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**Agenda for Quarterly Meeting on
MDUFA V (FY 2023-2027) Performance
February 23, 2026, 1:00 – 2:00 pm
Teams**

Welcome –

FDA MDUFA Performance — Actions through December 31, 2025

- Report on performance goals for 1st Quarter FY 2026

Guidance Development

Registration and Listing

Qualitative Update on Finances – 1st Quarter FY 2026

- User fee receipts through the 1st Quarter FY 2026

Annual Hiring Goals Update

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 31 December 2025**

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Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
IDE	Investigational Device Exemption
IVD	In Vitro Diagnostic
LDT	Laboratory Developed Test (as identified by the submitter)
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

Office Organizations

OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device

OHT2: Office of Cardiovascular Devices

OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics

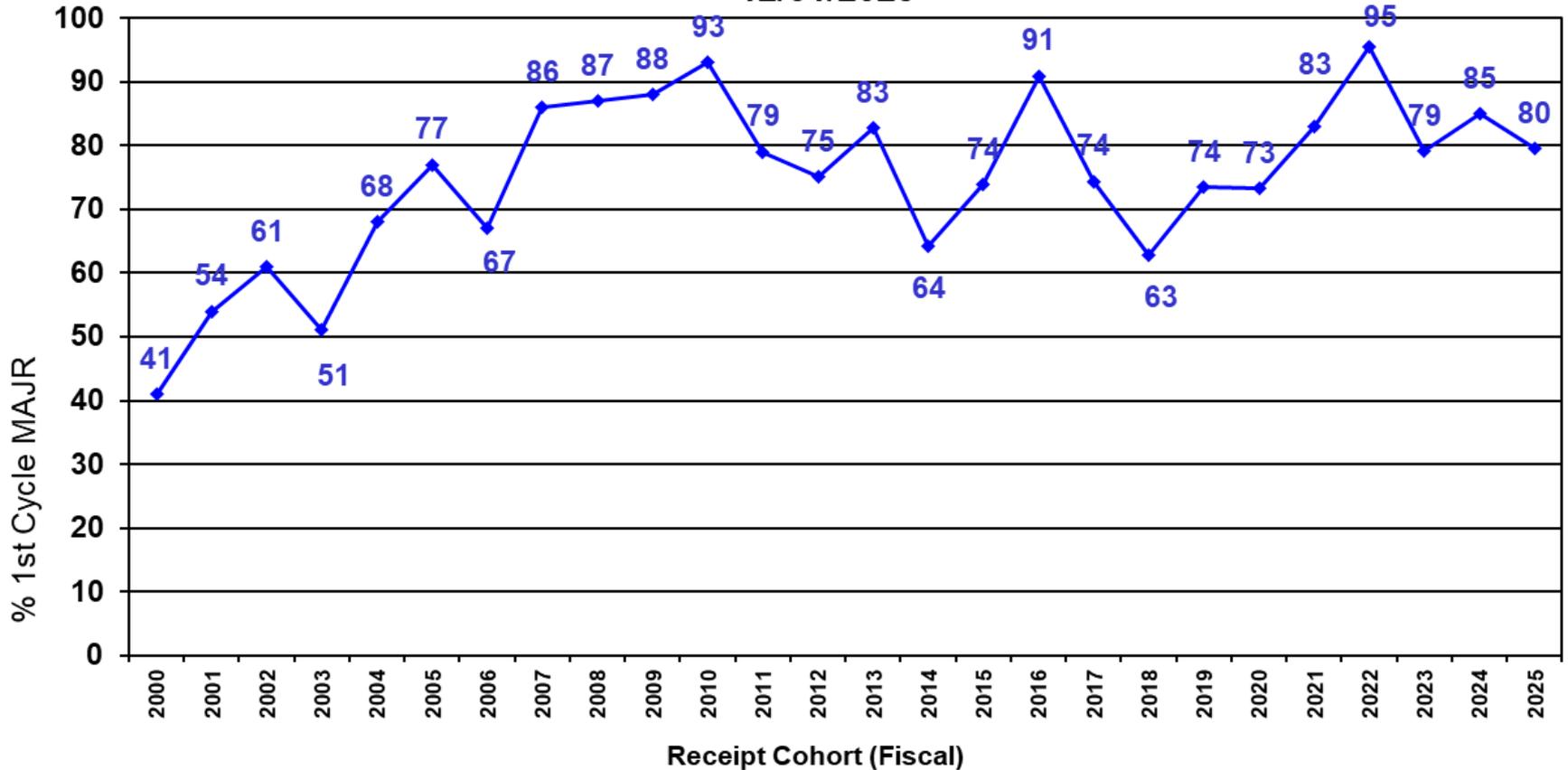
OHT8: Office of Radiological Health

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

PMA's

Q1FY2026

PMA Originals Filed as of 09/30/2025: 1st Cycle Major Deficiency Rate as of 12/31/2025

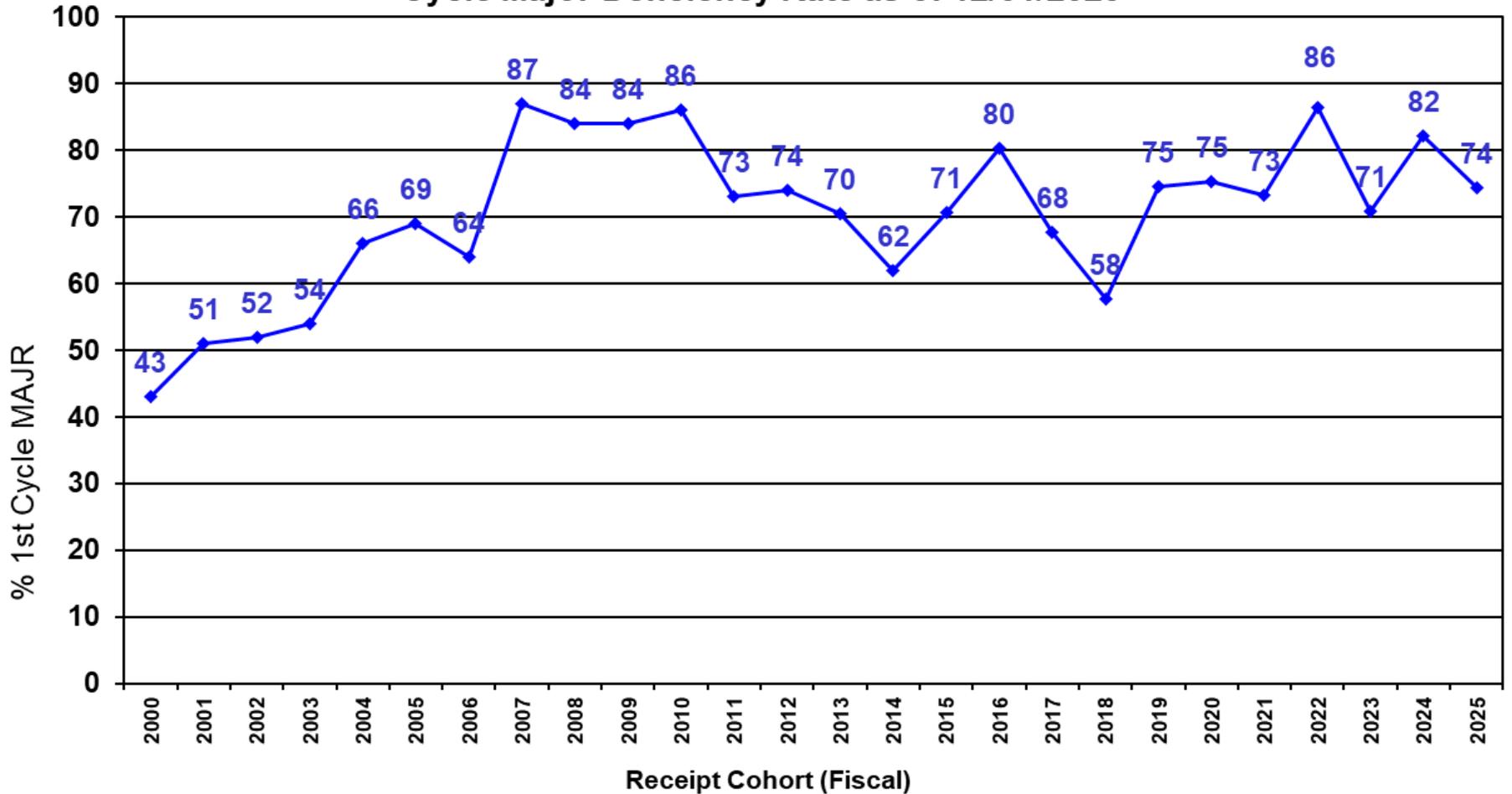


Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submission rec'd, accepted & filed as of 6/30/25.

Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO/PTS

PMA Originals and Panel track Supplements Filed as of 09/30/2025: 1st Cycle Major Deficiency Rate as of 12/31/2025

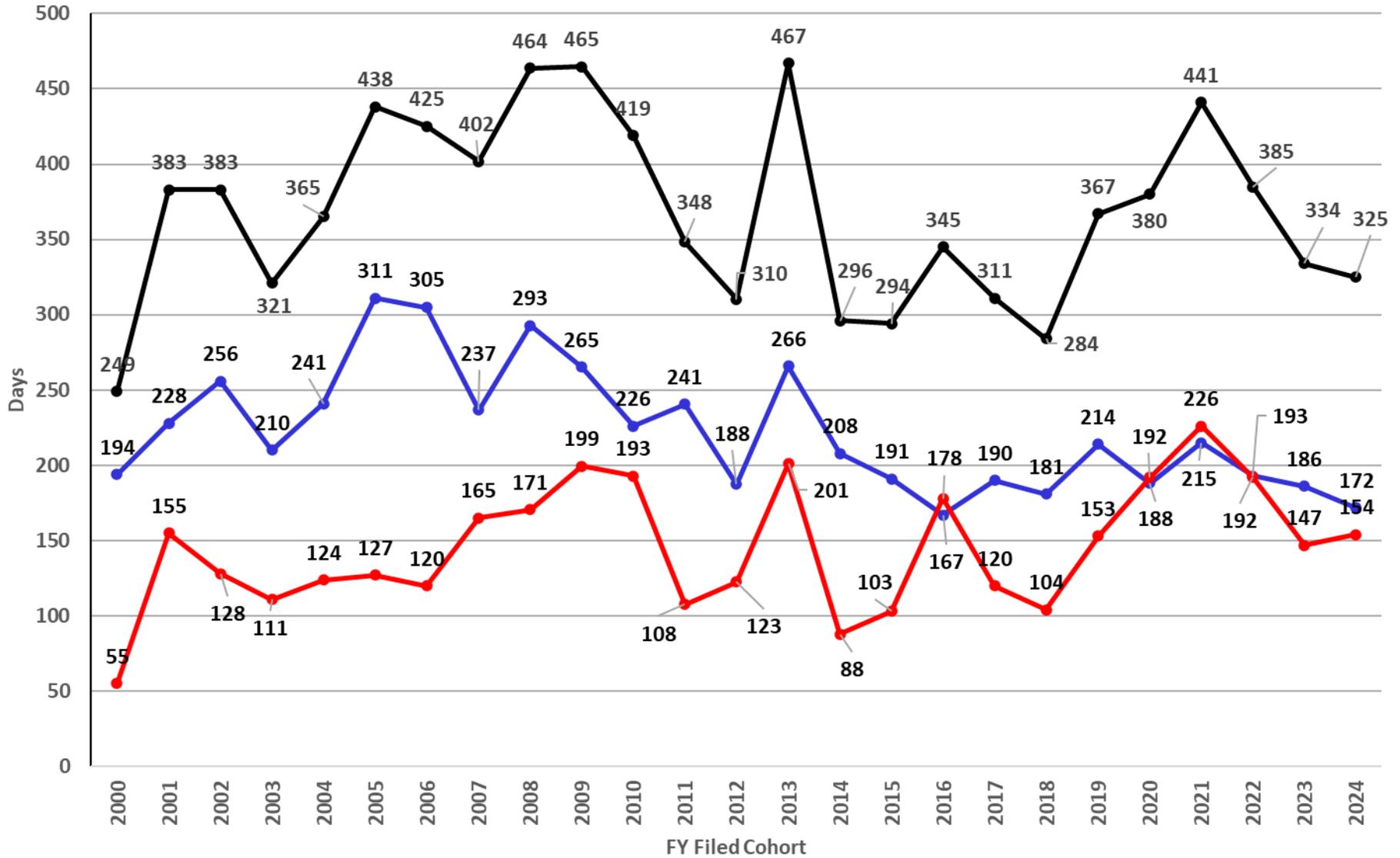


Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submission rec'd, accepted & filed as of 6/30/25.

Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO/PTS

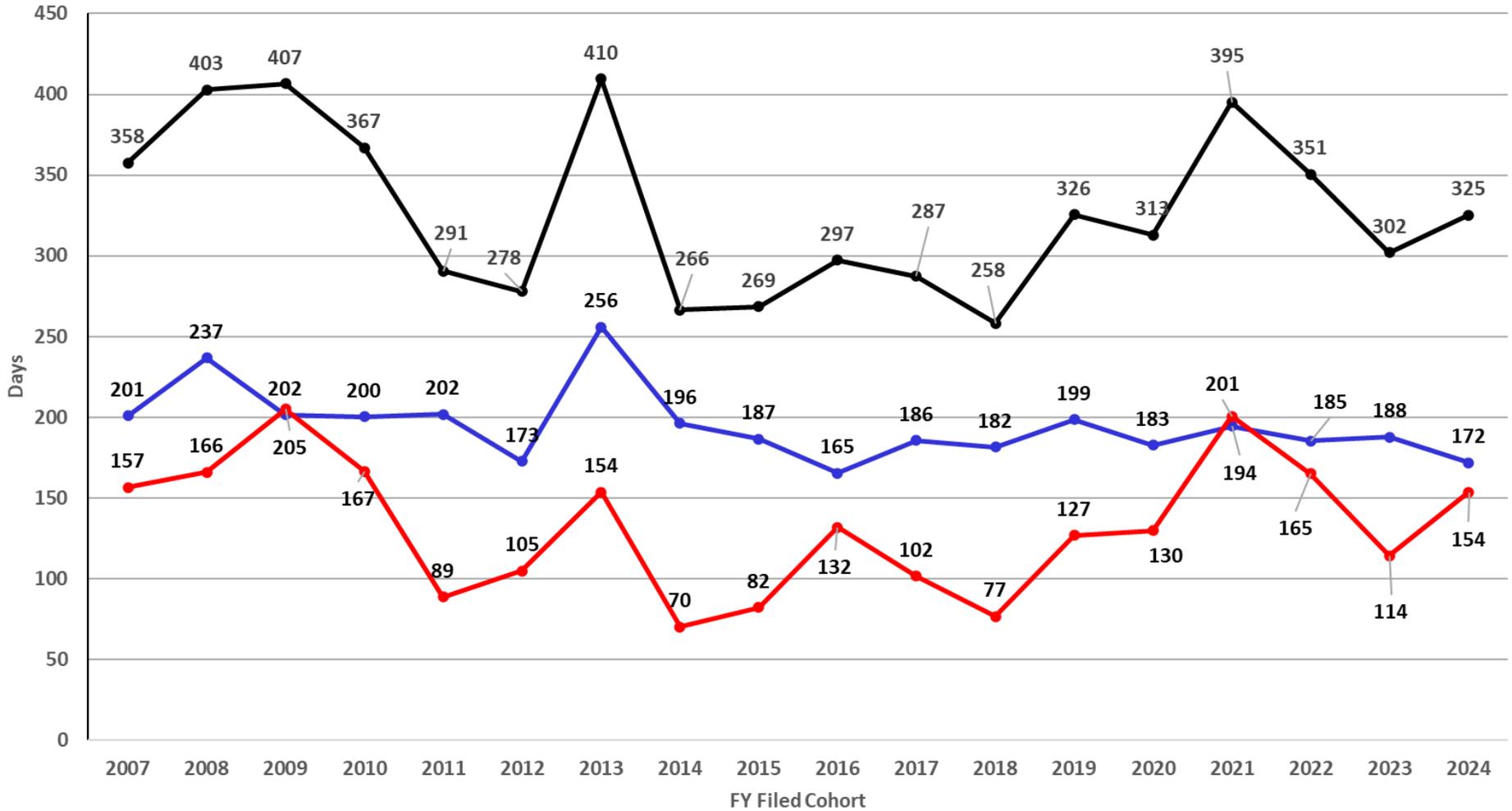
PMA Originals Filed As Of 12/31/2025: Average Time to MDUFA Decision



Cohorts not yet closed: 2024: 90.00%

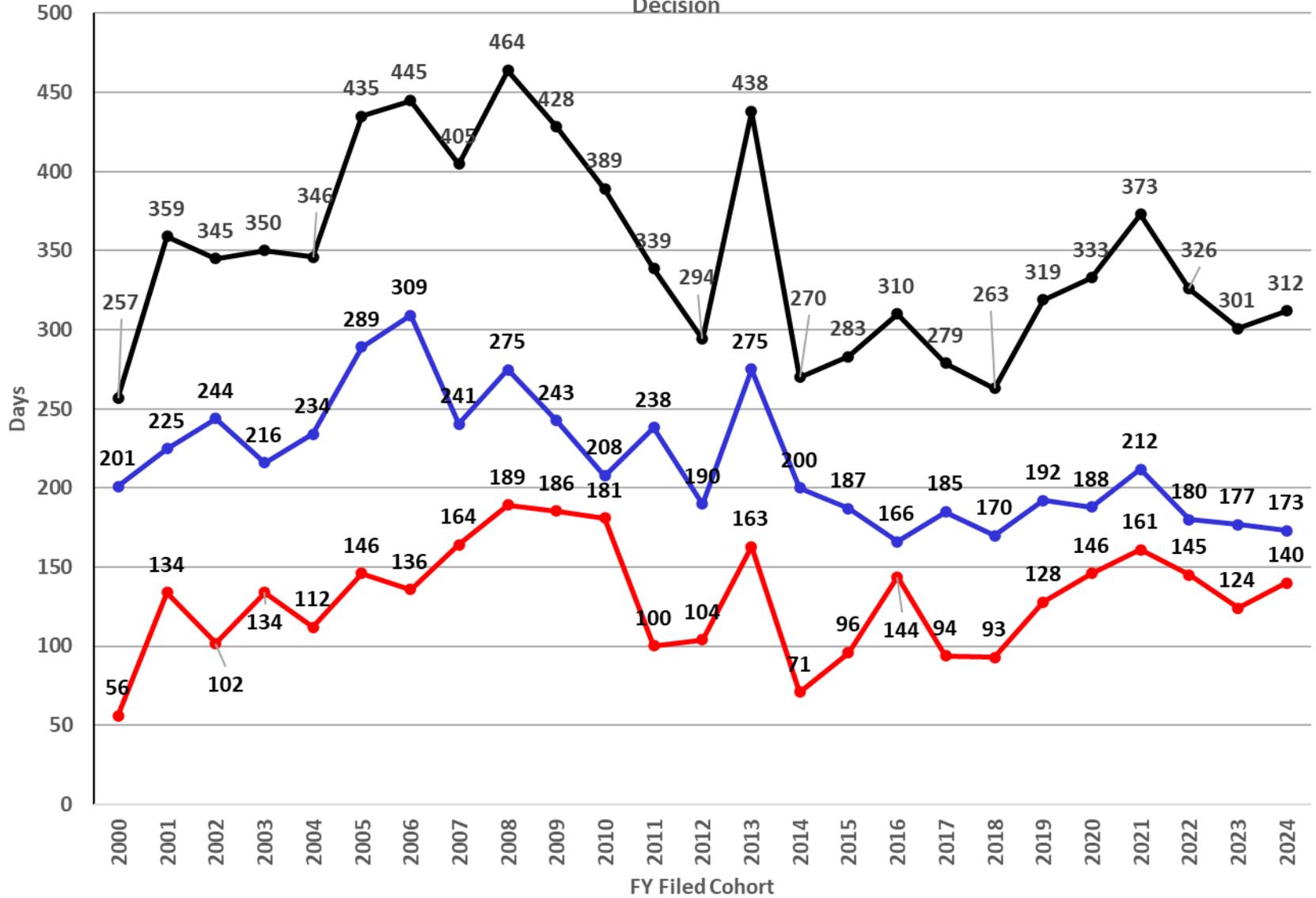
● Avg FDA Days to MDUFA Decision
 ● Avg MFR Days to MDUFA Decision
 ● Avg Total Days to MDUFA Decision

PMA Originals Filed As Of 12/31/2025: Average Time to MDUFA Decision
 Comparison of Cohorts at 90.00% Closure



—●— Avg FDA Days to MDUFA Decision
 —●— Avg MFR Days to MDUFA Decision
 —●— Avg Total Days to MDUFA Decision

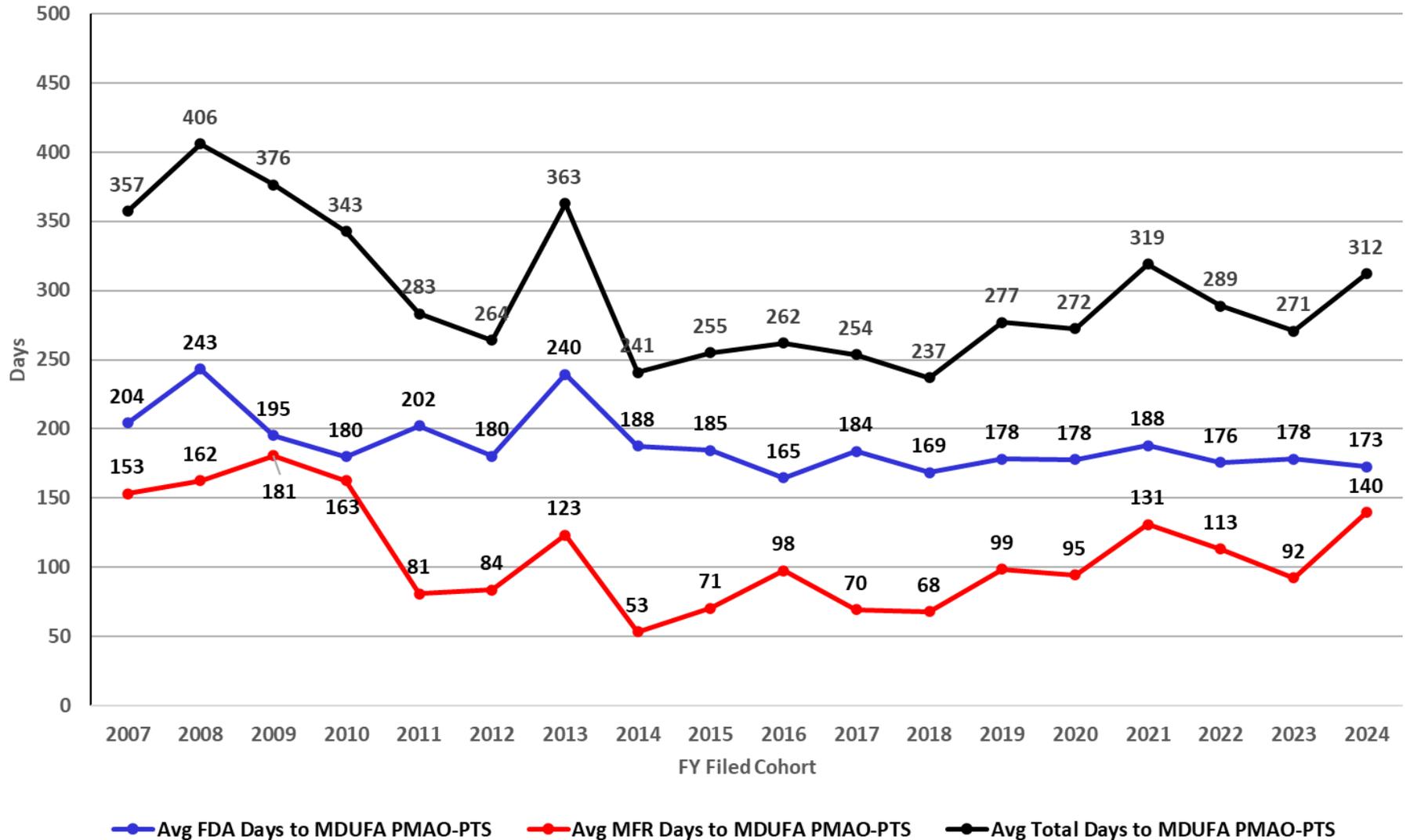
PMA Originals and Panel Track Supplements Filed As Of 12/31/2025: Average Time to MDUFA Decision



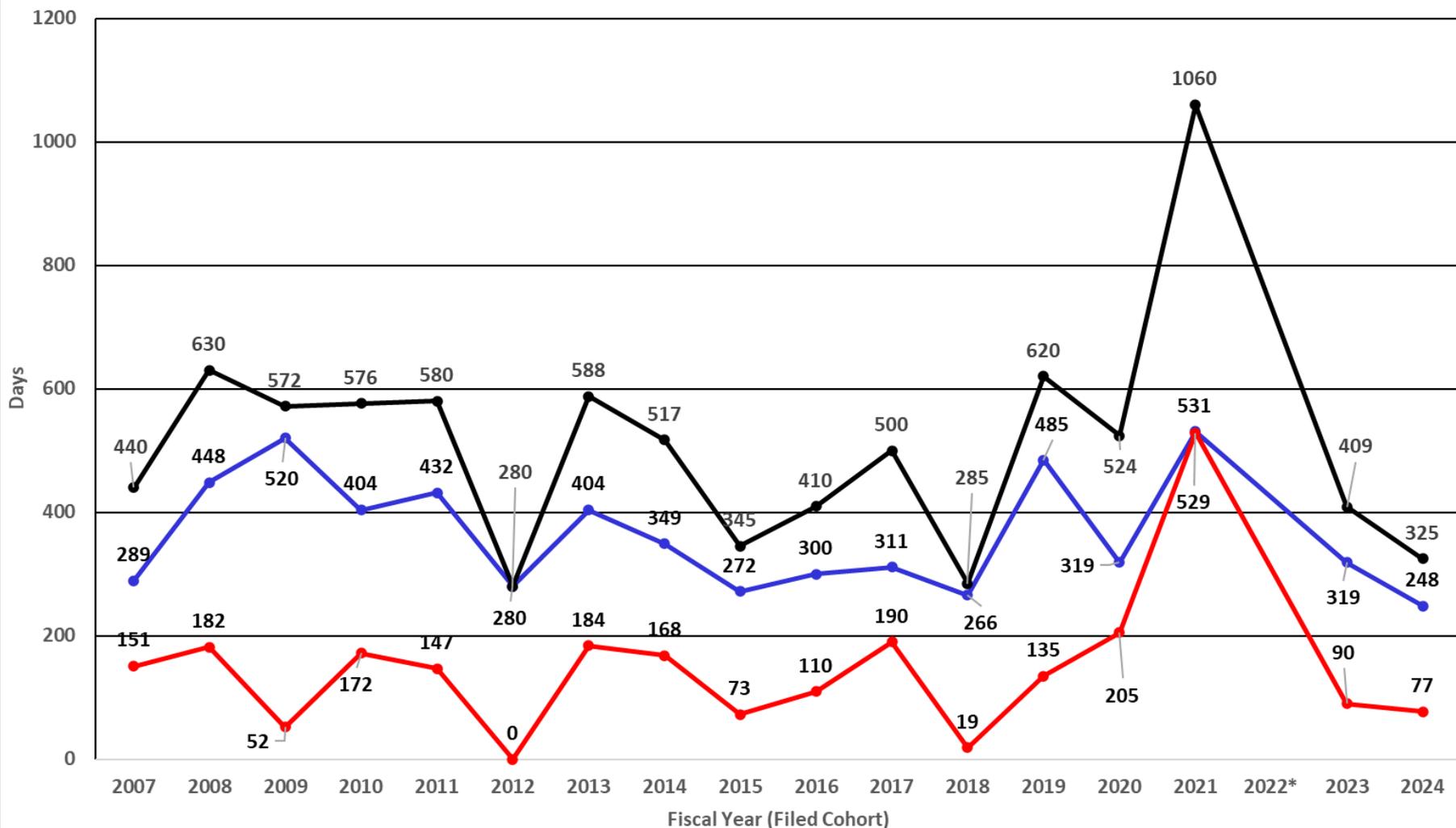
Cohorts not yet closed: 2024: 89.55%

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

PMA Originals and Panel Track Supplements Filed as of 12/31/2025: Average Time to MDUFA Decision
Comparison of Cohorts at 89.55% Closure



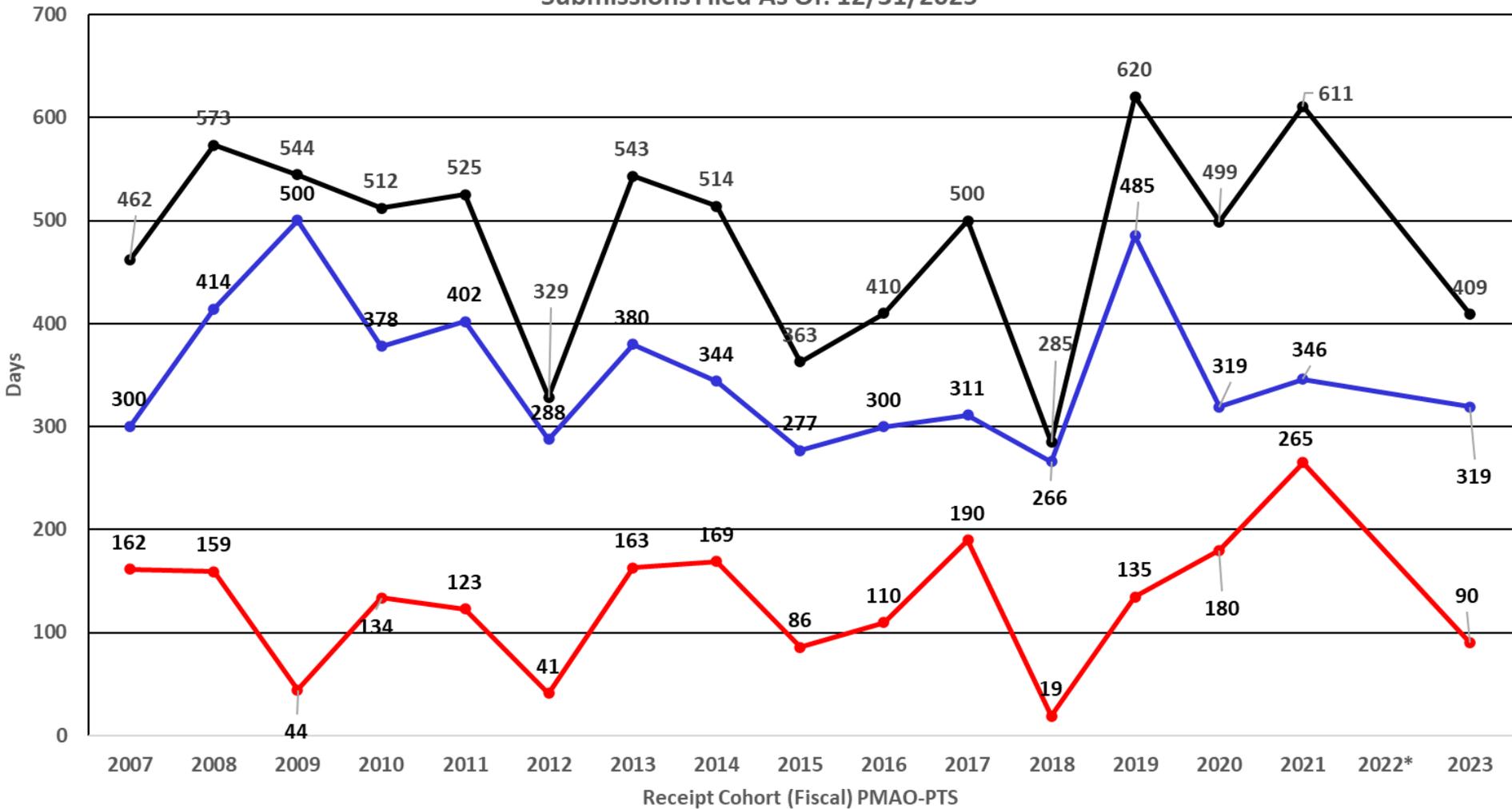
**PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of:
12/31/2025**



Numbers Closed/Filed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3; 2021 = 1/1; 2023 = 4/4; 2024 = 1/1

*Note: For FY22, there were no applicable MDUFA decisions for PMA Originals with Panel Review

PMA Originals and Panel Track Supplements With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 12/31/2025

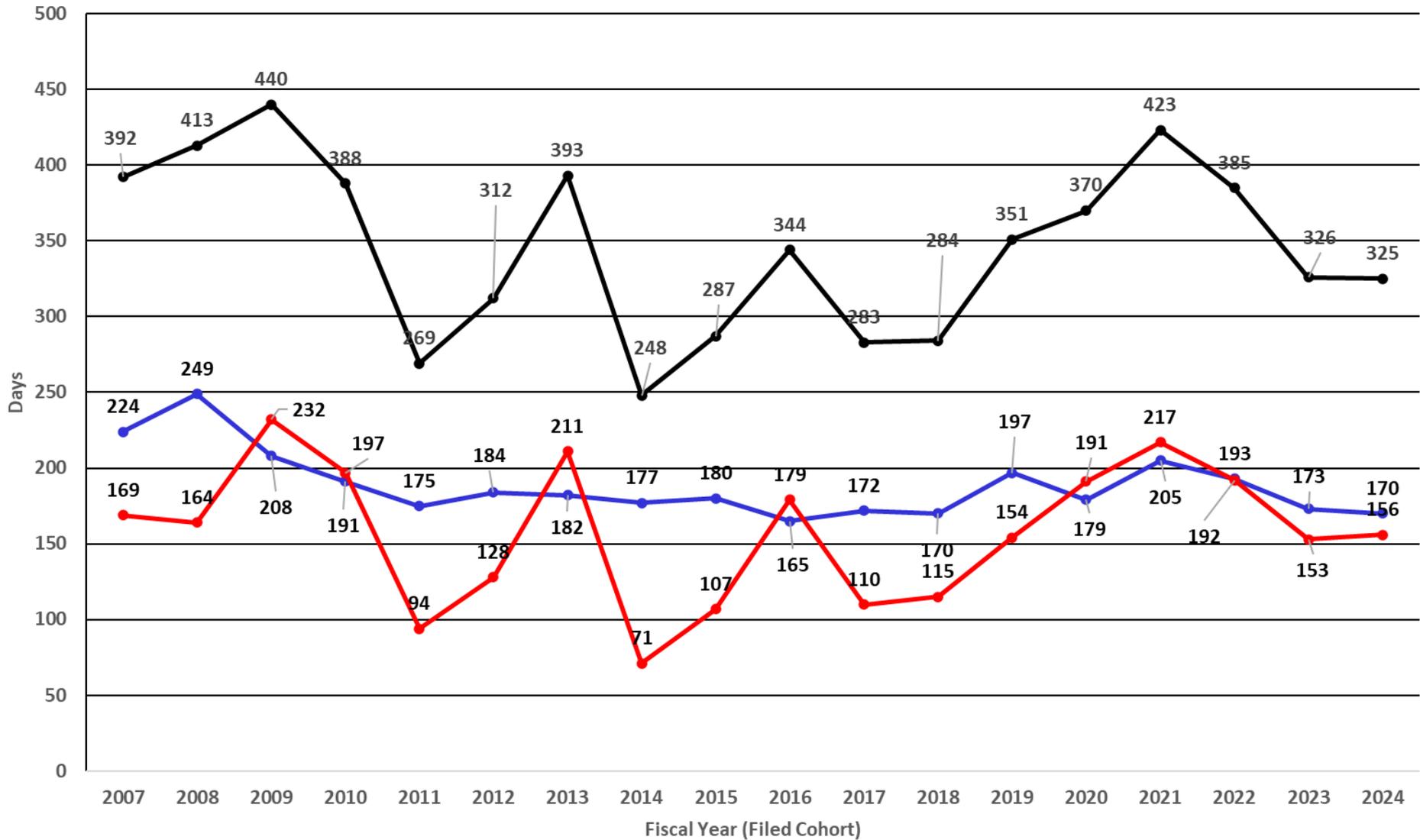


Numbers Closed/Filed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; 2012 = 2/2; 2013 = 17/17; 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/2; 2023 = 4/4

*Note: For FY22, there were no applicable MDUFA decisions for PMA Originals and Panel Track Supplements with Panel Review

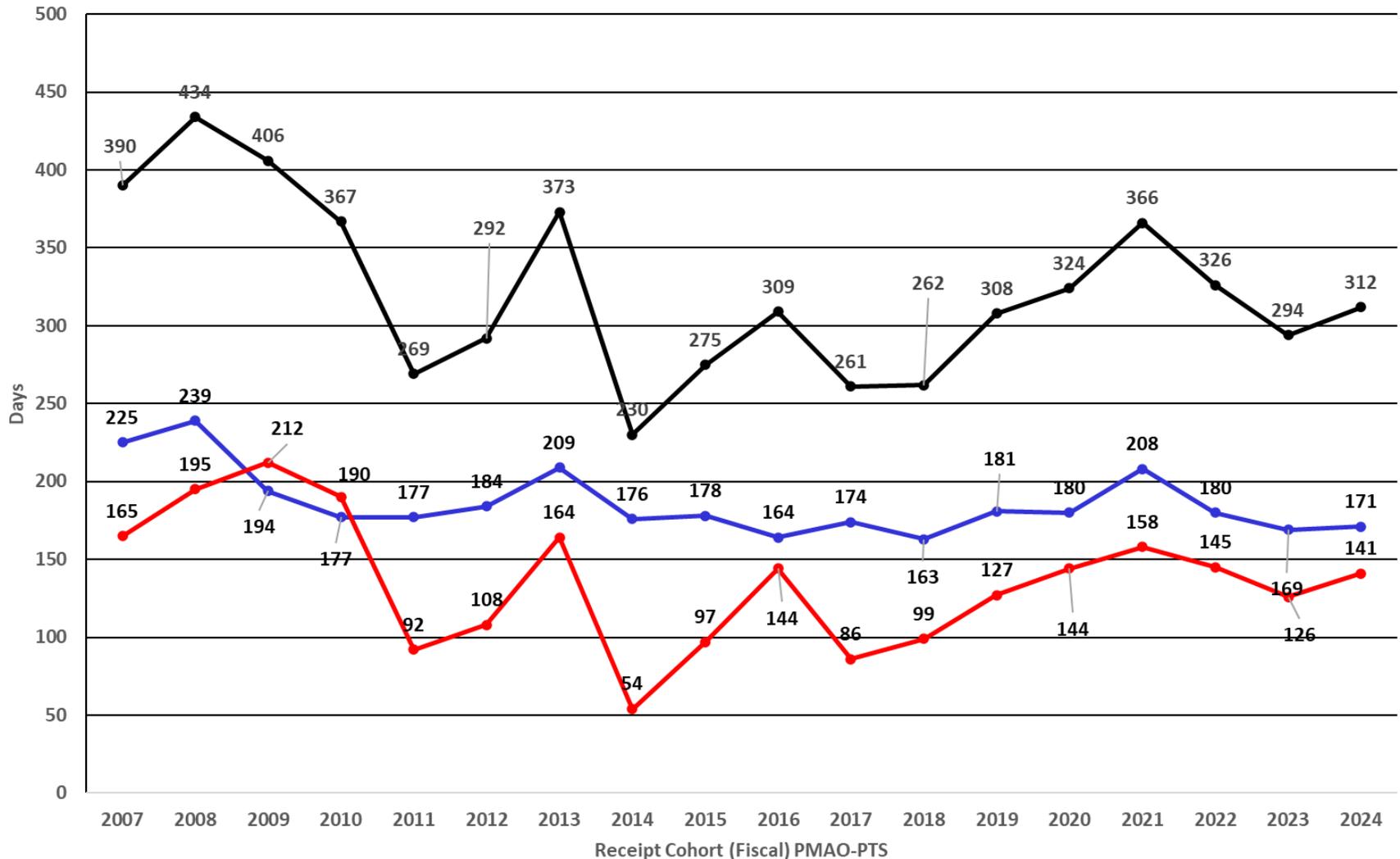
● Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ● Avg Total Days to MDUFA Decision PMAO-PTS

PMA Originals Without Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 12/31/2025



Numbers Closed/Filed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 22/22; 2023 = 39/39; 2024 = 35/39

**PMA Originals and Panel Track Supplements Without Panel Review: Average Time to MDUFA Decision
for Submissions Filed As Of: 12/31/2025**

