IV Decision	371	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	13	3			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	2	0			
Number Deleted	0	0			
Rate of Granted Decisions	33.33%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	66.67%	N/A			
Rate of Deleted	0%	0%			

Table 8.5 DNPMD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	208.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	163.00	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

Section 8 - De Novo Division Level Metrics

Table 8.1 DOD - ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	2			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

* RTA 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	4	2			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	4	2			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	1	0			
Current Performance Percent Within 150 FDA Days	0%	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	0.00			
Number with MDUFA IV Decision	0	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

Table 8.4 DOD - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	2			
Number with MDUFA IV Decision	0	0			
Number with Granted Decisions	0	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	N/A	N/A			
Rate of Declined Decisions	N/A	N/A			
Rate of Withdrawals	N/A	N/A			
Rate of Deleted	0%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Table 8.6 DOD - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics

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

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

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

Section 8 - De Novo Division Level Metrics

Table 8.1 DOED - ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	0			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 DOED - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	3	0			
De Novos Pending MDUFA IV Decision	2	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Table 8.3 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	1.33	0.00			
Number with MDUFA IV Decision	3	0			
Average FDA Days to MDUFA IV Decision	127.33	0.00			
20th Percentile FDA Days to MDUFA IV Decision	110	0			
40th Percentile FDA Days to MDUFA IV Decision	135	0			
60th Percentile FDA Days to MDUFA IV Decision	148	0			
80th Percentile FDA Days to MDUFA IV Decision	149	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
Average Industry Days to MDUFA IV Decision	18.67	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	11	0			
80th Percentile Industry Days to MDUFA IV Decision	34	0			
Maximum Industry Days to MDUFA IV Decision	56	0			
Average Total Days to MDUFA IV Decision	146.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	110	0			
40th Percentile Total Days to MDUFA IV Decision	135	0			
60th Percentile Total Days to MDUFA IV Decision	159	0			
80th Percentile Total Days to MDUFA IV Decision	182	0			
Maximum Total Days to MDUFA IV Decision	206	0			

Table 8.4 DOED - ODE - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	0			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	3	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	100%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	N/A			

Table 8.5 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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Table 8.6 DOED - ODE - CDRH - LDT De Novo MDUFA IV Decision Metrics

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

Table 8.7 DOED - ODE - CDRH - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metric

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

Section 8 - De Novo Division Level Metrics

Table 8.1 DRGUD - ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	5			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

* RTA 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	4	5			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	3	0			
MDUFA IV Decisions Within 150 FDA Days	2	0			
De Novos Pending MDUFA IV Decision	1	5			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	66.67%	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	1.67	0.00			
Number with MDUFA IV Decision	3	0			
Average FDA Days to MDUFA IV Decision	105.33	0.00			
20th Percentile FDA Days to MDUFA IV Decision	69	0			
40th Percentile FDA Days to MDUFA IV Decision	122	0			
60th Percentile FDA Days to MDUFA IV Decision	149	0			
80th Percentile FDA Days to MDUFA IV Decision	150	0			
Maximum FDA Days to MDUFA IV Decision	151	0			
Average Industry Days to MDUFA IV Decision	114.67	0.00			
20th Percentile Industry Days to MDUFA IV Decision	67	0			
40th Percentile Industry Days to MDUFA IV Decision	134	0			
60th Percentile Industry Days to MDUFA IV Decision	169	0			
80th Percentile Industry Days to MDUFA IV Decision	173	0			
Maximum Industry Days to MDUFA IV Decision	177	0			
Average Total Days to MDUFA IV Decision	220.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	137	0			
40th Percentile Total Days to MDUFA IV Decision	258	0			
60th Percentile Total Days to MDUFA IV Decision	319	0			
80th Percentile Total Days to MDUFA IV Decision	322	0			
Maximum Total Days to MDUFA IV Decision	325	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	4	5			
Number with MDUFA IV Decision	3	0			
Number with Granted Decisions	0	0			
Number with Declined Decisions	3	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	0%	N/A			
Rate of Declined Decisions	100%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	0%			

Table 8.5 DRGUD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	151.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	167.00	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

Section 8 - De Novo Division Level Metrics

Table 8.1 DSD - ODE - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	1			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 DSD - ODE - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	4	0			
MDUFA IV Decisions Within 150 FDA Days	3	0			
De Novos Pending MDUFA IV Decision	1	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	75.00%	N/A			

Table 8.3 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	1.75	0.00			
Number with MDUFA IV Decision	4	0			
Average FDA Days to MDUFA IV Decision	129.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	115	0			
40th Percentile FDA Days to MDUFA IV Decision	150	0			
60th Percentile FDA Days to MDUFA IV Decision	150	0			
80th Percentile FDA Days to MDUFA IV Decision	151	0			
Maximum FDA Days to MDUFA IV Decision	153	0			
Average Industry Days to MDUFA IV Decision	68.75	0.00			
20th Percentile Industry Days to MDUFA IV Decision	9	0			
40th Percentile Industry Days to MDUFA IV Decision	32	0			
60th Percentile Industry Days to MDUFA IV Decision	81	0			
80th Percentile Industry Days to MDUFA IV Decision	124	0			
Maximum Industry Days to MDUFA IV Decision	162	0			
Average Total Days to MDUFA IV Decision	197.75	0.00			
20th Percentile Total Days to MDUFA IV Decision	124	0			
40th Percentile Total Days to MDUFA IV Decision	182	0			
60th Percentile Total Days to MDUFA IV Decision	231	0			
80th Percentile Total Days to MDUFA IV Decision	275	0			
Maximum Total Days to MDUFA IV Decision	315	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	5	1			
Number with MDUFA IV Decision	4	0			
Number with Granted Decisions	2	0			
Number with Declined Decisions	1	0			
Number of Withdrawals	1	0			
Number Deleted	0	0			
Rate of Granted Decisions	50.00%	N/A			
Rate of Declined Decisions	25.00%	N/A			
Rate of Withdrawals	25.00%	N/A			
Rate of Deleted	0%	0%			

Table 8.5 DSD - ODE - CDRH - De Novo Performance Metrics-Submissions Missing Performance

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	0			
Mean FDA Days for Submissions that Missed the Goal	153.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	162.00	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

Section 8 - De Novo Division Level Metrics

Table 8.1 DCTD - OIR - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	7	3			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 DCTD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	7	3			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	6	0			
MDUFA IV Decisions Within 150 FDA Days	6	0			
De Novos Pending MDUFA IV Decision	1	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Table 8.3 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	1.50	0.00			
Number with MDUFA IV Decision	6	0			
Average FDA Days to MDUFA IV Decision	134.67	0.00			
20th Percentile FDA Days to MDUFA IV Decision	122	0			
40th Percentile FDA Days to MDUFA IV Decision	132	0			
60th Percentile FDA Days to MDUFA IV Decision	147	0			
80th Percentile FDA Days to MDUFA IV Decision	148	0			
Maximum FDA Days to MDUFA IV Decision	150	0			
Average Industry Days to MDUFA IV Decision	80.33	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	121	0			
80th Percentile Industry Days to MDUFA IV Decision	180	0			
Maximum Industry Days to MDUFA IV Decision	181	0			
Average Total Days to MDUFA IV Decision	215.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	147	0			
40th Percentile Total Days to MDUFA IV Decision	148	0			
60th Percentile Total Days to MDUFA IV Decision	271	0			
80th Percentile Total Days to MDUFA IV Decision	303	0			
Maximum Total Days to MDUFA IV Decision	312	0			

Table 8.4 DCTD - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	7	3			
Number with MDUFA IV Decision	6	0			
Number with Granted Decisions	5	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	1	0			
Number Deleted	0	0			
Rate of Granted Decisions	83.33%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	16.67%	N/A			
Rate of Deleted	0%	0%			

Table 8.5 DCTD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	7	3			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	6	0			
MDUFA IV Decisions Within 150 FDA Days	6	0			
De Novos Pending MDUFA IV Decision	1	3			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Section 8 - De Novo Division Level Metrics

Table 8.1 DIHD - OIR - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	0			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 DIHD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	3	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	2	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Table 8.3 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	1.00	0.00			
Number with MDUFA IV Decision	1	0			
Average FDA Days to MDUFA IV Decision	75.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	75	0			
40th Percentile FDA Days to MDUFA IV Decision	75	0			
60th Percentile FDA Days to MDUFA IV Decision	75	0			
80th Percentile FDA Days to MDUFA IV Decision	75	0			
Maximum FDA Days to MDUFA IV Decision	75	0			
Average Industry Days to MDUFA IV Decision	161.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	161	0			
40th Percentile Industry Days to MDUFA IV Decision	161	0			
60th Percentile Industry Days to MDUFA IV Decision	161	0			
80th Percentile Industry Days to MDUFA IV Decision	161	0			
Maximum Industry Days to MDUFA IV Decision	161	0			
Average Total Days to MDUFA IV Decision	236.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	236	0			
40th Percentile Total Days to MDUFA IV Decision	236	0			
60th Percentile Total Days to MDUFA IV Decision	236	0			
80th Percentile Total Days to MDUFA IV Decision	236	0			
Maximum Total Days to MDUFA IV Decision	236	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	3	0			
Number with MDUFA IV Decision	1	0			
Number with Granted Decisions	0	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	1	0			
Number Deleted	0	0			
Rate of Granted Decisions	0%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	100%	N/A			
Rate of Deleted	0%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Table 8.6 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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	3	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	2	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Section 8 - De Novo Division Level Metrics

Table 8.1 DMD - OIR - CDRH - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	1			
Closed Before RTA Action	N/A	N/A			
Number Accepted First RTA Cycle	N/A	N/A			
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A			
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A			
Number Not Accepted	N/A	N/A			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 DMD - OIR - CDRH - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	4	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Table 8.3 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	1.00	0.00			
Number with MDUFA IV Decision	1	0			
Average FDA Days to MDUFA IV Decision	123.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	123	0			
40th Percentile FDA Days to MDUFA IV Decision	123	0			
60th Percentile FDA Days to MDUFA IV Decision	123	0			
80th Percentile FDA Days to MDUFA IV Decision	123	0			
Maximum FDA Days to MDUFA IV Decision	123	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	123.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	123	0			
40th Percentile Total Days to MDUFA IV Decision	123	0			
60th Percentile Total Days to MDUFA IV Decision	123	0			
80th Percentile Total Days to MDUFA IV Decision	123	0			
Maximum Total Days to MDUFA IV Decision	123	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	5	1			
Number with MDUFA IV Decision	1	0			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	100%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	0%			

Table 8.5 DMD - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	4	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Section 8 - De Novo Division Level Metrics

Table 8.1 DMGP - OIR - CDRH - De Novo Acceptance Review Decision*

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

* RTA 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	1	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

Table 8.3 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	1.00	0.00			
Number with MDUFA IV Decision	1	0			
Average FDA Days to MDUFA IV Decision	62.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	62	0			
40th Percentile FDA Days to MDUFA IV Decision	62	0			
60th Percentile FDA Days to MDUFA IV Decision	62	0			
80th Percentile FDA Days to MDUFA IV Decision	62	0			
Maximum FDA Days to MDUFA IV Decision	62	0			
Average Industry Days to MDUFA IV Decision	189.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	189	0			
40th Percentile Industry Days to MDUFA IV Decision	189	0			
60th Percentile Industry Days to MDUFA IV Decision	189	0			
80th Percentile Industry Days to MDUFA IV Decision	189	0			
Maximum Industry Days to MDUFA IV Decision	189	0			
Average Total Days to MDUFA IV Decision	251.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	251	0			
40th Percentile Total Days to MDUFA IV Decision	251	0			
60th Percentile Total Days to MDUFA IV Decision	251	0			
80th Percentile Total Days to MDUFA IV Decision	251	0			
Maximum Total Days to MDUFA IV Decision	251	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	1	1			
Number with MDUFA IV Decision	1	0			
Number with Granted Decisions	0	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	1	0			
Rate of Granted Decisions	0%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	100%	0%			

Table 8.5 DMGP - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	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	1	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	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	1			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	1			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

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

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

Table 8.2 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	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	1	0			
MDUFA IV Decisions Within 150 FDA Days	1	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	100%	N/A			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.00	0.00			
Number with MDUFA IV Decision	1	0			
Average FDA Days to MDUFA IV Decision	108.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	108	0			
40th Percentile FDA Days to MDUFA IV Decision	108	0			
60th Percentile FDA Days to MDUFA IV Decision	108	0			
80th Percentile FDA Days to MDUFA IV Decision	108	0			
Maximum FDA Days to MDUFA IV Decision	108	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	108.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	108	0			
40th Percentile Total Days to MDUFA IV Decision	108	0			
60th Percentile Total Days to MDUFA IV Decision	108	0			
80th Percentile Total Days to MDUFA IV Decision	108	0			
Maximum Total Days to MDUFA IV Decision	108	0			

Table 8.4 DRH - OIR - CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	0			
Number with MDUFA IV Decision	1	0			
Number with Granted Decisions	1	0			
Number with Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	100%	N/A			
Rate of Declined Decisions	0%	N/A			
Rate of Withdrawals	0%	N/A			
Rate of Deleted	0%	N/A			

Table 8.5 DRH - OIR - CDRH - De Novo Performance Metrics-Submissions Missing Performance

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

Table 8.6 DRH - OIR - CDRH - LDT De Novo MDUFA IV Decision Metrics

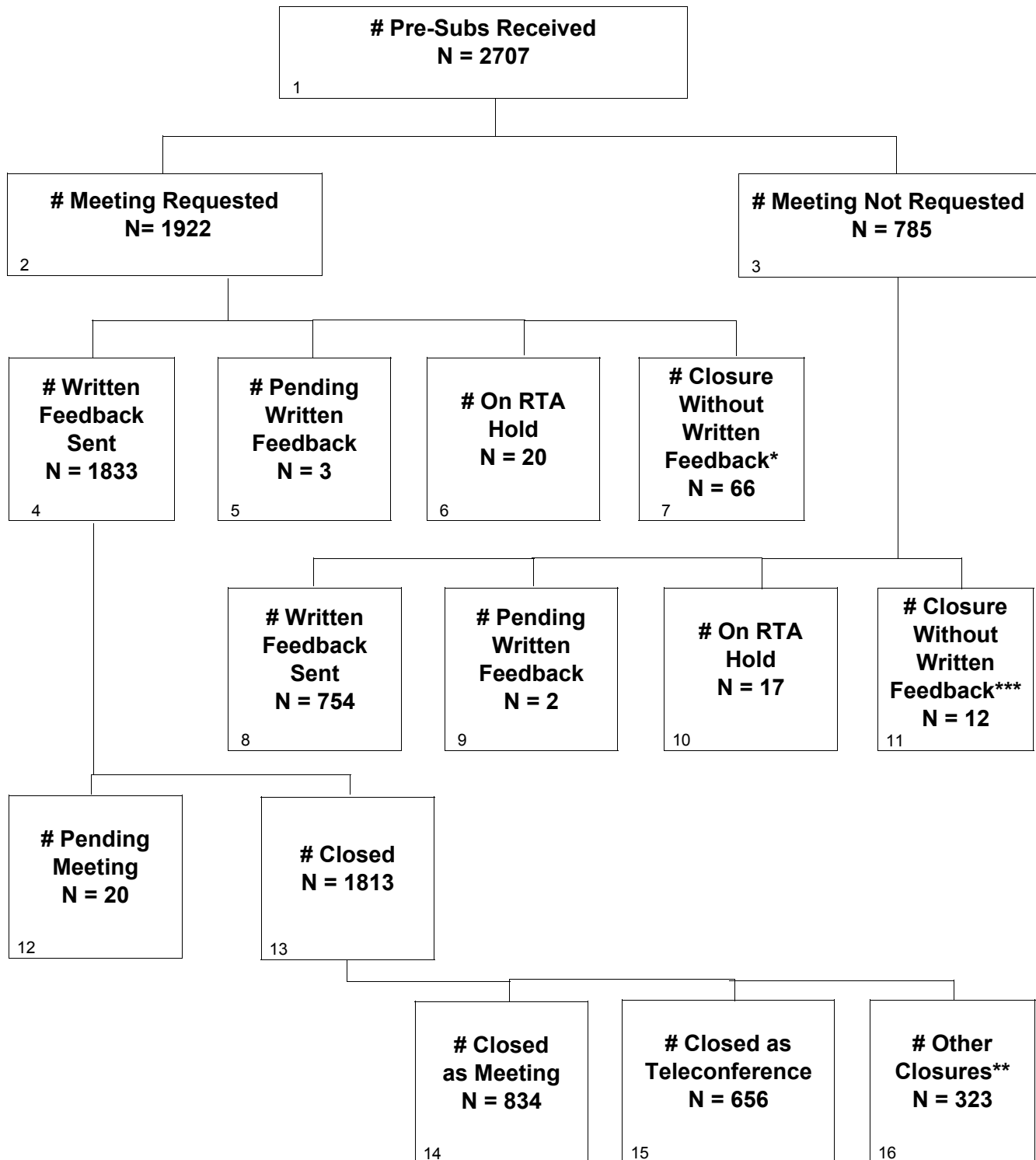
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance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

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

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

CDRH Pre-Sub - FY 2018

as of 12/31/18



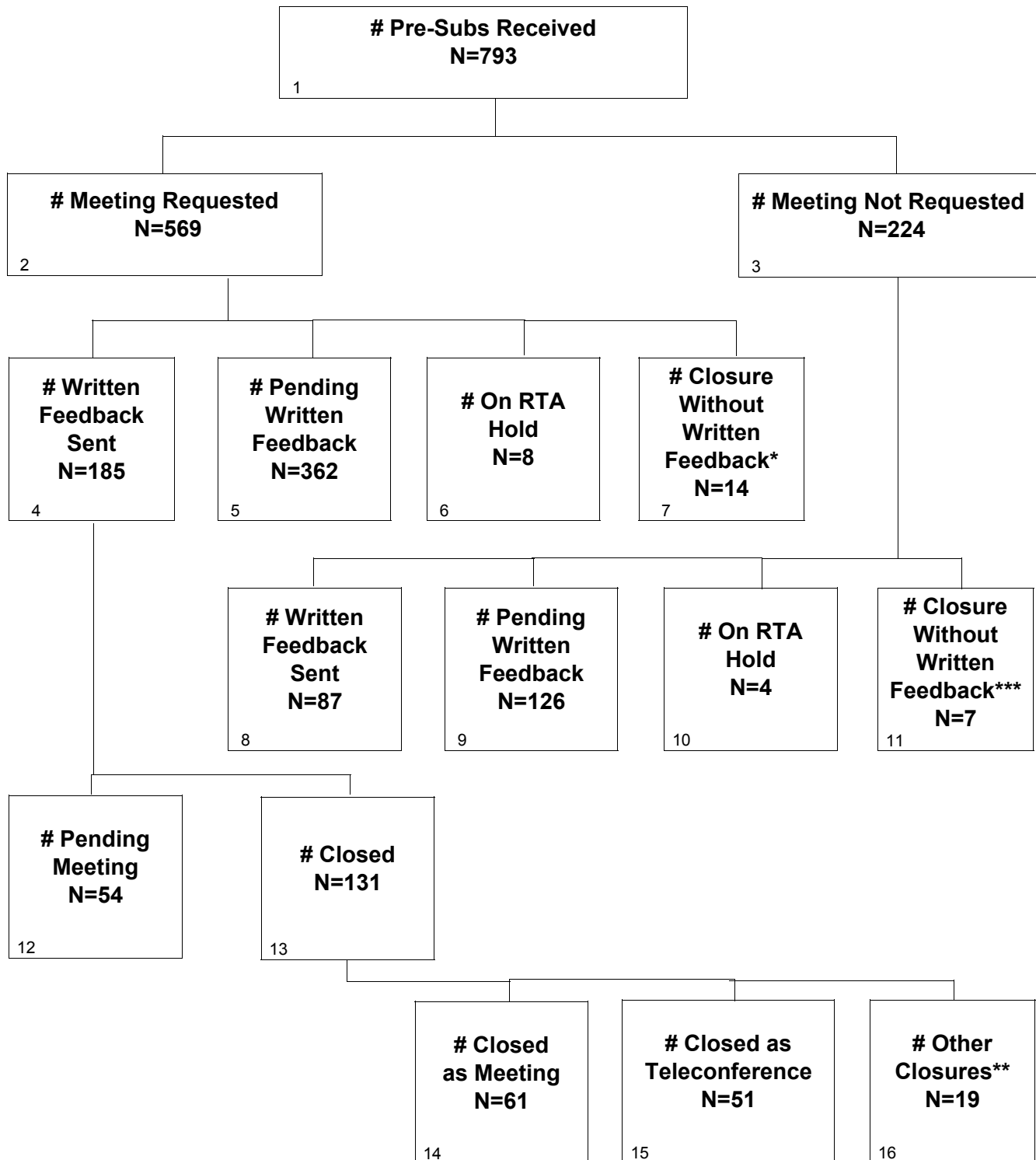
* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