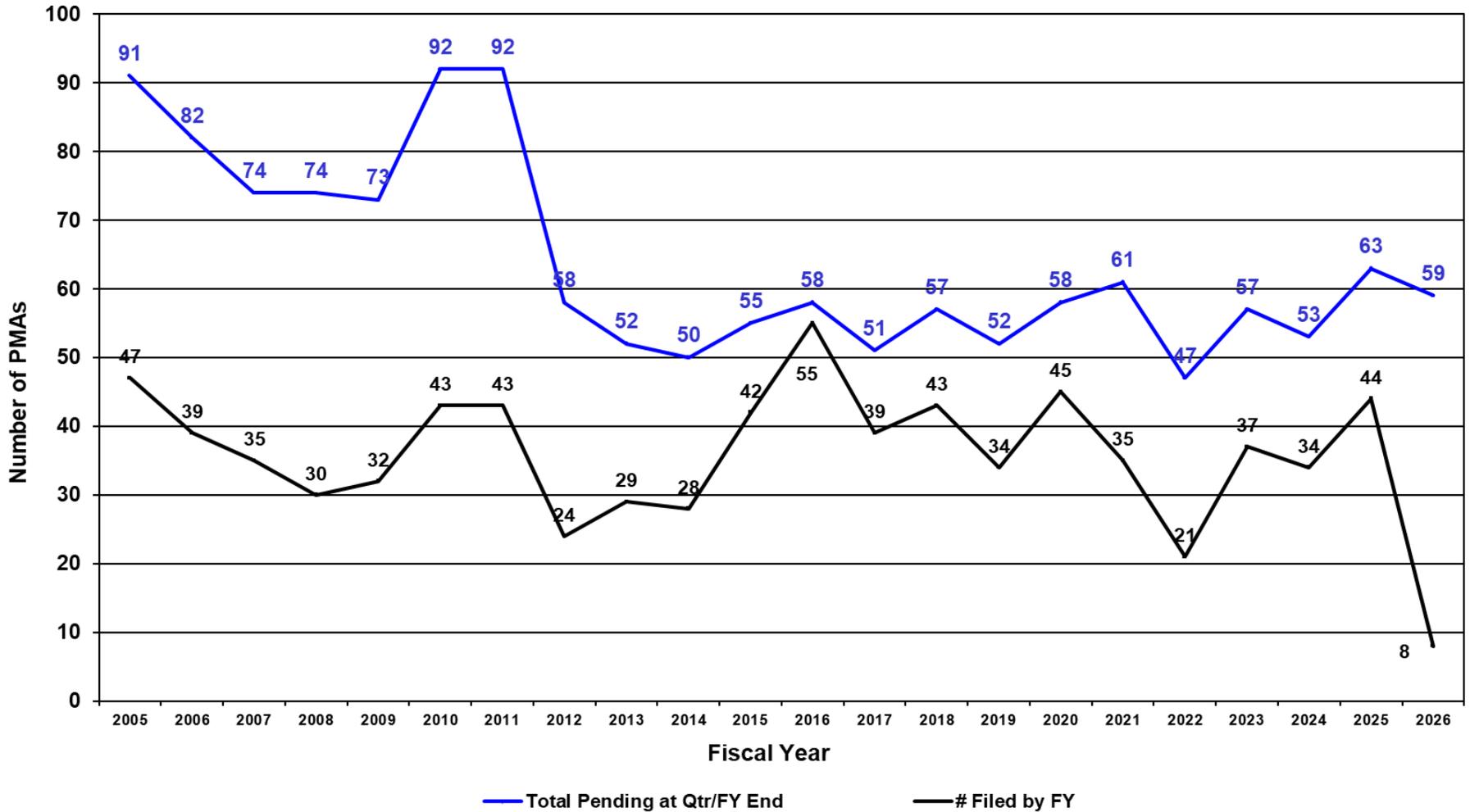


Numbers Closed/Filed: 2007 = 31/31; 2008 = 29/29; 2009 = 36/36; 2010 = 50/50; 2011 = 37/37; 2012 = 32/32; ; 2013 = 27/27; 2014 = 36/36; 2015 = 62/62; 2016 = 70/70; 2017 = 60/60; 2018 = 66/66; 2019 = 53/53; 2020 = 69/69; 2021 = 69/69; 2022 = 44/44; 2023 = 68/68; 2024 = 59/64

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

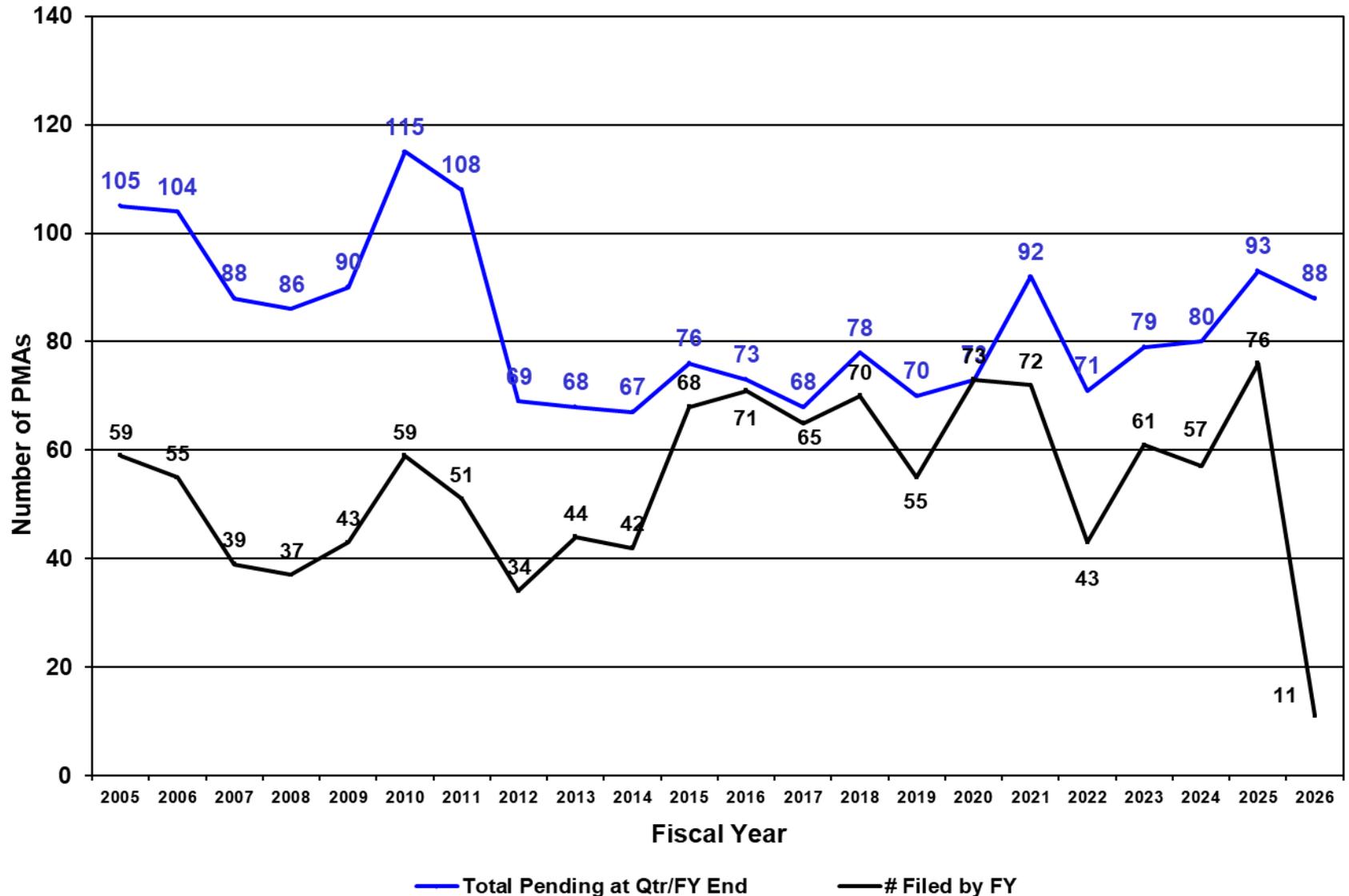
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year



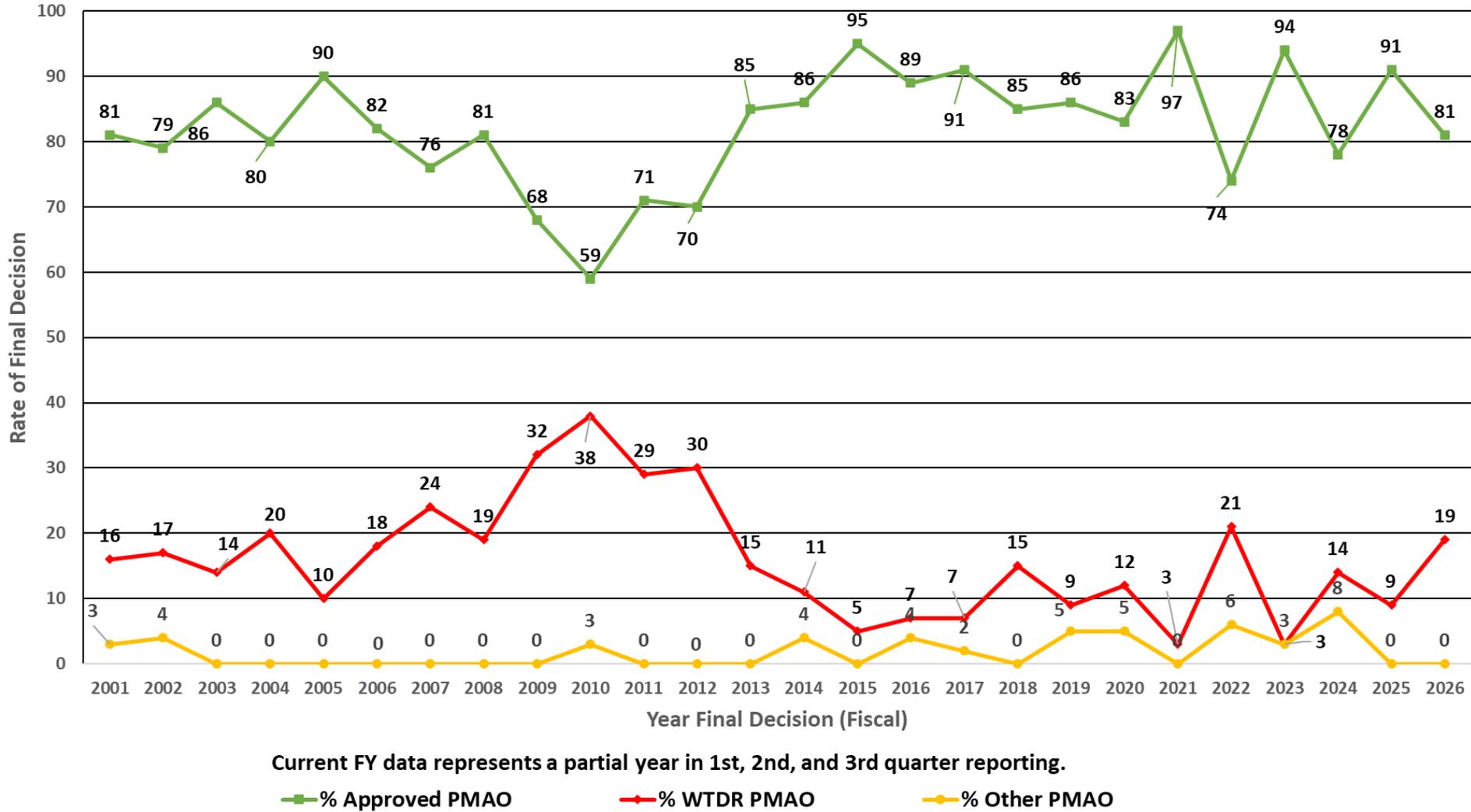
*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

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



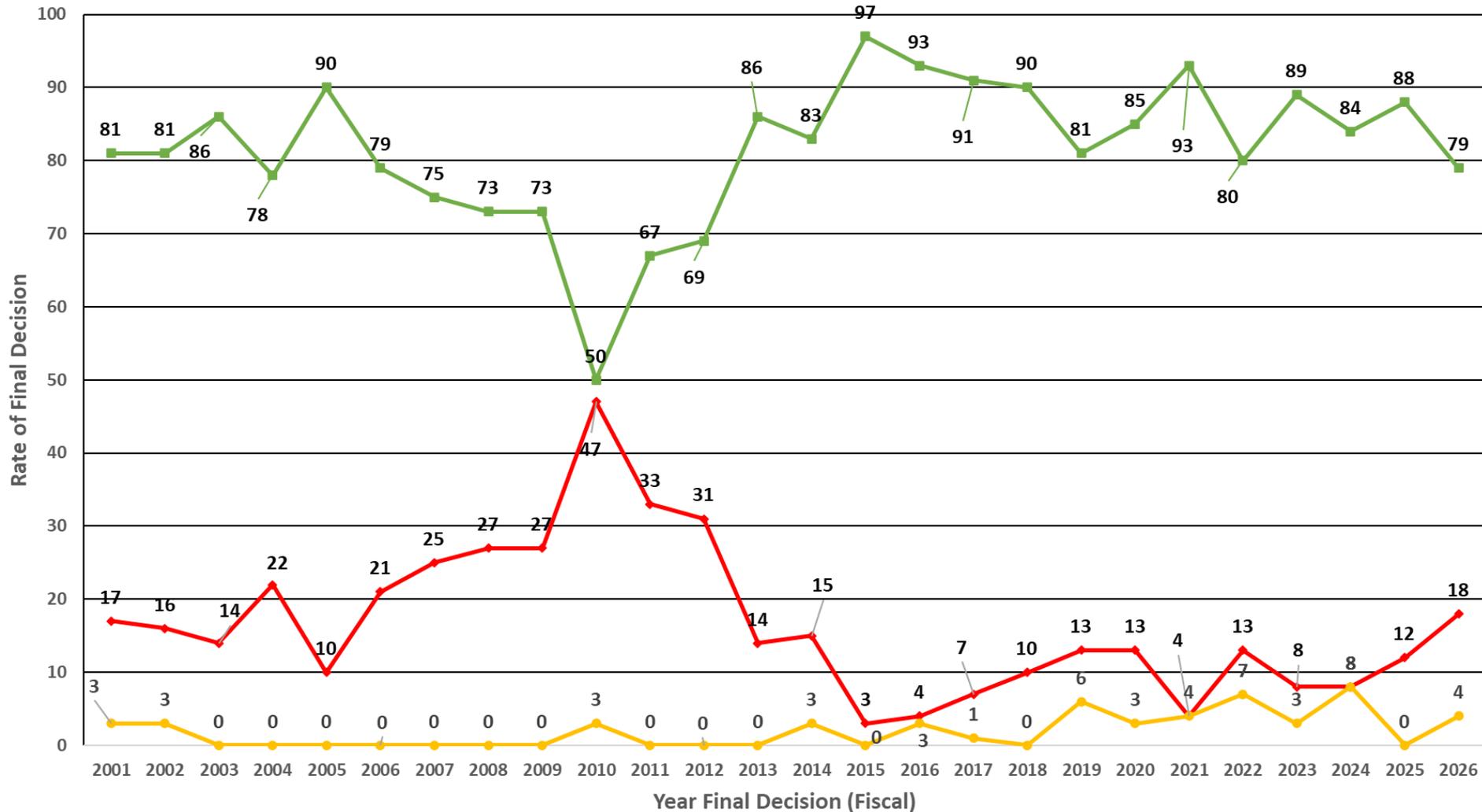
*Original PMAs/PTS awaiting filing, MDUFA or final decision, under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

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



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

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

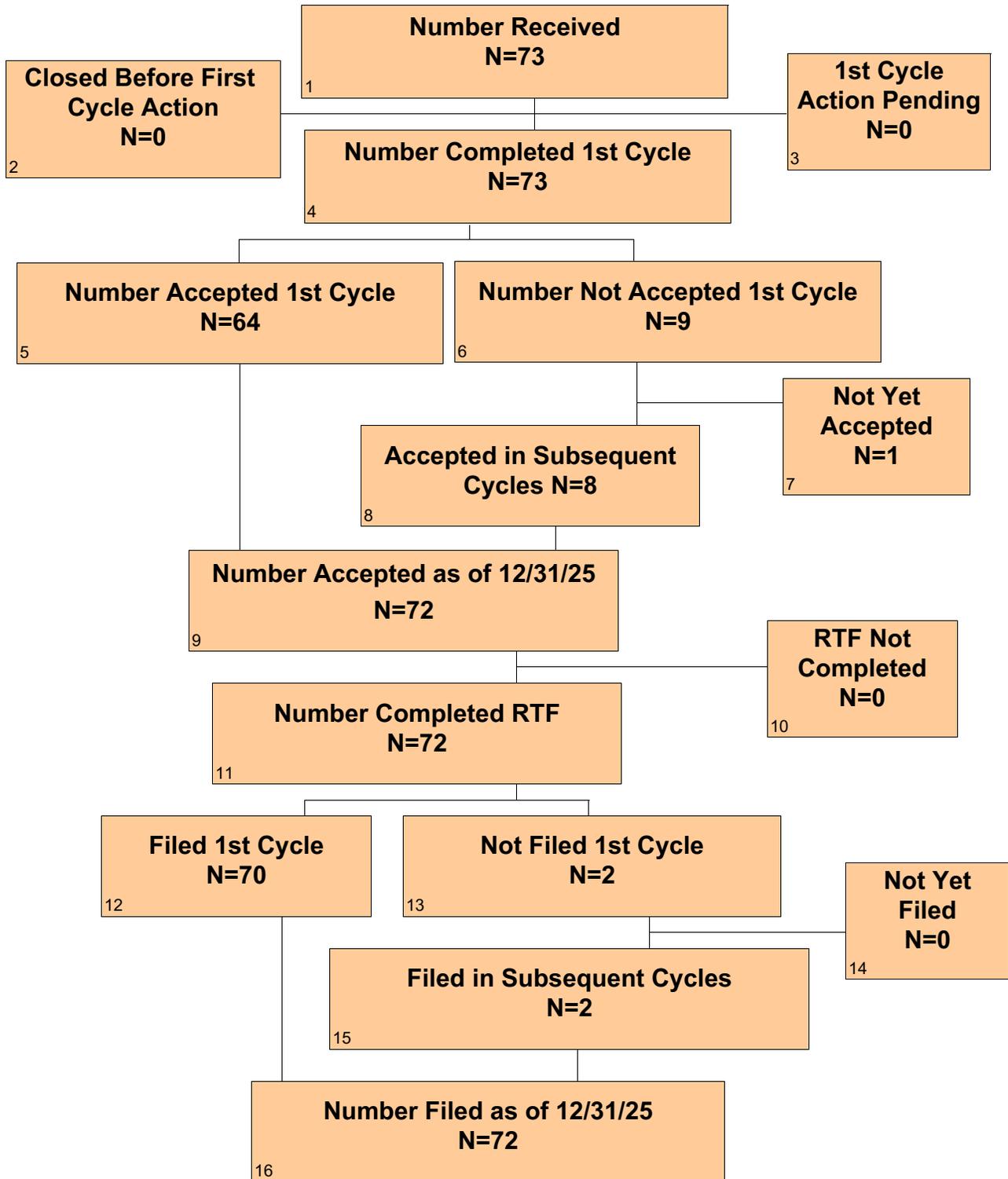


Current FY data represents a partial year in 1st, 2nd, and 3rd quarter reporting.

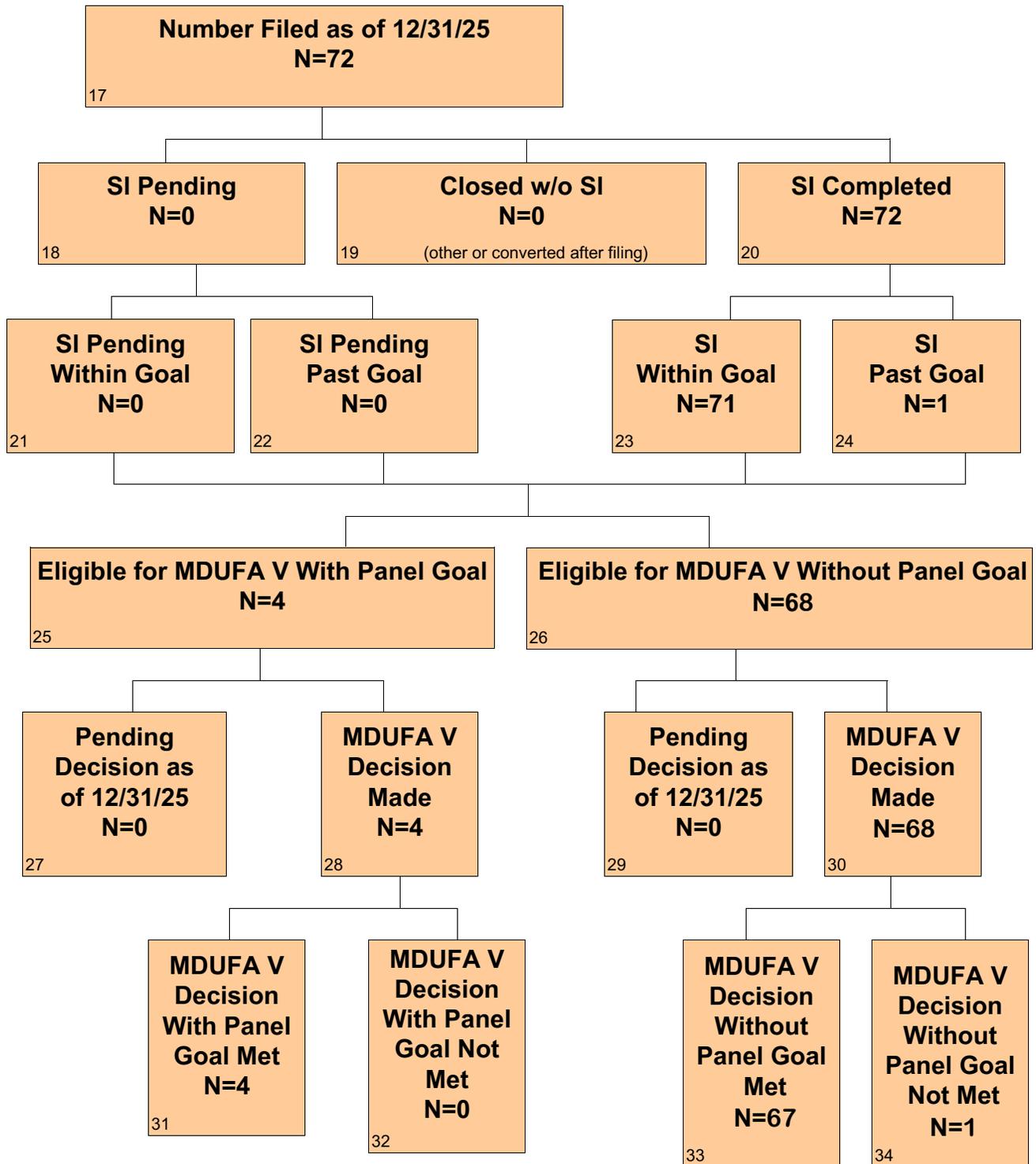
■ % Approved PMAO-PTS
 ■ % WTDR PMAO-PTS
 ■ % Other PMAO-PTS

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

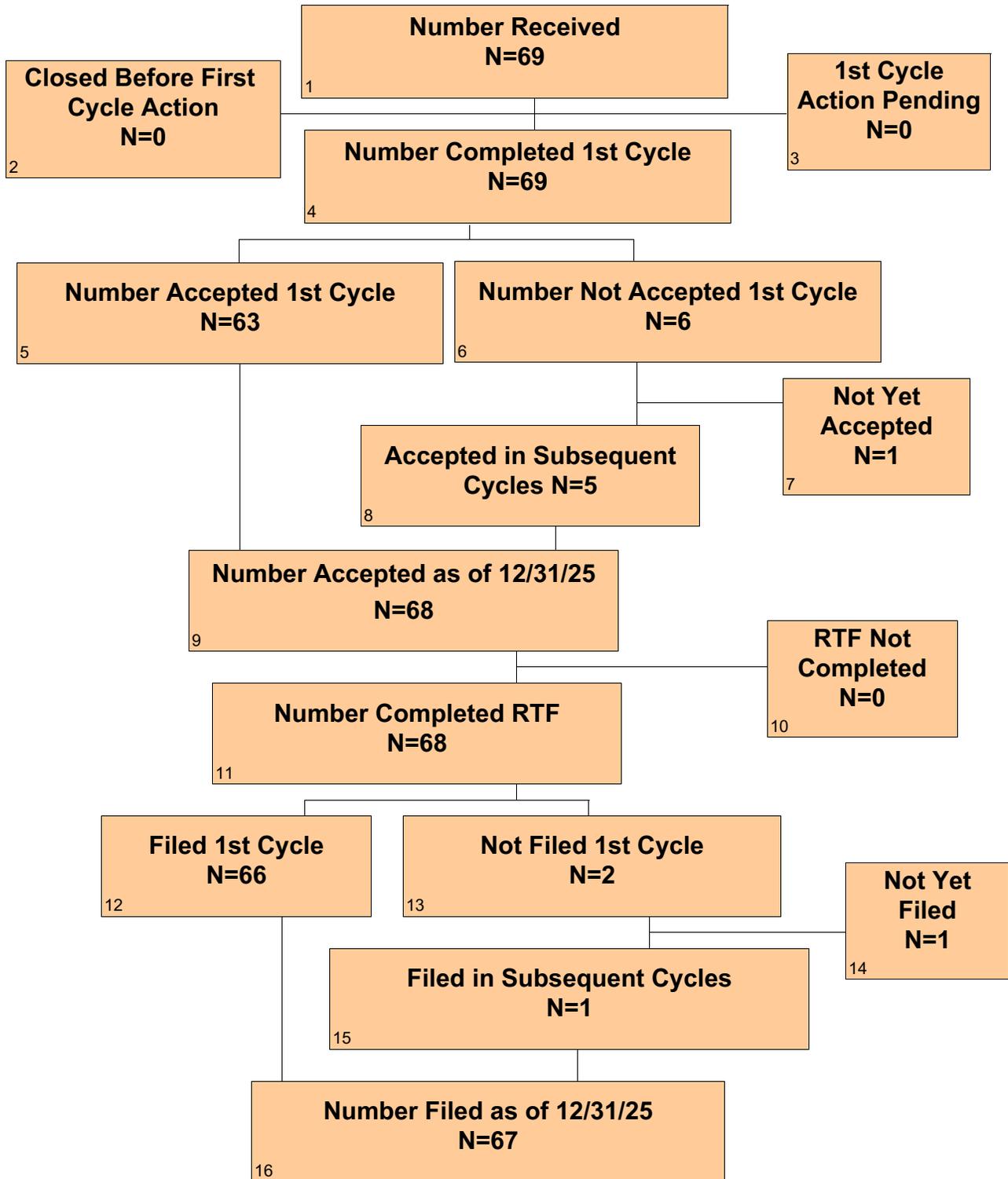
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/25



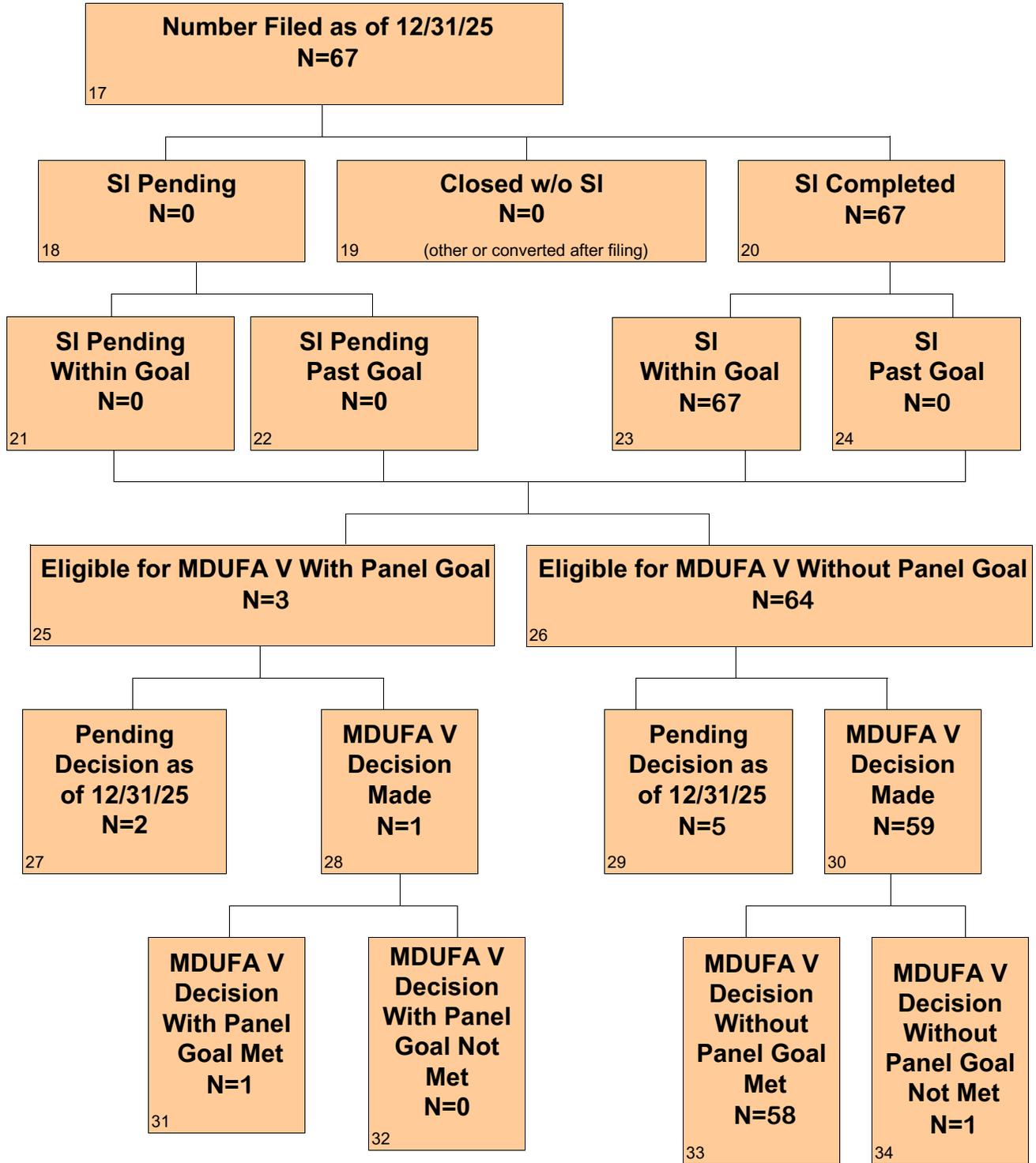
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 12/31/25 Con't



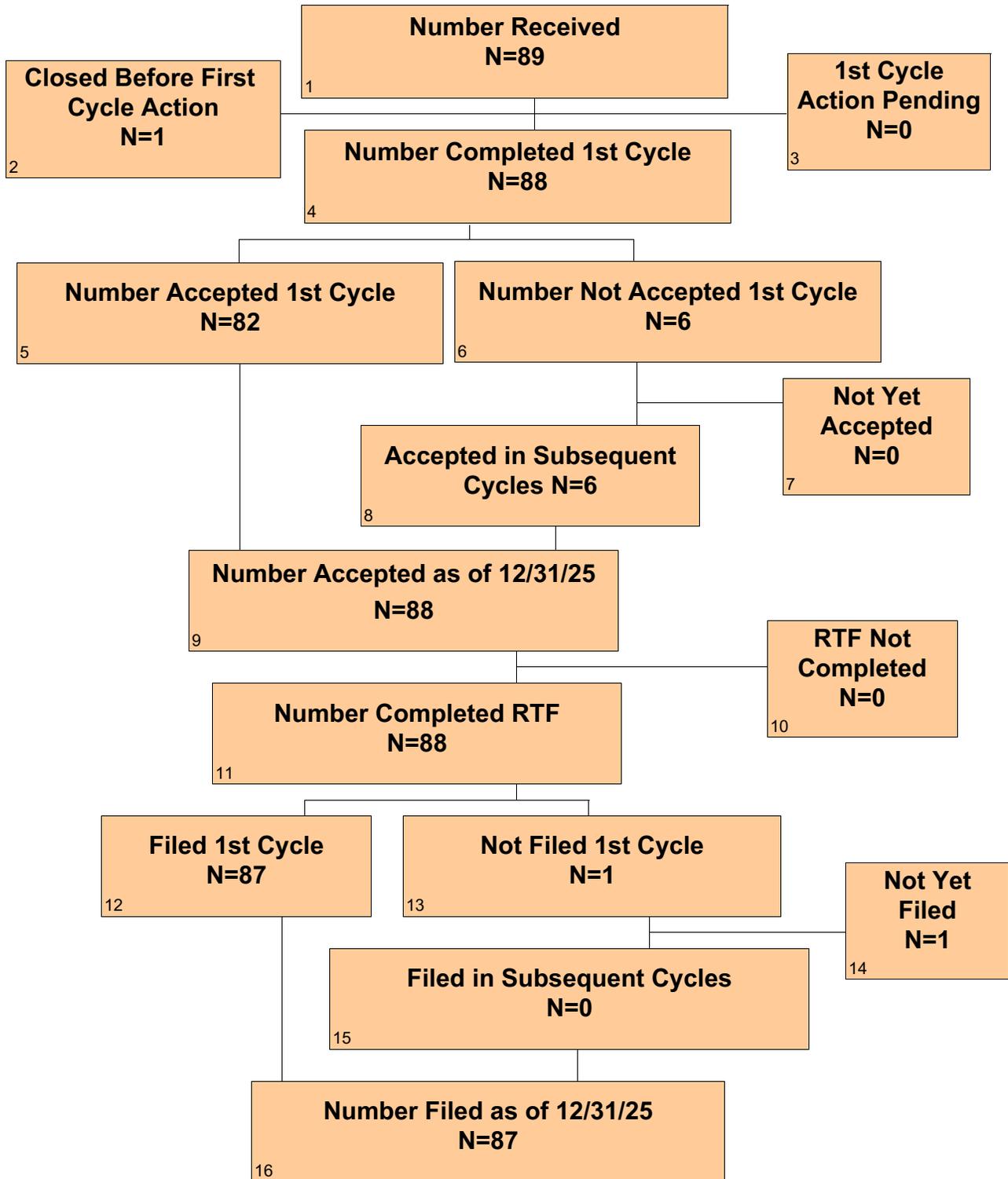
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 12/31/25



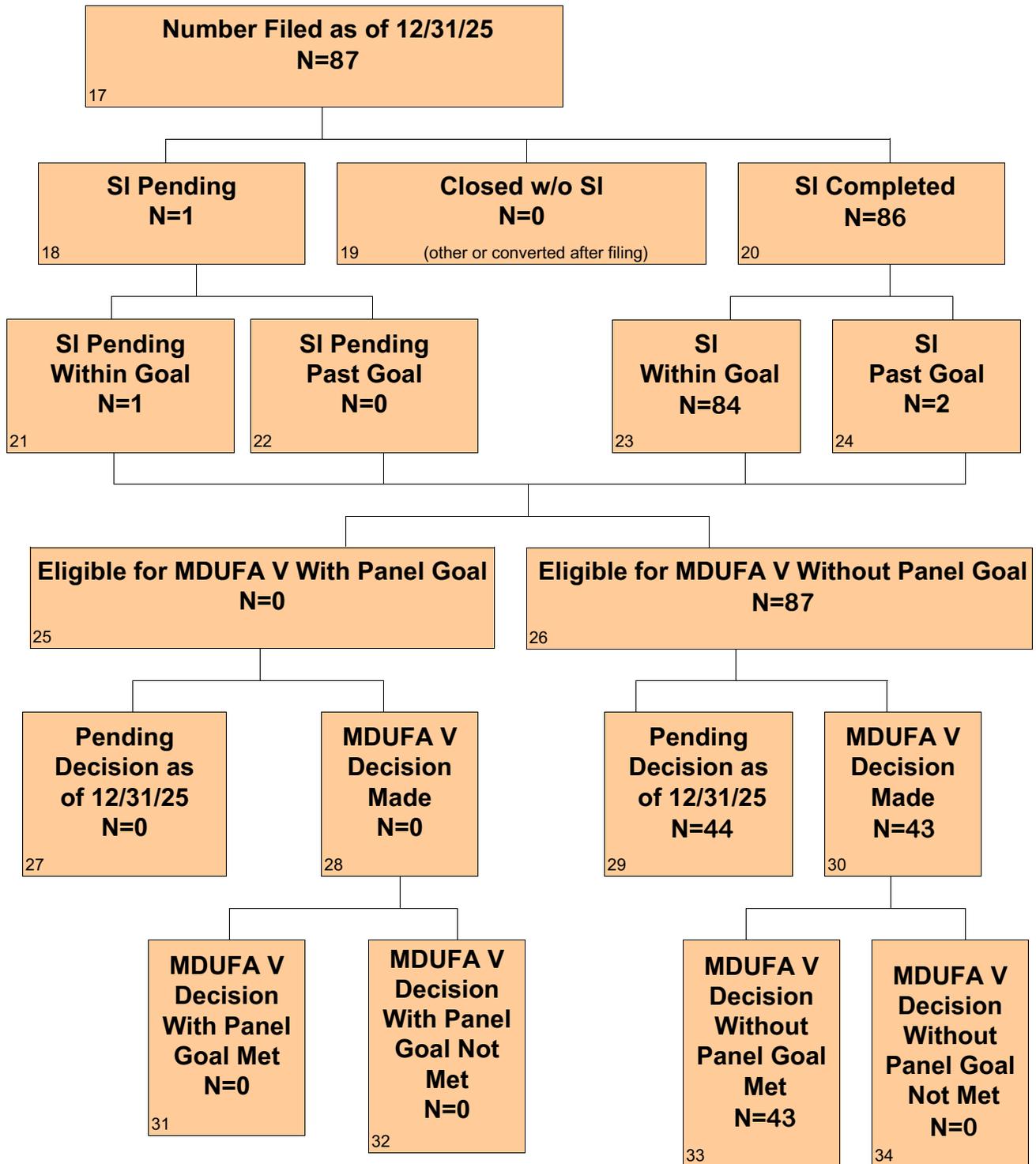
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 12/31/25 Con't



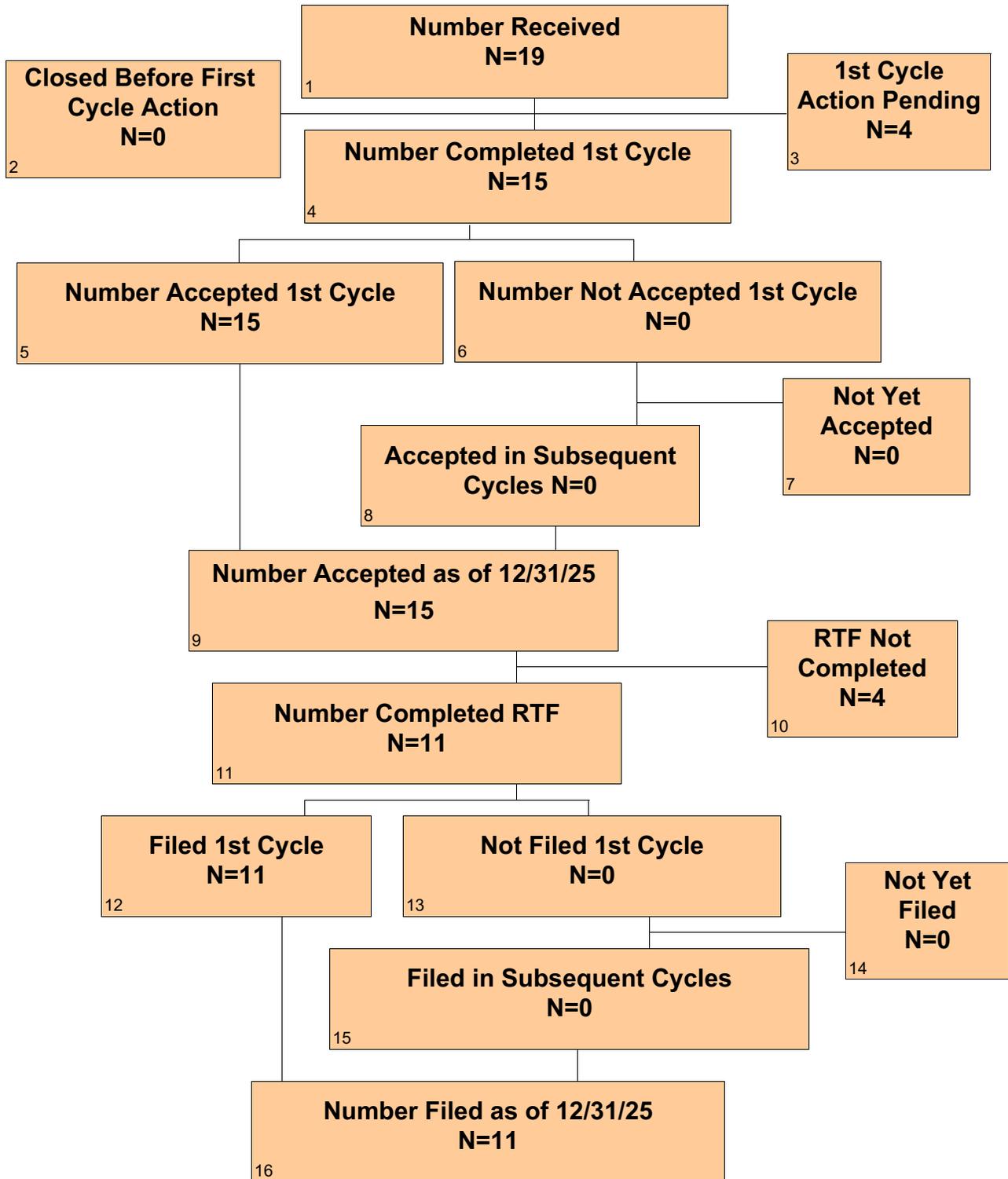
CDRH PMA Original and Panel Track Supplements - FY 2025 as of 12/31/25