*** Closures include JTRX, JPND, DELE & WTDR

CDRH Pre-Sub - FY 2019

as of 12/31/18



* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

*** Closures include JTRX, JPND, DELE & WTDR

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2,707	793			
Closed Before RTA Action	27	7			
Number Accepted First RTA Cycle	2,565	655			
Number Without a RTA Review and > 15 Days Since Date Received	49	11			
Number Without a RTA Review and <= 15 Days Since Date Received	0	100			
Number Not Accepted	66	20			
Rate of Submissions Not Accepted for Review	2.46%	2.92%			

Table 9.2 CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	2,588	272			
Written Feedback Provided Within MDUFA IV Goal	2,435	262			

Table 9.3 CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	2,588	272			
Average FDA Days to Written Feedback	58.78	52.19			
20th Percentile FDA Days to Written Feedback	49	41			
40th Percentile FDA Days to Written Feedback	59	51			
60th Percentile FDA Days to Written Feedback	65	57			
80th Percentile FDA Days to Written Feedback	69	65			
Maximum FDA Days to Written Feedback	172	75			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	37	11			
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.18			

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	1,490	112			
Meeting Minutes Submitted Within 15 Days of Meeting	966	60			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2	25			
Meeting Minutes Past 15 Days of Meeting	459	14			
Meeting Minutes Not Submitted and >15 Days Since Meeting	63	13			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.92%	68.97%			

Section 9 Pre-Sub Office Level Metrics

Table 9.1 ODE - CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1,820	531			
Closed Before RTA Action	19	6			
Number Accepted First RTA Cycle	1,694	433			
Number Without a RTA Review and > 15 Days Since Date Received	49	9			
Number Without a RTA Review and <= 15 Days Since Date Received	0	66			
Number Not Accepted	58	17			
Rate of Submissions Not Accepted for Review	3.22%	3.70%			

Table 9.2 ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	1,719	164			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	1,570	156			

Table 9.3 ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	1,719	164			
Average FDA Days to Written Feedback	59.53	53.62			
20th Percentile FDA Days to Written Feedback	49	43			
40th Percentile FDA Days to Written Feedback	59	52			
60th Percentile FDA Days to Written Feedback	65	59			
80th Percentile FDA Days to Written Feedback	70	65			
Maximum FDA Days to Written Feedback	172	75			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	31	10			
Average Days to Scheduling for Meetings Scheduled After Day 30	35.94	36.20			

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	1,018	65			
Meeting Minutes Submitted Within 15 Days of Meeting	660	35			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1	13			
Meeting Minutes Past 15 Days of Meeting	313	7			
Meeting Minutes Not Submitted and >15 Days Since Meeting	44	10			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.90%	67.31%			

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	887	262			
Closed Before RTA Action	8	1			
Number Accepted First RTA Cycle	871	222			
Number Without a RTA Review and > 15 Days Since Date Received	0	2			
Number Without a RTA Review and <= 15 Days Since Date Received	0	34			
Number Not Accepted	8	3			
Rate of Submissions Not Accepted for Review	0.91%	1.32%			

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	869	108			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	865	106			

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	869	108			
Average FDA Days to Written Feedback	57.31	50.03			
20th Percentile FDA Days to Written Feedback	48	37			
40th Percentile FDA Days to Written Feedback	57	50			
60th Percentile FDA Days to Written Feedback	63	56			
80th Percentile FDA Days to Written Feedback	68	64			
Maximum FDA Days to Written Feedback	85	70			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	6	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.83	36.00			

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	472	47			
Meeting Minutes Submitted Within 15 Days of Meeting	306	25			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1	12			
Meeting Minutes Past 15 Days of Meeting	146	7			
Meeting Minutes Not Submitted and >15 Days Since Meeting	19	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.97%	71.43%			

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	330	98			
Closed Before RTA Action	3	1			
Number Accepted First RTA Cycle	282	74			
Number Without a RTA Review and > 15 Days Since Date Received	12	3			
Number Without a RTA Review and <= 15 Days Since Date Received	0	10			
Number Not Accepted	33	10			
Rate of Submissions Not Accepted for Review	10.09%	11.49%			

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	295	24			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	251	21			

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	295	24			
Average FDA Days to Written Feedback	63.87	56.42			
20th Percentile FDA Days to Written Feedback	57	41			
40th Percentile FDA Days to Written Feedback	64	58			
60th Percentile FDA Days to Written Feedback	68	66			
80th Percentile FDA Days to Written Feedback	70	70			
Maximum FDA Days to Written Feedback	139	72			

Table 9.4 DAGRID - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	10	3			
Average Days to Scheduling for Meetings Scheduled After Day 30	41.30	34.00			

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	168	7			
Meeting Minutes Submitted Within 15 Days of Meeting	111	3			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1	2			
Meeting Minutes Past 15 Days of Meeting	45	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	66.47%	60.00%			

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	534	152			
Closed Before RTA Action	6	3			
Number Accepted First RTA Cycle	510	124			
Number Without a RTA Review and > 15 Days Since Date Received	12	3			
Number Without a RTA Review and <= 15 Days Since Date Received	0	21			
Number Not Accepted	6	1			
Rate of Submissions Not Accepted for Review	1.14%	0.78%			

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	516	52			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	484	50			

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	516	52			
Average FDA Days to Written Feedback	53.11	48.02			
20th Percentile FDA Days to Written Feedback	39	37			
40th Percentile FDA Days to Written Feedback	50	43			
60th Percentile FDA Days to Written Feedback	59	51			
80th Percentile FDA Days to Written Feedback	67	60			
Maximum FDA Days to Written Feedback	91	70			

Table 9.4 DCD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	8	4			
Average Days to Scheduling for Meetings Scheduled After Day 30	32.13	40.75			

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	312	24			
Meeting Minutes Submitted Within 15 Days of Meeting	185	13			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	113	3			
Meeting Minutes Not Submitted and >15 Days Since Meeting	14	5			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	59.29%	61.90%			

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	250	75			
Closed Before RTA Action	3	0			
Number Accepted First RTA Cycle	233	61			
Number Without a RTA Review and > 15 Days Since Date Received	7	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	11			
Number Not Accepted	7	3			
Rate of Submissions Not Accepted for Review	2.83%	4.69%			

Table 9.2 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	15			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	202	13			

Table 9.3 DNPMD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	15			
Average FDA Days to Written Feedback	64.60	58.33			
20th Percentile FDA Days to Written Feedback	58	51			
40th Percentile FDA Days to Written Feedback	65	55			
60th Percentile FDA Days to Written Feedback	69	62			
80th Percentile FDA Days to Written Feedback	70	66			
Maximum FDA Days to Written Feedback	172	75			

Table 9.4 DNPMD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	5	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	33.00			

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	149	5			
Meeting Minutes Submitted Within 15 Days of Meeting	96	2			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	45	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.43%	100%			

Section 9 Pre-Sub Division Level Metrics

Table 9.1 DOD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	133	38			
Closed Before RTA Action	1	0			
Number Accepted First RTA Cycle	127	33			
Number Without a RTA Review and > 15 Days Since Date Received	5	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	3			
Number Not Accepted	0	2			
Rate of Submissions Not Accepted for Review	0%	5.71%			

Table 9.2 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	17			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	115	17			

Table 9.3 DOD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	17			
Average FDA Days to Written Feedback	61.91	57.59			
20th Percentile FDA Days to Written Feedback	52	51			
40th Percentile FDA Days to Written Feedback	62	56			
60th Percentile FDA Days to Written Feedback	67	60			
80th Percentile FDA Days to Written Feedback	70	66			
Maximum FDA Days to Written Feedback	106	70			

Table 9.4 DOD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	33.00			

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	76	5			
Meeting Minutes Submitted Within 15 Days of Meeting	54	1			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	1			
Meeting Minutes Past 15 Days of Meeting	18	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.05%	25.00%			

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	126	42			
Closed Before RTA Action	0	0			
Number Accepted First RTA Cycle	116	38			
Number Without a RTA Review and > 15 Days Since Date Received	5	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	4			
Number Not Accepted	5	0			
Rate of Submissions Not Accepted for Review	3.97%	0%			

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	117	14			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	114	14			

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	117	14			
Average FDA Days to Written Feedback	62.43	58.29			
20th Percentile FDA Days to Written Feedback	57	53			
40th Percentile FDA Days to Written Feedback	63	56			
60th Percentile FDA Days to Written Feedback	67	59			
80th Percentile FDA Days to Written Feedback	70	66			
Maximum FDA Days to Written Feedback	73	70			

Table 9.4 DOED - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	37.00	0.00			

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	76	5			
Meeting Minutes Submitted Within 15 Days of Meeting	57	3			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	2			
Meeting Minutes Past 15 Days of Meeting	19	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.00%	100%			

Section 9 Pre-Sub Division Level Metrics

Table 9.1 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	231	67			
Closed Before RTA Action	2	1			
Number Accepted First RTA Cycle	225	57			
Number Without a RTA Review and > 15 Days Since Date Received	2	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	8			
Number Not Accepted	2	1			
Rate of Submissions Not Accepted for Review	0.87%	1.72%			

Table 9.2 DRGUD - ODE - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	224	21			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	219	21			

Table 9.3 DRGUD - ODE - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	224	21			
Average FDA Days to Written Feedback	59.75	54.86			
20th Percentile FDA Days to Written Feedback	51	46			
40th Percentile FDA Days to Written Feedback	60	56			
60th Percentile FDA Days to Written Feedback	65	59			
80th Percentile FDA Days to Written Feedback	69	65			
Maximum FDA Days to Written Feedback	156	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	1	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	31.00			

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	127	10			
Meeting Minutes Submitted Within 15 Days of Meeting	75	6			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	2			
Meeting Minutes Past 15 Days of Meeting	50	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	1			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	59.06%	75.00%			

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	216	59			
Closed Before RTA Action	4	1			
Number Accepted First RTA Cycle	201	46			
Number Without a RTA Review and > 15 Days Since Date Received	6	3			
Number Without a RTA Review and <= 15 Days Since Date Received	0	9			
Number Not Accepted	5	0			
Rate of Submissions Not Accepted for Review	2.36%	0%			

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	203	21			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	185	20			

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	203	21			
Average FDA Days to Written Feedback	60.28	53.33			
20th Percentile FDA Days to Written Feedback	51	46			
40th Percentile FDA Days to Written Feedback	58	51			
60th Percentile FDA Days to Written Feedback	64	60			
80th Percentile FDA Days to Written Feedback	69	63			
Maximum FDA Days to Written Feedback	121	72			

Table 9.4 DSD - ODE - CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.50	0.00			

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	110	9			
Meeting Minutes Submitted Within 15 Days of Meeting	82	7			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	23	2			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.55%	77.78%			

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	220	72			
Closed Before RTA Action	3	0			
Number Accepted First RTA Cycle	216	60			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	12			
Number Not Accepted	1	0			
Rate of Submissions Not Accepted for Review	0.46%	0%			

Table 9.2 DCTD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	216	28			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	215	27			

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	216	28			
Average FDA Days to Written Feedback	56.98	49.00			
20th Percentile FDA Days to Written Feedback	46	39			
40th Percentile FDA Days to Written Feedback	58	44			
60th Percentile FDA Days to Written Feedback	63	51			
80th Percentile FDA Days to Written Feedback	68	59			
Maximum FDA Days to Written Feedback	71	70			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	2	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	36.00	0.00			

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	125	15			
Meeting Minutes Submitted Within 15 Days of Meeting	87	5			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	5			
Meeting Minutes Past 15 Days of Meeting	33	2			
Meeting Minutes Not Submitted and >15 Days Since Meeting	5	3			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	69.60%	50.00%			

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	116	28			
Closed Before RTA Action	4	0			
Number Accepted First RTA Cycle	112	27			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted	0	0			
Rate of Submissions Not Accepted for Review	0%	0%			

Table 9.2 DIHD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	111	11			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	110	11			

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	111	11			
Average FDA Days to Written Feedback	62.64	54.36			
20th Percentile FDA Days to Written Feedback	57	44			
40th Percentile FDA Days to Written Feedback	63	54			
60th Percentile FDA Days to Written Feedback	67	64			
80th Percentile FDA Days to Written Feedback	70	67			
Maximum FDA Days to Written Feedback	71	70			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	3	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	33.33	0			

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	70	4			
Meeting Minutes Submitted Within 15 Days of Meeting	49	1			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	2			
Meeting Minutes Past 15 Days of Meeting	17	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	70.00%	50.00%			

Section 9 Pre-Sub Division Level Metrics

Table 9.1 DMD - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	224	61			
Closed Before RTA Action	0	0			
Number Accepted First RTA Cycle	223	53			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	7			
Number Not Accepted	1	1			
Rate of Submissions Not Accepted for Review	0.45%	1.85%			

Table 9.2 DMD - OIR - CDRH - MDUFA IV Pre-Sub Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	28			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	221	28			

Table 9.3 DMD - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	222	28			
Average FDA Days to Written Feedback	57.66	50.86			
20th Percentile FDA Days to Written Feedback	48	35			
40th Percentile FDA Days to Written Feedback	58	54			
60th Percentile FDA Days to Written Feedback	65	57			
80th Percentile FDA Days to Written Feedback	69	64			
Maximum FDA Days to Written Feedback	85	70			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00			

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	69	7			
Meeting Minutes Submitted Within 15 Days of Meeting	33	5			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1	1			
Meeting Minutes Past 15 Days of Meeting	28	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	48.53%	83.33%			

Section 9 Pre-Sub Division Level Metrics

Table 9.1 DMGP - OIR - CDRH - MDUFA IV Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	193	62			
Closed Before RTA Action	0	0			
Number Accepted First RTA Cycle	192	49			
Number Without a RTA Review and > 15 Days Since Date Received	0	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	12			
Number Not Accepted	1	0			
Rate of Submissions Not Accepted for Review	0.52%	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	191	24			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	191	24			

Table 9.3 DMGP - OIR - CDRH - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	191	24			
Average FDA Days to Written Feedback	58.07	48.63			
20th Percentile FDA Days to Written Feedback	51	35			
40th Percentile FDA Days to Written Feedback	59	49			
60th Percentile FDA Days to Written Feedback	63	56			
80th Percentile FDA Days to Written Feedback	67	61			
Maximum FDA Days to Written Feedback	70	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	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00			

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	121	12			
Meeting Minutes Submitted Within 15 Days of Meeting	70	7			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	3			
Meeting Minutes Past 15 Days of Meeting	49	2			
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	57.85%	77.78%			

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	134	39			
Closed Before RTA Action	1	1			
Number Accepted First RTA Cycle	128	33			
Number Without a RTA Review and > 15 Days Since Date Received	0	1			
Number Without a RTA Review and <= 15 Days Since Date Received	0	2			
Number Not Accepted	5	2			
Rate of Submissions Not Accepted for Review	3.76%	5.56%			

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	129	17			
Written Feedback Provided by Day 70 Or 5 Days Prior to Meeting, Whichever is Sooner	128	16			

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	129	17			
Average FDA Days to Written Feedback	51.52	49.53			
20th Percentile FDA Days to Written Feedback	44	37			
40th Percentile FDA Days to Written Feedback	49	52			
60th Percentile FDA Days to Written Feedback	56	55			
80th Percentile FDA Days to Written Feedback	61	61			
Maximum FDA Days to Written Feedback	70	68			

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

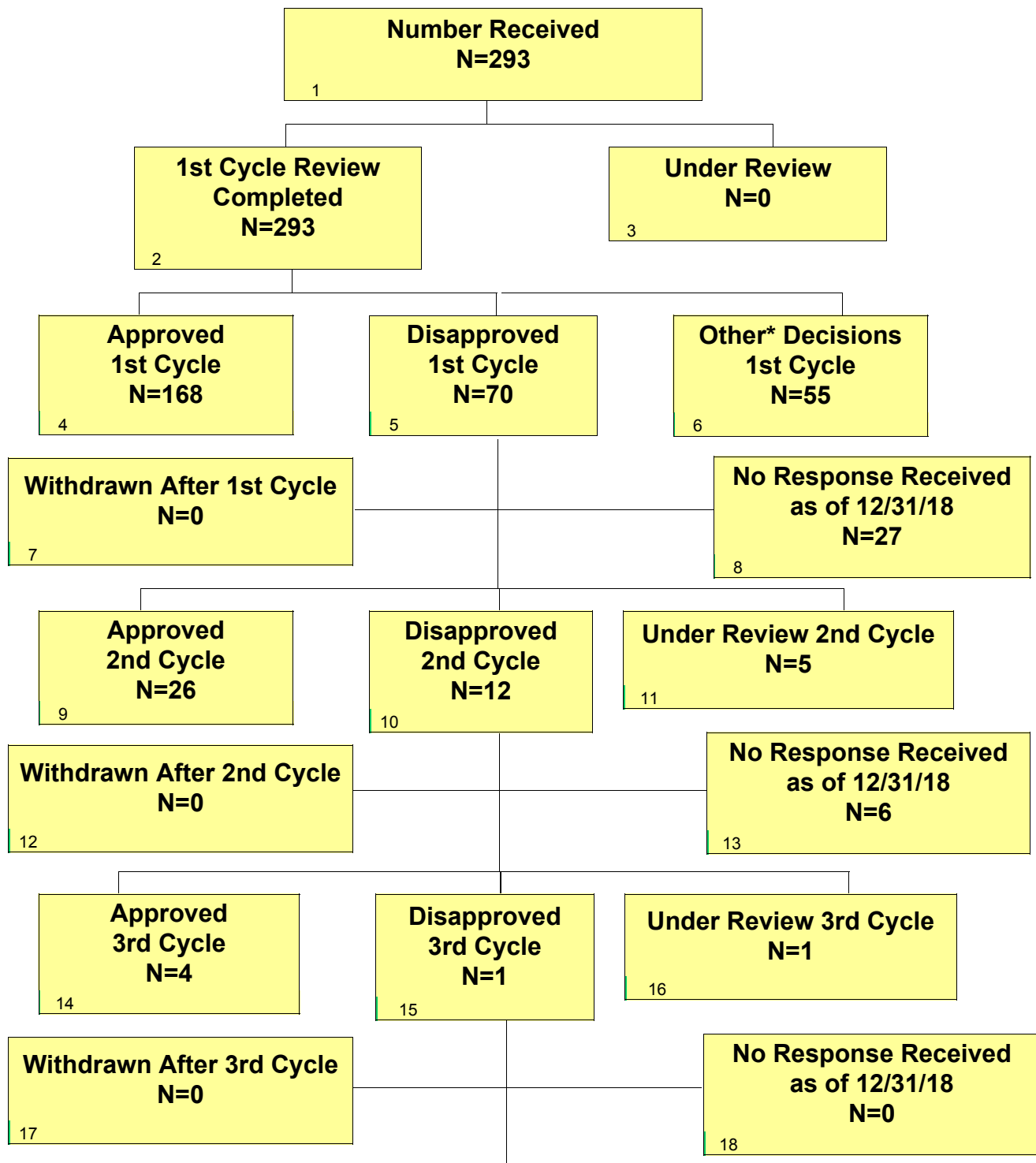
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	1	1			
Average Days to Scheduling for Meetings Scheduled After Day 30	31.00	36.00			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	87	9			
Meeting Minutes Submitted Within 15 Days of Meeting	67	7			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	1			
Meeting Minutes Past 15 Days of Meeting	19	1			
Meeting Minutes Not Submitted and >15 Days Since Meeting	1	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.01%	87.50%			