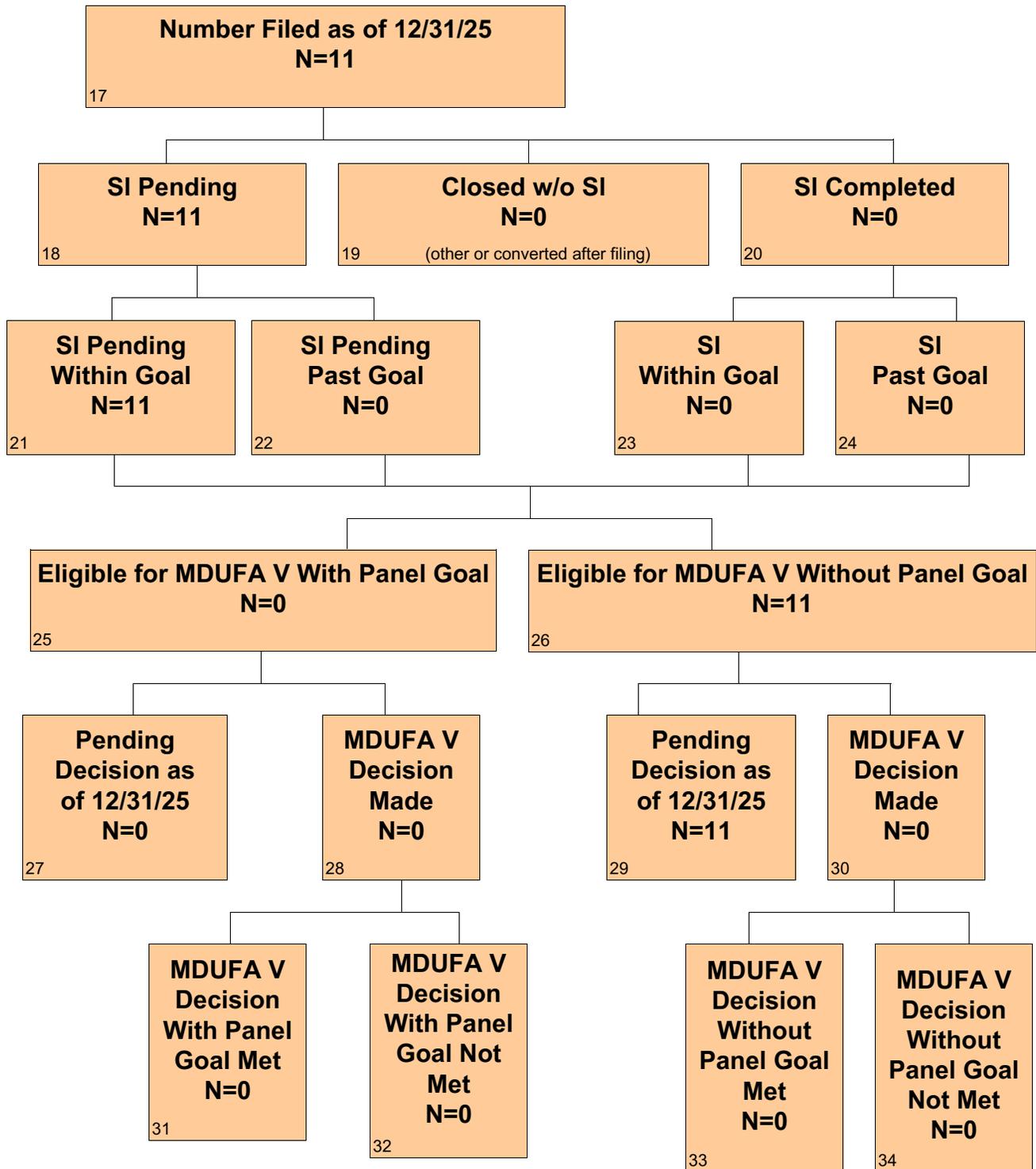
CDRH PMA Original and Panel Track Supplements - FY 2025 as of 12/31/25 Con't



CDRH PMA Original and Panel Track Supplements - FY 2026 as of 12/31/25



CDRH PMA Original and Panel Track Supplements - FY 2026 as of 12/31/25 Con't



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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69	89	19	
Number Closed Before First RTA Action	0	0	1	0	
Number Accepted First RTA Review	64	61	80	15	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	2	0	
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	4	
Number Not Accepted for Filing Review on First Cycle	9	6	6	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	8.70%	6.82%	0.00%	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69	89	19	
Number Accepted	64	63	82	15	
Completed RTF	72	68	88	11	
Number Not Filed	2	2	1	0	
Rate of Submissions Not Filed	2.78%	2.94%	1.14%	0.00%	

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

Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	72	67	87	11	
SI Goal Met	71	67	84	0	
SI Goal Not Met	1	0	2	0	
SI Pending Within Goal	0	0	1	11	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	98.61%	100.00%	97.67%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	72	67	86	0	
Average Number of FDA Days to Substantive Interaction	87.42	89.13	87.43	N/A	
20th Percentile FDA Days to Substantive Interaction	86	88	86	0	
40th Percentile FDA Days to Substantive Interaction	88	89	88	0	
60th Percentile FDA Days to Substantive Interaction	90	90	89	0	
80th Percentile FDA Days to Substantive Interaction	90	90	90	0	
Maximum FDA Days to Substantive Interaction	91	153	151	0	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	68	64	87	11	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	68	59	43	0	
MDUFA Decision Goal Met	67	58	43	0	
PMAs Pending MDUFA Decision	0	5	44	11	
PMAs Pending MDUFA Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	98.53%	98.31%	97.73%	N/A	

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	4	3	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	4	1	0	0	
MDUFA Decision Goal Met	4	1	0	0	
PMAs Pending MDUFA Decision	0	2	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	68	59	43	0	
Average FDA Days to MDUFA Decision	168.60	171.29	168.53	N/A	
20th Percentile FDA Days to MDUFA Decision	171	176	175	0	
40th Percentile FDA Days to MDUFA Decision	178	178	178	0	
60th Percentile FDA Days to MDUFA Decision	180	180	179	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	271	228	180	0	
Average Industry Days to MDUFA Decision	125.78	140.68	60.19	N/A	
20th Percentile Industry Days to MDUFA Decision	0	6	0	0	
40th Percentile Industry Days to MDUFA Decision	40	58	17	0	
60th Percentile Industry Days to MDUFA Decision	100	140	72	0	
80th Percentile Industry Days to MDUFA Decision	284	307	105	0	
Maximum Industry Days to MDUFA Decision	629	368	241	0	
Average Total Days to MDUFA Decision	294.38	311.97	228.72	N/A	
20th Percentile Total Days to MDUFA Decision	179	194	178	0	
40th Percentile Total Days to MDUFA Decision	219	232	189	0	
60th Percentile Total Days to MDUFA Decision	284	319	249	0	
80th Percentile Total Days to MDUFA Decision	449	455	280	0	
Maximum Total Days to MDUFA Decision	809	537	419	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	4	1	0	0	
Average FDA Days to MDUFA Decision	319.00	248.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	318	248	0	0	
40th Percentile FDA Days to MDUFA Decision	318	248	0	0	
60th Percentile FDA Days to MDUFA Decision	320	248	0	0	
80th Percentile FDA Days to MDUFA Decision	320	248	0	0	
Maximum FDA Days to MDUFA Decision	320	248	0	0	
Average Industry Days to MDUFA Decision	90.00	77.00	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	51	77	0	0	
40th Percentile Industry Days to MDUFA Decision	61	77	0	0	
60th Percentile Industry Days to MDUFA Decision	72	77	0	0	
80th Percentile Industry Days to MDUFA Decision	120	77	0	0	
Maximum Industry Days to MDUFA Decision	186	77	0	0	
Average Total Days to MDUFA Decision	409.00	325.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	370	325	0	0	
40th Percentile Total Days to MDUFA Decision	381	325	0	0	
60th Percentile Total Days to MDUFA Decision	392	325	0	0	
80th Percentile Total Days to MDUFA Decision	439	325	0	0	
Maximum Total Days to MDUFA Decision	504	325	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	68	64	87	11	
Number with MDUFA Decision	68	59	43	0	
Number of Withdrawal	3	2	1	0	
Number of Not Approvable	13	8	2	0	
Number of Deleted	1	3	0	0	
Rate of Withdrawal	4.41%	3.39%	2.33%	N/A	
Rate of Not Approvable	19.12%	13.56%	4.65%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	4	3	0	0	
Number With MDUFA Decision	4	1	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	N/A	N/A	
Rate of Not Approvable	0.00%	100.00%	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1	1	0	
Mean FDA Days for Submissions that Missed the Goal	191.00	228.00	236.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	28.00	0.00	66.00	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	5	5	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	5	3	0	
MDUFA Decision Goal Met	6	5	3	0	
PMAs Pending MDUFA Decision	0	0	2	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

*Includes submission that went to panel

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	15	10	20	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	10	9	0	
MDUFA Decision Goal Met	15	10	9	0	
PMAs Pending MDUFA Decision	0	0	11	5	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

*Includes submission that went to panel

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

**Table 1.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	7	0	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	3	6	6	0	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	6	1	1	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	14.29%	14.29%	N/A	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	7	0	
Number Accepted	3	6	6	0	
Completed RTF	8	7	7	0	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	12.50%	0.00%	0.00%	N/A	

**Table 1.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	8	7	7	0	
SI Goal Met	8	7	7	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 1.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	8	7	7	0	
Average Number of FDA Days to Substantive Interaction	82.00	89.43	88.71	N/A	
20th Percentile FDA Days to Substantive Interaction	87	88	87	0	
40th Percentile FDA Days to Substantive Interaction	90	90	89	0	
60th Percentile FDA Days to Substantive Interaction	90	90	90	0	
80th Percentile FDA Days to Substantive Interaction	90	90	90	0	
Maximum FDA Days to Substantive Interaction	90	90	90	0	

**Table 1.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	8	7	7	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	8	7	4	0	
MDUFA Decision Goal Met	8	7	4	0	
PMAs Pending MDUFA Decision	0	0	3	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 1.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

**Table 1.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	8	7	4	0	
Average FDA Days to MDUFA Decision	138.00	180.00	178.75	N/A	
20th Percentile FDA Days to MDUFA Decision	90	180	178	0	
40th Percentile FDA Days to MDUFA Decision	157	180	179	0	
60th Percentile FDA Days to MDUFA Decision	179	180	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	217.75	145.43	79.25	N/A	
20th Percentile Industry Days to MDUFA Decision	65	65	39	0	
40th Percentile Industry Days to MDUFA Decision	247	102	60	0	
60th Percentile Industry Days to MDUFA Decision	295	148	95	0	
80th Percentile Industry Days to MDUFA Decision	337	236	119	0	
Maximum Industry Days to MDUFA Decision	362	311	136	0	
Average Total Days to MDUFA Decision	355.75	325.43	258.00	N/A	
20th Percentile Total Days to MDUFA Decision	245	245	217	0	
40th Percentile Total Days to MDUFA Decision	354	282	237	0	
60th Percentile Total Days to MDUFA Decision	456	328	274	0	
80th Percentile Total Days to MDUFA Decision	478	416	298	0	
Maximum Total Days to MDUFA Decision	536	491	315	0	

**Table 1.8 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0	0	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	0	0	0	

**Table 1.9 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	8	7	7	0	
Number with MDUFA Decision	8	7	4	0	
Number of Withdrawal	1	0	0	0	
Number of Not Approvable	0	1	1	0	
Number of Deleted	1	0	0	0	
Rate of Withdrawal	12.50%	0.00%	0.00%	N/A	
Rate of Not Approvable	0.00%	14.29%	25.00%	N/A	

**Table 1.10 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

**Table 1.11 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions
Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.12 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing
Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.14 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.1 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	20	20	28	5	
Number Closed Before First RTA Action	0	0	1	0	
Number Accepted First RTA Review	19	17	24	4	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	2	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	1	
Number Not Accepted for Filing Review on First Cycle	1	1	1	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	5.00%	3.70%	0.00%	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	20	20	28	5	
Number Accepted	19	19	26	4	
Completed RTF	20	20	27	4	
Number Not Filed	0	1	1	0	
Rate of Submissions Not Filed	0.00%	5.00%	3.70%	0.00%	

**Table 1.3 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	20	20	26	4	
SI Goal Met	20	20	25	0	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	4	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	96.15%	N/A	

Table 1.4 OHT2 - Office of Cardiovascular Devices

PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	20	20	26	0	
Average Number of FDA Days to Substantive Interaction	88.25	88.20	88.35	N/A	
20th Percentile FDA Days to Substantive Interaction	86	87	88	0	
40th Percentile FDA Days to Substantive Interaction	90	89	89	0	
60th Percentile FDA Days to Substantive Interaction	90	90	90	0	
80th Percentile FDA Days to Substantive Interaction	90	90	90	0	
Maximum FDA Days to Substantive Interaction	90	90	102	0	

Table 1.5 OHT2 - Office of Cardiovascular Devices

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	17	19	26	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	17	17	16	0	
MDUFA Decision Goal Met	17	16	16	0	
PMAs Pending MDUFA Decision	0	2	10	4	
PMAs Pending MDUFA Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	100.00%	94.12%	94.12%	N/A	

Table 1.6 OHT2 - Office of Cardiovascular Devices

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	3	1	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	1	0	0	
MDUFA Decision Goal Met	3	1	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

Table 1.7 OHT2 - Office of Cardiovascular Devices

PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	17	17	16	0	
Average FDA Days to MDUFA Decision	177.65	179.12	176.00	N/A	
20th Percentile FDA Days to MDUFA Decision	172	177	177	0	
40th Percentile FDA Days to MDUFA Decision	177	178	178	0	
60th Percentile FDA Days to MDUFA Decision	180	180	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	271	228	180	0	
Average Industry Days to MDUFA Decision	64.29	54.18	26.69	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	23	0	0	0	
60th Percentile Industry Days to MDUFA Decision	47	25	10	0	
80th Percentile Industry Days to MDUFA Decision	113	50	42	0	
Maximum Industry Days to MDUFA Decision	271	357	168	0	
Average Total Days to MDUFA Decision	241.94	233.29	202.69	N/A	
20th Percentile Total Days to MDUFA Decision	176	178	179	0	
40th Percentile Total Days to MDUFA Decision	201	184	180	0	
60th Percentile Total Days to MDUFA Decision	236	204	180	0	
80th Percentile Total Days to MDUFA Decision	305	230	220	0	
Maximum Total Days to MDUFA Decision	442	537	345	0	

Table 1.8 OHT2 - Office of Cardiovascular Devices

PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	3	1	0	0	
Average FDA Days to MDUFA Decision	319.33	248.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	319	248	0	0	
40th Percentile FDA Days to MDUFA Decision	320	248	0	0	
60th Percentile FDA Days to MDUFA Decision	320	248	0	0	
80th Percentile FDA Days to MDUFA Decision	320	248	0	0	
Maximum FDA Days to MDUFA Decision	320	248	0	0	
Average Industry Days to MDUFA Decision	58.00	77.00	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	47	77	0	0	
40th Percentile Industry Days to MDUFA Decision	54	77	0	0	
60th Percentile Industry Days to MDUFA Decision	61	77	0	0	
80th Percentile Industry Days to MDUFA Decision	68	77	0	0	
Maximum Industry Days to MDUFA Decision	76	77	0	0	
Average Total Days to MDUFA Decision	377.33	325.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	366	325	0	0	
40th Percentile Total Days to MDUFA Decision	373	325	0	0	
60th Percentile Total Days to MDUFA Decision	381	325	0	0	
80th Percentile Total Days to MDUFA Decision	388	325	0	0	
Maximum Total Days to MDUFA Decision	396	325	0	0	

Table 1.9 OHT2 - Office of Cardiovascular Devices

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	17	19	26	4	
Number with MDUFA Decision	17	17	16	0	
Number of Withdrawal	1	0	0	0	
Number of Not Approvable	3	0	1	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	5.88%	0.00%	0.00%	N/A	
Rate of Not Approvable	17.65%	0.00%	6.25%	N/A	

Table 1.10 OHT2 - Office of Cardiovascular Devices

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	1	0	0	
Number With MDUFA Decision	3	1	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	N/A	N/A	
Rate of Not Approvable	0.00%	100.00%	N/A	N/A	

Table 1.11 OHT2 - Office of Cardiovascular Devices

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	1	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	228.00	236.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	66.00	N/A	

Table 1.12 OHT2 - Office of Cardiovascular Devices

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT2 - Office of Cardiovascular Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.14 OHT2 - Office of Cardiovascular Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	5	3	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	3	6	5	2	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	1	
Number Not Accepted for Filing Review on First Cycle	0	1	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	14.29%	0.00%	0.00%	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	5	3	
Number Accepted	3	6	5	2	
Completed RTF	3	7	5	1	
Number Not Filed	0	1	0	0	
Rate of Submissions Not Filed	0.00%	14.29%	0.00%	0.00%	

**Table 1.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	3	6	5	1	
SI Goal Met	3	6	5	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 1.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	6	5	0	
Average Number of FDA Days to Substantive Interaction	88.33	96.67	87.80	N/A	
20th Percentile FDA Days to Substantive Interaction	87	88	87	0	
40th Percentile FDA Days to Substantive Interaction	88	88	88	0	
60th Percentile FDA Days to Substantive Interaction	88	90	88	0	
80th Percentile FDA Days to Substantive Interaction	89	90	88	0	
Maximum FDA Days to Substantive Interaction	90	153	90	0	

**Table 1.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	3	6	5	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	5	2	0	
MDUFA Decision Goal Met	2	5	2	0	
PMAs Pending MDUFA Decision	0	1	3	1	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	66.67%	100.00%	100.00%	N/A	

**Table 1.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

**Table 1.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	3	5	2	0	
Average FDA Days to MDUFA Decision	180.67	177.20	180.00	N/A	
20th Percentile FDA Days to MDUFA Decision	175	176	180	0	
40th Percentile FDA Days to MDUFA Decision	178	179	180	0	
60th Percentile FDA Days to MDUFA Decision	181	179	180	0	
80th Percentile FDA Days to MDUFA Decision	186	180	180	0	
Maximum FDA Days to MDUFA Decision	191	180	180	0	
Average Industry Days to MDUFA Decision	18.67	230.20	82.50	N/A	
20th Percentile Industry Days to MDUFA Decision	11	169	76	0	
40th Percentile Industry Days to MDUFA Decision	22	206	80	0	
60th Percentile Industry Days to MDUFA Decision	28	252	85	0	
80th Percentile Industry Days to MDUFA Decision	28	314	89	0	
Maximum Industry Days to MDUFA Decision	28	354	94	0	
Average Total Days to MDUFA Decision	199.33	407.40	262.50	N/A	
20th Percentile Total Days to MDUFA Decision	187	340	256	0	
40th Percentile Total Days to MDUFA Decision	196	381	260	0	
60th Percentile Total Days to MDUFA Decision	204	431	265	0	
80th Percentile Total Days to MDUFA Decision	211	494	269	0	
Maximum Total Days to MDUFA Decision	219	532	274	0	

**Table 1.8 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0	0	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	0	0	0	

**Table 1.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	6	5	1	
Number with MDUFA Decision	3	5	2	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	1	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	33.33%	20.00%	0.00%	N/A	

**Table 1.10 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

**Table 1.11 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions
Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	191.00	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	28.00	N/A	N/A	N/A	

**Table 1.12 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing
Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.14 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.1 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6	14	1	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	9	6	11	0	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	1	
Number Not Accepted for Filing Review on First Cycle	0	0	3	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%	21.43%	N/A	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6	14	1	
Number Accepted	9	6	11	0	
Completed RTF	9	6	14	0	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	N/A	

**Table 1.3 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	9	6	14	0	
SI Goal Met	9	6	13	0	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	92.86%	N/A	

Table 1.4 OHT4 - Office of Surgical and Infection Control Devices

PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	9	6	14	0	
Average Number of FDA Days to Substantive Interaction	88.78	89.33	92.64	N/A	
20th Percentile FDA Days to Substantive Interaction	88	89	87	0	
40th Percentile FDA Days to Substantive Interaction	90	89	89	0	
60th Percentile FDA Days to Substantive Interaction	90	90	90	0	
80th Percentile FDA Days to Substantive Interaction	90	90	90	0	
Maximum FDA Days to Substantive Interaction	90	90	151	0	

Table 1.5 OHT4 - Office of Surgical and Infection Control Devices

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	9	4	14	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	9	4	3	0	
MDUFA Decision Goal Met	9	4	3	0	
PMAs Pending MDUFA Decision	0	0	11	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT4 - Office of Surgical and Infection Control Devices

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	2	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	2	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

**Table 1.7 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	9	4	3	0	
Average FDA Days to MDUFA Decision	179.11	156.25	179.00	N/A	
20th Percentile FDA Days to MDUFA Decision	178	141	178	0	
40th Percentile FDA Days to MDUFA Decision	179	177	179	0	
60th Percentile FDA Days to MDUFA Decision	180	179	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	123.56	281.50	75.67	N/A	
20th Percentile Industry Days to MDUFA Decision	0	233	51	0	
40th Percentile Industry Days to MDUFA Decision	42	351	82	0	
60th Percentile Industry Days to MDUFA Decision	60	353	100	0	
80th Percentile Industry Days to MDUFA Decision	145	358	105	0	
Maximum Industry Days to MDUFA Decision	629	365	110	0	
Average Total Days to MDUFA Decision	302.67	437.75	254.67	N/A	
20th Percentile Total Days to MDUFA Decision	180	367	229	0	
40th Percentile Total Days to MDUFA Decision	221	469	262	0	
60th Percentile Total Days to MDUFA Decision	238	515	280	0	
80th Percentile Total Days to MDUFA Decision	325	530	285	0	
Maximum Total Days to MDUFA Decision	809	530	290	0	

**Table 1.8 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0	0	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	0	0	0	

**Table 1.9 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	9	4	14	0	
Number with MDUFA Decision	9	4	3	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	2	1	0	0	
Number of Deleted	0	1	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	22.22%	25.00%	0.00%	N/A	

**Table 1.10 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of
Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	2	0	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

**Table 1.11 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions
Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.12 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing
Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT4 - Office of Surgical and Infection Control Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.14 OHT4 - Office of Surgical and Infection Control Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.1 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	6	3	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	5	6	5	2	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	1	
Number Not Accepted for Filing Review on First Cycle	1	1	1	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	14.29%	16.67%	0.00%	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	6	3	
Number Accepted	5	6	5	2	
Completed RTF	6	7	6	0	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	N/A	

**Table 1.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	6	7	6	0	
SI Goal Met	5	7	5	0	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	1	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	83.33%	100.00%	100.00%	N/A	

Table 1.4 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	6	7	5	0	
Average Number of FDA Days to Substantive Interaction	88.50	86.43	89.00	N/A	
20th Percentile FDA Days to Substantive Interaction	88	86	88	0	
40th Percentile FDA Days to Substantive Interaction	90	89	89	0	
60th Percentile FDA Days to Substantive Interaction	90	90	89	0	
80th Percentile FDA Days to Substantive Interaction	90	90	90	0	
Maximum FDA Days to Substantive Interaction	91	90	90	0	

Table 1.5 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	7	6	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	7	4	0	
MDUFA Decision Goal Met	6	7	4	0	
PMAs Pending MDUFA Decision	0	0	2	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT5 - Office of Neurological and Physical Medicine Devices PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

**Table 1.7 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	6	7	4	0	
Average FDA Days to MDUFA Decision	175.33	165.14	179.50	N/A	
20th Percentile FDA Days to MDUFA Decision	179	176	179	0	
40th Percentile FDA Days to MDUFA Decision	180	177	179	0	
60th Percentile FDA Days to MDUFA Decision	180	178	180	0	
80th Percentile FDA Days to MDUFA Decision	180	179	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	55.17	133.57	141.25	N/A	
20th Percentile Industry Days to MDUFA Decision	0	43	96	0	
40th Percentile Industry Days to MDUFA Decision	37	84	108	0	
60th Percentile Industry Days to MDUFA Decision	71	114	130	0	
80th Percentile Industry Days to MDUFA Decision	101	223	178	0	
Maximum Industry Days to MDUFA Decision	122	355	239	0	
Average Total Days to MDUFA Decision	230.50	298.71	320.75	N/A	
20th Percentile Total Days to MDUFA Decision	180	221	275	0	
40th Percentile Total Days to MDUFA Decision	217	261	287	0	
60th Percentile Total Days to MDUFA Decision	251	292	309	0	
80th Percentile Total Days to MDUFA Decision	281	330	357	0	
Maximum Total Days to MDUFA Decision	301	534	419	0	

**Table 1.8 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V
Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0	0	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	0	0	0	

**Table 1.9 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	6	7	6	0	
Number with MDUFA Decision	6	7	4	0	
Number of Withdrawal	0	1	0	0	
Number of Not Approvable	1	2	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	14.29%	0.00%	N/A	
Rate of Not Approvable	16.67%	28.57%	0.00%	N/A	

**Table 1.10 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

**Table 1.11 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.12 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT5 - Office of Neurological and Physical Medicine Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.14 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.1 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3	4	1	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	4	3	4	1	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	1	0	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	20.00%	0.00%	0.00%	0.00%	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3	4	1	
Number Accepted	4	3	4	1	
Completed RTF	5	3	4	1	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	

**Table 1.3 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	5	3	4	1	
SI Goal Met	5	3	4	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.4 OHT6 - Office of Orthopedic Devices

PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	5	3	4	0	
Average Number of FDA Days to Substantive Interaction	85.40	88.00	84.00	N/A	
20th Percentile FDA Days to Substantive Interaction	84	87	81	0	
40th Percentile FDA Days to Substantive Interaction	86	87	84	0	
60th Percentile FDA Days to Substantive Interaction	87	88	85	0	
80th Percentile FDA Days to Substantive Interaction	88	89	87	0	
Maximum FDA Days to Substantive Interaction	88	90	88	0	

Table 1.5 OHT6 - Office of Orthopedic Devices

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	5	3	4	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	5	3	2	0	
MDUFA Decision Goal Met	5	3	2	0	
PMAs Pending MDUFA Decision	0	0	2	1	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT6 - Office of Orthopedic Devices

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

Table 1.7 OHT6 - Office of Orthopedic Devices

PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	5	3	2	0	
Average FDA Days to MDUFA Decision	173.80	179.33	142.50	N/A	
20th Percentile FDA Days to MDUFA Decision	169	179	121	0	
40th Percentile FDA Days to MDUFA Decision	175	180	135	0	
60th Percentile FDA Days to MDUFA Decision	178	180	150	0	
80th Percentile FDA Days to MDUFA Decision	179	180	164	0	
Maximum FDA Days to MDUFA Decision	180	180	178	0	
Average Industry Days to MDUFA Decision	194.80	169.00	95.50	N/A	
20th Percentile Industry Days to MDUFA Decision	77	144	38	0	
40th Percentile Industry Days to MDUFA Decision	142	145	76	0	
60th Percentile Industry Days to MDUFA Decision	243	160	115	0	
80th Percentile Industry Days to MDUFA Decision	351	189	153	0	
Maximum Industry Days to MDUFA Decision	356	218	191	0	
Average Total Days to MDUFA Decision	368.60	348.33	238.00	N/A	
20th Percentile Total Days to MDUFA Decision	241	323	159	0	
40th Percentile Total Days to MDUFA Decision	309	324	212	0	
60th Percentile Total Days to MDUFA Decision	417	340	264	0	
80th Percentile Total Days to MDUFA Decision	530	369	317	0	
Maximum Total Days to MDUFA Decision	536	398	369	0	

Table 1.8 OHT6 - Office of Orthopedic Devices

PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0	0	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	0	0	0	

Table 1.9 OHT6 - Office of Orthopedic Devices

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	5	3	4	1	
Number with MDUFA Decision	5	3	2	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	3	2	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	60.00%	66.67%	0.00%	N/A	

Table 1.10 OHT6 - Office of Orthopedic Devices

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

Table 1.11 OHT6 - Office of Orthopedic Devices

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Table 1.12 OHT6 - Office of Orthopedic Devices

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT6 - Office of Orthopedic Devices
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.14 OHT6 - Office of Orthopedic Devices
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

**Table 1.1 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	25	6	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	21	14	25	6	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	0	2	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	12.50%	0.00%	0.00%	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	25	6	
Number Accepted	21	14	25	6	
Completed RTF	21	15	25	5	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	4.76%	0.00%	0.00%	0.00%	

**Table 1.3 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	21	15	25	5	
SI Goal Met	21	15	25	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	5	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.4 OHT7 - Office of In Vitro Diagnostics

PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	21	15	25	0	
Average Number of FDA Days to Substantive Interaction	88.14	88.60	83.36	N/A	
20th Percentile FDA Days to Substantive Interaction	87	88	83	0	
40th Percentile FDA Days to Substantive Interaction	87	89	87	0	
60th Percentile FDA Days to Substantive Interaction	89	89	89	0	
80th Percentile FDA Days to Substantive Interaction	90	90	90	0	
Maximum FDA Days to Substantive Interaction	90	90	90	0	

Table 1.5 OHT7 - Office of In Vitro Diagnostics

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	20	15	25	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	20	15	12	0	
MDUFA Decision Goal Met	20	15	12	0	
PMAs Pending MDUFA Decision	0	0	13	5	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT7 - Office of In Vitro Diagnostics

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	1	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	0	0	0	
MDUFA Decision Goal Met	1	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	N/A	N/A	N/A	

Table 1.7 OHT7 - Office of In Vitro Diagnostics

PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	20	15	12	0	
Average FDA Days to MDUFA Decision	163.30	161.40	151.33	N/A	
20th Percentile FDA Days to MDUFA Decision	136	150	133	0	
40th Percentile FDA Days to MDUFA Decision	178	177	170	0	
60th Percentile FDA Days to MDUFA Decision	179	180	177	0	
80th Percentile FDA Days to MDUFA Decision	180	180	178	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	162.25	152.33	58.00	N/A	
20th Percentile Industry Days to MDUFA Decision	0	23	0	0	
40th Percentile Industry Days to MDUFA Decision	68	59	18	0	
60th Percentile Industry Days to MDUFA Decision	236	138	59	0	
80th Percentile Industry Days to MDUFA Decision	322	352	96	0	
Maximum Industry Days to MDUFA Decision	354	368	241	0	
Average Total Days to MDUFA Decision	325.55	313.73	209.33	N/A	
20th Percentile Total Days to MDUFA Decision	179	202	176	0	
40th Percentile Total Days to MDUFA Decision	247	226	189	0	
60th Percentile Total Days to MDUFA Decision	364	318	229	0	
80th Percentile Total Days to MDUFA Decision	502	459	261	0	
Maximum Total Days to MDUFA Decision	534	532	290	0	

Table 1.8 OHT7 - Office of In Vitro Diagnostics

PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	1	0	0	0	
Average FDA Days to MDUFA Decision	318.00	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	318	0	0	0	
40th Percentile FDA Days to MDUFA Decision	318	0	0	0	
60th Percentile FDA Days to MDUFA Decision	318	0	0	0	
80th Percentile FDA Days to MDUFA Decision	318	0	0	0	
Maximum FDA Days to MDUFA Decision	318	0	0	0	
Average Industry Days to MDUFA Decision	186.00	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	186	0	0	0	
40th Percentile Industry Days to MDUFA Decision	186	0	0	0	
60th Percentile Industry Days to MDUFA Decision	186	0	0	0	
80th Percentile Industry Days to MDUFA Decision	186	0	0	0	
Maximum Industry Days to MDUFA Decision	186	0	0	0	
Average Total Days to MDUFA Decision	504.00	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	504	0	0	0	
40th Percentile Total Days to MDUFA Decision	504	0	0	0	
60th Percentile Total Days to MDUFA Decision	504	0	0	0	
80th Percentile Total Days to MDUFA Decision	504	0	0	0	
Maximum Total Days to MDUFA Decision	504	0	0	0	

Table 1.9 OHT7 - Office of In Vitro Diagnostics

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	20	15	25	5	
Number with MDUFA Decision	20	15	12	0	
Number of Withdrawal	1	1	1	0	
Number of Not Approvable	3	1	0	0	
Number of Deleted	0	2	0	0	
Rate of Withdrawal	5.00%	6.67%	8.33%	N/A	
Rate of Not Approvable	15.00%	6.67%	0.00%	N/A	

Table 1.10 OHT7 - Office of In Vitro Diagnostics

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	1	0	0	0	
Number With MDUFA Decision	1	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	N/A	N/A	N/A	
Rate of Not Approvable	0.00%	N/A	N/A	N/A	

Table 1.11 OHT7 - Office of In Vitro Diagnostics

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Table 1.12 OHT7 - Office of In Vitro Diagnostics

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT7 - Office of In Vitro Diagnostics
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	5	5	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	5	3	0	
MDUFA Decision Goal Met	6	5	3	0	
PMAs Pending MDUFA Decision	0	0	2	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

*Includes submission that went to panel

**Table 1.14 OHT7 - Office of In Vitro Diagnostics
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	15	10	20	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	10	9	0	
MDUFA Decision Goal Met	15	10	9	0	
PMAs Pending MDUFA Decision	0	0	11	5	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

*Includes submission that went to panel

**Table 1.1 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0	3	0	0	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	0	3	0	0	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	0	0	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	N/A	0.00%	N/A	N/A	

*The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Review", to determine the total number of submissions accepted on the first RTA cycle (see box 5 in flowchart).

**Table 1.2 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0	3	0	0	
Number Accepted	0	3	0	0	
Completed RTF	0	3	0	0	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	N/A	0.00%	N/A	N/A	

**Table 1.3 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	0	3	0	0	
SI Goal Met	0	3	0	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	N/A	100.00%	N/A	N/A	

Table 1.4 OHT8 - Office of Radiological Health

PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	0	3	0	0	
Average Number of FDA Days to Substantive Interaction	N/A	89.33	N/A	N/A	
20th Percentile FDA Days to Substantive Interaction	0	89	0	0	
40th Percentile FDA Days to Substantive Interaction	0	90	0	0	
60th Percentile FDA Days to Substantive Interaction	0	90	0	0	
80th Percentile FDA Days to Substantive Interaction	0	90	0	0	
Maximum FDA Days to Substantive Interaction	0	90	0	0	

Table 1.5 OHT8 - Office of Radiological Health

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	0	3	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	1	0	0	
MDUFA Decision Goal Met	0	1	0	0	
PMAs Pending MDUFA Decision	0	2	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	100.00%	N/A	N/A	

Table 1.6 OHT8 - Office of Radiological Health

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA Decision	0	0	0	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

Table 1.7 OHT8 - Office of Radiological Health

PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	1	0	0	
Average FDA Days to MDUFA Decision	N/A	175.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	175	0	0	
40th Percentile FDA Days to MDUFA Decision	0	175	0	0	
60th Percentile FDA Days to MDUFA Decision	0	175	0	0	
80th Percentile FDA Days to MDUFA Decision	0	175	0	0	
Maximum FDA Days to MDUFA Decision	0	175	0	0	
Average Industry Days to MDUFA Decision	N/A	357.00	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	357	0	0	
40th Percentile Industry Days to MDUFA Decision	0	357	0	0	
60th Percentile Industry Days to MDUFA Decision	0	357	0	0	
80th Percentile Industry Days to MDUFA Decision	0	357	0	0	
Maximum Industry Days to MDUFA Decision	0	357	0	0	
Average Total Days to MDUFA Decision	N/A	532.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	532	0	0	
40th Percentile Total Days to MDUFA Decision	0	532	0	0	
60th Percentile Total Days to MDUFA Decision	0	532	0	0	
80th Percentile Total Days to MDUFA Decision	0	532	0	0	
Maximum Total Days to MDUFA Decision	0	532	0	0	

Table 1.8 OHT8 - Office of Radiological Health

PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	0	0	0	
Average FDA Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA Decision	0	0	0	0	
Maximum FDA Days to MDUFA Decision	0	0	0	0	
Average Industry Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA Decision	0	0	0	0	
Maximum Industry Days to MDUFA Decision	0	0	0	0	
Average Total Days to MDUFA Decision	N/A	N/A	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	0	0	0	
40th Percentile Total Days to MDUFA Decision	0	0	0	0	
60th Percentile Total Days to MDUFA Decision	0	0	0	0	
80th Percentile Total Days to MDUFA Decision	0	0	0	0	
Maximum Total Days to MDUFA Decision	0	0	0	0	

Table 1.9 OHT8 - Office of Radiological Health

PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	3	0	0	
Number with MDUFA Decision	0	1	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	0.00%	N/A	N/A	
Rate of Not Approvable	N/A	0.00%	N/A	N/A	

Table 1.10 OHT8 - Office of Radiological Health

PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	N/A	N/A	

Table 1.11 OHT8 - Office of Radiological Health

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Table 1.12 OHT8 - Office of Radiological Health

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 1.13 OHT8 - Office of Radiological Health
LDT PMA Original and Panel-Track Supplements MDUFA V Metric***

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

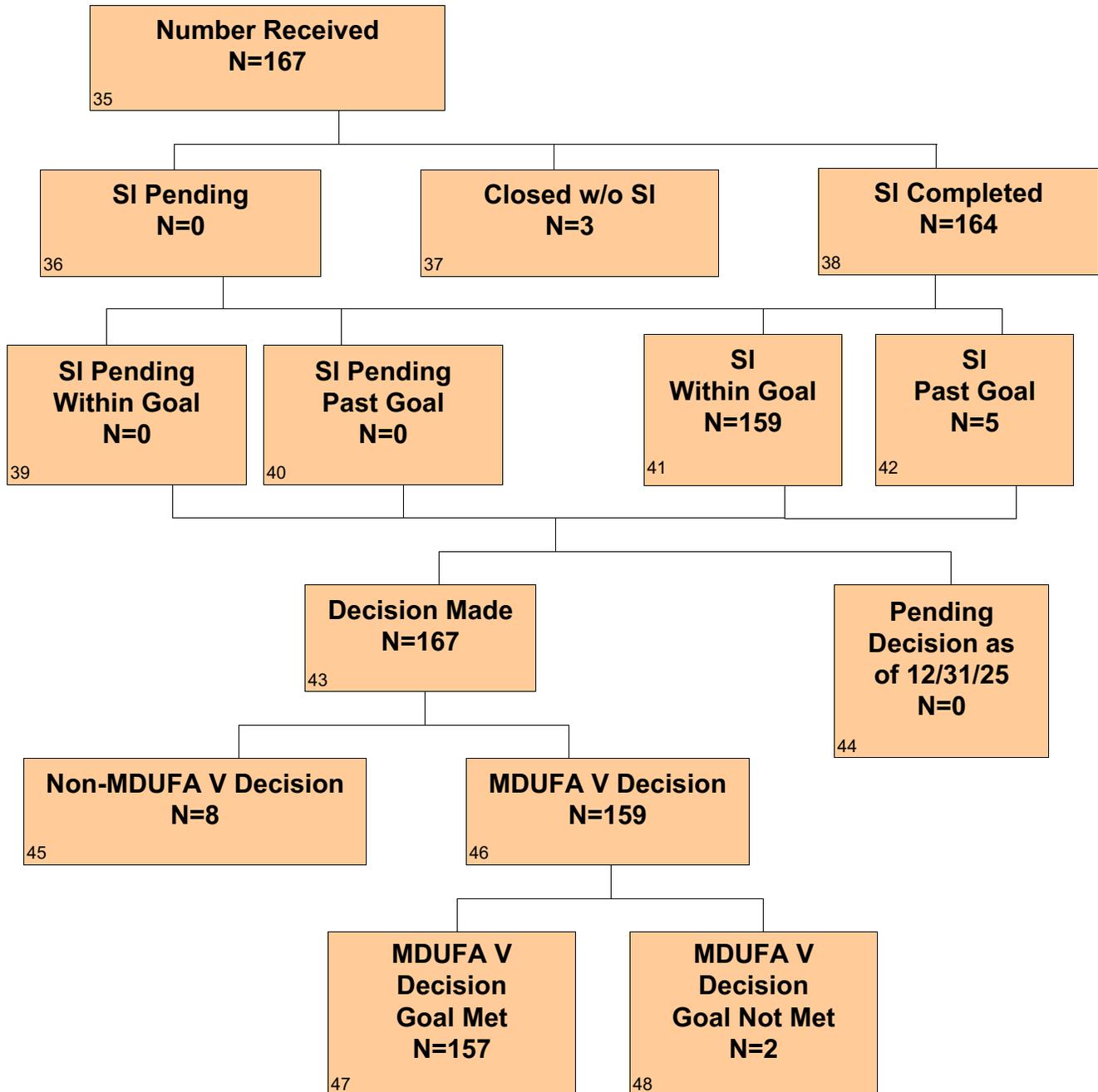
*Includes submission that went to panel

**Table 1.14 OHT8 - Office of Radiological Health
Conventional IVD (Non-LDT) PMA Original and Panel-Track Supplements MDUFA V Metric***

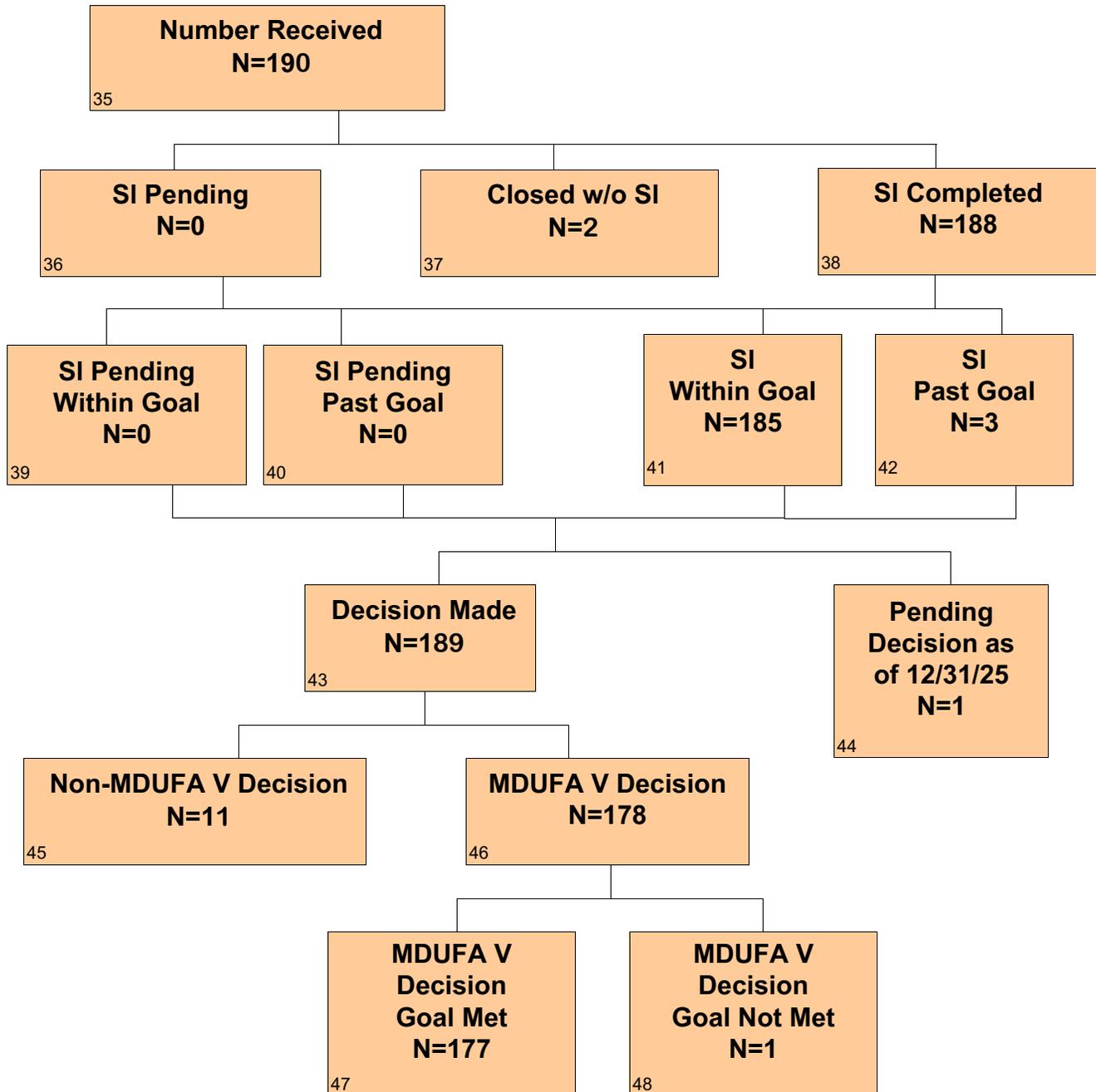
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal Met	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision	N/A	N/A	N/A	N/A	
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A	N/A	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

*Includes submission that went to panel

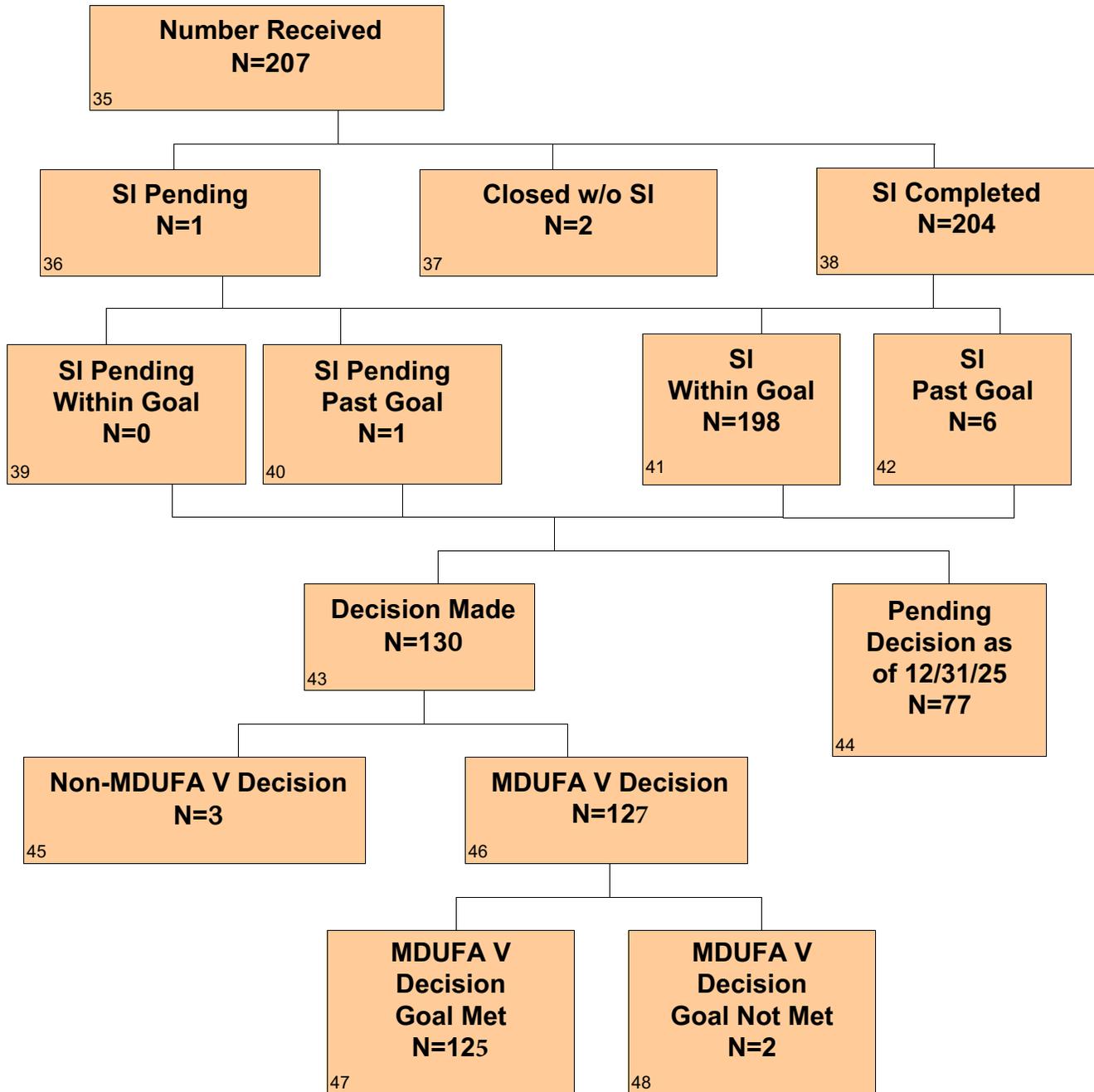
CDRH PMA 180 Day Supplements - FY 2023 as of 12/31/25



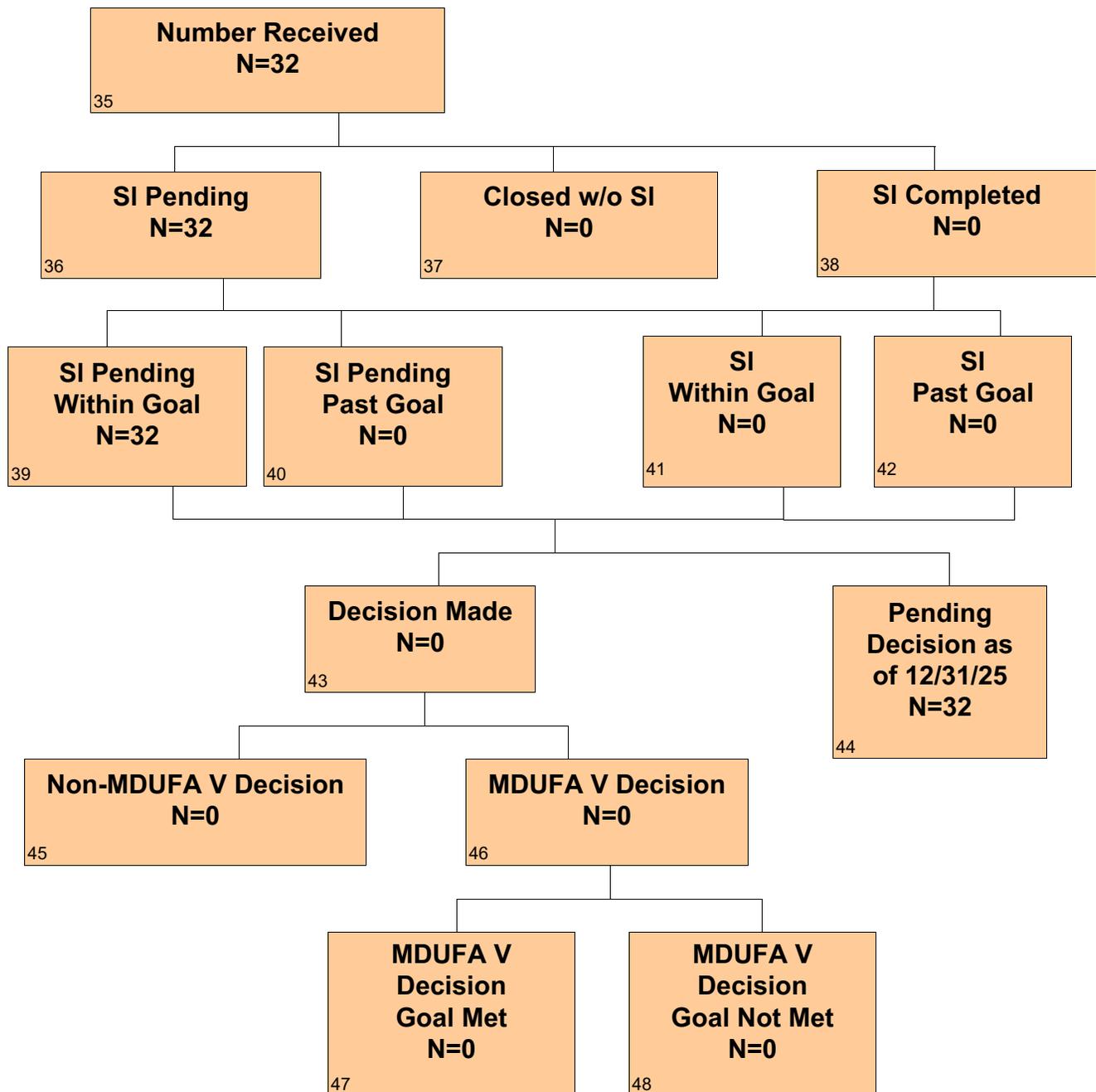
CDRH PMA 180 Day Supplements - FY 2024 as of 12/31/25



CDRH PMA 180 Day Supplements - FY 2025 as of 12/31/25



CDRH PMA 180 Day Supplements - FY 2026 as of 12/31/25



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 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	167	190	207	32	
SI Goal Met	159	185	198	0	
SI Goal Not Met	5	3	6	0	
SI Pending Within Goal	0	0	0	32	
SI Pending Past Goal	0	0	1	0	
Closed Without SI	3	2	2	0	
Current SI Performance Percent Goal Met	96.95%	98.40%	96.59%	N/A	

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	167	190	207	32	
Non-MDUFA Decision	8	11	3	0	
MDUFA Decision	159	178	127	0	
MDUFA Decision Goal Met	157	177	125	0	
Supplements Pending MDUFA Decision	0	1	77	32	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	98.74%	99.44%	98.43%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	167	190	207	32	
Number with MDUFA Decision	159	178	127	0	
Number of Not Approvable	7	15	7	0	
Rate of Not Approvable	4.40%	8.43%	5.51%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	1	2	0	
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	184.50	N/A	
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	0.00	N/A	

Section 2 PMA 180-Day Supplements - Office Level Metric

**Table 2.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	16	15	21	2	
SI Goal Met	16	15	0	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	2	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

**Table 2.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	16	15	21	2	
Non-MDUFA Decision	1	2	0	0	
MDUFA Decision	15	13	11	0	
MDUFA Decision Goal Met	15	13	11	0	
Supplements Pending MDUFA Decision	0	0	10	2	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 2.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	15	21	2	
Number with MDUFA Decision	15	13	11	0	
Number of Not Approvable	1	1	2	0	
Rate of Not Approvable	6.67%	7.69%	18.18%	N/A	

**Table 2.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 2.1 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	56	81	77	19	
SI Goal Met	55	80	71	0	
SI Goal Not Met	0	0	3	0	
SI Pending Within Goal	0	0	0	19	
SI Pending Past Goal	0	0	1	0	
Closed Without SI	1	1	2	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	94.67%	N/A	

**Table 2.2 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	56	81	77	19	
Non-MDUFA Decision	3	6	2	0	
MDUFA Decision	53	75	53	0	
MDUFA Decision Goal Met	53	75	52	0	
Supplements Pending MDUFA Decision	0	0	22	19	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	98.11%	N/A	

**Table 2.3 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	56	81	77	19	
Number with MDUFA Decision	53	75	53	0	
Number of Not Approvable	1	12	1	0	
Rate of Not Approvable	1.89%	16.00%	1.89%	N/A	

**Table 2.4 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	187.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00	N/A	

**Table 2.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	21	17	19	5	
SI Goal Met	20	17	18	0	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	5	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	95.24%	100.00%	94.74%	N/A	

**Table 2.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	21	17	19	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	21	17	13	0	
MDUFA Decision Goal Met	21	17	12	0	
Supplements Pending MDUFA Decision	0	0	6	5	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	92.31%	N/A	

**Table 2.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	17	19	5	
Number with MDUFA Decision	21	17	13	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

**Table 2.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	182.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00	N/A	

**Table 2.1 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	12	13	0	
SI Goal Met	8	12	13	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 2.2 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	8	12	13	0	
Non-MDUFA Decision	0	1	0	0	
MDUFA Decision	8	11	5	0	
MDUFA Decision Goal Met	8	11	5	0	
Supplements Pending MDUFA Decision	0	0	8	0	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 2.3 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	8	12	13	0	
Number with MDUFA Decision	8	11	5	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

**Table 2.4 OHT4 - Office of Surgical and Infection Control Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 2.1 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	23	20	31	2	
SI Goal Met	20	17	30	0	
SI Goal Not Met	3	3	1	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	86.96%	85.00%	96.77%	N/A	

**Table 2.2 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	23	20	31	2	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	23	19	21	0	
MDUFA Decision Goal Met	21	18	21	0	
Supplements Pending MDUFA Decision	0	1	9	2	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	91.30%	94.74%	100.00%	N/A	

**Table 2.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20	31	2	
Number with MDUFA Decision	23	19	21	0	
Number of Not Approvable	3	1	3	0	
Rate of Not Approvable	13.04%	5.26%	14.29%	N/A	

**Table 2.4 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	1	0	0	
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	N/A	N/A	

**Table 2.1 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	6	5	11	1	
SI Goal Met	6	5	11	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 2.2 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	6	5	11	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	5	6	0	
MDUFA Decision Goal Met	6	5	6	0	
Supplements Pending MDUFA Decision	0	0	5	1	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 2.3 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	5	11	1	
Number with MDUFA Decision	6	5	6	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

**Table 2.4 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 2.1 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	36	38	34	2	
SI Goal Met	33	37	33	0	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	2	1	0	0	
Current SI Performance Percent Goal Met	97.06%	100.00%	97.06%	N/A	

**Table 2.2 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	36	38	34	2	
Non-MDUFA Decision	4	2	0	0	
MDUFA Decision	32	36	17	0	
MDUFA Decision Goal Met	32	36	17	0	
Supplements Pending MDUFA Decision	0	0	17	2	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 2.3 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	36	38	34	2	
Number with MDUFA Decision	32	36	17	0	
Number of Not Approvable	2	1	1	0	
Rate of Not Approvable	6.25%	2.78%	5.88%	N/A	

**Table 2.4 OHT7 - Office of In Vitro Diagnostics
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 2.1 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Substantive Interaction Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	1	2	1	1	
SI Goal Met	1	2	1	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 2.2 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Decision**

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Supplements Received	1	2	1	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	2	1	0	
MDUFA Decision Goal Met	1	2	1	0	
Supplements Pending MDUFA Decision	0	0	0	1	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

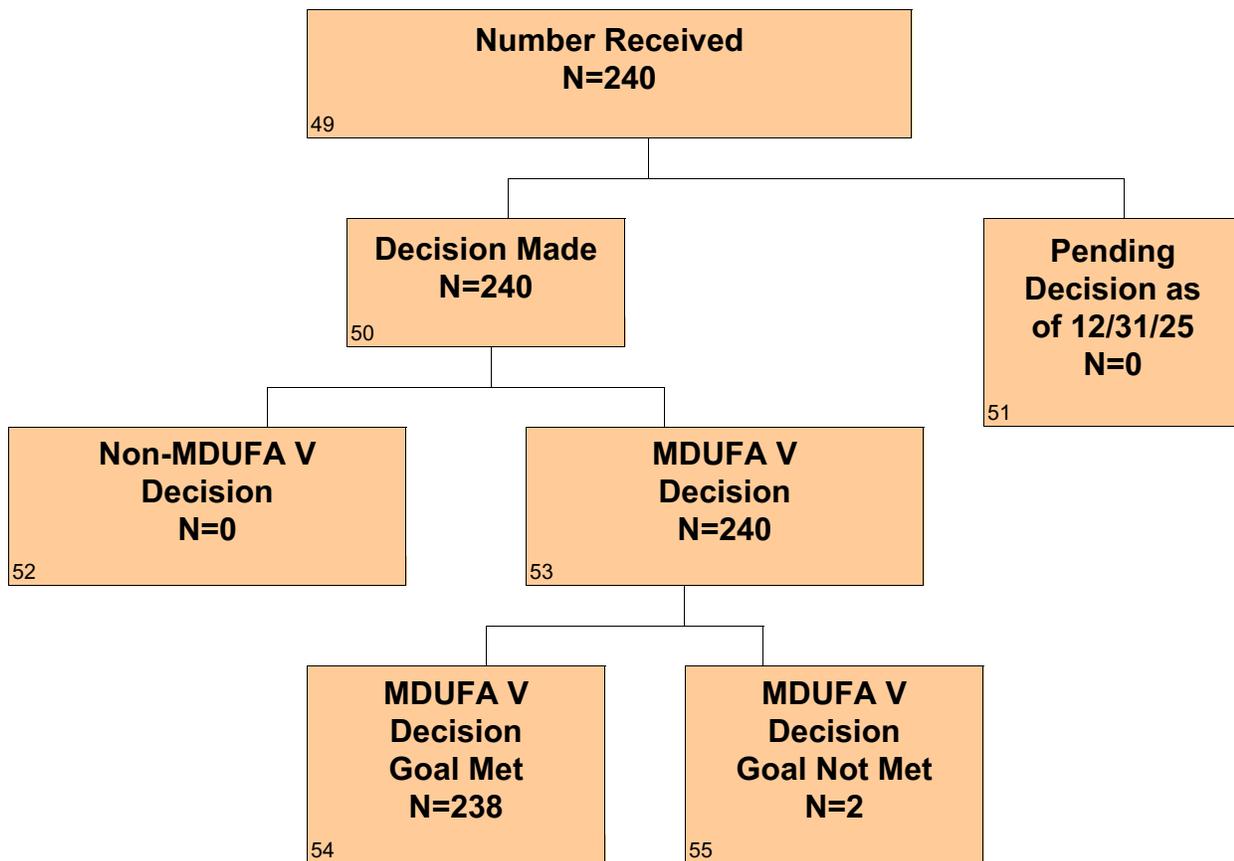
**Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	1	2	1	1	
Number with MDUFA Decision	1	2	1	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

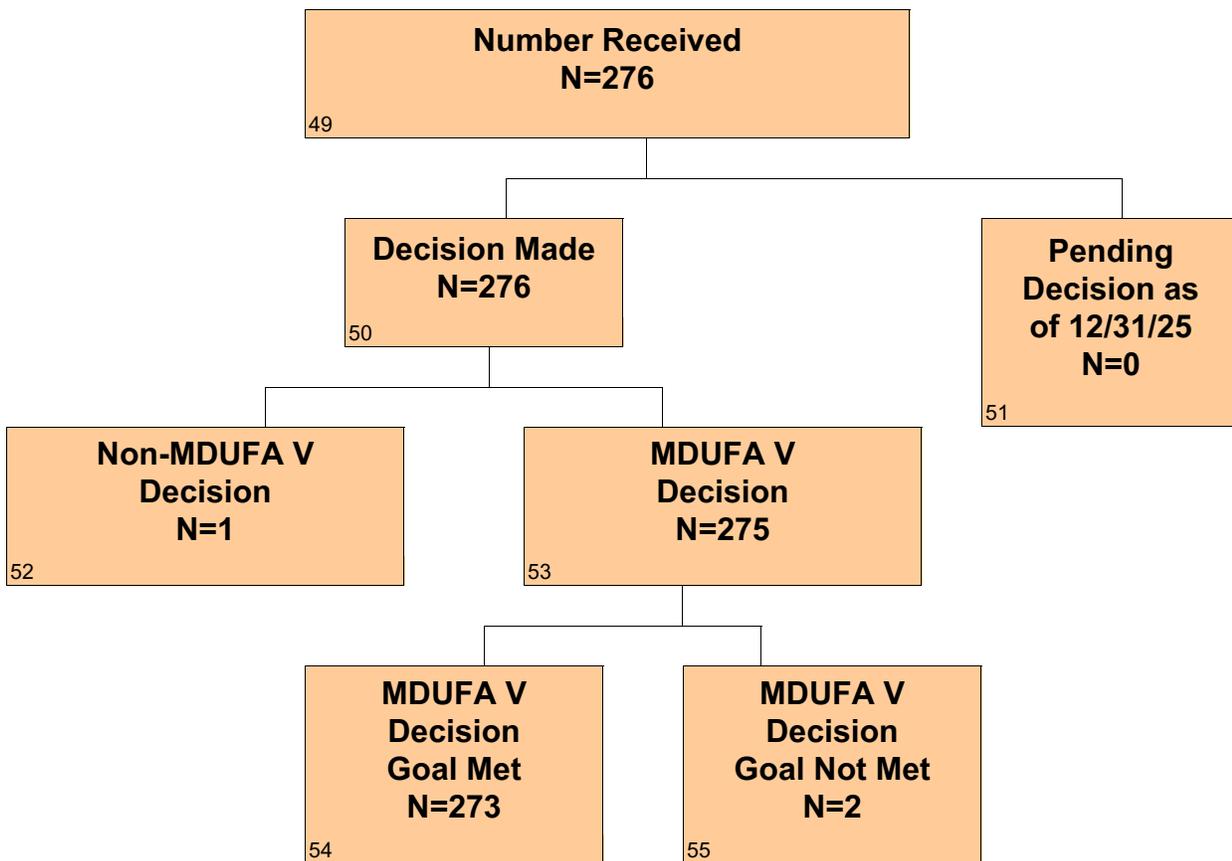
**Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

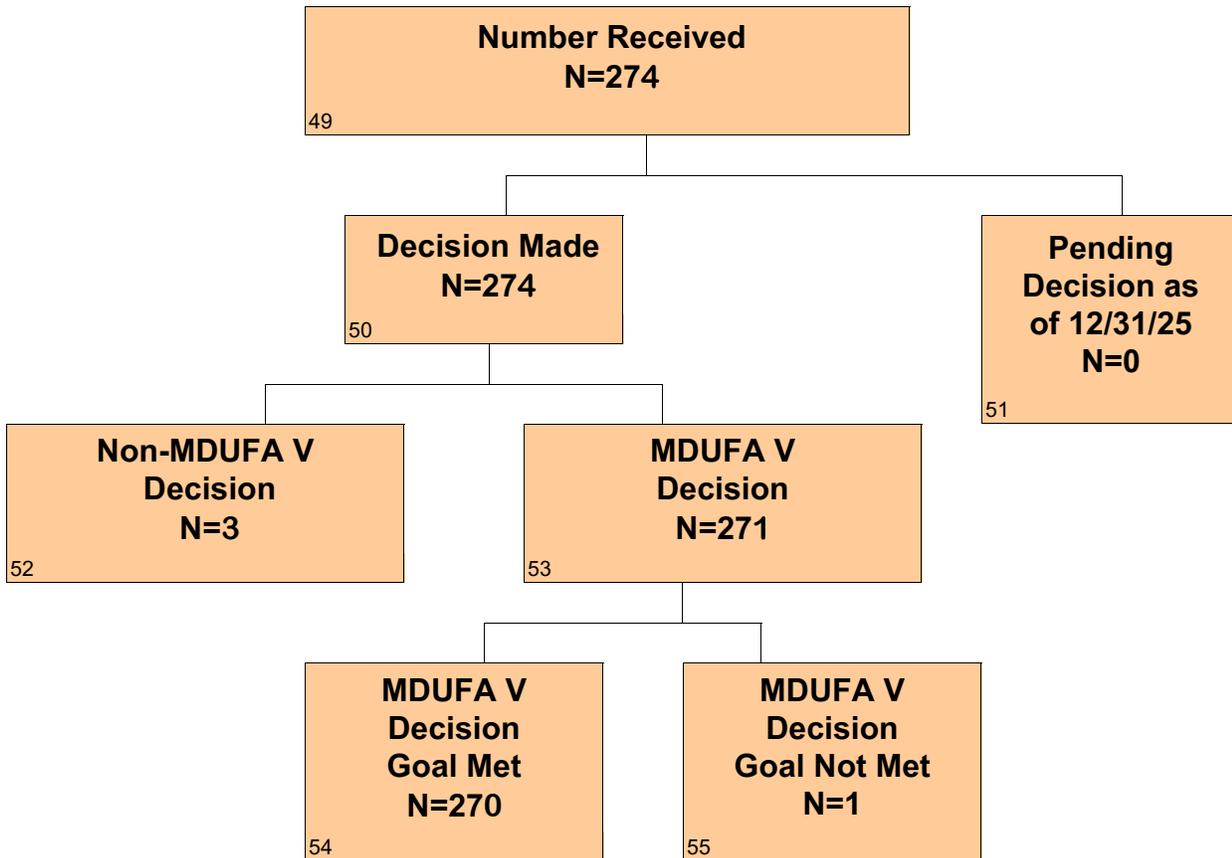
CDRH PMA Real Time Supplements - FY 2023 as of 12/31/25



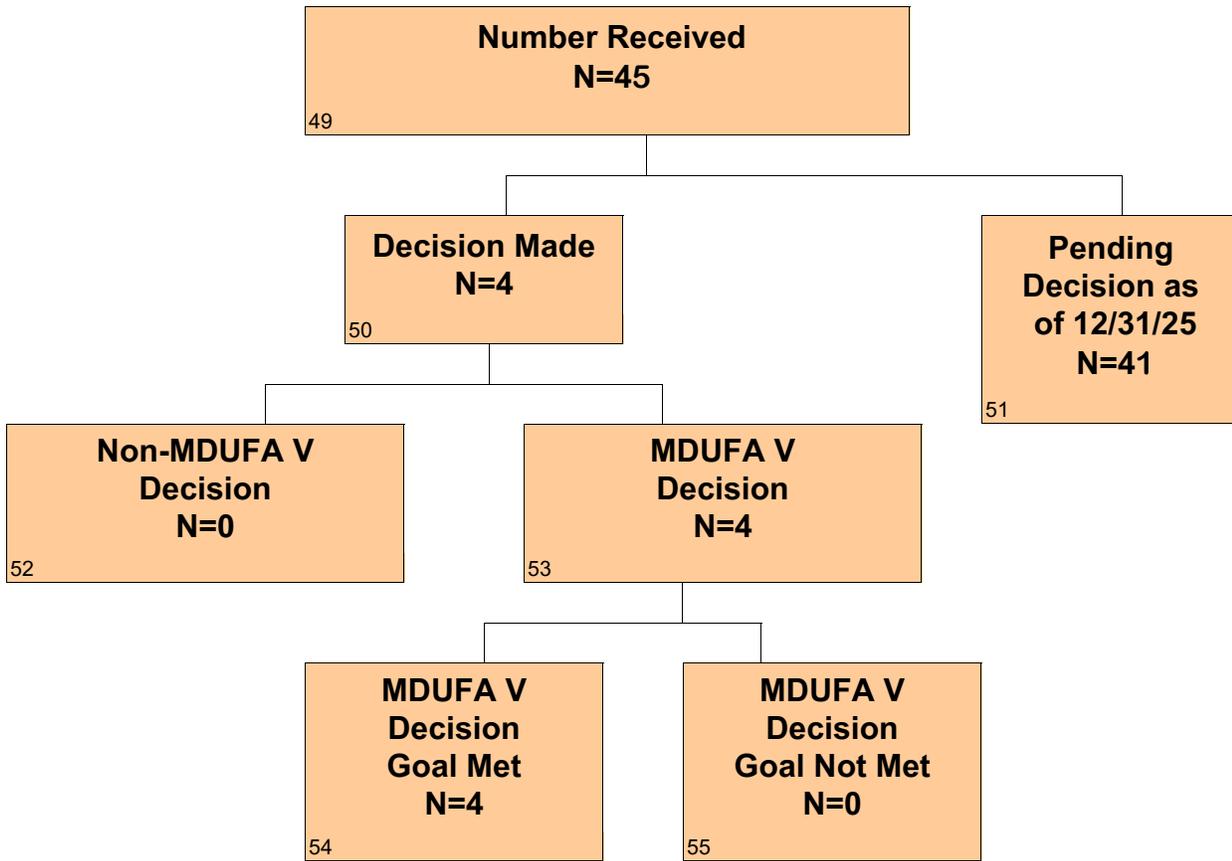
CDRH PMA Real Time Supplements - FY 2024 as of 12/31/25



CDRH PMA Real Time Supplements - FY 2025 as of 12/31/25



CDRH PMA Real Time Supplements - FY 2026 as of 12/31/25



Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	240	276	274	45	
Non-MDUFA Decision	0	1	3	0	
MDUFA Decision	240	275	271	4	
MDUFA Decision Goal Met	238	273	270	4	
Supplements Pending MDUFA Decision	0	0	0	41	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	99.17%	99.27%	99.63%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	240	276	274	45	
Number With MDUFA Decision	240	275	271	4	
Number of Not Approvable	11	10	20	0	
Rate of Not Approvable	4.58%	3.64%	7.38%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	2	1	0	
Mean FDA Days for Submissions that Missed the Goal	109.50	119.50	102.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	N/A	

Section 3 PMA Real-Time Supplements - Office Level Metric

**Table 3.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	24	19	27	3	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	24	19	26	0	
MDUFA Decision Goal Met	24	19	26	0	
Supplements Pending MDUFA Decision	0	0	0	3	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 3.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	24	19	27	3	
Number With MDUFA Decision	24	19	26	0	
Number of Not Approvable	3	2	1	0	
Rate of Not Approvable	12.50%	10.53%	3.85%	N/A	

**Table 3.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 3.1 OHT2 - Office of Cardiovascular Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	136	142	125	20	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	136	142	124	3	
MDUFA Decision Goal Met	136	142	123	3	
Supplements Pending MDUFA Decision	0	0	0	17	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	99.19%	100.00%	

**Table 3.2 OHT2 - Office of Cardiovascular Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	136	142	125	20	
Number With MDUFA Decision	136	142	124	3	
Number of Not Approvable	4	1	12	0	
Rate of Not Approvable	2.94%	0.70%	9.68%	0.00%	

**Table 3.3 OHT2 - Office of Cardiovascular Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	102.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00	N/A	

**Table 3.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	19	23	17	7	
Non-MDUFA Decision	0	1	0	0	
MDUFA Decision	19	22	17	0	
MDUFA Decision Goal Met	18	21	17	0	
Supplements Pending MDUFA Decision	0	0	0	7	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	94.74%	95.45%	100.00%	N/A	

**Table 3.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	19	23	17	7	
Number With MDUFA Decision	19	22	17	0	
Number of Not Approvable	2	4	2	0	
Rate of Not Approvable	10.53%	18.18%	11.76%	N/A	

**Table 3.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1	0	0	
Mean FDA Days for Submissions that Missed the Goal	92.00	91.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A	N/A	

**Table 3.1 OHT4 - Office of Surgical and Infection Control Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	7	10	10	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	7	10	10	1	
MDUFA Decision Goal Met	7	10	10	1	
Supplements Pending MDUFA Decision	0	0	0	1	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

**Table 3.2 OHT4 - Office of Surgical and Infection Control Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	7	10	10	2	
Number With MDUFA Decision	7	10	10	1	
Number of Not Approvable	2	1	3	0	
Rate of Not Approvable	28.57%	10.00%	30.00%	0.00%	

**Table 3.3 OHT4 - Office of Surgical and Infection Control Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 3.1 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	16	37	50	8	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	16	37	50	0	
MDUFA Decision Goal Met	15	36	50	0	
Supplements Pending MDUFA Decision	0	0	0	8	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	93.75%	97.30%	100.00%	N/A	

**Table 3.2 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	16	37	50	8	
Number With MDUFA Decision	16	37	50	0	
Number of Not Approvable	0	1	2	0	
Rate of Not Approvable	0.00%	2.70%	4.00%	N/A	

**Table 3.3 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1	0	0	
Mean FDA Days for Submissions that Missed the Goal	127.00	148.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A	N/A	

**Table 3.1 OHT6 - Office of Orthopedic Devices
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	4	11	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	4	11	0	0	
MDUFA Decision Goal Met	4	11	0	0	
Supplements Pending MDUFA Decision	0	0	0	0	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

**Table 3.2 OHT6 - Office of Orthopedic Devices
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	11	0	0	
Number With MDUFA Decision	4	11	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	N/A	N/A	

**Table 3.3 OHT6 - Office of Orthopedic Devices
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 3.1 OHT7 - Office of In Vitro Diagnostics
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	32	33	45	5	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	32	33	44	0	
MDUFA Decision Goal Met	32	33	44	0	
Supplements Pending MDUFA Decision	0	0	0	5	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

**Table 3.2 OHT7 - Office of In Vitro Diagnostics
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	32	33	45	5	
Number With MDUFA Decision	32	33	44	0	
Number of Not Approvable	0	1	0	0	
Rate of Not Approvable	0.00%	3.03%	0.00%	N/A	

**Table 3.3 OHT7 - Office of In Vitro Diagnostics
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

**Table 3.1 OHT8 - Office of Radiological Health
PMA Real-Time Supplements MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	2	1	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	2	1	0	0	
MDUFA Decision Goal Met	2	1	0	0	
Supplements Pending MDUFA Decision	0	0	0	0	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

**Table 3.2 OHT8 - Office of Radiological Health
PMA Real-Time Supplements MDUFA V Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	2	1	0	0	
Number With MDUFA Decision	2	1	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	N/A	N/A	

**Table 3.3 OHT8 - Office of Radiological Health
PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2025 and December 31, 2025.

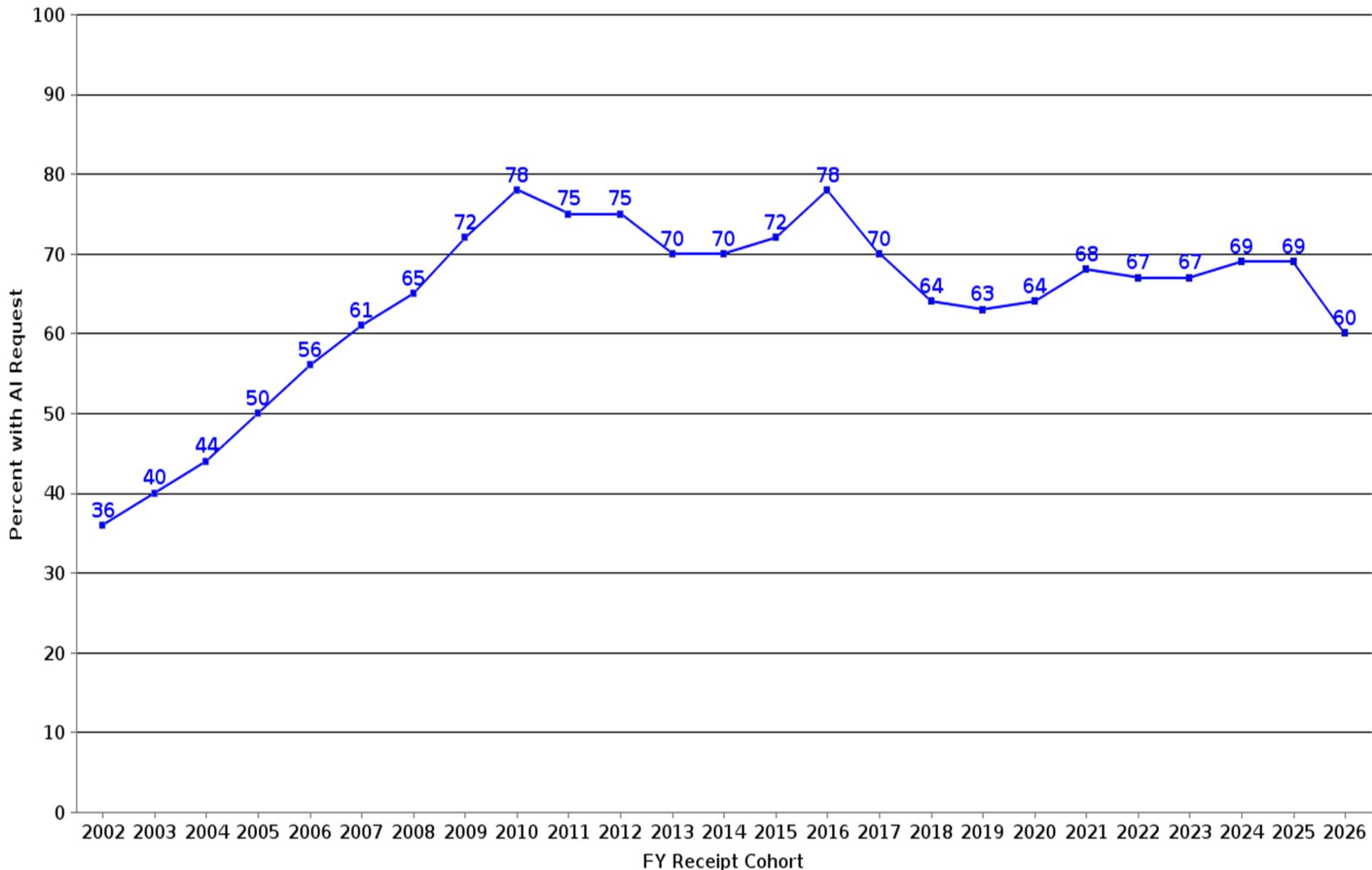
Section 5 PMA Annual Metrics and Goals

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

510(k)s

Q1FY2026

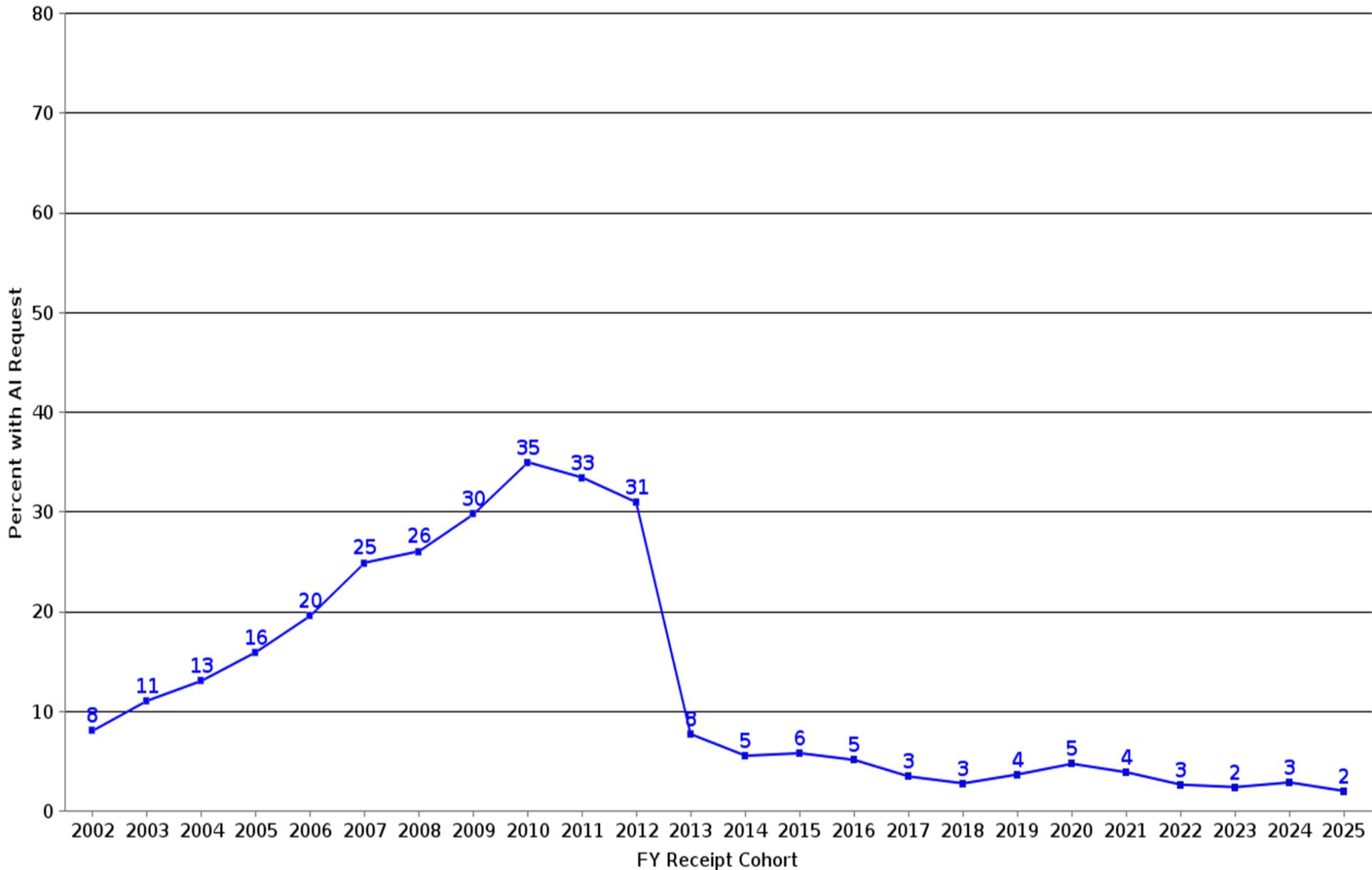
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 10/31/25