CDRH IDEs - FY 2018

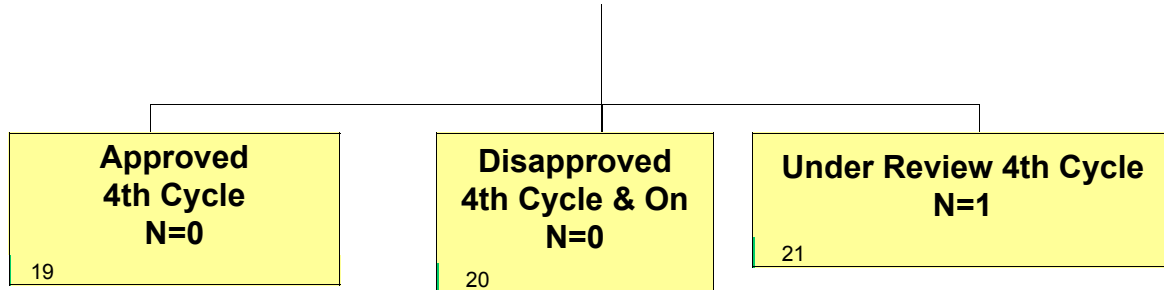
as of 12/31/18



* Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

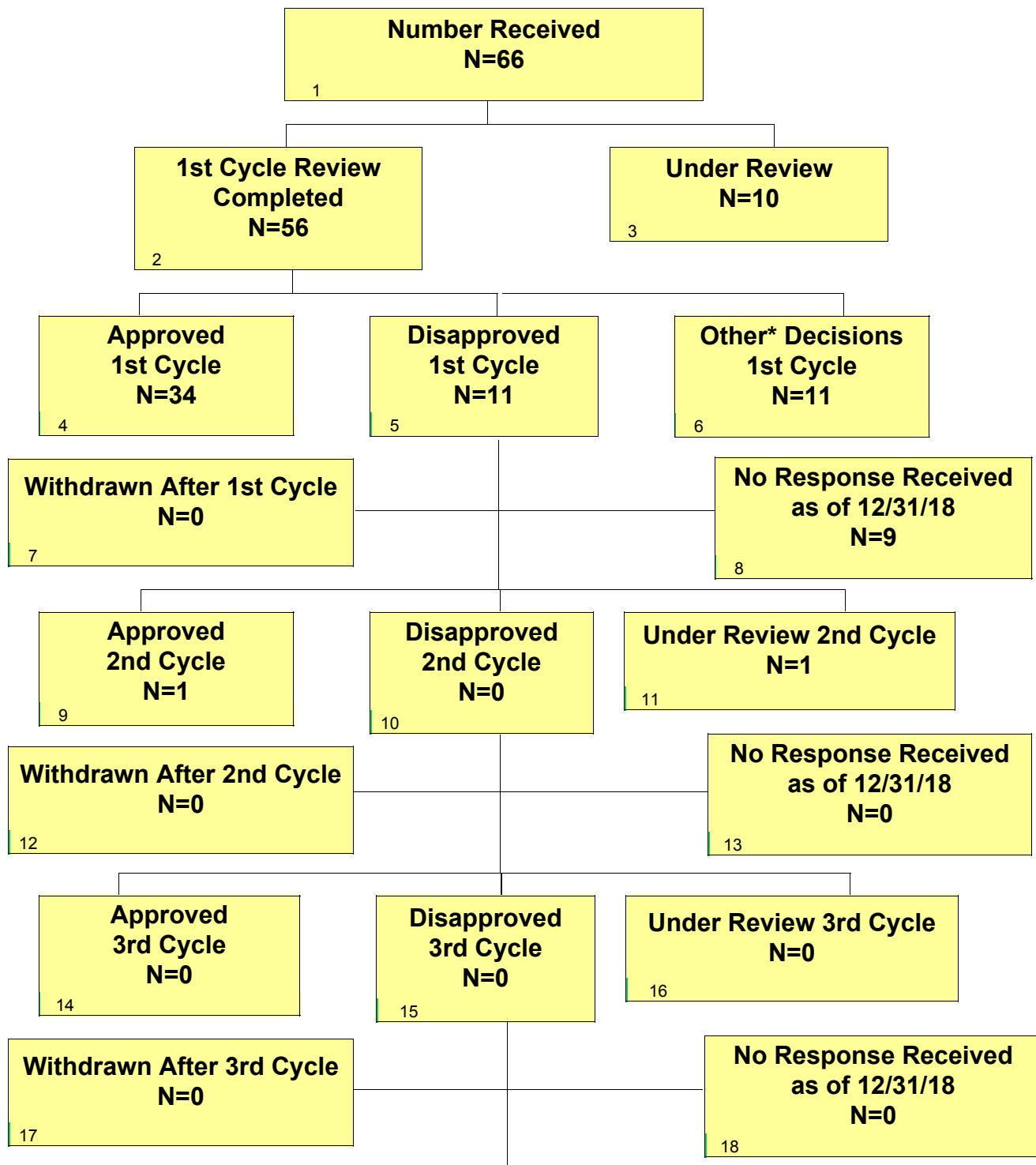
CDRH IDEs - FY 2018

as of 12/31/18



CDRH IDEs - FY 2019

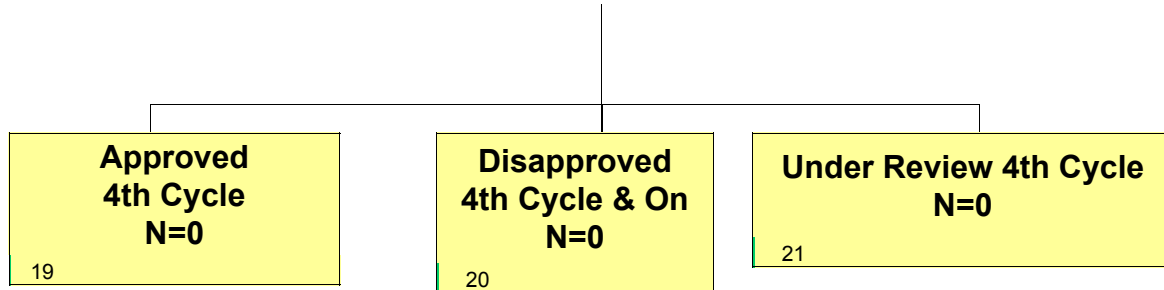
as of 12/31/18



* Other decisions include withdrawn (N=2), withdrawn and converted (N=5), RTA (N=0), nonsignificant risk device (N=3), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).

CDRH IDEs - FY 2019

as of 12/31/18



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	293	66			
Average Number of Cycles to IDE Approval or Conditional Approval	1.17	1.03			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.17	0.03			

Section 10 IDE - Office Level Metric

Table 10.1 ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	241	54			
Average Number of Cycles to IDE Approval or Conditional Approval	1.22	1.04			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.22	0.04			

Section 10 IDE - Office Level Metric

Table 10.1 OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	52	12			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

Section 10 IDE - Division Level Metric

Table 10.1 DAGRID - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	14	2			
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	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	57	17			
Average Number of Cycles to IDE Approval or Conditional Approval	1.24	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.24	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	61	12			
Average Number of Cycles to IDE Approval or Conditional Approval	1.08	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	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	17	3			
Average Number of Cycles to IDE Approval or Conditional Approval	1.09	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.09	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	31	8			
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.00			

Section 10 IDE - Division Level Metric

Table 10.1 DRGUD - ODE - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	31	10			
Average Number of Cycles to IDE Approval or Conditional Approval	1.47	1.25			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.47	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	30	2			
Average Number of Cycles to IDE Approval or Conditional Approval	1.13	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.13	N/A			

Section 10 IDE - Division Level Metric

Table 10.1 DCTD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	24	7			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

Section 10 IDE - Division Level Metric

Table 10.1 DIHD - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	1	1			
Average Number of Cycles to IDE Approval or Conditional Approval	N/A	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	N/A	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	1			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	N/A			

Section 10 IDE - Division Level Metric

Table 10.1 DMGP - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	17	1			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00			

Section 10 IDE - Division Level Metric

Table 10.1 DRH - OIR - CDRH - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs received	8	2			
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	N/A			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	N/A			

Section 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).

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 submissions that went to panel

Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements Metric* MDUFA Decision Performance Goals - Definitions

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA(other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA Decision Performance Goals – Definitions

#	Measure	Description
1	Supplements filed	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa).
3	MDUFA IV Decisions	Supplements received (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements pending MDUFA IV Decision	Number of supplements received (line 1) that do not have a MDUFA IV decision or a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 2.3 and Tables 2.3.x**PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable – Definitions**

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

Table 2.4 and Tables 2.4.x**PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions

#	Measure	Description
1	Supplements received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) within goal.
5	Supplements pending MDUFA IV Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA IV decision and are not closed with a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

Table 3.3 and Tables 3.3.x**Real Time PMA Supplements Performance Metrics – Submissions
Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

Section 5 PMA Annual Metrics and Goals

Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

Table 5.2 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number with a decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

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

#	Measure	Description
1	Number with MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with MDUFA decision after trimming the upper and lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA IV decision and 5% of submissions with the highest number of Total Days to MDUFA IV decision.
3	Three-year Rolling Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

Section 6 510(k) MDUFA IV Performance (Quarterly Data Exclude Third Party Review)

Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision in the first RTA review cycle.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that received a "Did not perform RTA" (RTAN, RTAS or RTAW) decision in the first RTA review cycle. An RTAN decision is automatically recorded by CTS at the end of day 15 of RTA review, if no other RTA decision is made. This RTA decision means that the 510(k) is deemed accepted.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle and have not yet reached the 15 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
1	510(k)s accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA IV Decision over 90 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric – Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).

Section 7 510(k) Annual General Metrics (Annual data includes Third Party reviews)

Table 7.1 CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type – Definitions

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

Table 7.2**CDRH - 510(k) Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions..
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA IV decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA IV Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA IV decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA IV decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA IV Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA IV decision and the 2% of submissions with the highest number of Total Days to MDUFA IV decision.
7	Average Total Time to MDUFA IV decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

Table 7.3**CDRH - 510(k) Third Party Performance – Definitions**

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90 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 Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).

Section 8 Annual Metrics for De Novo Requests

Table 8.8 CDRH – Annual General Metric Report for De Novo Requests - Definitions

#	Measure	Description
1	Number Accepted First RTA Cycle	Number of De Novo submissions accepted in the first RTA cycle in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept*	Average number of days in the first RTA review cycle De Novo submissions..

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

Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Sub Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of Pre-Subs submissions received in this fiscal year.
2	Closed before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that had "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days Since Date Received	Number Received (line 1) that had "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review.
5	Number Without a RTA Review and <= 15 days Since Date Received	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that had "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

Table 9.2 and Tables 9.2.x Pre-Submissions Performance Metrics – Definitions

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either "Email Reply" (EMAL) or "Email Feedback Sent Before Meeting" (EMFB) in CTS. EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Written Feedback Provided Within MDUFA IV Goal	Number of Pre-Subs that had Written Feedback sent (line 1) by Day 70 (for Pre-Subs without a meeting request), or by 5 Days before the Meeting Date or Day 70, whichever is sooner (for Pre-Subs with a meeting request).

Table 9.3 and Tables 9.3.x Pre-Sub Time to MDUFA IV Metrics – Definitions

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either “Email Reply” (EMAL) or “Email Feedback Sent Before Meeting” (EMFB) EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Average FDA Days to Written Feedback	Average number of days from the start of FDA review to MDUFA IV Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1).
3	20 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.

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**Quarterly Update on
Medical Device Performance Goals
----MDUFA IV CBER Performance Data ----
Action through 31 Dec 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	3	1			
Closed Before RTA Action	0	0			
Number with Accepted RTA Review	1	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted for Filing Review	2	1			
Rate of Submissions Not Accepted for Filing Review	67%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	1			
Number Accepted	1	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of Submissions Not Filed	N/A	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	2	1			
SI Goal Met	2	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed Without SI	0	0			
Current SI Performance Percent Goal Met	100.00%	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	2	0			
Average Number of FDA Days to Substantive Interaction	69.00	0.00			
20th Percentile FDA Days to Substantive Interaction	50.00	0.00			
40th Percentile FDA Days to Substantive Interaction	50.00	0.00			
60th Percentile FDA Days to Substantive Interaction	88.00	0.00			
80th Percentile FDA Days to Substantive Interaction	88.00	0.00			
Maximum FDA Days to Substantive Interaction	88.00	0.00			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	2	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	1	0			
MDUFA IV Decision Goal Met	1	0			
PMAs Pending MDUFA IV Decision	1	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	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	0			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	0	0			
MDUFA IV Decision Goal Met	0	0			
PMAs Pending MDUFA IV Decision	0	0			
PMAs Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

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

Performance Metric - Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	0			
Average FDA Days to MDUFA IV Decision	156.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
40th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
60th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
80th Percentile FDA Days to MDUFA IV Decision	156.00	0.00			
Maximum FDA Days to MDUFA IV Decision	156.00	0.00			
Average Industry Days to MDUFA IV Decision	105.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
40th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
60th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
80th Percentile Industry Days to MDUFA IV Decision	105.00	0.00			
Maximum Industry Days to MDUFA IV Decision	105.00	0.00			
Average Total Days to MDUFA IV Decision	261.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
40th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
60th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
80th Percentile Total Days to MDUFA IV Decision	261.00	0.00			
Maximum Total Days to MDUFA IV Decision	261.00	0.00			

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

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

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

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

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

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

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

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

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

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

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

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

*Includes submission that went to panel

Table 1.14 CBER - Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements

Metric*

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

*Includes submission that went to panel

Section 2 PMA 180-Day Supplements - Center Level Metric

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	8	1			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision	5	0			
MDUFA IV Decision Goal Met	5	0			
Supplements Pending MDUFA IV Decision	3	1			
Supplements Pending MDUFA IV Decision Past Goal	0	0			
Current Performance Percent Goal Met	100.00%	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	8	1			
Number with MDUFA IV Decision	5	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.00%	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	0			
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00			
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00			

Section 3 PMA Real-Time Supplements - Center Level Metric

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

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

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

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

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

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

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	53	16			
Closed Before RTA Action	0	0			
Number Accepted	40	12			
Number Without a RTA Review and > 15 Days Since Date Received	2	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	1			
Number Not Accepted	11	3			
Rate of Submissions Not Accepted for Review	20.75%	20.00%			

Table 6.2 CBER - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	49	12			
Deleted or Withdrawn Prior to SI	0	0			
SI Within 60 FDA Days	48	7			
SI Over 60 FDA Days	0	0			
SI Pending Within 60 FDA Days	1	5			
SI Pending Over 60 FDA Days	0	0			
510(k)s NSE Without SI	0	0			
Current SI Performance Percent Within 60 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	48	7			
Average Number of FDA Days to Substantive Interaction	50.50	33.14			
20th Percentile FDA Days to Substantive Interaction	43	18			
40th Percentile FDA Days to Substantive Interaction	58	21			
60th Percentile FDA Days to Substantive Interaction	59	50			
80th Percentile FDA Days to Substantive Interaction	60	59			
Maximum FDA Days to Substantive Interaction	60	60			

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

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	49	12			
Non-MDUFA IV Decision	3	0			
MDUFA IV Decision (SE/NSE)	41	4			
MDUFA IV Decision Within 90 FDA Days	41	4			
510(k)s Pending MDUFA IV Decision	5	8			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100%	100%			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.29	1.00			
Number With MDUFA IV Decision	41	4			
Average Number of FDA Days to MDUFA IV Decision	75.50	33.25			
20th Percentile FDA Days to MDUFA IV Decision	76	76			
40th Percentile FDA Days to MDUFA IV Decision	85	18			
60th Percentile FDA Days to MDUFA IV Decision	88	26			
80th Percentile FDA Days to MDUFA IV Decision	88	30			
Maximum FDA Days to MDUFA IV Decision	90	59			
Average Number of Industry Days to MDUFA IV Decision	23.34	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
40th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
60th Percentile Industry Days to MDUFA IV Decision	0.00	0.00			
80th Percentile Industry Days to MDUFA IV Decision	57.00	0.00			
Maximum Industry Days to MDUFA IV Decision	178.00	0.00			
Average Number of Total Days to MDUFA IV Decision	98.85	33.25			
20th Percentile Total Days to MDUFA IV Decision	78	76			
40th Percentile Total Days to MDUFA IV Decision	86	18			
60th Percentile Total Days to MDUFA IV Decision	90	26			
80th Percentile Total Days to MDUFA IV Decision	126	30			
Maximum Total Days to MDUFA IV Decision	268	59			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	49	12			
Number With MDUFA IV Decision	41	4			
Number of SE Decision	41	4			
Number of NSE Decision	0	0			
Number of Withdrawal	2	0			
Number of Deleted	0	0			
Rate of SE Decision	100%	100%			
Rate of NSE Decision	0%	0%			
Rate of Withdrawal	4%	0%			
Rate of Deleted	0%	0%			

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	14	3			
Non-MDUFA IV Decision	0	0			
MDUFA IV Decision (SE/NSE)	14	0			
MDUFA IV Decision Within 90 FDA Days	14	0			
510(k)s Pending MDUFA IV Decision	0	3			
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0			
Current Performance Percent Within 90 FDA Days	100.00%	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	0			
Closed Before RTA Action	0	0			
Number Accepted First RTA Cycle	0	0			
Number Without a RTA Review and > 15 Days Since Date Received	0	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	0			
Number Not Accepted	0	0			
Rate of Submissions Not Accepted for Review	N/A	N/A			

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

Table 8.2 CBER - De Novo MDUFA IV Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	65% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	0	0			
Non-MDUFA IV Decisions	0	0			
MDUFA IV Decisions	0	0			
MDUFA IV Decisions Within 150 FDA Days	0	0			
De Novos Pending MDUFA IV Decision	0	0			
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0			
Current Performance Percent Within 150 FDA Days	N/A	N/A			

Table 8.3 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	0.00			
Number With MDUFA IV Decision	0	0			
Average FDA Days to MDUFA IV Decision	0.00	0.00			
20th Percentile FDA Days to MDUFA IV Decision	0	0			
40th Percentile FDA Days to MDUFA IV Decision	0	0			
60th Percentile FDA Days to MDUFA IV Decision	0	0			
80th Percentile FDA Days to MDUFA IV Decision	0	0			
Maximum FDA Days to MDUFA IV Decision	0	0			
Average Industry Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Industry Days to MDUFA IV Decision	0	0			
40th Percentile Industry Days to MDUFA IV Decision	0	0			
60th Percentile Industry Days to MDUFA IV Decision	0	0			
80th Percentile Industry Days to MDUFA IV Decision	0	0			
Maximum Industry Days to MDUFA IV Decision	0	0			
Average Total Days to MDUFA IV Decision	0.00	0.00			
20th Percentile Total Days to MDUFA IV Decision	0	0			
40th Percentile Total Days to MDUFA IV Decision	0	0			
60th Percentile Total Days to MDUFA IV Decision	0	0			
80th Percentile Total Days to MDUFA IV Decision	0	0			
Maximum Total Days to MDUFA IV Decision	0	0			