■ % with 1st Cycle AI Request

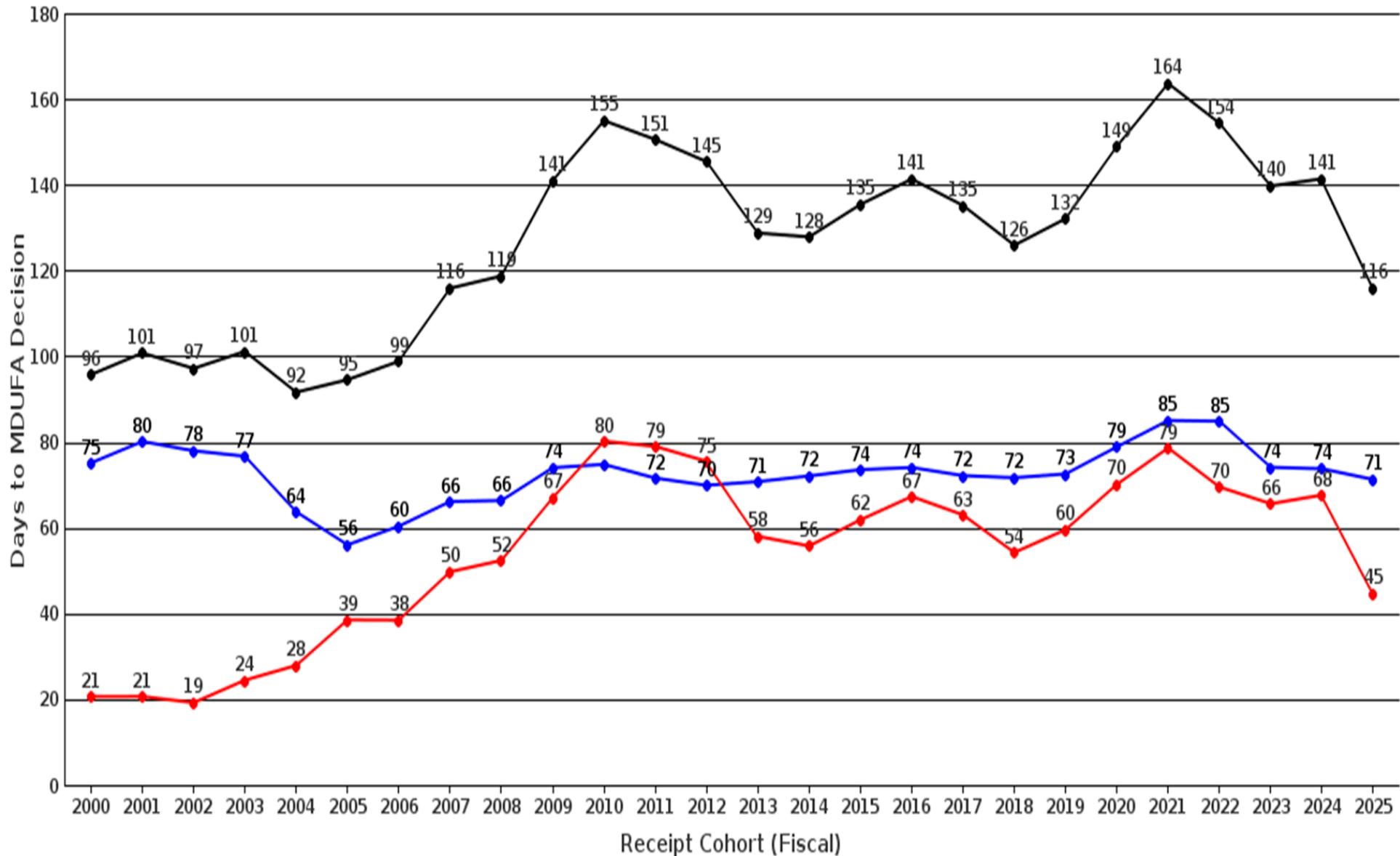
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 5/31/25

■ % with 2nd Cycle AI Request

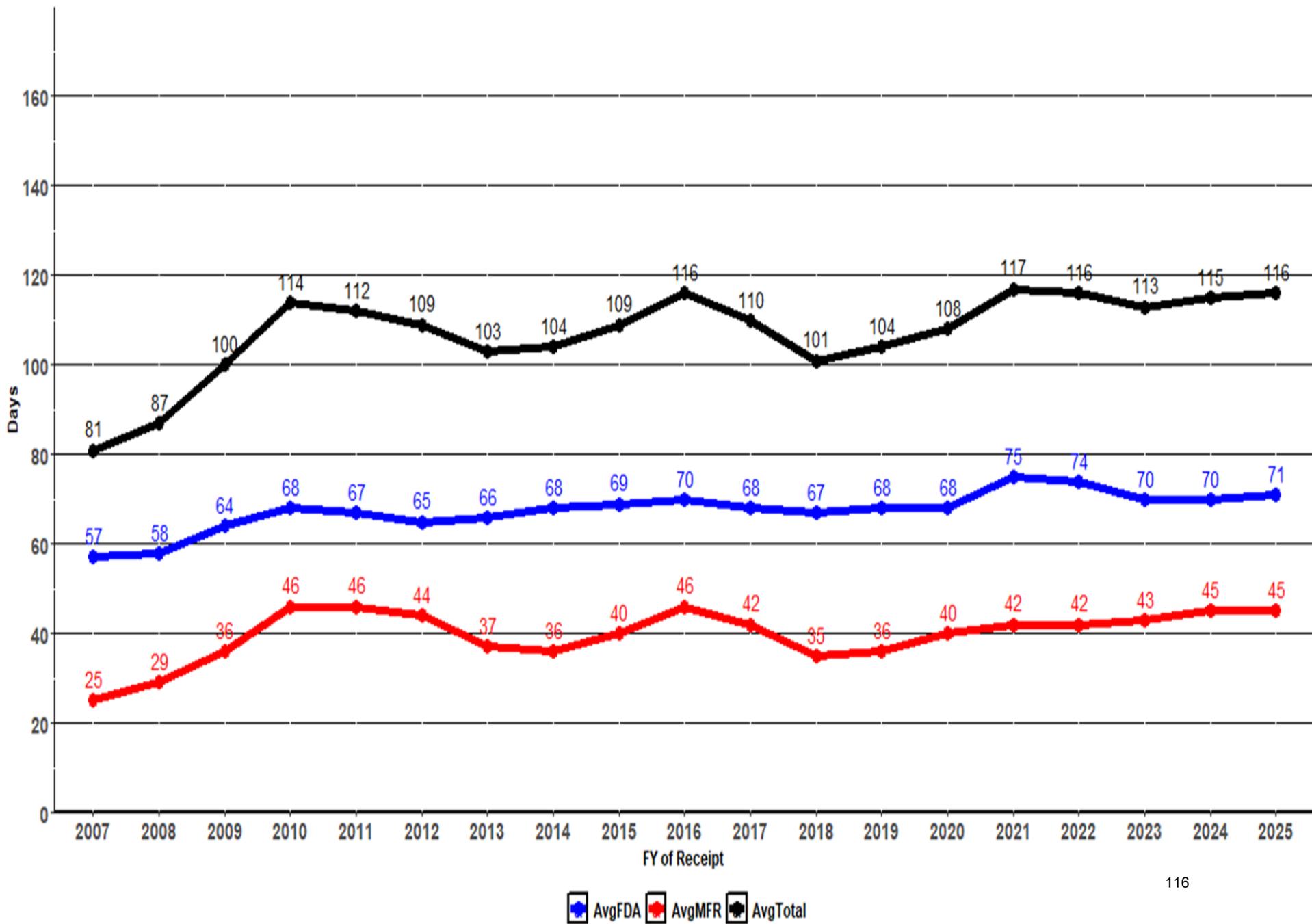
510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 12/31/25



Cohorts not yet closed: 2021: 99.88%; 2024: 99.58%; 2025: 72.23%

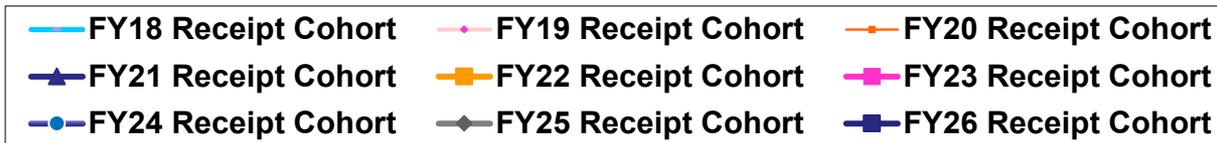
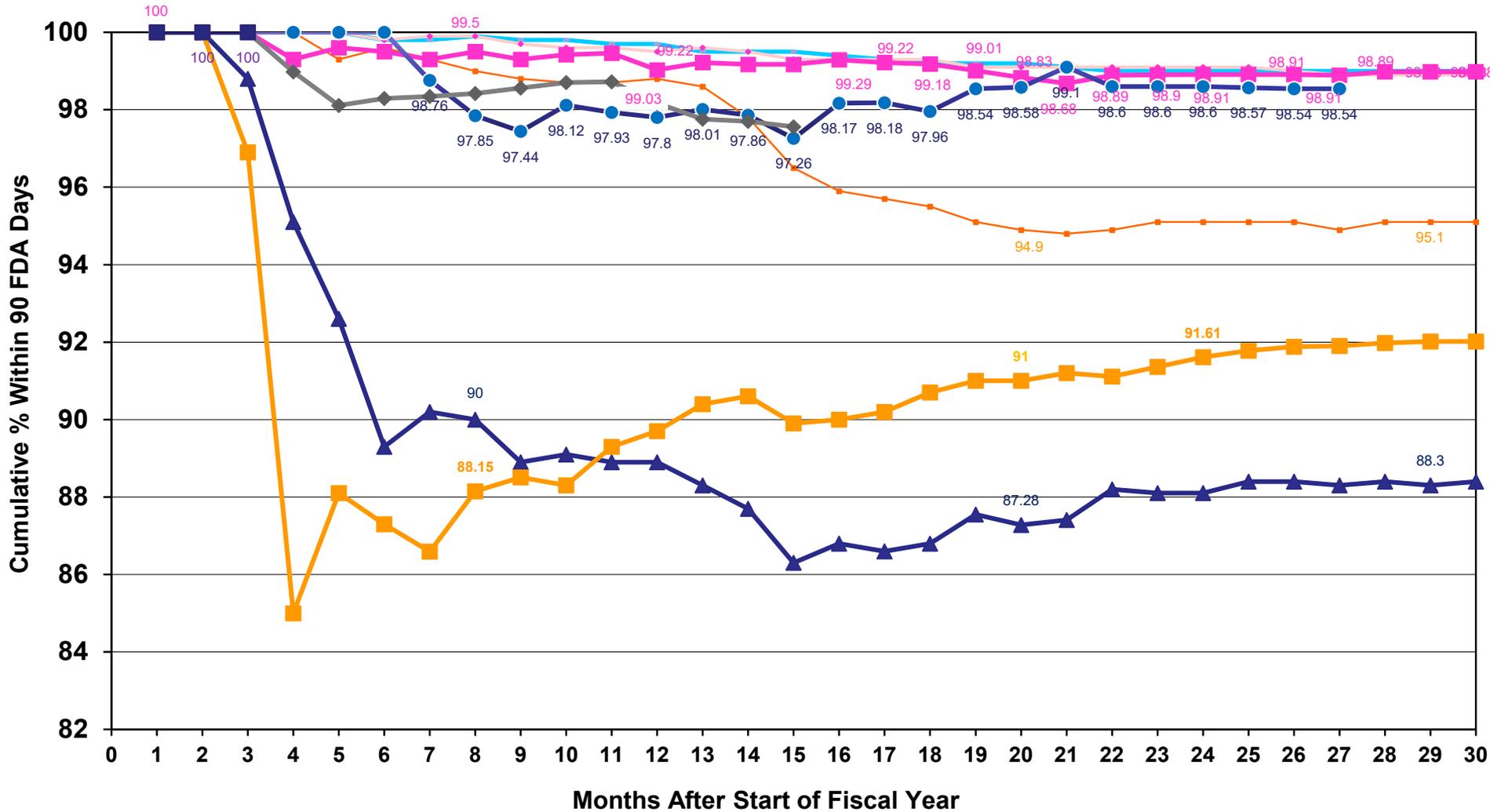
● Avg FDA Days to MDUFA Decision ● Avg Applicant Days to MDUFA Decision ● Avg Total Elapsed Days to MDUFA Decision

510(k) Average Days to MDUFA (SE/NSE) Decision at 72.23 % Cohort Closure by FY of Receipt

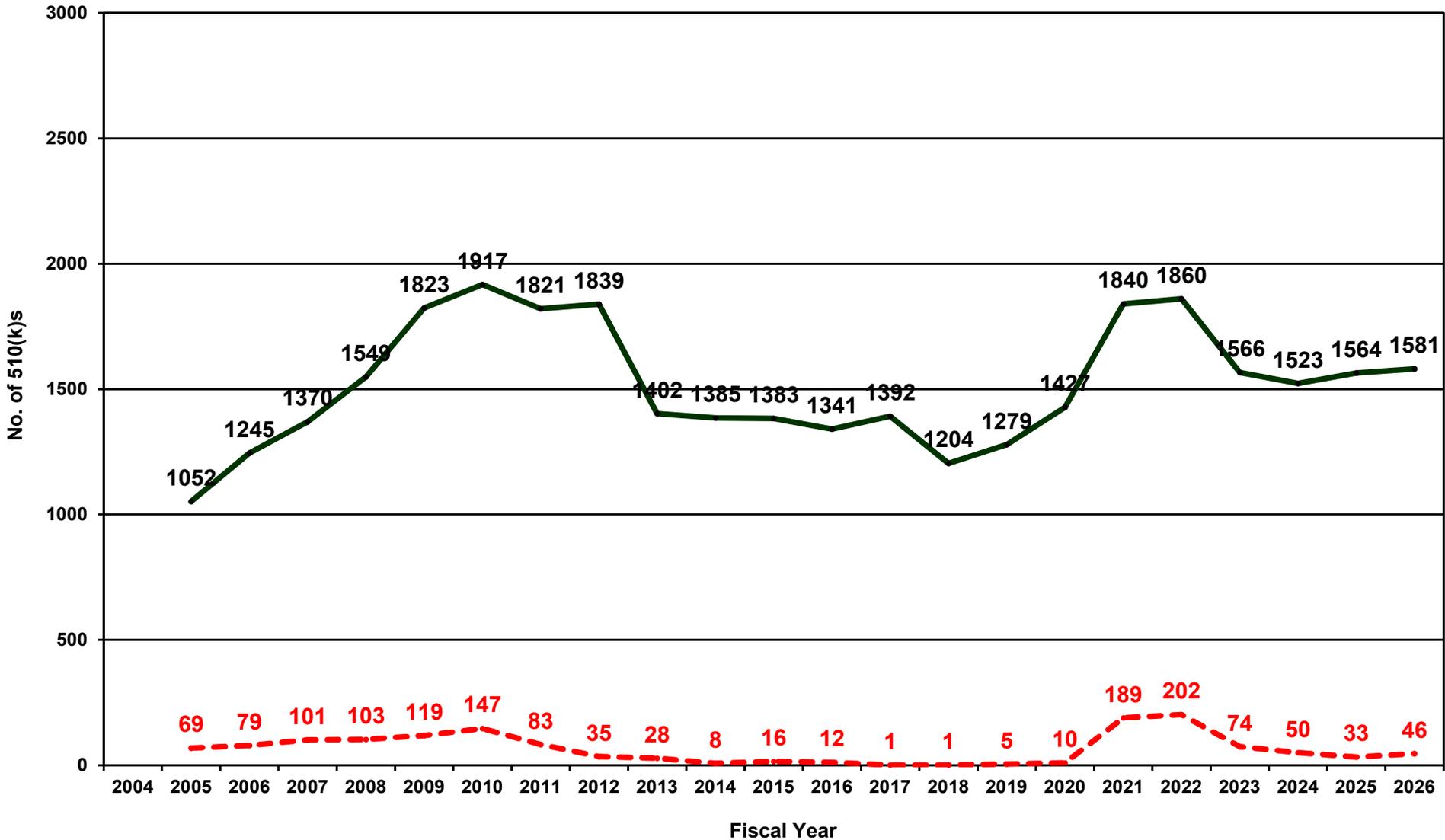


Trend in 510(k) MDUFA Decision Goal Performance

Comparison of FY18 – FY26 Receipt Cohorts



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

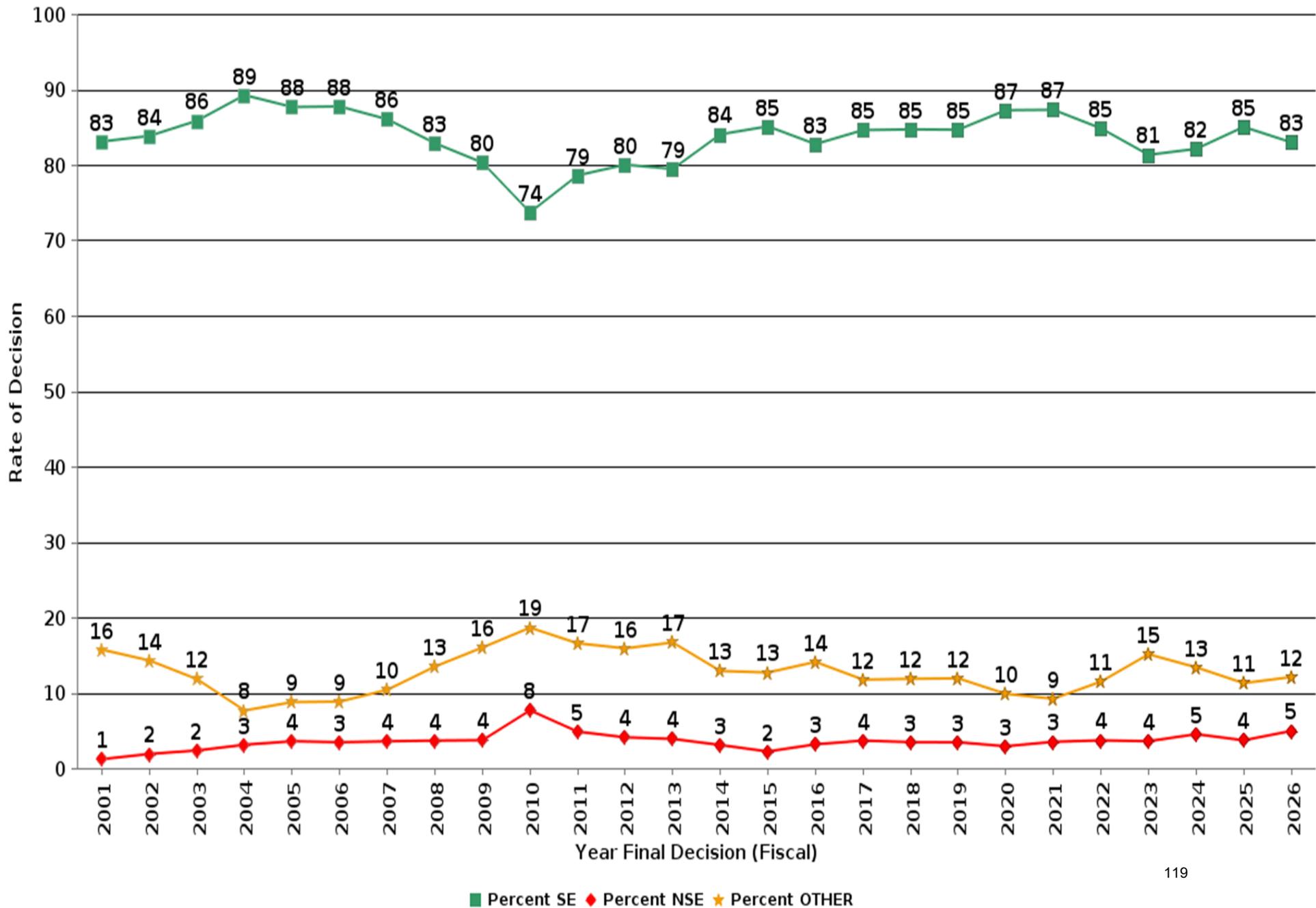


— Total Pending

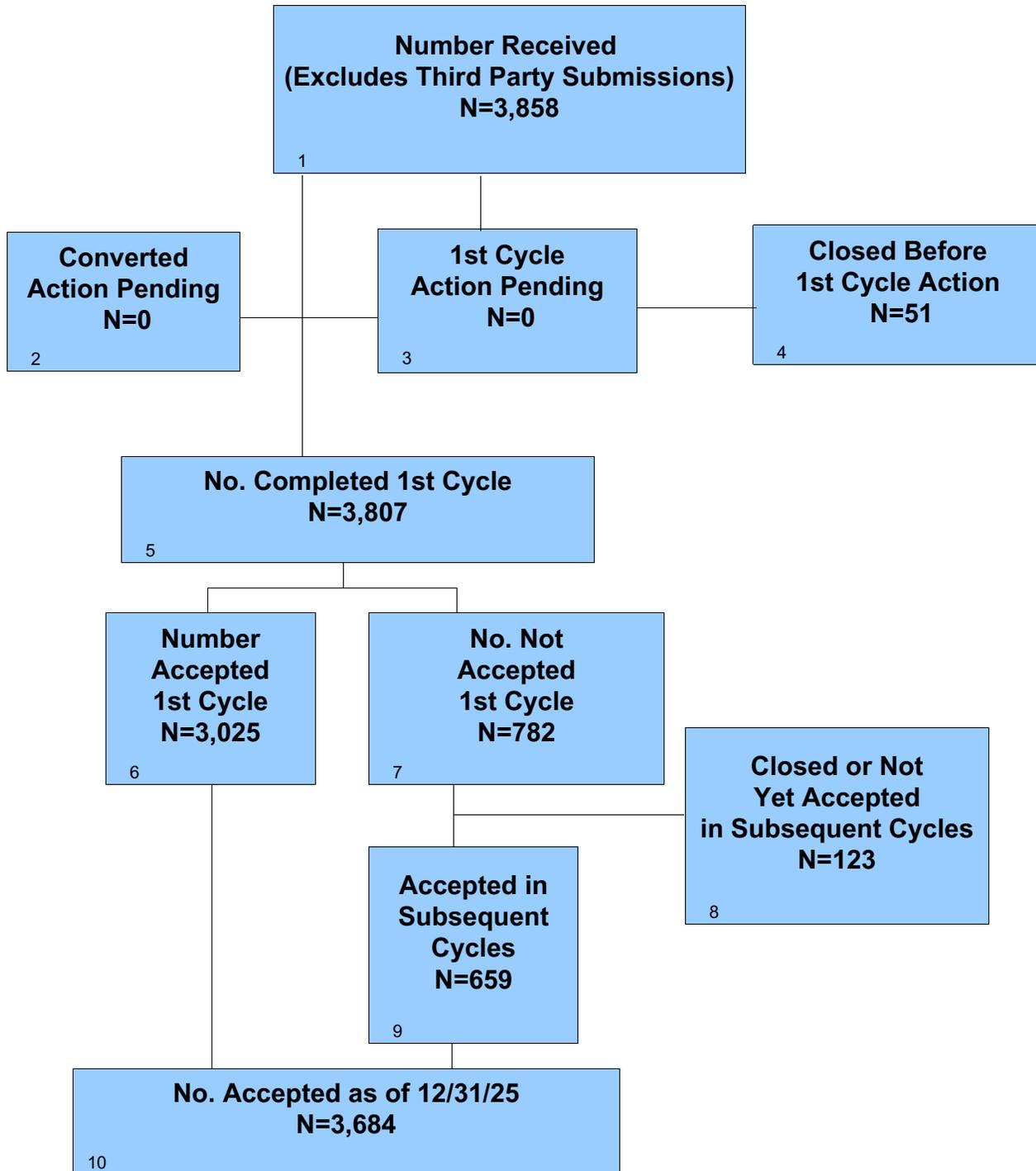
- - - Pending With More Than 90 FDA Days

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

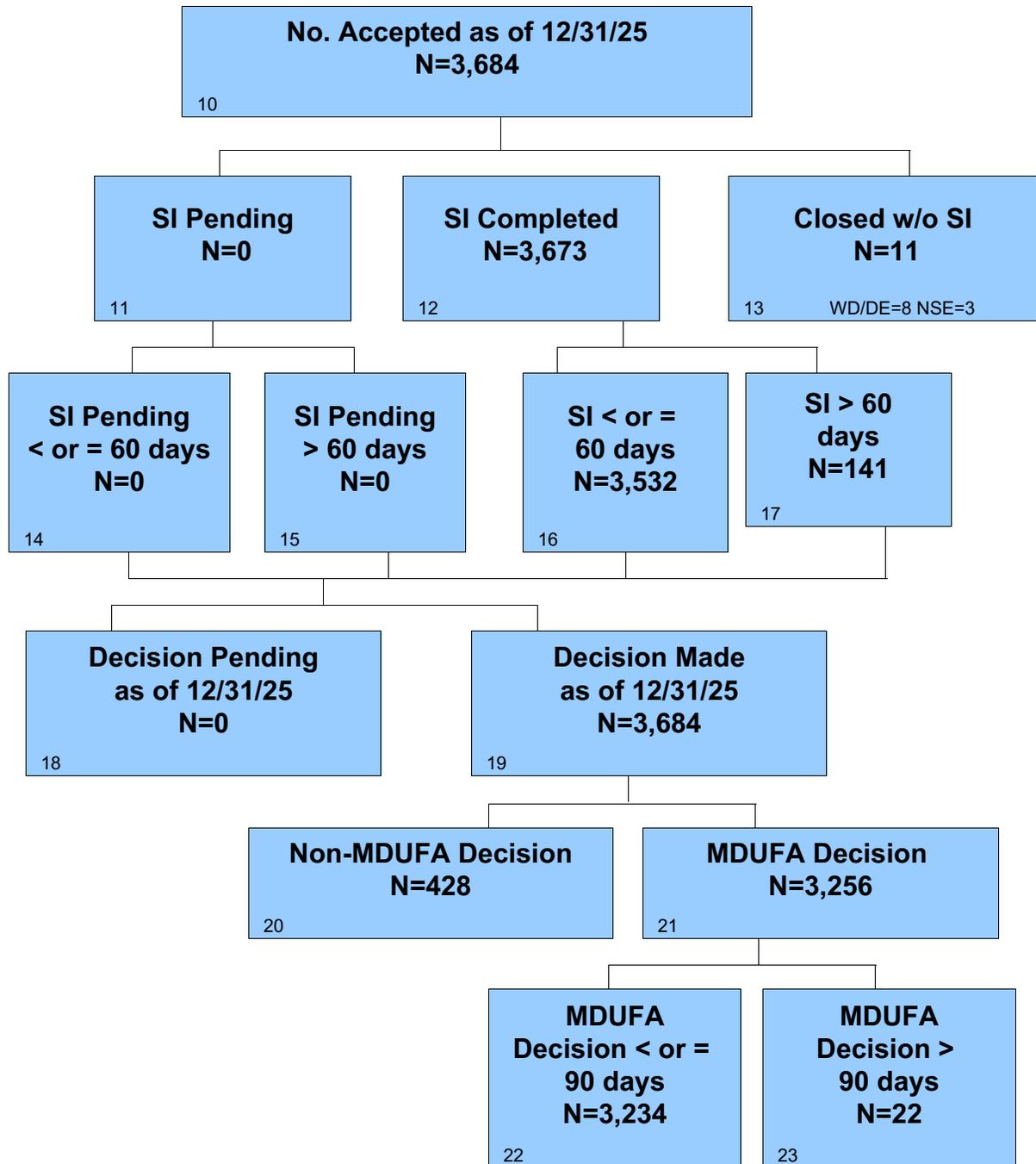
Rates of SE, NSE and Other Decisions by FY of Decision



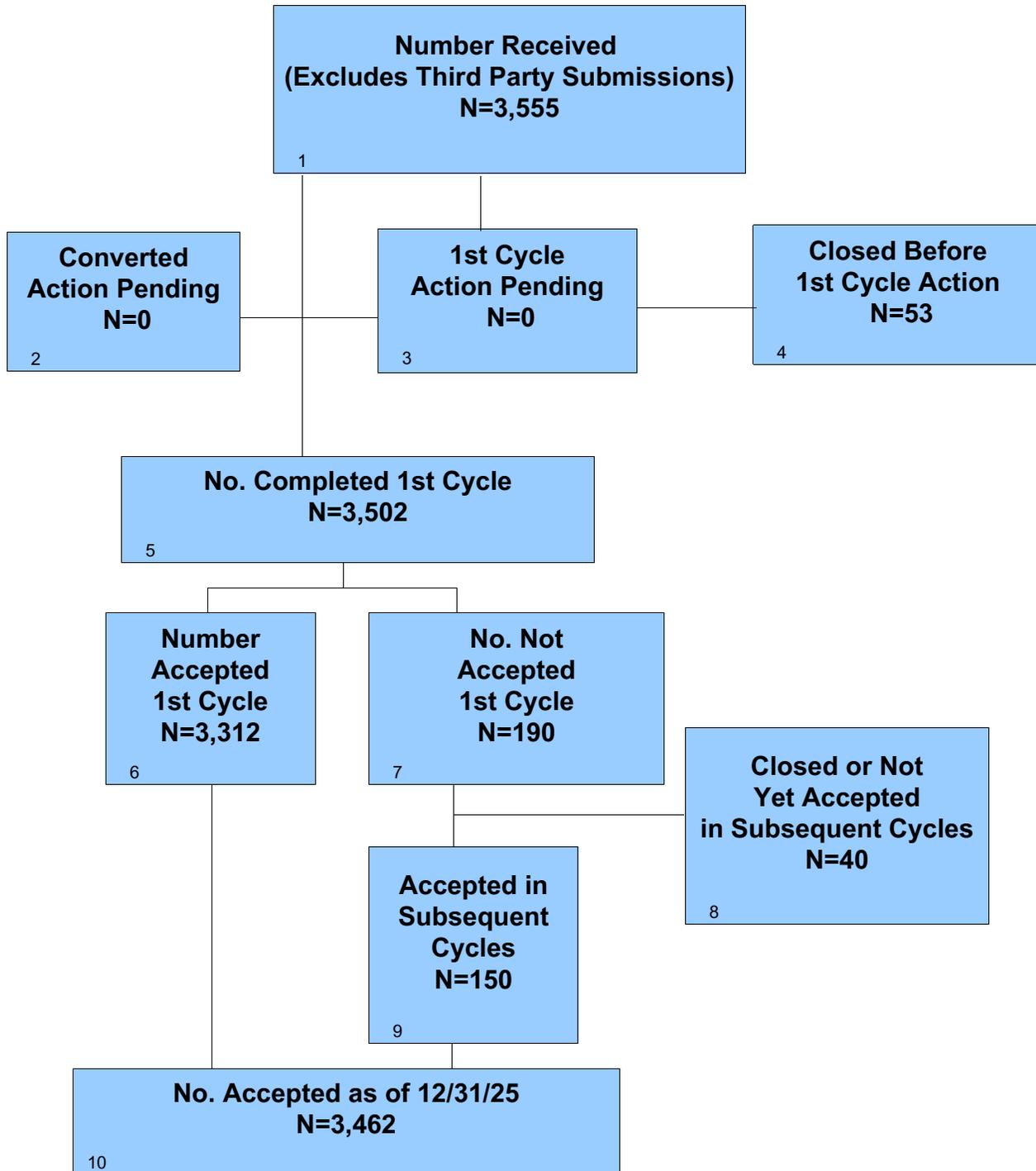
CDRH 510(k)s - FY 2023 as of 12/31/25



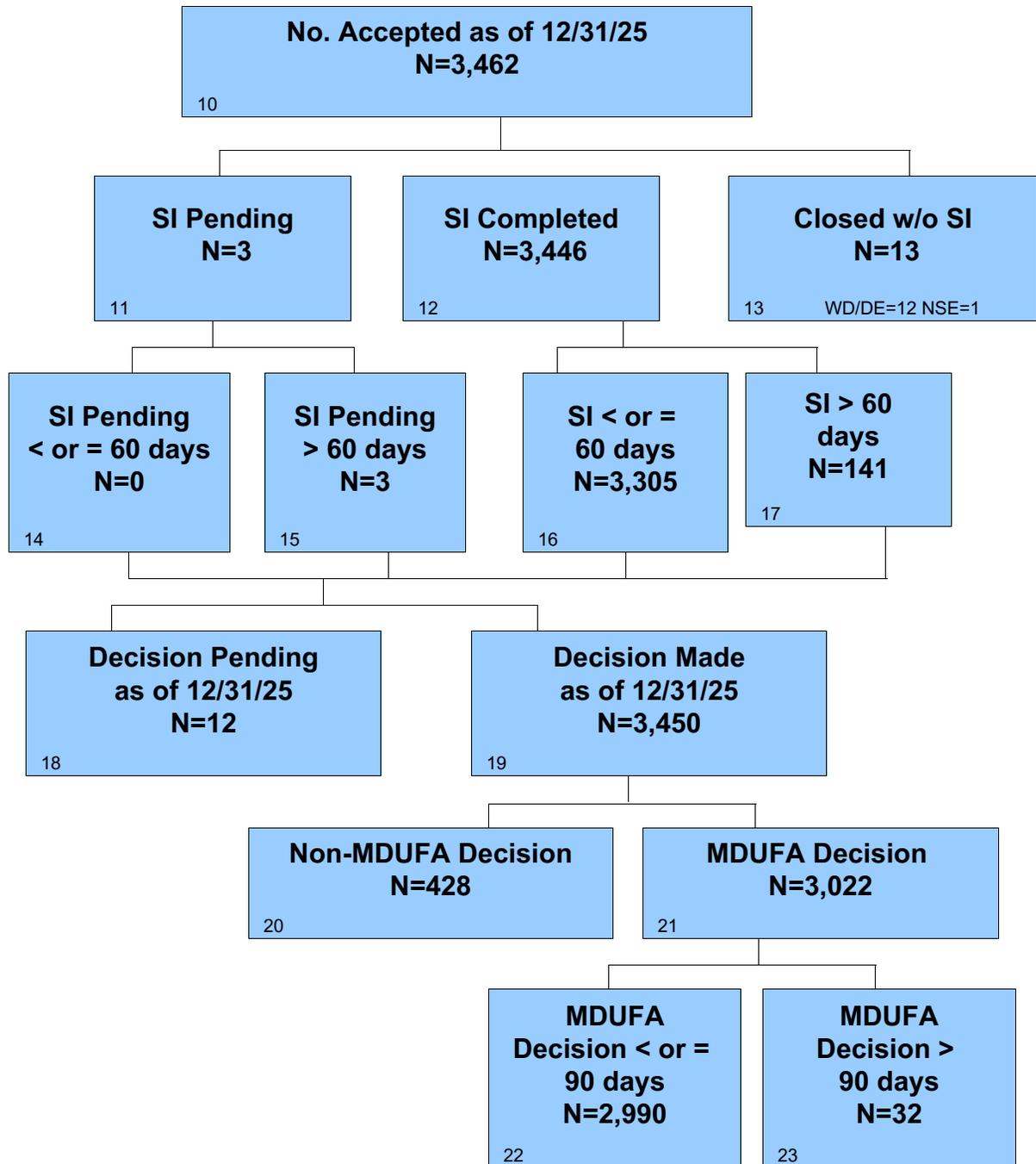
CDRH 510(k)s - FY 2023 as of 12/31/25 Continued



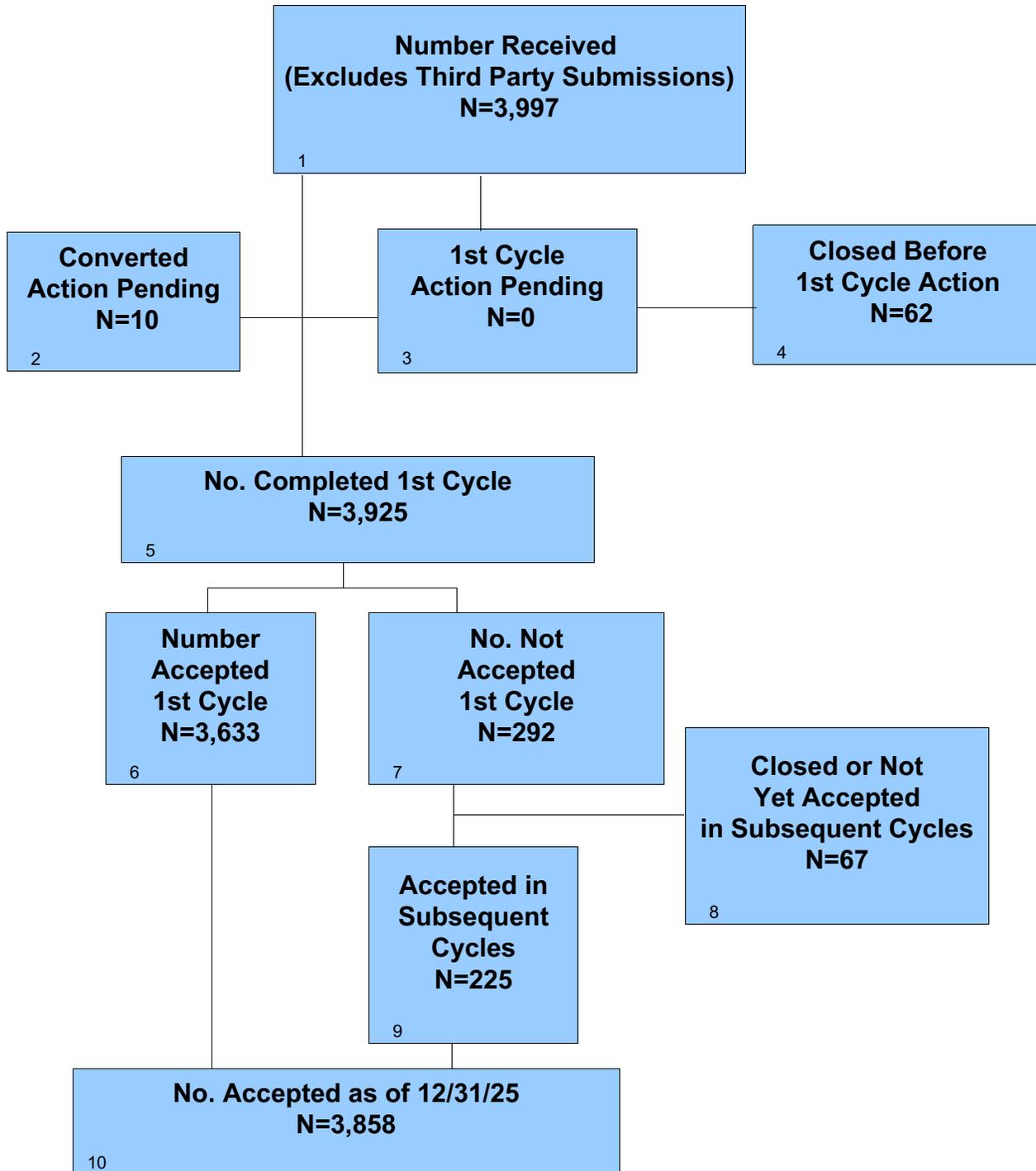
CDRH 510(k)s - FY 2024 as of 12/31/25



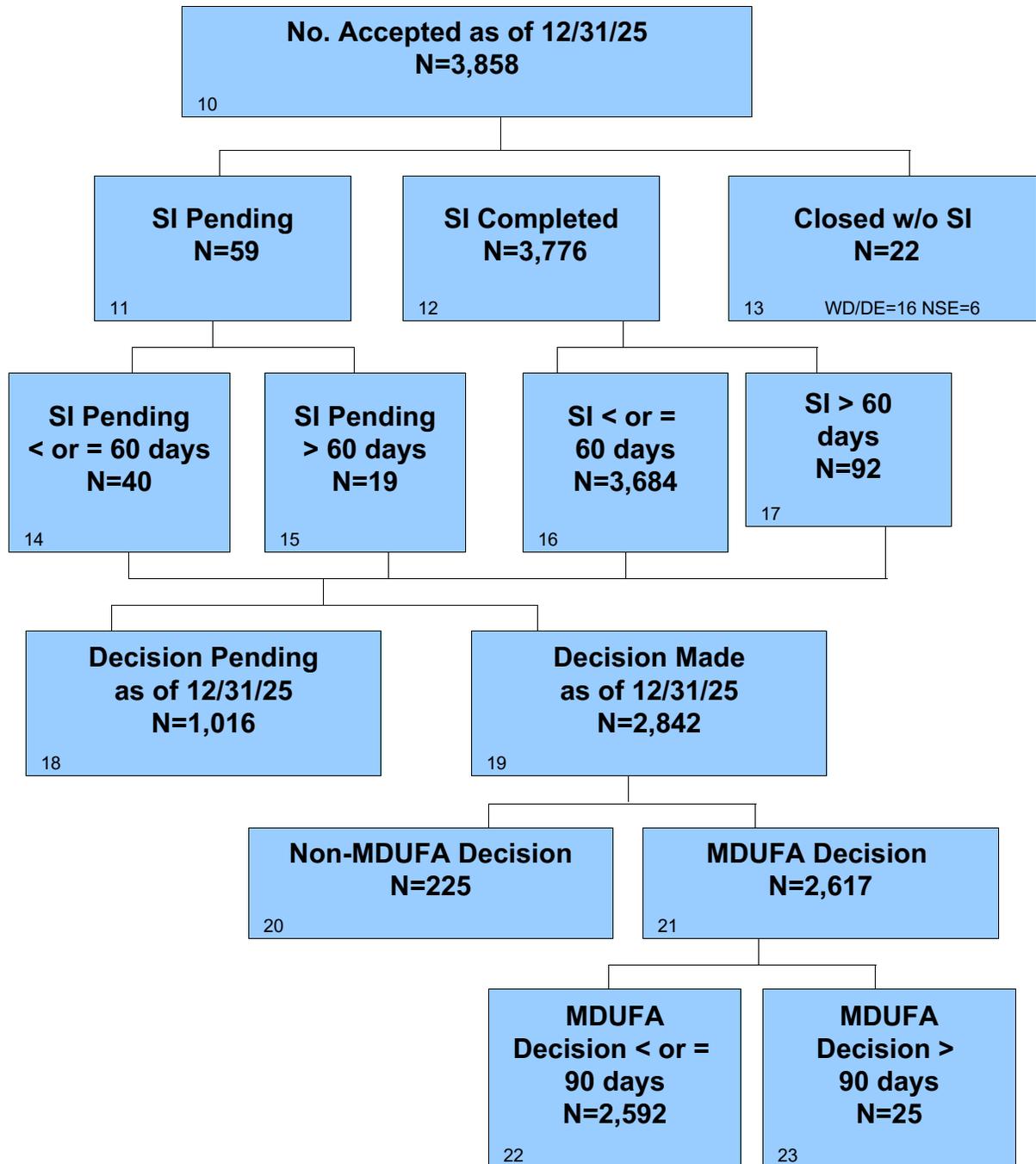
CDRH 510(k)s - FY 2024 as of 12/31/25 Continued



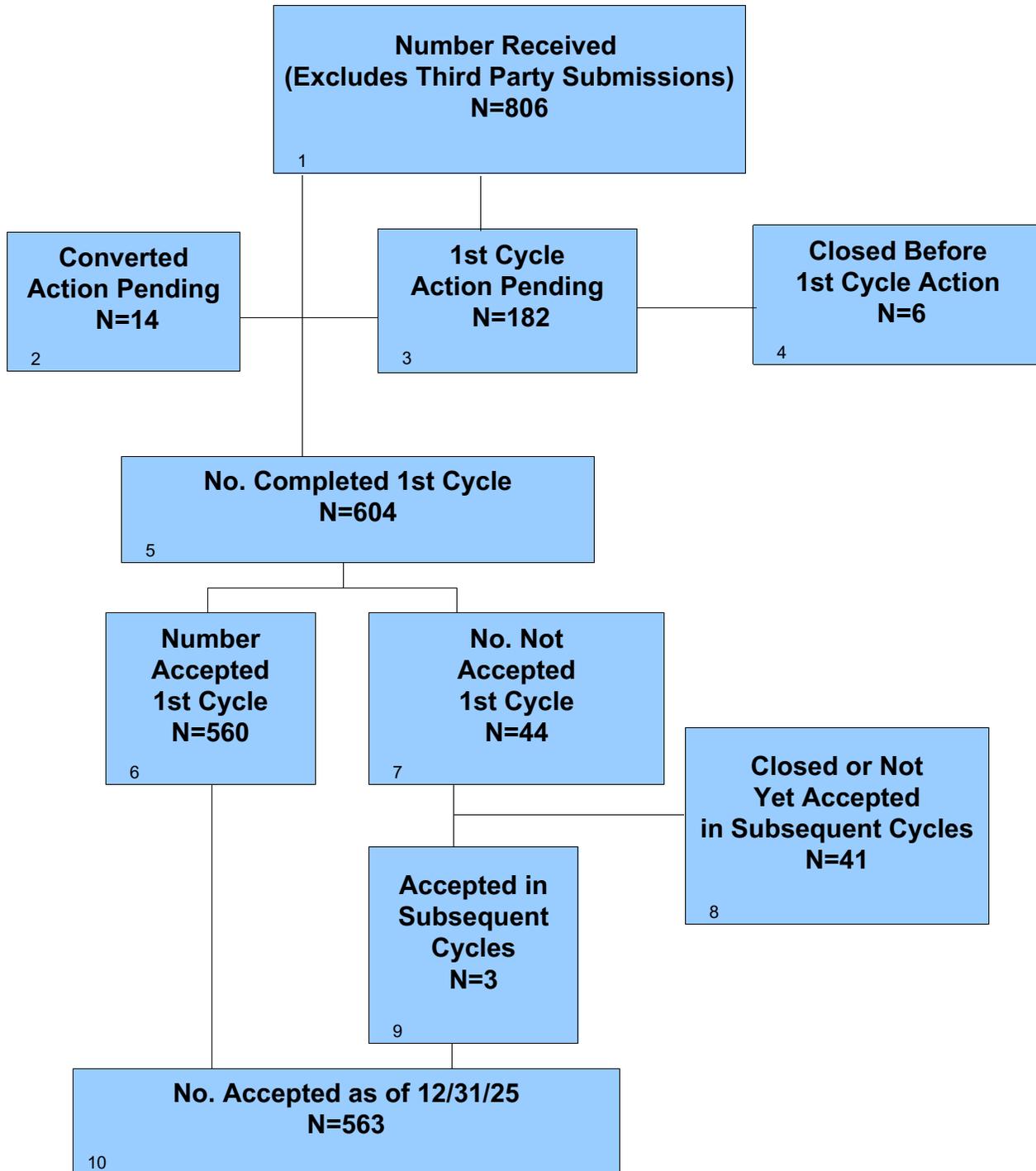
CDRH 510(k)s - FY 2025 as of 12/31/25



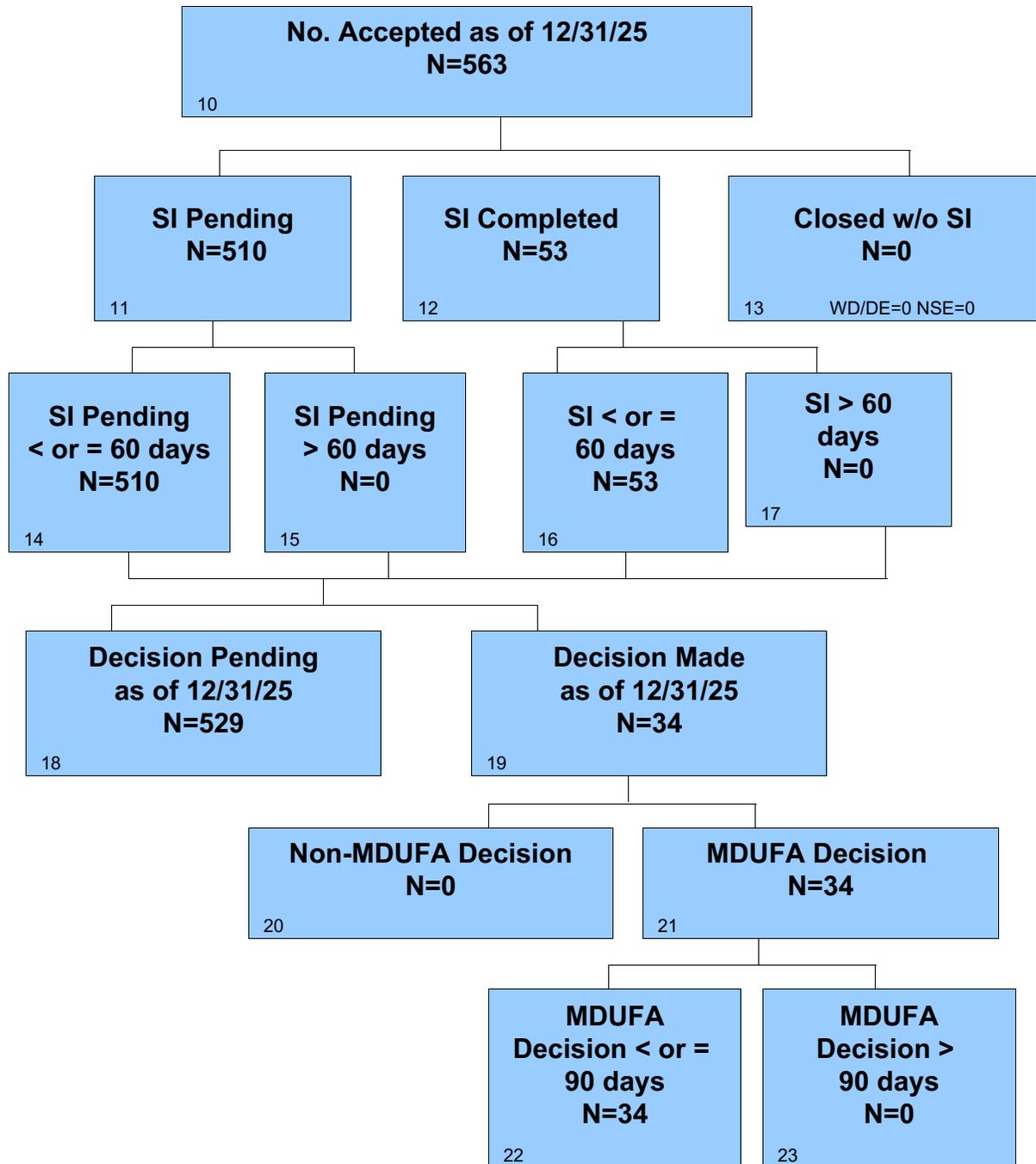
CDRH 510(k)s - FY 2025 as of 12/31/25 Continued



CDRH 510(k)s - FY 2026 as of 12/31/25



CDRH 510(k)s - FY 2026 as of 12/31/25 Continued



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

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3858	3555	3997	806	
Closed Before First RTA or TS Action ¹	51	53	62	6	
Number Accepted or Passed TS on First Cycle ²	3007	3284	3592	553	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	18	28	41	7	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	10	196	
Number Not Accepted or Failed TS on First Cycle ²	782	190	292	44	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	20.54%	5.43%	7.44%	7.28%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

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

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days				
Eligible for SI	3684	3462	3858	563	
Deleted or Withdrawn Prior to SI	8	12	16	0	
SI Within 60 FDA Days	3532	3305	3684	53	
SI Over 60 FDA Days	141	141	92	0	
SI Pending Within 60 FDA Days	0	0	40	510	
SI Pending Over 60 FDA Days	0	3	19	0	
510(k)s NSE Without SI	3	1	6	0	
Current SI Performance Percent Within 60 FDA Days	96.08%	95.80%	96.92%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	3673	3446	3776	53	
Average Number of FDA Days to Substantive Interaction	52.70	52.47	52.39	24.36	
20th Percentile FDA Days to Substantive Interaction	48	48	48	18	
40th Percentile FDA Days to Substantive Interaction	57	57	56	22	
60th Percentile FDA Days to Substantive Interaction	59	59	59	26	
80th Percentile FDA Days to Substantive Interaction	60	60	60	28	
Maximum FDA Days to Substantive Interaction	212	95	175	59	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	3684	3462	3858	563	
Non-MDUFA V Decision	428	428	225	0	
MDUFA V Decision (SE/NSE)	3256	3022	2617	34	
MDUFA V Decision Within 90 FDA Days	3234	2990	2592	34	
510(k)s Pending MDUFA V Decision	0	12	1016	529	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	5	31	0	
Current Performance Percent Within 90 FDA Days	99.32%	98.78%	97.89%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	1.69	1.58	1.06	
Number With MDUFA V Decision	3256	3022	2617	34	
Average Number of FDA Days to MDUFA V Decision	75.02	74.68	71.98	23.50	
20th Percentile FDA Days to MDUFA V Decision	57	57	52	19	
40th Percentile FDA Days to MDUFA V Decision	84	85	81	23	
60th Percentile FDA Days to MDUFA V Decision	88	88	88	26	
80th Percentile FDA Days to MDUFA V Decision	90	90	89	28	
Maximum FDA Days to MDUFA V Decision	448	203	301	33	
Average Number of Industry Days to MDUFA V Decision	66.44	68.82	45.74	0.12	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	14	18	0	0	
60th Percentile Industry Days to MDUFA V Decision	70	73	35	0	
80th Percentile Industry Days to MDUFA V Decision	152	157	97	0	
Maximum Industry Days to MDUFA V Decision	417	392	284	3	
Average Number of Total Days to MDUFA V Decision	141.54	143.52	117.27	23.62	
20th Percentile Total Days to MDUFA V Decision	59	58	54	19	
40th Percentile Total Days to MDUFA V Decision	97	100	88	23	
60th Percentile Total Days to MDUFA V Decision	155	158	120	26	
80th Percentile Total Days to MDUFA V Decision	238	242	179	28	
Maximum Total Days to MDUFA V Decision	865	546	401	36	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	3684	3462	3858	563	
Number With MDUFA V Decision	3256	3022	2617	34	
Number of SE Decision	3109	2882	2534	34	
Number of NSE Decision	147	140	83	0	
Number of Withdrawal	225	228	133	0	
Number of Deleted	194	193	86	0	
Rate of SE Decision	95.49%	95.37%	96.83%	100.00%	
Rate of NSE Decision	4.51%	4.63%	3.17%	0.00%	
Rate of Withdrawal	6.11%	6.59%	3.45%	0.00%	
Rate of Deleted	5.27%	5.57%	2.23%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	22	32	25	0	
Mean FDA Days for Submissions that Missed the Goal	150.86	108.66	125.88	N/A	
Mean Industry Days for Submissions that Missed the Goal	152.27	145.31	88.12	N/A	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4	1	0	
Non-MDUFA V Decision	0	0	1	0	
MDUFA V Decision (SE/NSE)	2	4	0	0	
MDUFA V Decision Within 90 FDA Days	2	4	0	0	
510(k)s Pending MDUFA V Decision	0	0	0	0	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	N/A	N/A	

Table 6.9 CDRH - Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	236	274	42	
Non-MDUFA V Decision	51	45	29	0	
MDUFA V Decision (SE/NSE)	218	191	183	3	
MDUFA V Decision Within 90 FDA Days	218	191	183	3	
510(k)s Pending MDUFA V Decision	0	0	62	39	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

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

**Table 6.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	577	530	585	111	
Closed Before First RTA or TS Action ¹	8	8	7	0	
Number Accepted or Passed TS on First Cycle ²	313	467	495	64	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	3	4	3	1	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	0	35	
Number Not Accepted or Failed TS on First Cycle ²	253	51	80	11	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	44.46%	9.77%	13.84%	14.47%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	533	513	559	66	
Deleted or Withdrawn Prior to SI	2	2	3	0	
SI Within 60 FDA Days	425	427	523	2	
SI Over 60 FDA Days	105	84	17	0	
SI Pending Within 60 FDA Days	0	0	13	64	
SI Pending Over 60 FDA Days	0	0	1	0	
510(k)s NSE Without SI	1	0	1	0	
Current SI Performance Percent Within 60 FDA Days	80.04%	83.56%	96.49%	100.00%	

**Table 6.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	530	511	540	2	
Average Number of FDA Days to Substantive Interaction	56.90	55.87	54.07	19.00	
20th Percentile FDA Days to Substantive Interaction	55	53	50	18	
40th Percentile FDA Days to Substantive Interaction	58	57	56	19	
60th Percentile FDA Days to Substantive Interaction	60	59	58	19	
80th Percentile FDA Days to Substantive Interaction	60	60	60	20	
Maximum FDA Days to Substantive Interaction	212	80	79	20	

**Table 6.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	533	513	559	66	
Non-MDUFA V Decision	84	68	41	0	
MDUFA V Decision (SE/NSE)	449	444	338	2	
MDUFA V Decision Within 90 FDA Days	439	438	334	2	
510(k)s Pending MDUFA V Decision	0	1	180	64	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	2	0	
Current Performance Percent Within 90 FDA Days	97.77%	98.65%	98.24%	100.00%	

**Table 6.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.76	1.79	1.71	1.50	
Number With MDUFA V Decision	449	444	338	2	
Average Number of FDA Days to MDUFA V Decision	83.61	82.28	78.02	26.50	
20th Percentile FDA Days to MDUFA V Decision	82	83	67	23	
40th Percentile FDA Days to MDUFA V Decision	88	87	86	25	
60th Percentile FDA Days to MDUFA V Decision	89	89	88	28	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	30	
Maximum FDA Days to MDUFA V Decision	448	120	127	33	
Average Number of Industry Days to MDUFA V Decision	77.09	86.10	56.71	1.50	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	1	
40th Percentile Industry Days to MDUFA V Decision	39	42	18	1	
60th Percentile Industry Days to MDUFA V Decision	88	106	56	2	
80th Percentile Industry Days to MDUFA V Decision	162	174	117	2	
Maximum Industry Days to MDUFA V Decision	417	392	221	3	
Average Number of Total Days to MDUFA V Decision	160.85	168.28	133.93	28.00	
20th Percentile Total Days to MDUFA V Decision	87	89	73	23	
40th Percentile Total Days to MDUFA V Decision	126	128	103	26	
60th Percentile Total Days to MDUFA V Decision	179	192	140	30	
80th Percentile Total Days to MDUFA V Decision	252	261	196	33	
Maximum Total Days to MDUFA V Decision	865	482	310	36	

**Table 6.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	533	513	559	66	
Number With MDUFA V Decision	449	444	338	2	
Number of SE Decision	413	413	322	2	
Number of NSE Decision	36	31	16	0	
Number of Withdrawal	41	31	22	0	
Number of Deleted	42	36	18	0	
Rate of SE Decision	91.98%	93.02%	95.27%	100.00%	
Rate of NSE Decision	8.02%	6.98%	4.73%	0.00%	
Rate of Withdrawal	7.69%	6.04%	3.94%	0.00%	
Rate of Deleted	7.88%	7.02%	3.22%	0.00%	

**Table 6.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	10	6	4	0	
Mean FDA Days for Submissions that Missed the Goal	178.70	102.67	102.25	N/A	
Mean Industry Days for Submissions that Missed the Goal	150.40	165.83	88.25	N/A	

**Table 6.8 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.9 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.1 OHT2 - Office of Cardiovascular Devices
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	379	378	417	96	
Closed Before First RTA or TS Action ¹	8	6	7	3	
Number Accepted or Passed TS on First Cycle ²	332	354	364	60	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	1	6	5	2	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	1	24	
Number Not Accepted or Failed TS on First Cycle ²	38	12	40	7	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	10.24%	3.23%	9.78%	10.14%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT2 - Office of Cardiovascular Devices
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	365	370	400	63	
Deleted or Withdrawn Prior to SI	0	0	1	0	
SI Within 60 FDA Days	355	345	367	6	
SI Over 60 FDA Days	10	22	24	0	
SI Pending Within 60 FDA Days	0	0	2	57	
SI Pending Over 60 FDA Days	0	3	3	0	
510(k)s NSE Without SI	0	0	3	0	
Current SI Performance Percent Within 60 FDA Days	97.26%	93.24%	92.44%	100.00%	

**Table 6.3 OHT2 - Office of Cardiovascular Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	365	367	391	6	
Average Number of FDA Days to Substantive Interaction	51.40	51.09	52.69	24.67	
20th Percentile FDA Days to Substantive Interaction	44	30	44	20	
40th Percentile FDA Days to Substantive Interaction	56	56	57	23	
60th Percentile FDA Days to Substantive Interaction	59	59	59	28	
80th Percentile FDA Days to Substantive Interaction	60	60	60	30	
Maximum FDA Days to Substantive Interaction	86	85	86	30	

**Table 6.4 OHT2 - Office of Cardiovascular Devices
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	365	370	400	63	
Non-MDUFA V Decision	34	45	17	0	
MDUFA V Decision (SE/NSE)	331	320	259	5	
MDUFA V Decision Within 90 FDA Days	327	310	250	5	
510(k)s Pending MDUFA V Decision	0	5	124	58	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	5	6	0	
Current Performance Percent Within 90 FDA Days	98.79%	95.38%	94.34%	100.00%	

**Table 6.5 OHT2 - Office of Cardiovascular Devices
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.77	1.67	1.00	
Number With MDUFA V Decision	331	320	259	5	
Average Number of FDA Days to MDUFA V Decision	73.39	73.02	73.33	23.60	
20th Percentile FDA Days to MDUFA V Decision	55	52	54	19	
40th Percentile FDA Days to MDUFA V Decision	84	83	80	22	
60th Percentile FDA Days to MDUFA V Decision	88	89	88	25	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	28	
Maximum FDA Days to MDUFA V Decision	95	203	301	30	
Average Number of Industry Days to MDUFA V Decision	71.75	79.06	52.71	N/A	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	27	34	11	0	
60th Percentile Industry Days to MDUFA V Decision	78	92	55	0	
80th Percentile Industry Days to MDUFA V Decision	155	171	104	0	
Maximum Industry Days to MDUFA V Decision	360	360	284	0	
Average Number of Total Days to MDUFA V Decision	145.14	151.93	125.95	23.60	
20th Percentile Total Days to MDUFA V Decision	57	56	56	19	
40th Percentile Total Days to MDUFA V Decision	107	113	90	22	
60th Percentile Total Days to MDUFA V Decision	162	176	129	25	
80th Percentile Total Days to MDUFA V Decision	238	259	191	28	
Maximum Total Days to MDUFA V Decision	448	462	401	30	

Table 6.6 OHT2 - Office of Cardiovascular Devices

510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	365	370	400	63	
Number With MDUFA V Decision	331	320	259	5	
Number of SE Decision	308	294	231	5	
Number of NSE Decision	23	26	28	0	
Number of Withdrawal	17	26	8	0	
Number of Deleted	17	17	9	0	
Rate of SE Decision	93.05%	91.88%	89.19%	100.00%	
Rate of NSE Decision	6.95%	8.13%	10.81%	0.00%	
Rate of Withdrawal	4.66%	7.03%	2.00%	0.00%	
Rate of Deleted	4.66%	4.59%	2.25%	0.00%	

Table 6.7 OHT2 - Office of Cardiovascular Devices

510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	10	9	0	
Mean FDA Days for Submissions that Missed the Goal	92.75	122.10	135.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	82.50	183.00	114.44	N/A	

Table 6.8 OHT2 - Office of Cardiovascular Devices

LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 OHT2 - Office of Cardiovascular Devices

Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	477	445	551	89	
Closed Before First RTA or TS Action ¹	5	11	8	1	
Number Accepted or Passed TS on First Cycle ²	389	417	506	61	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	2	1	4	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	3	23	
Number Not Accepted or Failed TS on First Cycle ²	81	16	30	4	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	17.16%	3.69%	5.56%	6.15%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.
2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.
3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	459	431	532	61	
Deleted or Withdrawn Prior to SI	1	0	3	0	
SI Within 60 FDA Days	448	430	507	5	
SI Over 60 FDA Days	10	0	11	0	
SI Pending Within 60 FDA Days	0	0	7	56	
SI Pending Over 60 FDA Days	0	0	4	0	
510(k)s NSE Without SI	0	1	0	0	
Current SI Performance Percent Within 60 FDA Days	97.82%	99.77%	97.13%	100.00%	

**Table 6.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	458	430	518	5	
Average Number of FDA Days to Substantive Interaction	54.93	52.87	53.20	24.00	
20th Percentile FDA Days to Substantive Interaction	55	49	49	20	
40th Percentile FDA Days to Substantive Interaction	58	57	57	23	
60th Percentile FDA Days to Substantive Interaction	59	59	59	26	
80th Percentile FDA Days to Substantive Interaction	60	60	60	28	
Maximum FDA Days to Substantive Interaction	77	60	175	30	

**Table 6.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	459	431	532	61	
Non-MDUFA V Decision	54	69	34	0	
MDUFA V Decision (SE/NSE)	405	360	334	4	
MDUFA V Decision Within 90 FDA Days	404	358	330	4	
510(k)s Pending MDUFA V Decision	0	2	164	57	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	6	0	
Current Performance Percent Within 90 FDA Days	99.75%	99.44%	97.06%	100.00%	

**Table 6.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.78	1.78	1.62	1.00	
Number With MDUFA V Decision	405	360	334	4	
Average Number of FDA Days to MDUFA V Decision	79.93	76.54	73.25	25.75	
20th Percentile FDA Days to MDUFA V Decision	79	58	56	23	
40th Percentile FDA Days to MDUFA V Decision	88	87	83	25	
60th Percentile FDA Days to MDUFA V Decision	89	89	88	27	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	29	
Maximum FDA Days to MDUFA V Decision	93	160	170	30	
Average Number of Industry Days to MDUFA V Decision	85.37	82.24	53.78	N/A	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	48	41	9	0	
60th Percentile Industry Days to MDUFA V Decision	106	105	47	0	
80th Percentile Industry Days to MDUFA V Decision	172	169	121	0	
Maximum Industry Days to MDUFA V Decision	354	349	251	0	
Average Number of Total Days to MDUFA V Decision	165.30	158.95	126.28	25.75	
20th Percentile Total Days to MDUFA V Decision	87	68	57	23	
40th Percentile Total Days to MDUFA V Decision	133	124	90	25	
60th Percentile Total Days to MDUFA V Decision	193	192	132	27	
80th Percentile Total Days to MDUFA V Decision	260	258	210	29	
Maximum Total Days to MDUFA V Decision	443	438	286	30	

**Table 6.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	459	431	532	61	
Number With MDUFA V Decision	405	360	334	4	
Number of SE Decision	378	332	323	4	
Number of NSE Decision	27	28	11	0	
Number of Withdrawal	24	38	14	0	
Number of Deleted	29	29	17	0	
Rate of SE Decision	93.33%	92.22%	96.71%	100.00%	
Rate of NSE Decision	6.67%	7.78%	3.29%	0.00%	
Rate of Withdrawal	5.23%	8.82%	2.63%	0.00%	
Rate of Deleted	6.32%	6.73%	3.20%	0.00%	

**Table 6.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	2	4	0	
Mean FDA Days for Submissions that Missed the Goal	93.00	125.50	126.75	N/A	
Mean Industry Days for Submissions that Missed the Goal	192.00	51.50	62.50	N/A	

**Table 6.8 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.9 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.1 OHT4 - Office of Surgical and Infection Control Devices
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	709	614	642	129	
Closed Before First RTA or TS Action ¹	10	6	8	0	
Number Accepted or Passed TS on First Cycle ²	558	561	565	79	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	1	12	21	4	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	3	38	
Number Not Accepted or Failed TS on First Cycle ²	140	35	45	8	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	20.03%	5.76%	7.13%	8.79%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT4 - Office of Surgical and Infection Control Devices
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	677	599	616	84	
Deleted or Withdrawn Prior to SI	1	5	2	0	
SI Within 60 FDA Days	671	580	587	15	
SI Over 60 FDA Days	5	14	22	0	
SI Pending Within 60 FDA Days	0	0	3	69	
SI Pending Over 60 FDA Days	0	0	1	0	
510(k)s NSE Without SI	0	0	1	0	
Current SI Performance Percent Within 60 FDA Days	99.26%	97.64%	96.07%	100.00%	

**Table 6.3 OHT4 - Office of Surgical and Infection Control Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	676	594	609	15	
Average Number of FDA Days to Substantive Interaction	52.62	52.84	53.02	21.93	
20th Percentile FDA Days to Substantive Interaction	49	50	49	18	
40th Percentile FDA Days to Substantive Interaction	56	57	57	22	
60th Percentile FDA Days to Substantive Interaction	58	58	59	25	
80th Percentile FDA Days to Substantive Interaction	60	60	60	27	
Maximum FDA Days to Substantive Interaction	122	66	121	28	

**Table 6.4 OHT4 - Office of Surgical and Infection Control Devices
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	677	599	616	84	
Non-MDUFA V Decision	89	83	37	0	
MDUFA V Decision (SE/NSE)	588	515	439	9	
MDUFA V Decision Within 90 FDA Days	586	510	435	9	
510(k)s Pending MDUFA V Decision	0	1	140	75	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	3	0	
Current Performance Percent Within 90 FDA Days	99.66%	99.03%	98.42%	100.00%	

**Table 6.5 OHT4 - Office of Surgical and Infection Control Devices
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.62	1.61	1.49	1.00	
Number With MDUFA V Decision	588	515	439	9	
Average Number of FDA Days to MDUFA V Decision	75.12	74.47	72.41	20.78	
20th Percentile FDA Days to MDUFA V Decision	58	57	55	15	
40th Percentile FDA Days to MDUFA V Decision	83	84	81	22	
60th Percentile FDA Days to MDUFA V Decision	87	88	87	25	
80th Percentile FDA Days to MDUFA V Decision	89	90	89	25	
Maximum FDA Days to MDUFA V Decision	101	95	234	27	
Average Number of Industry Days to MDUFA V Decision	56.52	52.95	36.13	N/A	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	47	40	20	0	
80th Percentile Industry Days to MDUFA V Decision	124	119	71	0	
Maximum Industry Days to MDUFA V Decision	359	360	241	0	
Average Number of Total Days to MDUFA V Decision	131.74	127.34	108.47	20.78	
20th Percentile Total Days to MDUFA V Decision	60	58	55	15	
40th Percentile Total Days to MDUFA V Decision	88	90	86	22	
60th Percentile Total Days to MDUFA V Decision	128	125	105	25	
80th Percentile Total Days to MDUFA V Decision	211	205	158	25	
Maximum Total Days to MDUFA V Decision	449	462	328	27	

**Table 6.6 OHT4 - Office of Surgical and Infection Control Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	677	599	616	84	
Number With MDUFA V Decision	588	515	439	9	
Number of SE Decision	571	508	430	9	
Number of NSE Decision	17	7	9	0	
Number of Withdrawal	52	40	24	0	
Number of Deleted	36	42	12	0	
Rate of SE Decision	97.11%	98.64%	97.95%	100.00%	
Rate of NSE Decision	2.89%	1.36%	2.05%	0.00%	
Rate of Withdrawal	7.68%	6.68%	3.90%	0.00%	
Rate of Deleted	5.32%	7.01%	1.95%	0.00%	

**Table 6.7 OHT4 - Office of Surgical and Infection Control Devices
510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	5	4	0	
Mean FDA Days for Submissions that Missed the Goal	96.50	92.20	157.25	N/A	
Mean Industry Days for Submissions that Missed the Goal	59.50	118.60	14.00	N/A	

**Table 6.8 OHT4 - Office of Surgical and Infection Control Devices
LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.9 OHT4 - Office of Surgical and Infection Control Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.1 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	314	306	396	85	
Closed Before First RTA or TS Action ¹	3	3	10	1	
Number Accepted or Passed TS on First Cycle ²	214	275	341	58	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	1	1	7	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	1	19	
Number Not Accepted or Failed TS on First Cycle ²	96	27	37	7	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	30.87%	8.91%	9.61%	10.77%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	298	300	378	58	
Deleted or Withdrawn Prior to SI	0	0	2	0	
SI Within 60 FDA Days	287	281	349	1	
SI Over 60 FDA Days	11	19	11	0	
SI Pending Within 60 FDA Days	0	0	6	57	
SI Pending Over 60 FDA Days	0	0	9	0	
510(k)s NSE Without SI	0	0	1	0	
Current SI Performance Percent Within 60 FDA Days	96.31%	93.67%	94.32%	100.00%	

**Table 6.3 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	298	300	360	1	
Average Number of FDA Days to Substantive Interaction	54.67	54.90	52.60	59.00	
20th Percentile FDA Days to Substantive Interaction	56	53	47	59	
40th Percentile FDA Days to Substantive Interaction	58	58	57	59	
60th Percentile FDA Days to Substantive Interaction	60	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	59	
Maximum FDA Days to Substantive Interaction	80	95	89	59	

**Table 6.4 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	298	300	378	58	
Non-MDUFA V Decision	34	32	18	0	
MDUFA V Decision (SE/NSE)	264	268	255	0	
MDUFA V Decision Within 90 FDA Days	259	259	252	0	
510(k)s Pending MDUFA V Decision	0	0	105	58	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	13	0	
Current Performance Percent Within 90 FDA Days	98.11%	96.64%	94.03%	N/A	

**Table 6.5 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.75	1.78	1.67	N/A	
Number With MDUFA V Decision	264	268	255	0	
Average Number of FDA Days to MDUFA V Decision	79.01	78.52	73.57	N/A	
20th Percentile FDA Days to MDUFA V Decision	59	61	54	0	
40th Percentile FDA Days to MDUFA V Decision	87	87	85	0	
60th Percentile FDA Days to MDUFA V Decision	89	89	88	0	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	0	
Maximum FDA Days to MDUFA V Decision	382	126	100	0	
Average Number of Industry Days to MDUFA V Decision	77.26	78.00	47.44	N/A	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	35	37	11	0	
60th Percentile Industry Days to MDUFA V Decision	91	91	42	0	
80th Percentile Industry Days to MDUFA V Decision	168	160	91	0	
Maximum Industry Days to MDUFA V Decision	367	268	224	0	
Average Number of Total Days to MDUFA V Decision	156.72	156.89	120.63	N/A	
20th Percentile Total Days to MDUFA V Decision	62	83	58	0	
40th Percentile Total Days to MDUFA V Decision	118	124	90	0	
60th Percentile Total Days to MDUFA V Decision	177	181	124	0	
80th Percentile Total Days to MDUFA V Decision	255	241	173	0	
Maximum Total Days to MDUFA V Decision	732	471	281	0	

**Table 6.6 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	298	300	378	58	
Number With MDUFA V Decision	264	268	255	0	
Number of SE Decision	246	247	244	0	
Number of NSE Decision	18	21	11	0	
Number of Withdrawal	10	10	11	0	
Number of Deleted	21	21	7	0	
Rate of SE Decision	93.18%	92.16%	95.69%	N/A	
Rate of NSE Decision	6.82%	7.84%	4.31%	N/A	
Rate of Withdrawal	3.36%	3.33%	2.91%	0.00%	
Rate of Deleted	7.05%	7.00%	1.85%	0.00%	

**Table 6.7 OHT5 - Office of Neurological and Physical Medicine Devices
510(k) Performance Metric - Submission Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	5	9	3	0	
Mean FDA Days for Submissions that Missed the Goal	175.00	103.11	96.67	N/A	
Mean Industry Days for Submissions that Missed the Goal	241.00	125.44	146.00	N/A	

**Table 6.8 OHT5 - Office of Neurological and Physical Medicine Devices
LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.9 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.1 OHT6 - Office of Orthopedic Devices
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	619	563	614	125	
Closed Before First RTA or TS Action ¹	6	4	7	0	
Number Accepted or Passed TS on First Cycle ²	517	535	576	97	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	3	0	1	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	0	25	
Number Not Accepted or Failed TS on First Cycle ²	93	24	30	3	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	15.17%	4.29%	4.94%	3.00%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT6 - Office of Orthopedic Devices
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	605	554	604	97	
Deleted or Withdrawn Prior to SI	1	2	1	0	
SI Within 60 FDA Days	604	552	593	14	
SI Over 60 FDA Days	0	0	2	0	
SI Pending Within 60 FDA Days	0	0	7	83	
SI Pending Over 60 FDA Days	0	0	1	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	99.50%	100.00%	

**Table 6.3 OHT6 - Office of Orthopedic Devices
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	604	552	595	14	
Average Number of FDA Days to Substantive Interaction	49.84	50.07	49.54	24.07	
20th Percentile FDA Days to Substantive Interaction	30	30	30	20	
40th Percentile FDA Days to Substantive Interaction	56	56	56	24	
60th Percentile FDA Days to Substantive Interaction	58	58	58	27	
80th Percentile FDA Days to Substantive Interaction	60	60	59	28	
Maximum FDA Days to Substantive Interaction	60	60	61	31	

**Table 6.4 OHT6 - Office of Orthopedic Devices
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	605	554	604	97	
Non-MDUFA V Decision	51	53	31	0	
MDUFA V Decision (SE/NSE)	554	498	447	9	
MDUFA V Decision Within 90 FDA Days	554	498	446	9	
510(k)s Pending MDUFA V Decision	0	3	126	88	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	1	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	99.55%	100.00%	

**Table 6.5 OHT6 - Office of Orthopedic Devices
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.48	1.47	1.38	1.00	
Number With MDUFA V Decision	554	498	447	9	
Average Number of FDA Days to MDUFA V Decision	65.77	65.63	61.58	23.78	
20th Percentile FDA Days to MDUFA V Decision	30	30	29	20	
40th Percentile FDA Days to MDUFA V Decision	59	60	57	24	
60th Percentile FDA Days to MDUFA V Decision	85	85	82	26	
80th Percentile FDA Days to MDUFA V Decision	89	89	88	28	
Maximum FDA Days to MDUFA V Decision	90	90	97	29	
Average Number of Industry Days to MDUFA V Decision	42.82	44.81	26.56	N/A	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	18	12	0	0	
80th Percentile Industry Days to MDUFA V Decision	92	111	45	0	
Maximum Industry Days to MDUFA V Decision	354	344	217	0	
Average Number of Total Days to MDUFA V Decision	108.59	110.64	87.58	23.78	
20th Percentile Total Days to MDUFA V Decision	30	30	29	20	
40th Percentile Total Days to MDUFA V Decision	60	60	57	24	
60th Percentile Total Days to MDUFA V Decision	98	98	88	26	
80th Percentile Total Days to MDUFA V Decision	179	191	127	28	
Maximum Total Days to MDUFA V Decision	443	546	272	29	

Table 6.6 OHT6 - Office of Orthopedic Devices

510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	605	554	604	97	
Number With MDUFA V Decision	554	498	447	9	
Number of SE Decision	544	490	444	9	
Number of NSE Decision	10	8	3	0	
Number of Withdrawal	37	37	20	0	
Number of Deleted	12	16	10	0	
Rate of SE Decision	98.19%	98.39%	99.33%	100.00%	
Rate of NSE Decision	1.81%	1.61%	0.67%	0.00%	
Rate of Withdrawal	6.12%	6.68%	3.31%	0.00%	
Rate of Deleted	1.98%	2.89%	1.66%	0.00%	

Table 6.7 OHT6 - Office of Orthopedic Devices

510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	97.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	76.00	N/A	

Table 6.8 OHT6 - Office of Orthopedic Devices

LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 OHT6 - Office of Orthopedic Devices

Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

**Table 6.1 OHT7 - Office of In Vitro Diagnostics
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	295	258	285	53	
Closed Before First RTA or TS Action ¹	7	13	8	1	
Number Accepted or Passed TS on First Cycle ²	243	228	264	42	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	5	4	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	0	10	
Number Not Accepted or Failed TS on First Cycle ²	40	13	13	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	13.89%	5.31%	4.69%	0.00%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT7 - Office of In Vitro Diagnostics
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	271	240	275	42	
Deleted or Withdrawn Prior to SI	3	0	3	0	
SI Within 60 FDA Days	266	239	270	5	
SI Over 60 FDA Days	0	1	2	0	
SI Pending Within 60 FDA Days	0	0	0	37	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	2	0	0	0	
Current SI Performance Percent Within 60 FDA Days	99.25%	99.58%	99.26%	100.00%	

**Table 6.3 OHT7 - Office of In Vitro Diagnostics
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	266	240	272	5	
Average Number of FDA Days to Substantive Interaction	52.54	51.18	51.74	29.20	
20th Percentile FDA Days to Substantive Interaction	47	43	45	20	
40th Percentile FDA Days to Substantive Interaction	56	55	56	28	
60th Percentile FDA Days to Substantive Interaction	58	58	58	34	
80th Percentile FDA Days to Substantive Interaction	60	60	60	36	
Maximum FDA Days to Substantive Interaction	60	81	67	42	

**Table 6.4 OHT7 - Office of In Vitro Diagnostics
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	271	240	275	42	
Non-MDUFA V Decision	51	45	30	0	
MDUFA V Decision (SE/NSE)	220	195	183	3	
MDUFA V Decision Within 90 FDA Days	220	195	183	3	
510(k)s Pending MDUFA V Decision	0	0	62	39	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

**Table 6.5 OHT7 - Office of In Vitro Diagnostics
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.59	1.64	1.39	1.00	
Number With MDUFA V Decision	220	195	183	3	
Average Number of FDA Days to MDUFA V Decision	76.25	74.90	71.96	23.00	
20th Percentile FDA Days to MDUFA V Decision	59	54	43	17	
40th Percentile FDA Days to MDUFA V Decision	87	87	84	20	
60th Percentile FDA Days to MDUFA V Decision	89	89	88	23	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	28	
Maximum FDA Days to MDUFA V Decision	90	90	90	33	
Average Number of Industry Days to MDUFA V Decision	80.81	81.69	46.02	N/A	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	8	0	0	
60th Percentile Industry Days to MDUFA V Decision	119	110	0	0	
80th Percentile Industry Days to MDUFA V Decision	177	174	129	0	
Maximum Industry Days to MDUFA V Decision	361	361	209	0	
Average Number of Total Days to MDUFA V Decision	157.05	156.58	117.54	23.00	
20th Percentile Total Days to MDUFA V Decision	60	60	43	17	
40th Percentile Total Days to MDUFA V Decision	90	90	87	20	
60th Percentile Total Days to MDUFA V Decision	205	200	90	23	
80th Percentile Total Days to MDUFA V Decision	265	260	219	28	
Maximum Total Days to MDUFA V Decision	451	451	270	33	

Table 6.6 OHT7 - Office of In Vitro Diagnostics

510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	271	240	275	42	
Number With MDUFA V Decision	220	195	183	3	
Number of SE Decision	211	187	180	3	
Number of NSE Decision	9	8	3	0	
Number of Withdrawal	28	22	22	0	
Number of Deleted	23	23	8	0	
Rate of SE Decision	95.91%	95.90%	98.36%	100.00%	
Rate of NSE Decision	4.09%	4.10%	1.64%	0.00%	
Rate of Withdrawal	10.33%	9.17%	8.00%	0.00%	
Rate of Deleted	8.49%	9.58%	2.91%	0.00%	

Table 6.7 OHT7 - Office of In Vitro Diagnostics

510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Table 6.8 OHT7 - Office of In Vitro Diagnostics

LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	2	4	1	0	
Non-MDUFA V Decision	0	0	1	0	
MDUFA V Decision (SE/NSE)	2	4	0	0	
MDUFA V Decision Within 90 FDA Days	2	4	0	0	
510(k)s Pending MDUFA V Decision	0	0	0	0	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	N/A	N/A	

Table 6.9 OHT7 - Office of In Vitro Diagnostics

Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	236	274	42	
Non-MDUFA V Decision	51	45	29	0	
MDUFA V Decision (SE/NSE)	218	191	183	3	
MDUFA V Decision Within 90 FDA Days	218	191	183	3	
510(k)s Pending MDUFA V Decision	0	0	62	39	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

**Table 6.1 OHT8 - Office of Radiological Health
510(k) Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	488	461	507	118	
Closed Before First RTA or TS Action ¹	4	2	7	0	
Number Accepted or Passed TS on First Cycle ²	441	447	481	92	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	2	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	2	22	
Number Not Accepted or Failed TS on First Cycle ²	41	12	17	4	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	8.47%	2.61%	3.41%	4.17%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 6 in flowchart).