Table 8.4 CBER - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0			
Number With MDUFA IV Decisions	0	0			
Number With Granted Decisions	0	0			
Number With Declined Decisions	0	0			
Number of Withdrawals	0	0			
Number Deleted	0	0			
Rate of Granted Decisions	N/A	N/A			
Rate of Declined Decisions	N/A	N/A			
Rate of Withdrawals	N/A	N/A			
Rate of Deleted	N/A	N/A			

Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goals

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

Table 8.6 CBER - LDT De Novo MDUFA IV Decision Metrics

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

Table 8.7 CBER - Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	76	19			
Closed Before RTA Action	5	1			
Number Accepted First RTA Cycle	69	14			
Number Without a RTA Review and > 15 Days Since Date Received	1	0			
Number Without a RTA Review and <= 15 Days Since Date Received	0	4			
Number Not Accepted	1	0			
Rate of Submissions Not Accepted for Review	1.41%	0.00%			

Table 9.2 CBER - MDUFA IV Pre-Sub Performance Goals

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	70	5			
Written Feedback Provided Within MDUFA IV Goal	70	5			

Table 9.3 CBER - Pre-Sub Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	70	5			
Average FDA Days to Written Feedback	57.85	58.40			
20th Percentile FDA Days to Written Feedback	47	41			
40th Percentile FDA Days to Written Feedback	58	58			
60th Percentile FDA Days to Written Feedback	64	60			
80th Percentile FDA Days to Written Feedback	67	63			
Maximum FDA Days to Written Feedback	72	70			

Table 9.4 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0			
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00			

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	42	1			
Meeting Minutes Submitted Within 15 Days of Meeting	33	1			
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0			
Meeting Minutes Past 15 Days of Meeting	9	0			
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0			
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	100.00%			

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	15	6			
Average Number of Cycles to IDE Approval or Conditional Approval	1.10	1.00			
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.10	0.00			

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

FY 2019 Medical Device User Fee Collections
as of December 31th, 2018
Excludes Unearned Fees

	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$106,773,973	\$0	\$106,773,973		
Application Fees	\$15,750,305	\$5,154	\$15,745,151		
Total	\$122,524,278	\$5,154	\$122,519,124	\$204,730,000	60%

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	\$34,417,751	\$28,031,569
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
MD II	\$47,706,236	\$57,554,216	\$63,932,631	\$70,139,400	\$65,811,376
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
MD III	\$101,249,618	\$121,120,517	\$134,494,699	\$146,271,953	\$136,973,741
	FY 2018	FY 2019			
MD IV	\$189,522,755	\$122,519,124			

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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 FY2019 by Submission type	# Waived	# Reduced
Full Fee applications^{2/}		
PMA	1	3
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	1	3
De Novo Classification	5	8
180-Day Supplements	0	5
Real-Time Supplements	0	8
510(k)s	14	278
30-day Notices	1	22
513(g)s	0	4
PMA Annual Report	0	0
Total	22	331

^{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.

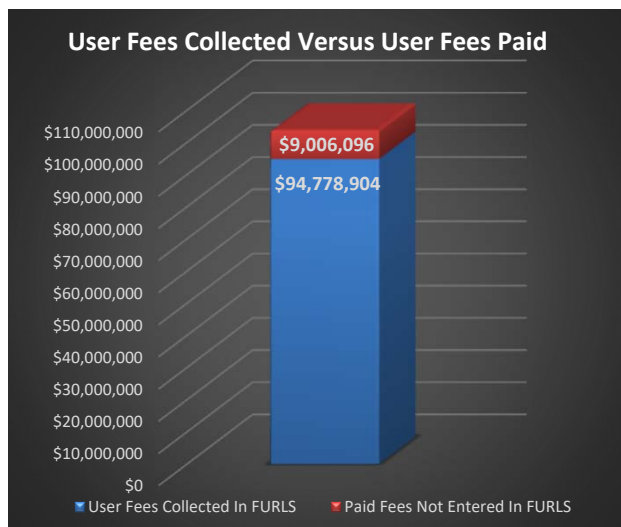
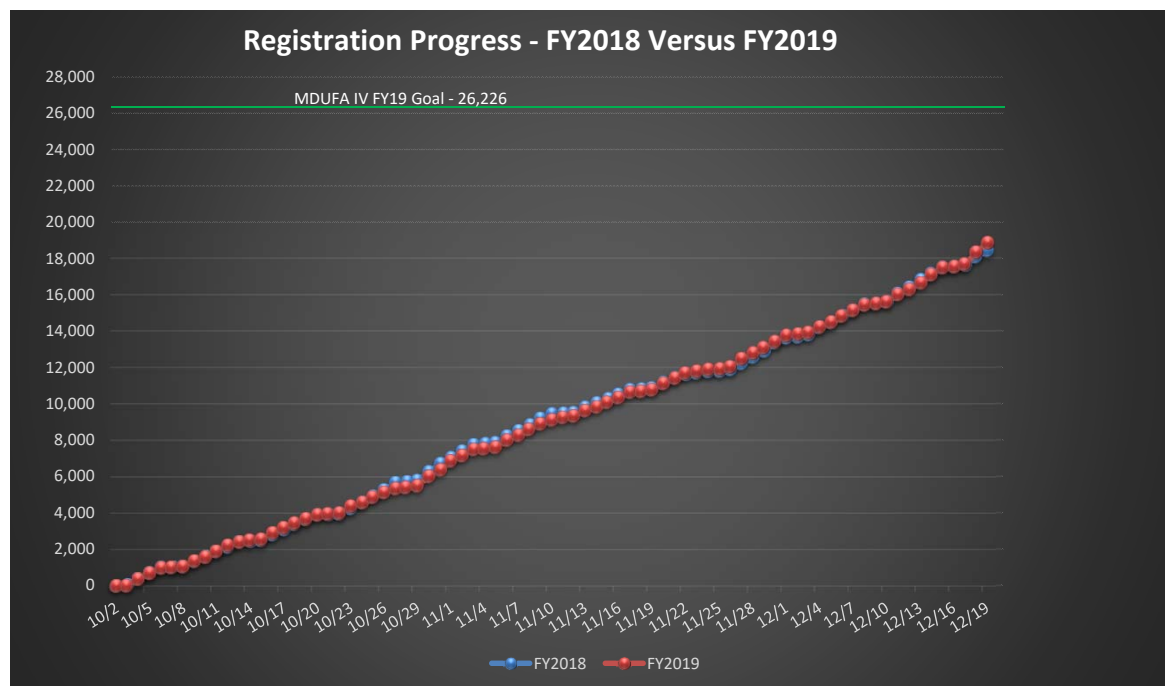
^{2/} As specified in the MDUFA 4 Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually.

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MDUFA IV Registrations - First Quarter Summary FY2019*

*No registration and listing analysis activities were performed during the 5-week lapse in appropriations. FY2019 Q1 data are reported until 12/20/2018

Current Active Registrations by Type	FY19 Q1 (until 12/20/18)			FY18 Year End Active Totals			FY19 vs End FY18
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	4,627	7,309	11,936	6,199	9,926	16,125	74.02%
Contract Manufacturer	821	1,207	2,028	1,113	1,481	2,594	78.18%
Contract Sterilizer	63	116	179	73	140	213	84.04%
Specification Developer	1,110	376	1,486	1,708	502	2,210	67.24%
Reprocessor of Single Use Devices	18	2	20	25	3	28	71.43%
U.S. Manufacturer of Export Only Devices	89		89	137		137	64.96%
Repackager/Relabeler	727	129	856	1,144	185	1,329	64.41%
Remanufacturer	14	6	20	22	13	35	57.14%
Foreign Exporter/Private Label Distributor		671	671		976	976	68.75%
Initial Importer	2,121		2,121	3,264		3,264	64.98%
Unknown	6	5	11	17	13	30	36.67%
Total:	9,596	9,821	19,417	13,702	13,239	26,941	72.07%



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Center for Devices and Radiological Health Internal Training Summary Report

Q1 FY19

October 2018 – December 2018

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

As of: 2/8/2019

The FDA continues to invest in internal and external training opportunities supporting medical device regulation. The Division of Employee Training and Development (DETD) is CDRH's internal resource for scientific, regulatory, leadership training, career development programs, and customized learning opportunities. We help further the Center's mission by championing employee growth across the Center's eight offices. Our approach to improving performance combines classroom, experiential, and online learning with mentoring, self-study initiatives, and specialty programs. We are committed to providing CDRH employees with the knowledge and skills needed to maximize their organizational and individual potential.

Table X provides a summary of internal training conducted in CDRH between October 1, 2018 and December 31, 2018. DETD offered 242 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. The training was designed to support the Medical Device User Fee Amendment (MDUFA) goals and program activities.

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Table X – FY19 CDRH Internal Training Conducted by DETD:*October 1, 2018 and December 31, 2018*

Category	Program	# of Learning Events	Total # of Completions	Total Training Hours
Regulatory and Law (LAW) Training	MDUFA IV	5	117	93
	ELP	1	4	32
	Other LAW	153	2632	2492
<i>LAW Subtotal:</i>		<i>159</i>	<i>2753</i>	<i>2617</i>
Leadership Development Training (LED)	LEAD: Leadership for Managers	18	163	322
	Leadership for Non-Managers	1	16	112
	Other LED	6	97	945
<i>LED Subtotal:</i>		<i>25</i>	<i>276</i>	<i>1379</i>
Professional Development (PRO) Training	New Employee Orientation (NEO)	1	15	105
	Other PRO	18	244	2088
<i>PRO Subtotal:</i>		<i>19</i>	<i>259</i>	<i>2193</i>
Center-Specific Information Technology (CIT) Training	Premarket IT	6	70	70
	Other CIT	3	6	3
<i>CIT Subtotal:</i>		<i>9</i>	<i>76</i>	<i>73</i>
Science (SCI) Training	All SCI	<i>30</i>	<i>567</i>	<i>1120</i>
<i>SCI Subtotal:</i>		<i>30</i>	<i>567</i>	<i>1120</i>
Grand Total:		242	3931	7382

CDRH Informal Training

CDRH Informal Training:

DETD implemented a process for tracking Informal training in 2015. Unlike Formal Center-wide training managed by DETD, Informal training targets specific audiences and addresses specialized training topics. Informal training is offered at the Office, Division and Branch levels and is conducted as on-the-job training, All-Hands meetings, small group sessions and classroom and remote training. Formal and informal training is necessary to meet the mission-critical training needs of Center staff. Examples of informal training content include:

- Additional instruction provided following Formal training (e.g. Medical Device Regulation training)
- Policy change updates (e.g. Technology, MDUFA, new guidance)
- Best practices used in a specific product area

CDRH Informal Training: *October 1, 2018 and December 31, 2018*

Year	# of Learning Events	Total # of Participants	Total Contact Hours
FY'15	34	1249	3350
FY'16	42	978	2122
FY'17	113	2845	8956
FY'18	61	1692	5650
FY'19	9	110	161
Total:	259	6874	20239

Premarket Reviewer Training - RCP

Reviewer Certification Program (RCP):

The RCP curriculum is a 30.5-hour program consisting of online and classroom courses essential to new reviewers during their first 60 days of hire. The condensed course design results in reviewers receiving the most salient knowledge in a timely fashion. After completion of the RCP, reviewers enroll in advanced courses designed to further enhance their knowledge and skills. The curriculum consists of the following components:

- 11 classroom courses, including a program Orientation and Capstone, totaling 15.5 hours of training
- 11 online courses, totaling 15.0 hours
- 7 Advanced courses, to be taken within a year of employment
- Practical activities and hands-on exercises
- Knowledge assessments

RCP Training by Cohort: *October 1, 2018 and December 31, 2018*

Cohort	# of Classroom Learning Events	# of Online Learning Events	Office	# of Participants	# of Completions	# of Training Hours
Fall 1 2018 Cohort	11	11	OC	2	20	26
			OCD	1	12	15
			ODE	5	53	66
			OIR	10	164	202
			OSEL	4	72	88
			Subtotal:	22	321	397
Fall 2 2018 Cohort	11	11	OC	1	5	7
			OCD	2	11	15
			ODE	6	45	52
			OIR	2	30	33
			OSEL	8	59	69
			Subtotal:	19	150	176
Total:	22	22	-	41	471	573

Premarket Reviewer Training - ELP

Experiential Learning Program (ELP):

The Experiential Learning Program (ELP) is a collaborative approach to closing the knowledge gap between emerging and innovative technology and the review of resulting medical devices. The Program fosters an understanding of how medical devices are developed, clinically tested, manufactured, and utilized. Staff involved in medical device regulation visit ELP sites identified by training need and selected through a formalized proposal submission process.

ELP Training Completed: *October 1, 2018 and December 31, 2018*

# of Site Visits	# of Attendees	Total Training Hours	Focus Areas
1	4	32	• Innovation

ELP Training Completed by Office: *October 1, 2018 and December 31, 2018*

Office	Total # of Attendees	Total Training Hours
OC	1	8
OCD	1	8
OIR	1	8
OSB	1	8
Total:	4	32

Leadership Training - LEAD

Leadership Enhancement and Development (LEAD) Program:

The LEAD Program is a mandatory Supervisory Training Program targeting CDRH Supervisors, Managers, and Non-Bargaining Unit Team Leaders. The LEAD curriculum supports the CDRH Management Competencies and addresses the supervisory training requirements as mandated in 5 CFR 412.

LEAD Training Completed: *October 1, 2018 and December 31, 2018*

Category	# of Learning Events	Total # of Completions	Total Training Hours	Examples of Training Conducted
LEAD	18	163	322	<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 • CDRH Ethics Refresher Series: What is an Outside Activity?

LEAD Training Completed by ODE and OIR: *October 1, 2018 and December 31, 2018*

Office	Total # of Managers/Supervisors*	# of Training Participants	Training Hours Required**	% of Required Training Hours Completed
ODE	80	48	1280	22%
OIR	45	7	720	3%
Total:	125	55	2000	13%

*The number of supervisors may vary by quarter based on data provided from each Office.

**This data is based on the 16-hour minimum annual training requirement for managers with 3 or more years of experience. New supervisors within the federal government have an additional 24-hour training requirement, for a total of 40 hours.

Leadership Training - LRP

Leadership Readiness Program (LRP):

The Leadership Readiness Program (LRP) is a one-year learning opportunity for employees considering a supervisory career path. The LRP facilitates learning in the areas of mentoring, self-study, classroom-based courses, and other practical activities. The target audience is highly motivated, non-managers at the GS 12, 13, and non-supervisory 14 levels or equivalent Commissioned Corps Officers rank, with a minimum of two years of FDA experience. Participants are selected for the one-year program through a competitive process. They remain in their current position and participate in the LRP as a collateral activity.

LRP Participant Data:

LRP Program Year	Office	# of Enrolled Participants	# of Participant Completions
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
2018-2019	OIR	4	-
	ODE	11	-
	Other	7	-
Total:		148	123

CDRH Training Courses by Category:

The following section contains a sampling of DETD courses provided during FY19.

Regulatory and Law (LAW) Training:

Benefit-Risk Guidance – Online	This online course outlines the factors to consider when making benefit-risk determinations for Premarket Approval (PMA) applications and De novo petitions.
Master Four-Part Harmony	This course provides instruction on writing deficiencies that are clear, concise, and in the appropriate format.
Master Technical Writing	This course teaches the basic elements of plain language writing and how to use them to write clear and succinct technical documents.
Pre-Submission Program, Meetings with FDA, IDEs, and Clinical Trials	This course provides practical knowledge about the reviewer's roles and responsibilities related to the Pre-submission program, meetings and clinical trials.
Effective Communication Skills for Technical and Scientific Professionals	This course addresses real-world communication strategies for scientific and technical professionals.
Introduction to Premarket Review	This course describes the essential elements in premarket review.
Premarket programs: 510k and 513g	This course provides an understanding of the device classifications.
Conducting 510k Reviews	This course provides an overview of the 510(k) flowchart.
Basics of Writing Consult Requests and Reviews	This course provides examples of the essential elements of a written pre-market consulting review.
Premarket Programs: IDEs	This course provides an understanding of the regulatory submission that permits clinical investigation of medical devices.
Premarket Programs: PMA and HDE	This training outlines the types of PMA submissions and the information necessary to determine when a PMA is required.
Premarket Review Clinic	The training prepares the participant to complete the CAPSTONE assignments distributed following completion of the Reviewer Certification Program.
Reviewer Certification CAPSTONE	This training includes interactive sessions that discuss the varying types and requirements of medical device applications.
Regulatory Basics (online)	This training describes the source and effect of law, regulation, and guidance on the work conducted within CDRH.
MDUFA IV Overview	This training provides an overview of the Medical Device User Fee Act of 2017.

Basics of 4-Part Harmony in Lead and Consult Reviews	This training provides participants with instruction on the elements needed to write clear and concise deficiencies.
RCP: Standards Overview	This training provides an overview of Standards and how they are applied.
RCP: Standards Resources and Premarket Use	This training provides participants with instruction on how to find recognized Standards and discusses how Standards are used in premarket submissions.
RCP: Basics of Standards in Premarket Review	This training provides participants with instruction on locating recognized Standards, Standard's guidance, and accessing Standard's library resources.
Overview of FOIA	This training provides an overview of FOIA applications and discusses the impact of OPEN Government amendments to FOIA.
SMART Template	This class provides instruction for using a programmed Microsoft Word document to create review documents.
RCP Premarket Program: De Novo Classification	This class describes the legal basis for the De Novo pathway.

Leadership Development Training for Managers and Non-Managers (LED) Training:

Handling People with Diplomacy & Tact	This course provides participants with a big-picture mentality regarding their work and a blueprint for productivity. Participants also learn techniques for empowering their team and holding 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 course provides organizations with an understanding of unconscious bias, the tools to confront and combat its negative effects; and the ability to recognize when the impact on decision making.
LEAD: Managing Up, Communicating with Your Boss	This course focuses on the skills necessary for managing upward including effective communication, achieving goals and providing constructive feedback.
Negotiating with Confidence	This interactive program enables participants to better communicate their needs and negotiate with confidence using practical application.
Critical Thinking and Problem Solving	This two-day workshop is designed to provide an understanding of the differences between critical thinking styles and how they are applied in the everyday world.

Professional Development (PRO) Training:

Growing Creativity and Innovation	This course explores both the nature and nurture of creativity and innovation and the capacity for putting these vital skills into everyday practice.
Strategic Planning and Analytical Thinking	This course provides participants with an understanding of the different analytical styles and how they affect and inhibit analytical thinking. Tools used in analytical thinking and ways to increase creative thinking are also addressed.
Critical TOP Thinking	This training provides an overview and tools for Thought Optimized Processing (TOP) Thinking. Participants learn how to accomplish TOP in a pragmatic way while maintaining precision and accuracy. Instruction also addresses the ability to think creatively and critically while ensuring that reasoning is objective.
Influencing Others for High Impact	This seminar focuses on the skills and strategies necessary to increase the likelihood that others will say "yes". The course instruction includes an opportunity to translate theory into practice.

Science (SCI) Training:

Introduction to Public Health	This course provides the framework for understanding public health concepts, the fundamentals of epidemiology, medical product surveillance systems, and the public health determinants that influence medical device development.
CDRH Laboratory Waste Management – online	This course gives an overview of the requirements for waste handling in CDRH laboratories, as well as a brief description of the laboratory Emergency Procedures.
Regenerative Medicine Series	The Regenerative Medicine Seminar Series offers a variety of seminars that examine the restoration and function of the human form within the context of translational research involving medical devices and biologics.
Reprocessing Medical Devices in Health Care Settings	This course is designed to provide staff involved in medical device regulation with the knowledge necessary to perform routine labeling evaluations based on FDA's 2015 Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

Center-Specific IT (CIT) Training

Using IT Systems in Premarket Review	This online course is designed to provide an overview of the IT systems used in medical device regulation.
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