**Table 6.2 OHT8 - Office of Radiological Health
510(k) Substantive Interaction (SI) Performance Goal**

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	476	455	494	92	
Deleted or Withdrawn Prior to SI	0	3	1	0	
SI Within 60 FDA Days	476	451	488	5	
SI Over 60 FDA Days	0	1	3	0	
SI Pending Within 60 FDA Days	0	0	2	87	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	100.00%	99.78%	99.39%	100.00%	

**Table 6.3 OHT8 - Office of Radiological Health
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	476	452	491	5	
Average Number of FDA Days to Substantive Interaction	49.51	50.89	52.29	22.80	
20th Percentile FDA Days to Substantive Interaction	35	46	49	20	
40th Percentile FDA Days to Substantive Interaction	53	55	56	21	
60th Percentile FDA Days to Substantive Interaction	57	58	58	23	
80th Percentile FDA Days to Substantive Interaction	59	59	60	27	
Maximum FDA Days to Substantive Interaction	60	61	67	29	

**Table 6.4 OHT8 - Office of Radiological Health
510(k) MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	476	455	494	92	
Non-MDUFA V Decision	31	33	17	0	
MDUFA V Decision (SE/NSE)	445	422	362	2	
MDUFA V Decision Within 90 FDA Days	445	422	362	2	
510(k)s Pending MDUFA V Decision	0	0	115	90	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

**Table 6.5 OHT8 - Office of Radiological Health
510(k) Time to MDUFA V Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.76	1.77	1.50	
Number With MDUFA V Decision	445	422	362	2	
Average Number of FDA Days to MDUFA V Decision	71.52	74.77	75.41	27.50	
20th Percentile FDA Days to MDUFA V Decision	52	57	59	27	
40th Percentile FDA Days to MDUFA V Decision	79	84	83	27	
60th Percentile FDA Days to MDUFA V Decision	86	88	87	28	
80th Percentile FDA Days to MDUFA V Decision	89	89	89	28	
Maximum FDA Days to MDUFA V Decision	90	90	90	28	
Average Number of Industry Days to MDUFA V Decision	63.50	67.37	57.13	0.50	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	24	31	28	0	
60th Percentile Industry Days to MDUFA V Decision	62	71	58	1	
80th Percentile Industry Days to MDUFA V Decision	138	144	109	1	
Maximum Industry Days to MDUFA V Decision	182	226	181	1	
Average Number of Total Days to MDUFA V Decision	135.03	141.93	131.99	28.00	
20th Percentile Total Days to MDUFA V Decision	56	66	73	28	
40th Percentile Total Days to MDUFA V Decision	107	114	109	28	
60th Percentile Total Days to MDUFA V Decision	146	156	139	28	
80th Percentile Total Days to MDUFA V Decision	222	219	190	28	
Maximum Total Days to MDUFA V Decision	272	304	271	28	

Table 6.6 OHT8 - Office of Radiological Health

510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	476	455	494	92	
Number With MDUFA V Decision	445	422	362	2	
Number of SE Decision	438	411	360	2	
Number of NSE Decision	7	11	2	0	
Number of Withdrawal	16	24	12	0	
Number of Deleted	14	9	5	0	
Rate of SE Decision	98.43%	97.39%	99.45%	100.00%	
Rate of NSE Decision	1.57%	2.61%	0.55%	0.00%	
Rate of Withdrawal	3.36%	5.27%	2.43%	0.00%	
Rate of Deleted	2.94%	1.98%	1.01%	0.00%	

Table 6.7 OHT8 - Office of Radiological Health

510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Table 6.8 OHT8 - Office of Radiological Health

LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 OHT8 - Office of Radiological Health

Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

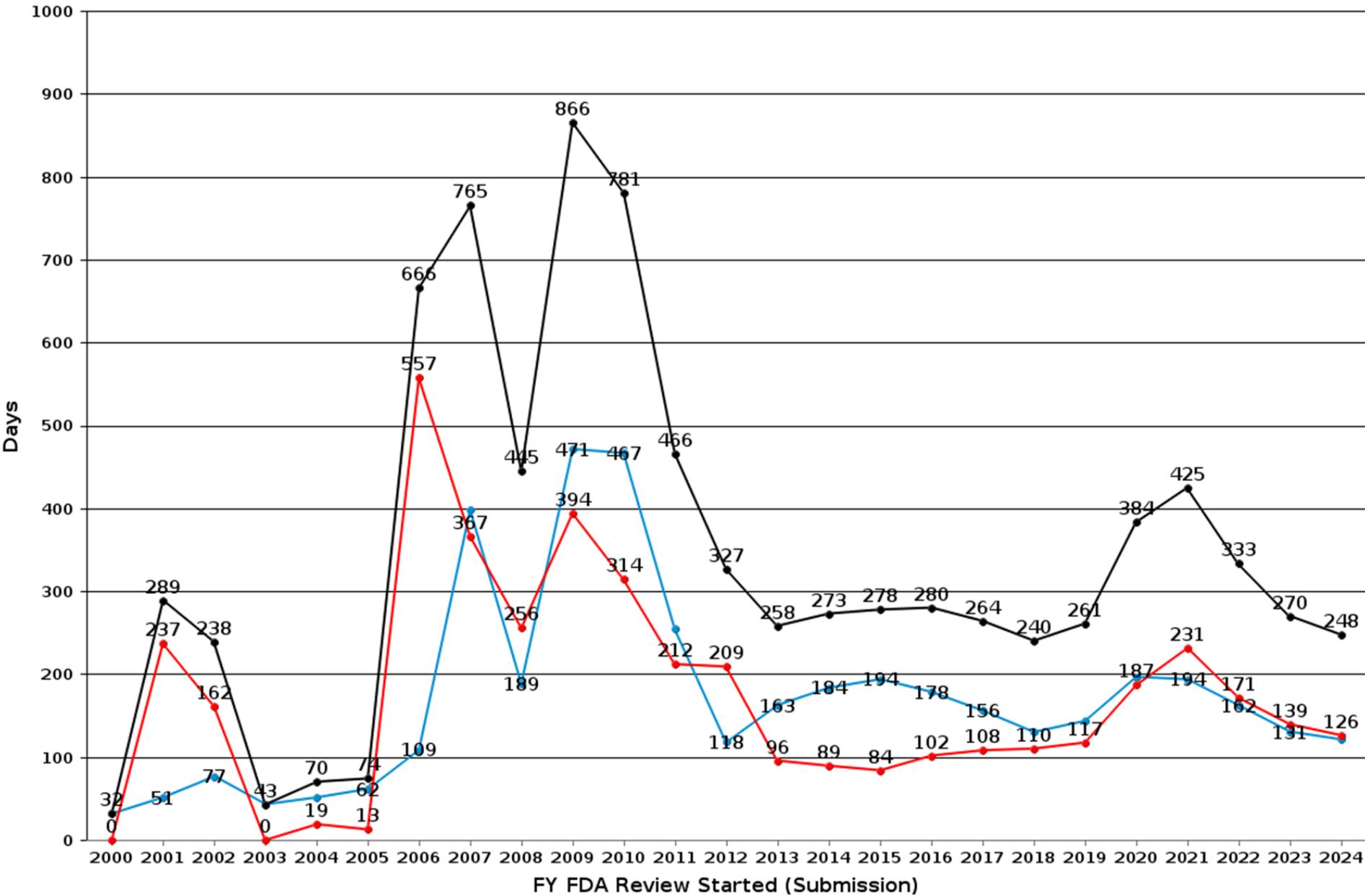
Section 7 510(k) Annual General Metrics

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

De Novos

Q1FY2026

De Novo Average Days to MDUFA Decision as of: 12/31/25

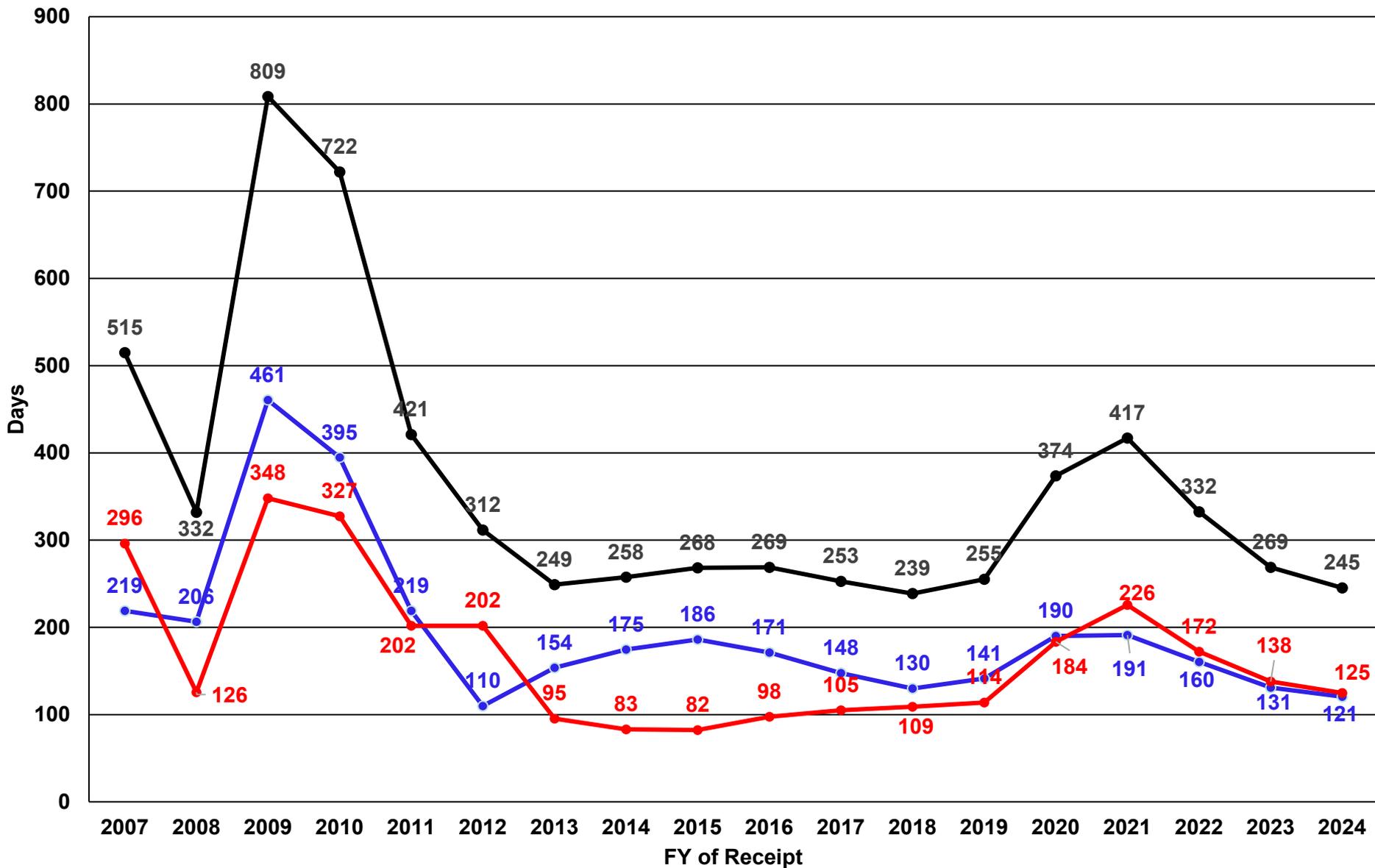


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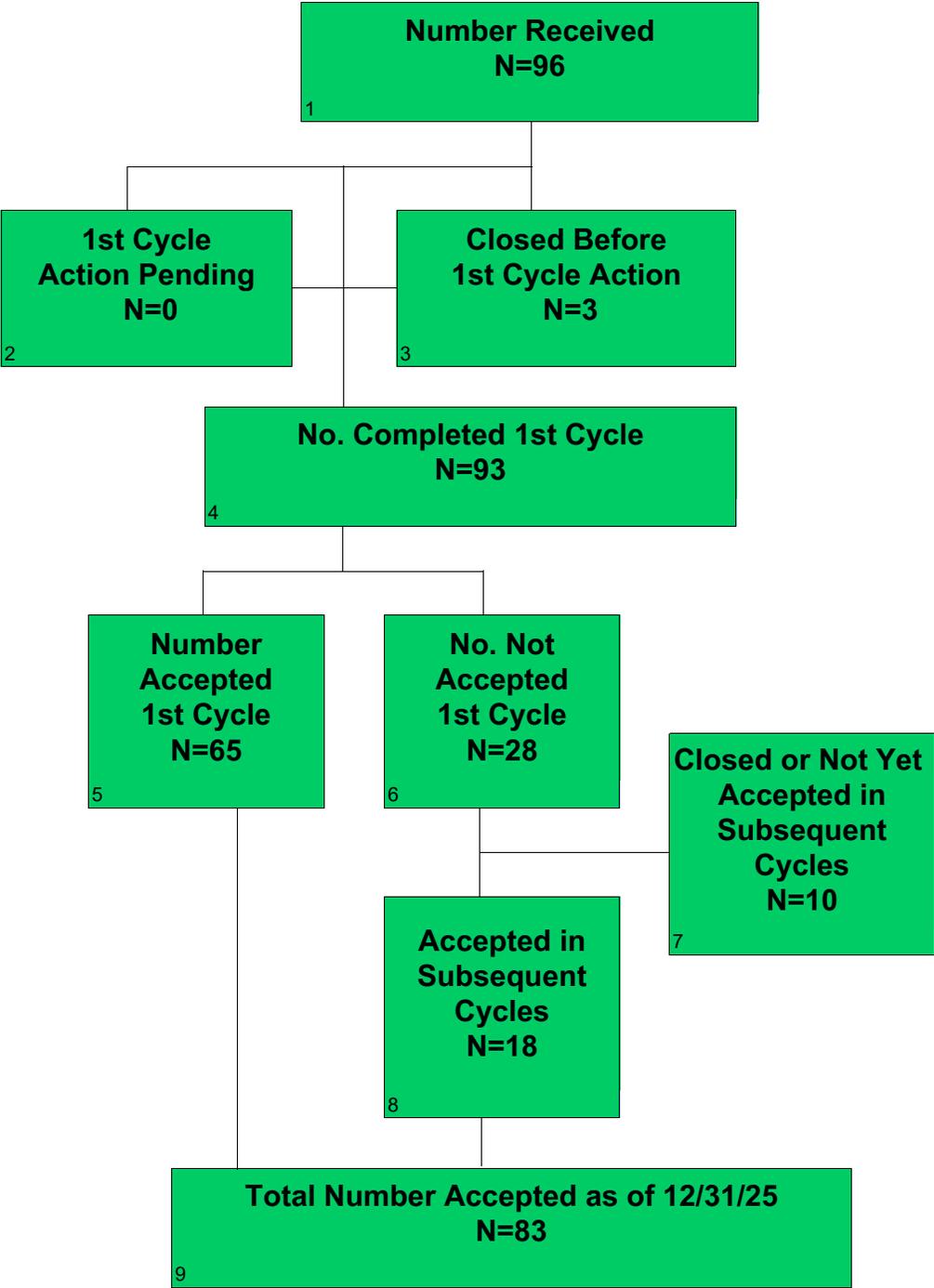
● Avg FDA Days to MDUFA ● Avg MFR Days to MDUFA ● Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos

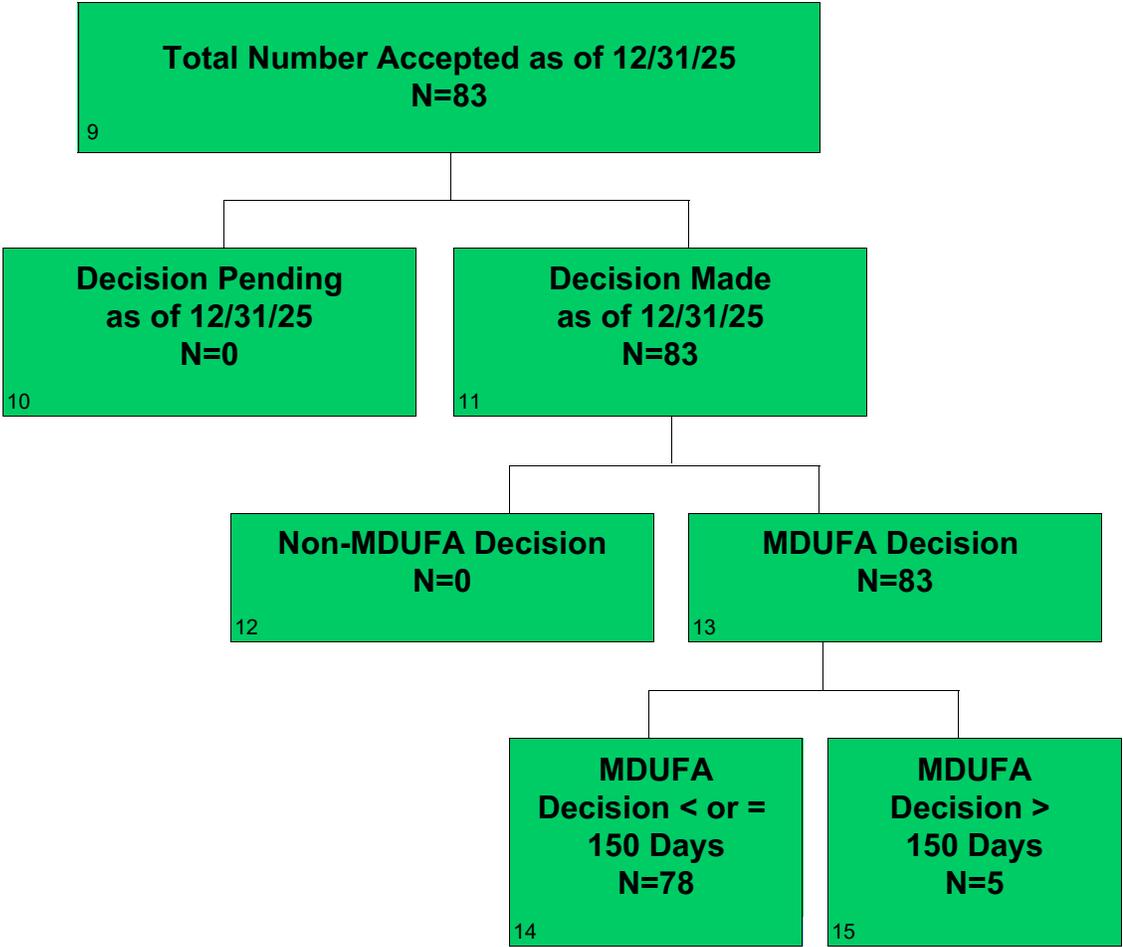
(98.6% closure comparison)



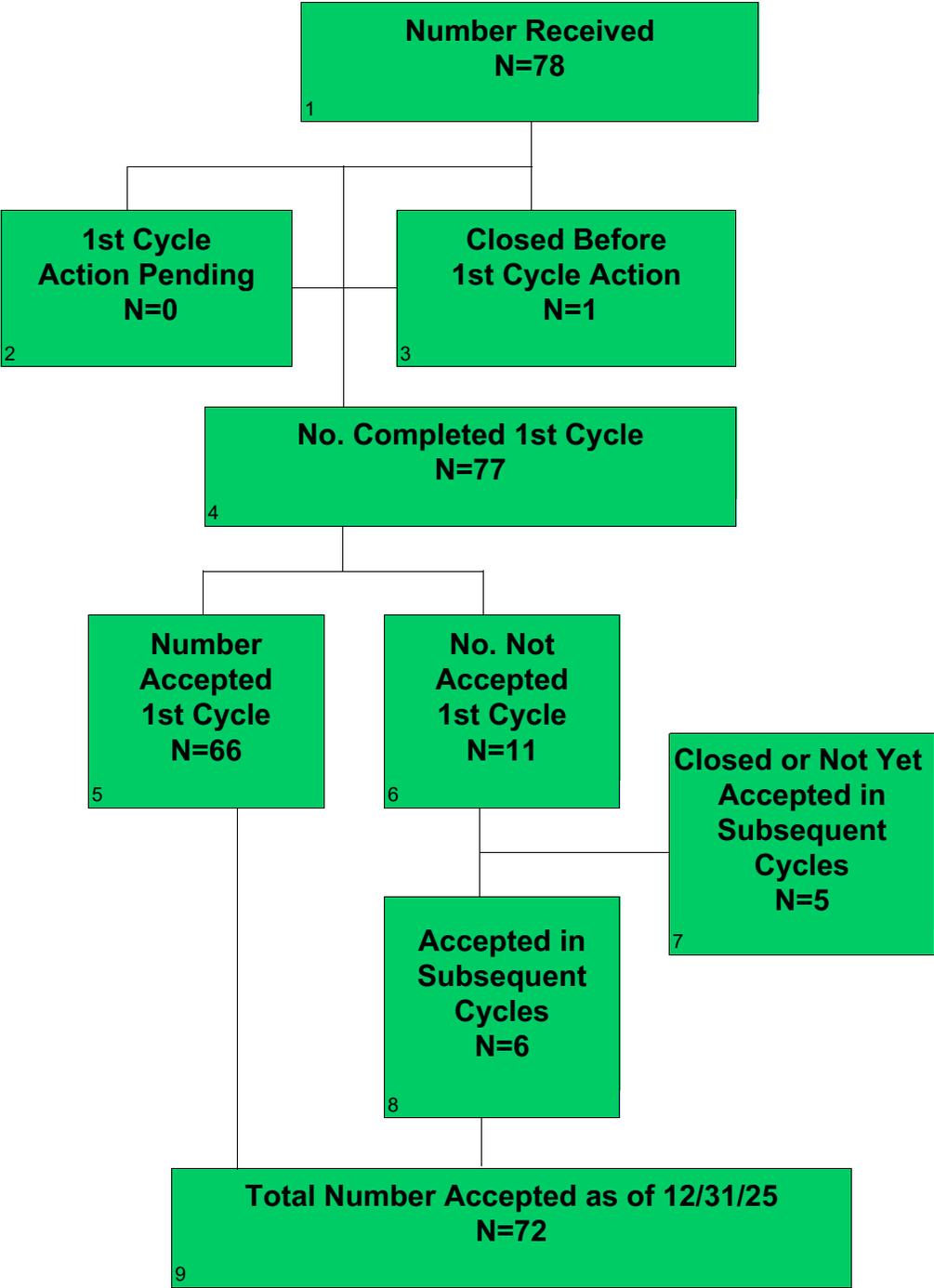
CDRH De Novo - FY 2023 as of 12/31/25



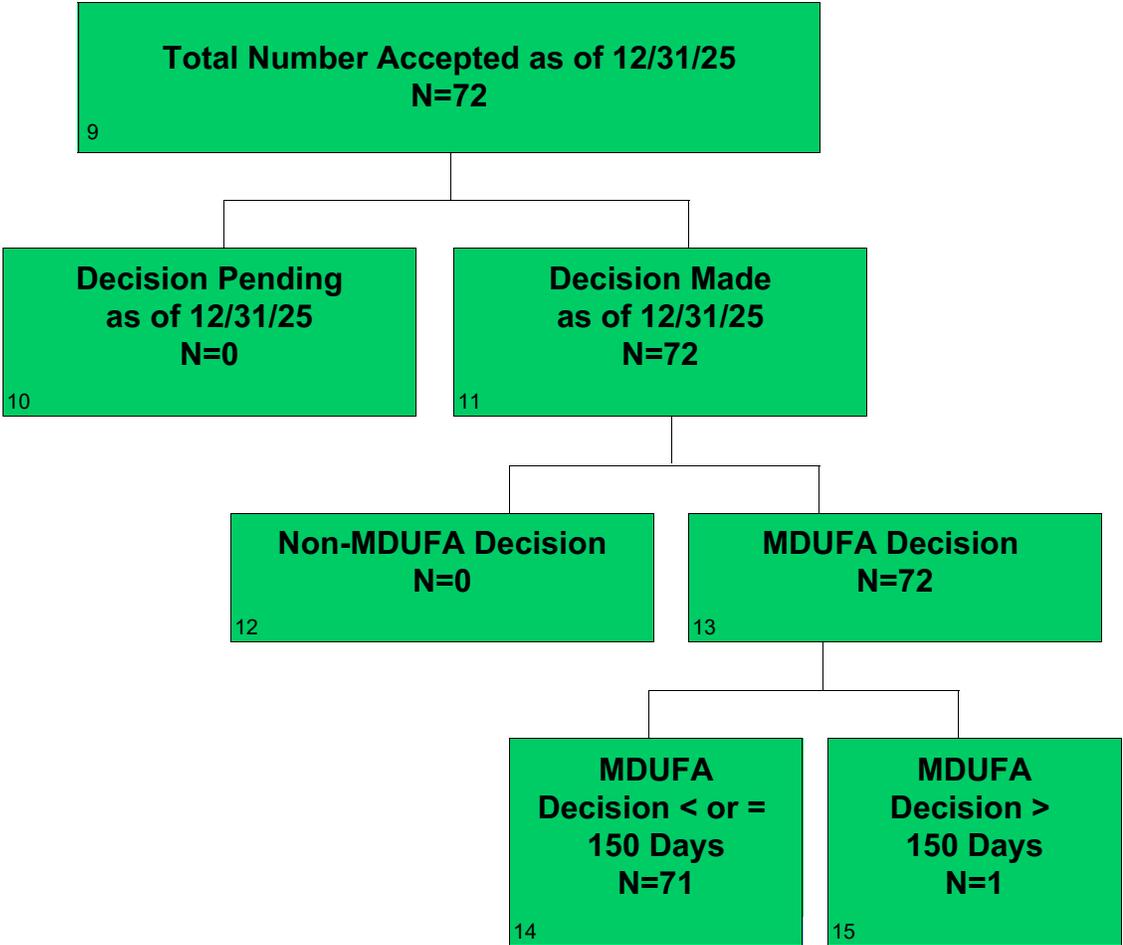
CDRH De Novo - FY 2023 as of 12/31/25 Continued



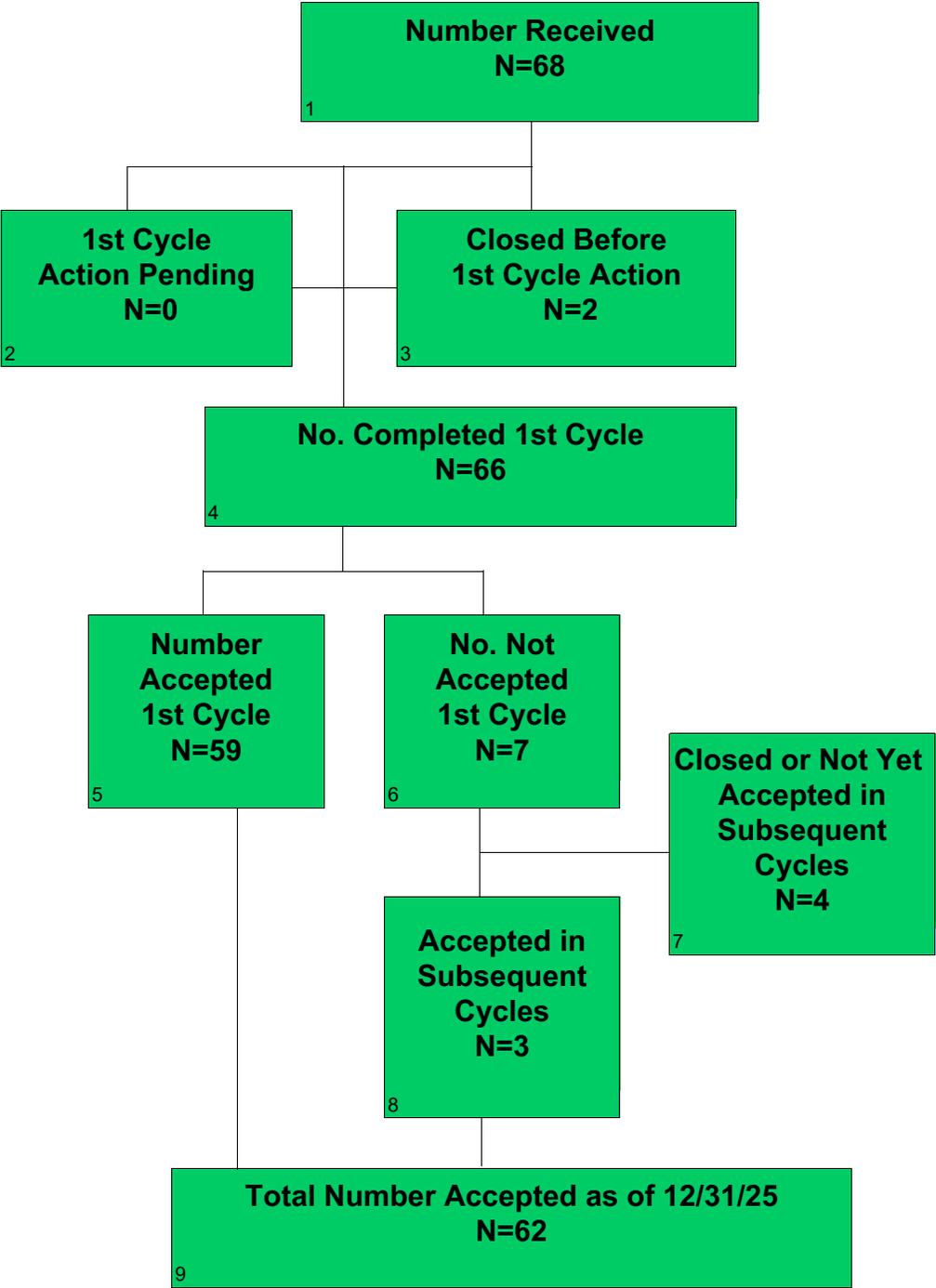
CDRH De Novo - FY 2024 as of 12/31/25



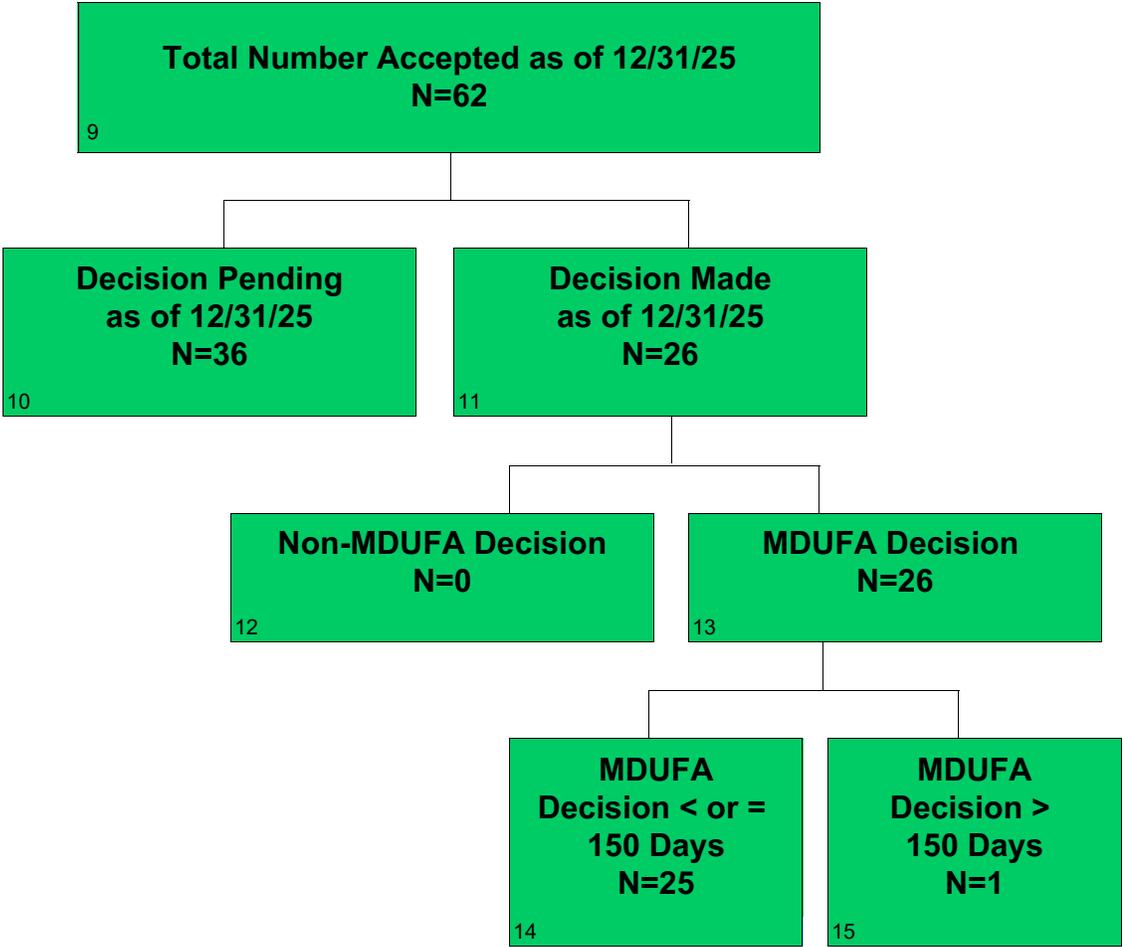
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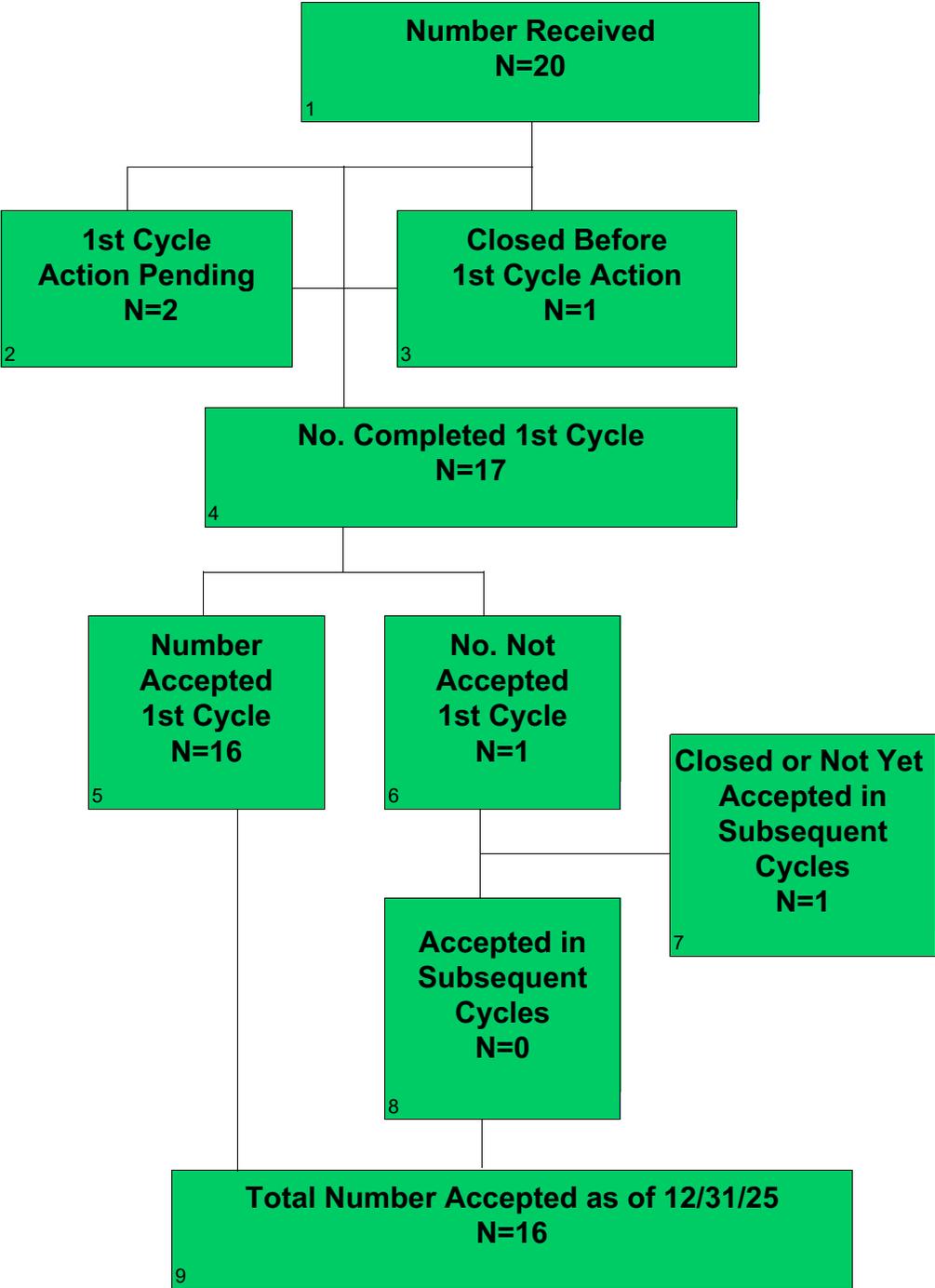
CDRH De Novo - FY 2025 as of 12/31/25



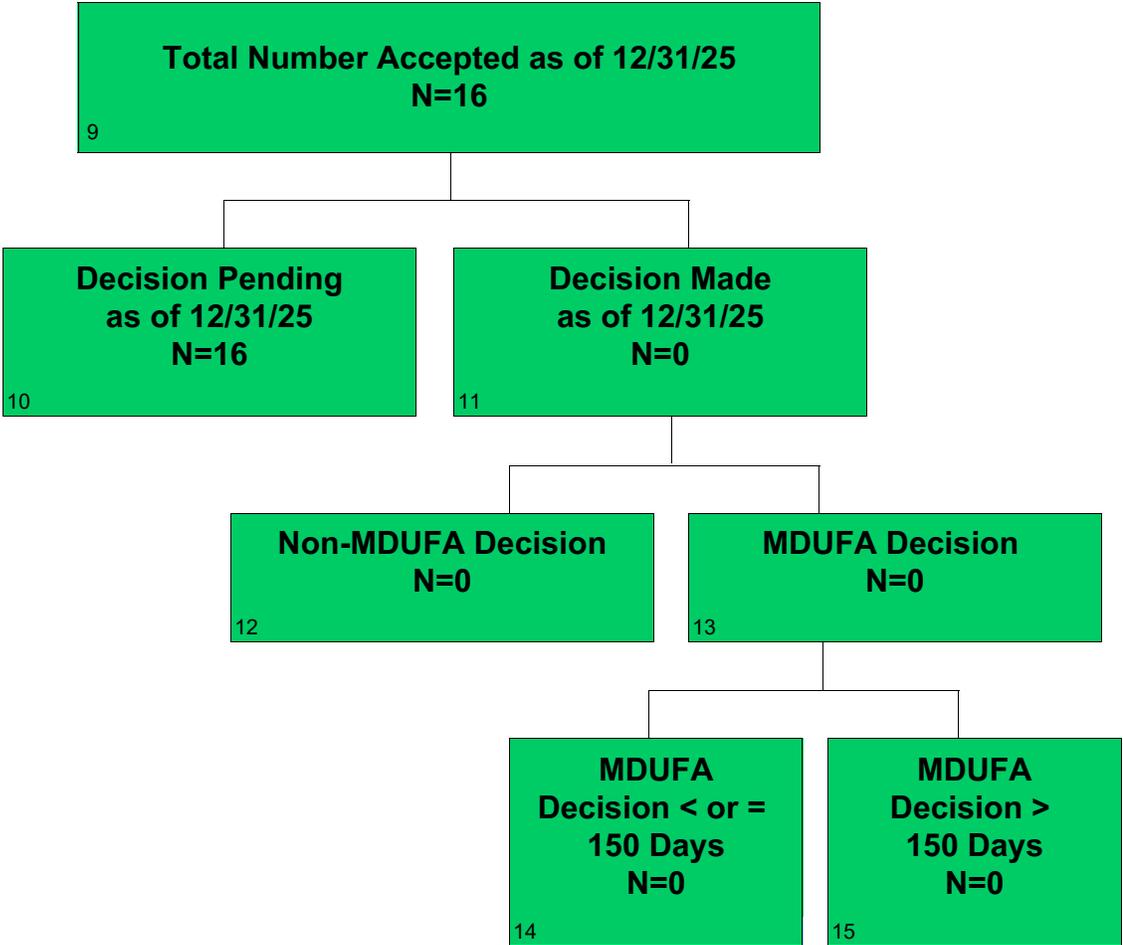
CDRH De Novo - FY 2025 as of 12/31/25 Continued



CDRH De Novo - FY 2026 as of 12/31/25



CDRH De Novo - FY 2026 as of 12/31/25 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	96	78	68	20	
Closed Before First RTA or TS Action	3	1	2	1	
Number Accepted or Passed TS on First Cycle	65	66	59	16	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	2	
Number Not Accepted or Failed TS on First Cycle	28	11	7	1	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	14.29%	10.61%	5.88%	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 5 in flowchart).

Table 8.2 CDRH - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	83	72	62	16	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	83	72	26	0	
MDUFA Decision Within 150 FDA Days	78	71	25	0	
De Novos Pending MDUFA Decision	0	0	36	16	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	1	0	
Current Performance Percent Within 150 FDA Days	93.98%	98.61%	92.59%	N/A	

Table 8.3 CDRH - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.69	1.60	1.58	N/A	
Number With MDUFA Decision	83	72	26	0	
Average FDA Days to MDUFA Decision	130.60	121.26	128.12	N/A	
20th Percentile FDA Days to MDUFA Decision	75	75	79	0	
40th Percentile FDA Days to MDUFA Decision	148	134	147	0	
60th Percentile FDA Days to MDUFA Decision	150	149	149	0	
80th Percentile FDA Days to MDUFA Decision	150	150	150	0	
Maximum FDA Days to MDUFA Decision	251	151	159	0	
Average Industry Days to MDUFA Decision	139.47	126.25	121.85	N/A	
20th Percentile Industry Days to MDUFA Decision	72	34	56	0	
40th Percentile Industry Days to MDUFA Decision	152	143	125	0	
60th Percentile Industry Days to MDUFA Decision	178	177	175	0	
80th Percentile Industry Days to MDUFA Decision	181	181	181	0	
Maximum Industry Days to MDUFA Decision	350	185	189	0	
Average Total Days to MDUFA Decision	270.07	247.51	249.96	N/A	
20th Percentile Total Days to MDUFA Decision	214	178	203	0	
40th Percentile Total Days to MDUFA Decision	256	255	247	0	
60th Percentile Total Days to MDUFA Decision	303	284	268	0	
80th Percentile Total Days to MDUFA Decision	329	327	301	0	
Maximum Total Days to MDUFA Decision	437	330	338	0	

Table 8.4 CDRH - De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	83	72	62	16	
Number With MDUFA Decision	83	72	26	0	
Number With Granted Decision	37	29	15	0	
Number With Declined Decision	18	18	3	0	
Number of Withdrawal	17	13	2	0	
Number of Deleted	11	12	6	0	
Rate of Granted Decision	44.58%	40.28%	57.69%	N/A	
Rate of Declined Decision	21.69%	25.00%	11.54%	N/A	
Rate of Withdrawal	20.48%	18.06%	7.69%	N/A	
Rate of Deleted	13.25%	16.67%	23.08%	N/A	

Table 8.5 CDRH - De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	5	1	1	0	
Mean FDA Days for Submissions that Missed the Goal	194.80	151.00	159.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	111.20	150.00	179.00	N/A	

Table 8.6 CDRH - LDT De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	0	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	0	0	0	
MDUFA Decision Within 150 FDA Days	1	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	1	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	N/A	N/A	N/A	

Table 8.7 CDRH - Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	11	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	19	18	6	0	
MDUFA Decision Within 150 FDA Days	19	18	6	0	
De Novos Pending MDUFA Decision	0	0	5	2	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

Table 8.8 CDRH - De Novo Annual General Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	83	72	62	16	
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	12.23	11.44	11.73	11.31	

Section 8 - De Novo Office Level Metrics

**Table 8.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	13	10	0	
Closed Before First RTA or TS Action	0	0	1	0	
Number Accepted or Passed TS on First Cycle	6	10	5	0	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	6	3	4	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	23.08%	44.44%	N/A	

1. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11	12	7	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	11	12	3	0	
MDUFA Decision Within 150 FDA Days	8	11	2	0	
De Novos Pending MDUFA Decision	0	0	4	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	72.73%	91.67%	66.67%	N/A	

**Table 8.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.58	1.33	N/A	
Number With MDUFA Decision	11	12	3	0	
Average FDA Days to MDUFA Decision	130.82	118.42	132.00	N/A	
20th Percentile FDA Days to MDUFA Decision	73	73	112	0	
40th Percentile FDA Days to MDUFA Decision	75	109	137	0	
60th Percentile FDA Days to MDUFA Decision	150	148	152	0	
80th Percentile FDA Days to MDUFA Decision	178	150	155	0	
Maximum FDA Days to MDUFA Decision	251	151	159	0	
Average Industry Days to MDUFA Decision	137.45	131.75	120.00	N/A	
20th Percentile Industry Days to MDUFA Decision	81	125	72	0	
40th Percentile Industry Days to MDUFA Decision	152	137	143	0	
60th Percentile Industry Days to MDUFA Decision	178	166	179	0	
80th Percentile Industry Days to MDUFA Decision	182	181	180	0	
Maximum Industry Days to MDUFA Decision	189	181	181	0	
Average Total Days to MDUFA Decision	268.27	250.17	252.00	N/A	
20th Percentile Total Days to MDUFA Decision	231	222	197	0	
40th Percentile Total Days to MDUFA Decision	255	261	244	0	
60th Percentile Total Days to MDUFA Decision	262	284	282	0	
80th Percentile Total Days to MDUFA Decision	328	321	310	0	
Maximum Total Days to MDUFA Decision	343	328	338	0	

**Table 8.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	12	7	0	
Number With MDUFA Decision	11	12	3	0	
Number With Granted Decision	5	3	2	0	
Number With Declined Decision	1	4	0	0	
Number of Withdrawal	1	3	0	0	
Number of Deleted	4	2	1	0	
Rate of Granted Decision	45.45%	25.00%	66.67%	N/A	
Rate of Declined Decision	9.09%	33.33%	0.00%	N/A	
Rate of Withdrawal	9.09%	25.00%	0.00%	N/A	
Rate of Deleted	36.36%	16.67%	33.33%	N/A	

**Table 8.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	3	1	1	0	
Mean FDA Days for Submissions That Missed the Goal	206.67	151.00	159.00	N/A	
Mean Industry Days for Submissions That Missed the Goal	122.33	150.00	179.00	N/A	

**Table 8.6 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
LDT De Novo MDUFA V Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.7 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.1 OHT2 - Office of Cardiovascular Devices
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	4	4	2	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	10	4	4	2	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	2	0	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	16.67%	0.00%	0.00%	0.00%	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	10	4	4	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	10	4	1	0	
MDUFA Decision Within 150 FDA Days	10	4	1	0	
De Novos Pending MDUFA Decision	0	0	3	2	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

**Table 8.3 OHT2 - Office of Cardiovascular Devices
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.75	1.00	N/A	
Number With MDUFA Decision	10	4	1	0	
Average FDA Days to MDUFA Decision	137.10	149.75	60.00	N/A	
20th Percentile FDA Days to MDUFA Decision	140	150	60	0	
40th Percentile FDA Days to MDUFA Decision	150	150	60	0	
60th Percentile FDA Days to MDUFA Decision	150	150	60	0	
80th Percentile FDA Days to MDUFA Decision	150	150	60	0	
Maximum FDA Days to MDUFA Decision	150	150	60	0	
Average Industry Days to MDUFA Decision	114.40	114.50	182.00	N/A	
20th Percentile Industry Days to MDUFA Decision	47	61	182	0	
40th Percentile Industry Days to MDUFA Decision	90	116	182	0	
60th Percentile Industry Days to MDUFA Decision	178	162	182	0	
80th Percentile Industry Days to MDUFA Decision	180	178	182	0	
Maximum Industry Days to MDUFA Decision	183	180	182	0	
Average Total Days to MDUFA Decision	251.50	264.25	242.00	N/A	
20th Percentile Total Days to MDUFA Decision	197	210	242	0	
40th Percentile Total Days to MDUFA Decision	238	266	242	0	
60th Percentile Total Days to MDUFA Decision	267	312	242	0	
80th Percentile Total Days to MDUFA Decision	328	328	242	0	
Maximum Total Days to MDUFA Decision	329	330	242	0	

**Table 8.4 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	10	4	4	2	
Number With MDUFA Decision	10	4	1	0	
Number With Granted Decision	6	3	0	0	
Number With Declined Decision	3	1	0	0	
Number of Withdrawal	0	0	0	0	
Number of Deleted	1	0	1	0	
Rate of Granted Decision	60.00%	75.00%	0.00%	N/A	
Rate of Declined Decision	30.00%	25.00%	0.00%	N/A	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Deleted	10.00%	0.00%	100.00%	N/A	

Table 8.5 OHT2 - Office of Cardiovascular Devices

De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	

Table 8.6 OHT2 - Office of Cardiovascular Devices

LDT De Novo MDUFA V Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 OHT2 - Office of Cardiovascular Devices

Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	11	8	12	2	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	9	7	11	2	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	2	1	1	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%	12.50%	8.33%	0.00%	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11	8	12	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	11	8	2	0	
MDUFA Decision Within 150 FDA Days	11	8	2	0	
De Novos Pending MDUFA Decision	0	0	10	2	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

**Table 8.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.88	2.00	N/A	
Number With MDUFA Decision	11	8	2	0	
Average FDA Days to MDUFA Decision	128.45	131.50	149.00	N/A	
20th Percentile FDA Days to MDUFA Decision	74	114	149	0	
40th Percentile FDA Days to MDUFA Decision	148	143	149	0	
60th Percentile FDA Days to MDUFA Decision	150	148	149	0	
80th Percentile FDA Days to MDUFA Decision	150	149	149	0	
Maximum FDA Days to MDUFA Decision	150	150	149	0	
Average Industry Days to MDUFA Decision	122.73	160.50	139.50	N/A	
20th Percentile Industry Days to MDUFA Decision	83	156	131	0	
40th Percentile Industry Days to MDUFA Decision	124	179	137	0	
60th Percentile Industry Days to MDUFA Decision	163	180	142	0	
80th Percentile Industry Days to MDUFA Decision	180	182	148	0	
Maximum Industry Days to MDUFA Decision	214	183	154	0	
Average Total Days to MDUFA Decision	251.18	292.00	288.50	N/A	
20th Percentile Total Days to MDUFA Decision	231	264	280	0	
40th Percentile Total Days to MDUFA Decision	247	288	286	0	
60th Percentile Total Days to MDUFA Decision	274	324	291	0	
80th Percentile Total Days to MDUFA Decision	293	327	297	0	
Maximum Total Days to MDUFA Decision	330	329	303	0	

**Table 8.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	8	12	2	
Number With MDUFA Decision	11	8	2	0	
Number With Granted Decision	7	2	1	0	
Number With Declined Decision	1	2	1	0	
Number of Withdrawal	1	3	0	0	
Number of Deleted	2	1	0	0	
Rate of Granted Decision	63.64%	25.00%	50.00%	N/A	
Rate of Declined Decision	9.09%	25.00%	50.00%	N/A	
Rate of Withdrawal	9.09%	37.50%	0.00%	N/A	
Rate of Deleted	18.18%	12.50%	0.00%	N/A	

**Table 8.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	

**Table 8.6 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
LDT De Novo MDUFA V Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.7 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.1 OHT4 - Office of Surgical and Infection Control Devices
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	14	5	4	
Closed Before First RTA or TS Action	1	0	0	0	
Number Accepted or Passed TS on First Cycle	11	11	5	4	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	9	3	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	45.00%	21.43%	0.00%	0.00%	

1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT4 - Office of Surgical and Infection Control Devices
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	15	12	5	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	12	2	0	
MDUFA Decision Within 150 FDA Days	13	12	2	0	
De Novos Pending MDUFA Decision	0	0	3	4	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	1	0	
Current Performance Percent Within 150 FDA Days	86.67%	100.00%	66.67%	N/A	

**Table 8.3 OHT4 - Office of Surgical and Infection Control Devices
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.80	1.50	1.50	N/A	
Number With MDUFA Decision	15	12	2	0	
Average FDA Days to MDUFA Decision	126.87	119.92	111.50	N/A	
20th Percentile FDA Days to MDUFA Decision	75	74	89	0	
40th Percentile FDA Days to MDUFA Decision	143	117	104	0	
60th Percentile FDA Days to MDUFA Decision	148	150	119	0	
80th Percentile FDA Days to MDUFA Decision	150	150	134	0	
Maximum FDA Days to MDUFA Decision	203	150	149	0	
Average Industry Days to MDUFA Decision	134.87	129.00	183.50	N/A	
20th Percentile Industry Days to MDUFA Decision	80	29	180	0	
40th Percentile Industry Days to MDUFA Decision	156	165	182	0	
60th Percentile Industry Days to MDUFA Decision	180	174	185	0	
80th Percentile Industry Days to MDUFA Decision	181	179	187	0	
Maximum Industry Days to MDUFA Decision	198	185	189	0	
Average Total Days to MDUFA Decision	261.73	248.92	295.00	N/A	
20th Percentile Total Days to MDUFA Decision	228	164	276	0	
40th Percentile Total Days to MDUFA Decision	254	247	289	0	
60th Percentile Total Days to MDUFA Decision	302	319	301	0	
80th Percentile Total Days to MDUFA Decision	329	326	314	0	
Maximum Total Days to MDUFA Decision	346	330	327	0	

**Table 8.4 OHT4 - Office of Surgical and Infection Control Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	15	12	5	4	
Number With MDUFA Decision	15	12	2	0	
Number With Granted Decision	7	7	1	0	
Number With Declined Decision	2	2	0	0	
Number of Withdrawal	5	2	0	0	
Number of Deleted	1	1	1	0	
Rate of Granted Decision	46.67%	58.33%	50.00%	N/A	
Rate of Declined Decision	13.33%	16.67%	0.00%	N/A	
Rate of Withdrawal	33.33%	16.67%	0.00%	N/A	
Rate of Deleted	6.67%	8.33%	50.00%	N/A	

**Table 8.5 OHT4 - Office of Surgical and Infection Control Devices
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	2	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	94.50	N/A	N/A	N/A	

**Table 8.6 OHT4 - Office of Surgical and Infection Control Devices
LDT De Novo MDUFA V Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.7 OHT4 - Office of Surgical and Infection Control Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.1 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	10	12	15	3	
Closed Before First RTA or TS Action	1	0	0	0	
Number Accepted or Passed TS on First Cycle	5	11	15	3	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	4	1	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	8.33%	0.00%	0.00%	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	9	12	15	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	9	12	8	0	
MDUFA Decision Within 150 FDA Days	9	12	8	0	
De Novos Pending MDUFA Decision	0	0	7	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

**Table 8.3 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.11	1.67	1.63	N/A	
Number With MDUFA Decision	9	12	8	0	
Average FDA Days to MDUFA Decision	141.44	118.92	140.75	N/A	
20th Percentile FDA Days to MDUFA Decision	149	76	148	0	
40th Percentile FDA Days to MDUFA Decision	150	109	150	0	
60th Percentile FDA Days to MDUFA Decision	150	148	150	0	
80th Percentile FDA Days to MDUFA Decision	150	150	150	0	
Maximum FDA Days to MDUFA Decision	150	150	150	0	
Average Industry Days to MDUFA Decision	145.56	110.58	69.25	N/A	
20th Percentile Industry Days to MDUFA Decision	112	6	12	0	
40th Percentile Industry Days to MDUFA Decision	154	111	51	0	
60th Percentile Industry Days to MDUFA Decision	172	176	62	0	
80th Percentile Industry Days to MDUFA Decision	182	179	121	0	
Maximum Industry Days to MDUFA Decision	231	183	181	0	
Average Total Days to MDUFA Decision	287.00	229.50	210.00	N/A	
20th Percentile Total Days to MDUFA Decision	237	105	162	0	
40th Percentile Total Days to MDUFA Decision	300	255	199	0	
60th Percentile Total Days to MDUFA Decision	313	263	212	0	
80th Percentile Total Days to MDUFA Decision	326	326	248	0	
Maximum Total Days to MDUFA Decision	381	328	299	0	

**Table 8.4 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	9	12	15	3	
Number With MDUFA Decision	9	12	8	0	
Number With Granted Decision	3	3	6	0	
Number With Declined Decision	5	6	1	0	
Number of Withdrawal	0	1	0	0	
Number of Deleted	1	2	1	0	
Rate of Granted Decision	33.33%	25.00%	75.00%	N/A	
Rate of Declined Decision	55.56%	50.00%	12.50%	N/A	
Rate of Withdrawal	0.00%	8.33%	0.00%	N/A	
Rate of Deleted	11.11%	16.67%	12.50%	N/A	

**Table 8.5 OHT5 - Office of Neurological and Physical Medicine Devices
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	

**Table 8.6 OHT5 - Office of Neurological and Physical Medicine Devices
LDT De Novo MDUFA V Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.7 OHT5 - Office of Neurological and Physical Medicine Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.1 OHT6 - Office of Orthopedic Devices
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2	6	3	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	3	2	5	2	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted or Failed TS on First Cycle	0	0	1	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	0.00%	16.67%	0.00%	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT6 - Office of Orthopedic Devices
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	3	2	5	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	2	2	0	
MDUFA Decision Within 150 FDA Days	3	2	2	0	
De Novos Pending MDUFA Decision	0	0	3	2	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

**Table 8.3 OHT6 - Office of Orthopedic Devices
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	1.50	1.50	N/A	
Number With MDUFA Decision	3	2	2	0	
Average FDA Days to MDUFA Decision	149.00	111.50	99.00	N/A	
20th Percentile FDA Days to MDUFA Decision	148	88	74	0	
40th Percentile FDA Days to MDUFA Decision	149	104	91	0	
60th Percentile FDA Days to MDUFA Decision	149	119	107	0	
80th Percentile FDA Days to MDUFA Decision	150	135	124	0	
Maximum FDA Days to MDUFA Decision	150	150	141	0	
Average Industry Days to MDUFA Decision	119.33	180.00	183.00	N/A	
20th Percentile Industry Days to MDUFA Decision	71	179	182	0	
40th Percentile Industry Days to MDUFA Decision	142	180	183	0	
60th Percentile Industry Days to MDUFA Decision	178	180	183	0	
80th Percentile Industry Days to MDUFA Decision	179	181	184	0	
Maximum Industry Days to MDUFA Decision	180	181	185	0	
Average Total Days to MDUFA Decision	268.33	291.50	282.00	N/A	
20th Percentile Total Days to MDUFA Decision	220	269	256	0	
40th Percentile Total Days to MDUFA Decision	292	284	273	0	
60th Percentile Total Days to MDUFA Decision	328	299	291	0	
80th Percentile Total Days to MDUFA Decision	329	314	308	0	
Maximum Total Days to MDUFA Decision	329	329	326	0	

**Table 8.4 OHT6 - Office of Orthopedic Devices
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	3	2	5	2	
Number With MDUFA Decision	3	2	2	0	
Number With Granted Decision	2	1	0	0	
Number With Declined Decision	1	0	1	0	
Number of Withdrawal	0	0	0	0	
Number of Deleted	0	1	1	0	
Rate of Granted Decision	66.67%	50.00%	0.00%	N/A	
Rate of Declined Decision	33.33%	0.00%	50.00%	N/A	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Deleted	0.00%	50.00%	50.00%	N/A	

**Table 8.5 OHT6 - Office of Orthopedic Devices
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	

**Table 8.6 OHT6 - Office of Orthopedic Devices
LDT De Novo MDUFA V Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.7 OHT6 - Office of Orthopedic Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.1 OHT7 - Office of In Vitro Diagnostics
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20	13	5	
Closed Before First RTA or TS Action	1	1	1	1	
Number Accepted or Passed TS on First Cycle	17	17	11	3	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	5	2	1	1	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	10.53%	8.33%	25.00%	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT7 - Office of In Vitro Diagnostics
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	20	18	11	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	20	18	6	0	
MDUFA Decision Within 150 FDA Days	20	18	6	0	
De Novos Pending MDUFA Decision	0	0	5	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

**Table 8.3 OHT7 - Office of In Vitro Diagnostics
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.60	1.50	1.67	N/A	
Number With MDUFA Decision	20	18	6	0	
Average FDA Days to MDUFA Decision	127.95	116.61	135.00	N/A	
20th Percentile FDA Days to MDUFA Decision	85	73	144	0	
40th Percentile FDA Days to MDUFA Decision	140	113	146	0	
60th Percentile FDA Days to MDUFA Decision	149	148	149	0	
80th Percentile FDA Days to MDUFA Decision	150	150	149	0	
Maximum FDA Days to MDUFA Decision	150	150	150	0	
Average Industry Days to MDUFA Decision	167.85	114.33	118.17	N/A	
20th Percentile Industry Days to MDUFA Decision	139	16	98	0	
40th Percentile Industry Days to MDUFA Decision	175	101	121	0	
60th Percentile Industry Days to MDUFA Decision	179	175	152	0	
80th Percentile Industry Days to MDUFA Decision	182	181	157	0	
Maximum Industry Days to MDUFA Decision	350	185	181	0	
Average Total Days to MDUFA Decision	295.80	230.94	253.17	N/A	
20th Percentile Total Days to MDUFA Decision	252	155	248	0	
40th Percentile Total Days to MDUFA Decision	299	235	253	0	
60th Percentile Total Days to MDUFA Decision	328	256	270	0	
80th Percentile Total Days to MDUFA Decision	330	322	301	0	
Maximum Total Days to MDUFA Decision	437	329	301	0	

**Table 8.4 OHT7 - Office of In Vitro Diagnostics
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	20	18	11	3	
Number With MDUFA Decision	20	18	6	0	
Number With Granted Decision	5	9	4	0	
Number With Declined Decision	5	2	0	0	
Number of Withdrawal	9	3	1	0	
Number of Deleted	1	4	1	0	
Rate of Granted Decision	25.00%	50.00%	66.67%	N/A	
Rate of Declined Decision	25.00%	11.11%	0.00%	N/A	
Rate of Withdrawal	45.00%	16.67%	16.67%	N/A	
Rate of Deleted	5.00%	22.22%	16.67%	N/A	

**Table 8.5 OHT7 - Office of In Vitro Diagnostics
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	

**Table 8.6 OHT7 - Office of In Vitro Diagnostics
LDT De Novo MDUFA V Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	0	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	0	0	0	
MDUFA Decision Within 150 FDA Days	1	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	1	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	N/A	N/A	N/A	

**Table 8.7 OHT7 - Office of In Vitro Diagnostics
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	11	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	19	18	6	0	
MDUFA Decision Within 150 FDA Days	19	18	6	0	
De Novos Pending MDUFA Decision	0	0	5	2	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

**Table 8.1 OHT8 - Office of Radiological Health
De Novo Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	3	1	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	4	4	3	0	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted or Failed TS on First Cycle	0	1	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	20.00%	0.00%	N/A	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

**Table 8.2 OHT8 - Office of Radiological Health
De Novo MDUFA V Decision Performance Goal**

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	4	4	3	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	4	4	2	0	
MDUFA Decision Within 150 FDA Days	4	4	2	0	
De Novos Pending MDUFA Decision	0	0	1	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

**Table 8.3 OHT8 - Office of Radiological Health
De Novo Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.25	1.50	1.50	N/A	
Number With MDUFA Decision	4	4	2	0	
Average FDA Days to MDUFA Decision	108.75	117.75	110.00	N/A	
20th Percentile FDA Days to MDUFA Decision	70	95	87	0	
40th Percentile FDA Days to MDUFA Decision	89	115	102	0	
60th Percentile FDA Days to MDUFA Decision	133	133	118	0	
80th Percentile FDA Days to MDUFA Decision	149	143	133	0	
Maximum FDA Days to MDUFA Decision	150	149	149	0	
Average Industry Days to MDUFA Decision	130.50	118.50	175.50	N/A	
20th Percentile Industry Days to MDUFA Decision	83	70	175	0	
40th Percentile Industry Days to MDUFA Decision	132	129	175	0	
60th Percentile Industry Days to MDUFA Decision	169	164	176	0	
80th Percentile Industry Days to MDUFA Decision	186	178	176	0	
Maximum Industry Days to MDUFA Decision	193	181	176	0	
Average Total Days to MDUFA Decision	239.25	236.25	285.50	N/A	
20th Percentile Total Days to MDUFA Decision	190	197	262	0	
40th Percentile Total Days to MDUFA Decision	258	257	278	0	
60th Percentile Total Days to MDUFA Decision	265	264	293	0	
80th Percentile Total Days to MDUFA Decision	297	286	309	0	
Maximum Total Days to MDUFA Decision	343	315	324	0	

**Table 8.4 OHT8 - Office of Radiological Health
De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	4	4	3	0	
Number With MDUFA Decision	4	4	2	0	
Number With Granted Decision	2	1	1	0	
Number With Declined Decision	0	1	0	0	
Number of Withdrawal	1	1	1	0	
Number of Deleted	1	1	0	0	
Rate of Granted Decision	50.00%	25.00%	50.00%	N/A	
Rate of Declined Decision	0.00%	25.00%	0.00%	N/A	
Rate of Withdrawal	25.00%	25.00%	50.00%	N/A	
Rate of Deleted	25.00%	25.00%	0.00%	N/A	

**Table 8.5 OHT8 - Office of Radiological Health
De Novo Performance Metrics-Submissions Missing Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A	N/A	

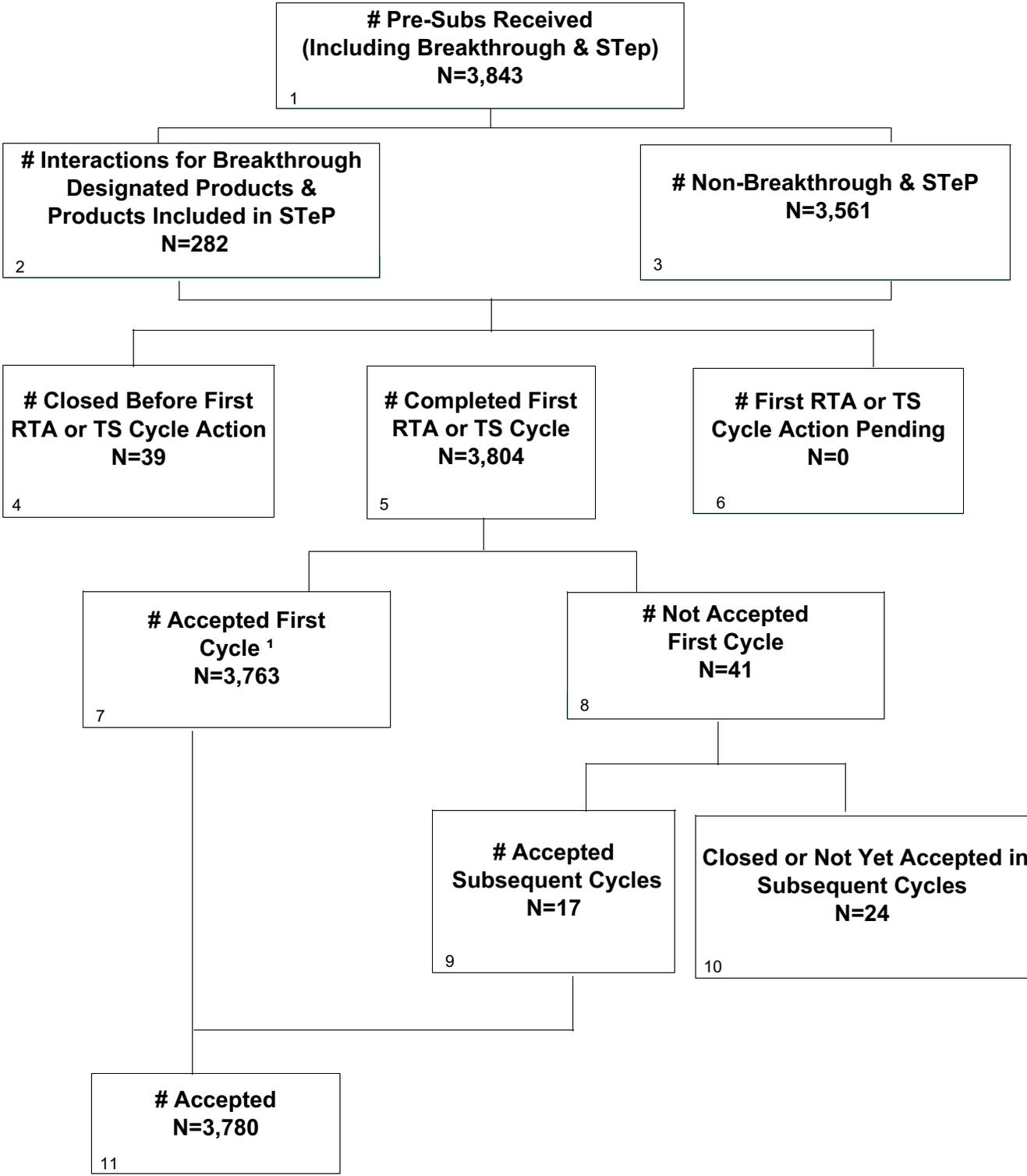
**Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

**Table 8.7 OHT8 - Office of Radiological Health
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics**

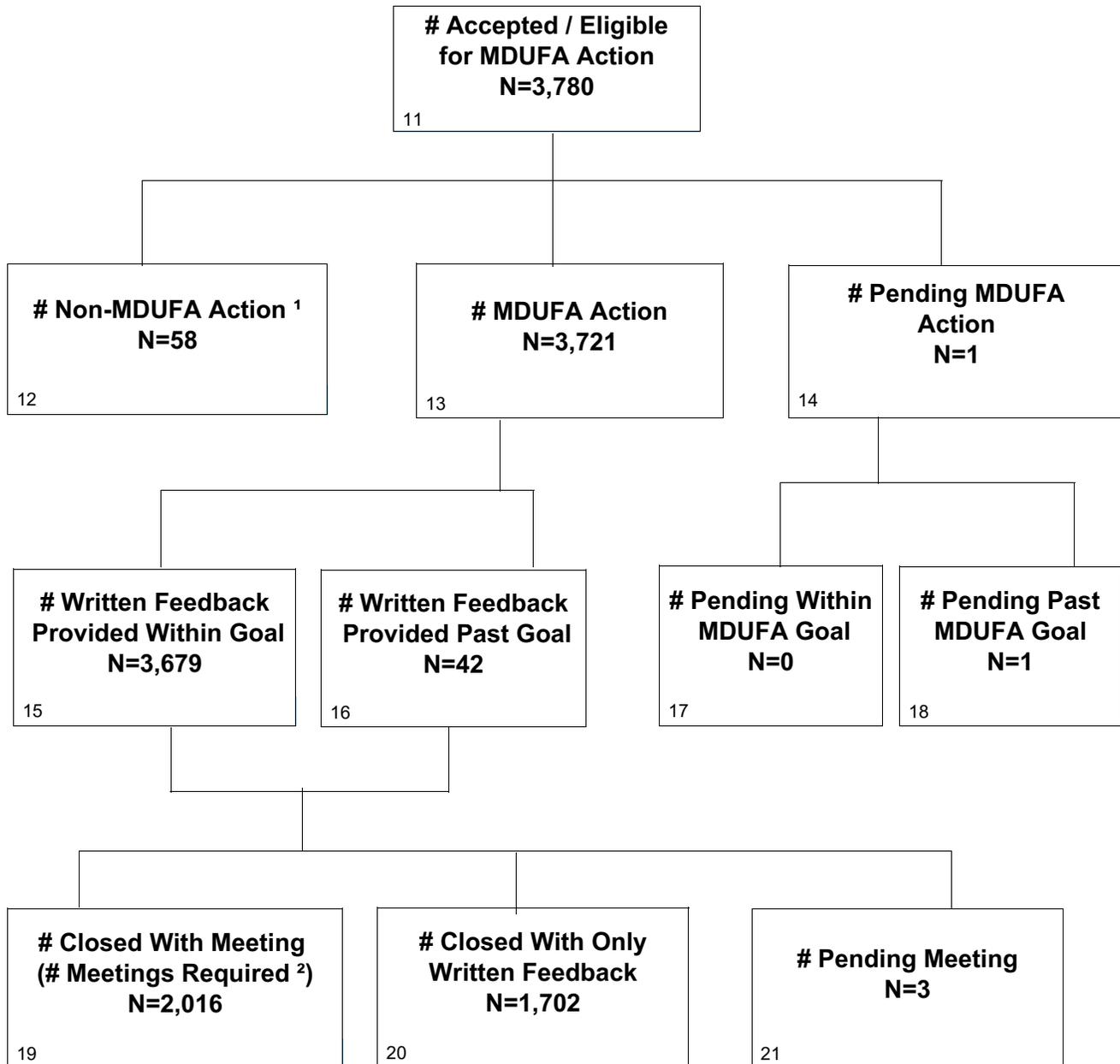
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

CDRH Pre-Sub - FY 2023 as of 12/31/25



1. This includes submissions accepted or passed TS on first cycle, submissions without a first cycle RTA or TS review, and those considered accepted upon receipt.

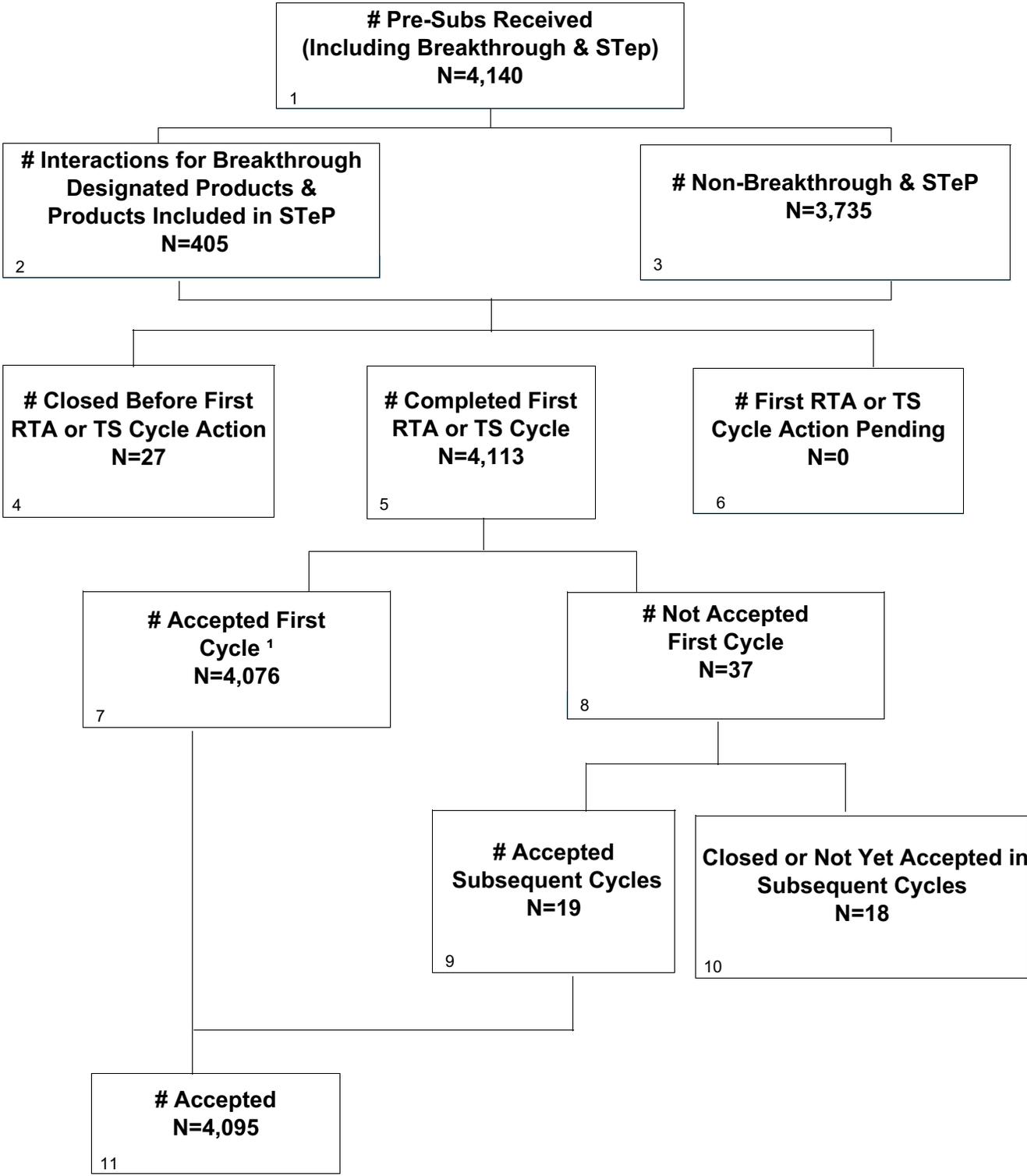
CDRH Pre-Sub - FY 2023 as of 12/31/25 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

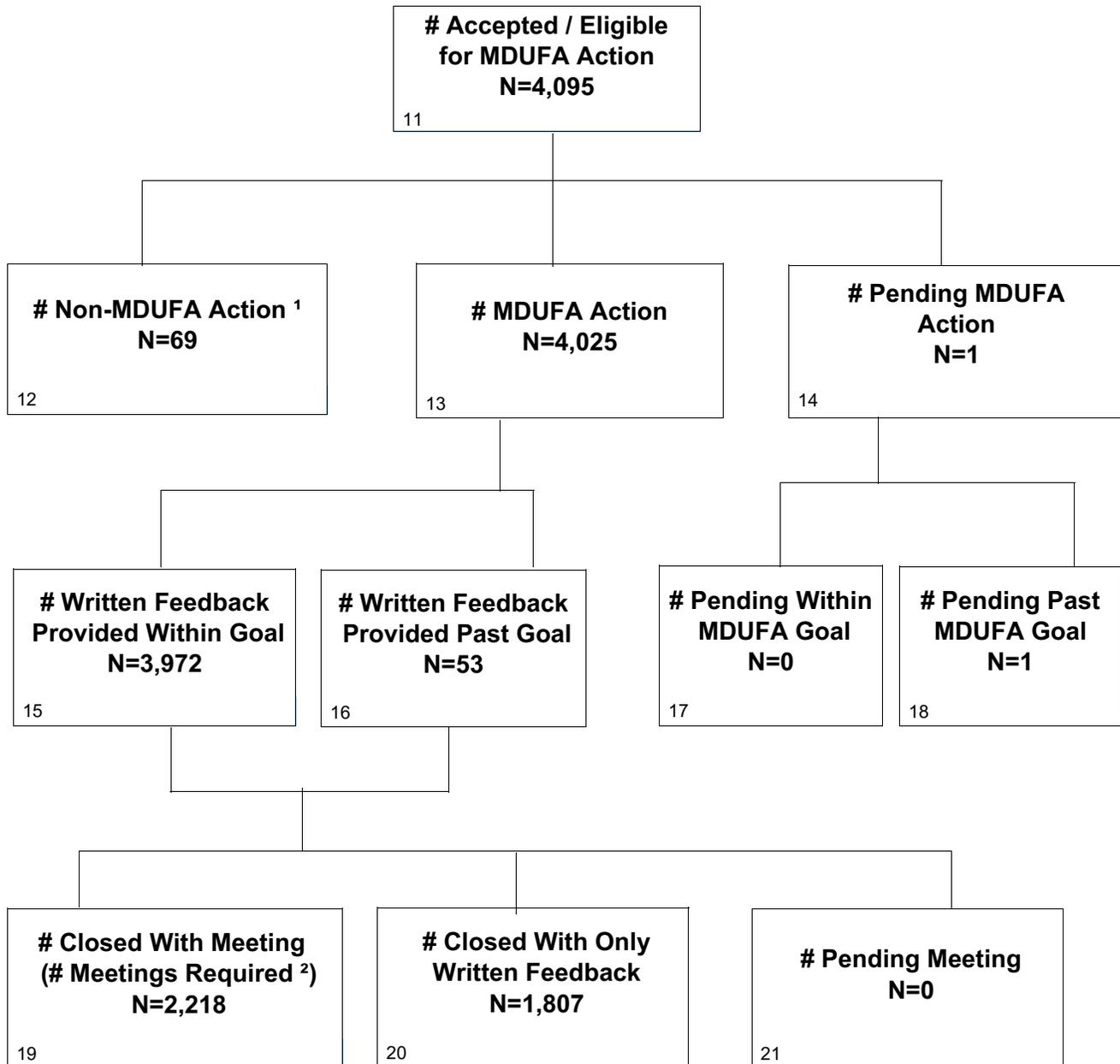
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024 as of 12/31/25



1. This includes submissions accepted or passed TS on first cycle, submissions without a first cycle RTA or TS review, and those considered accepted upon receipt.

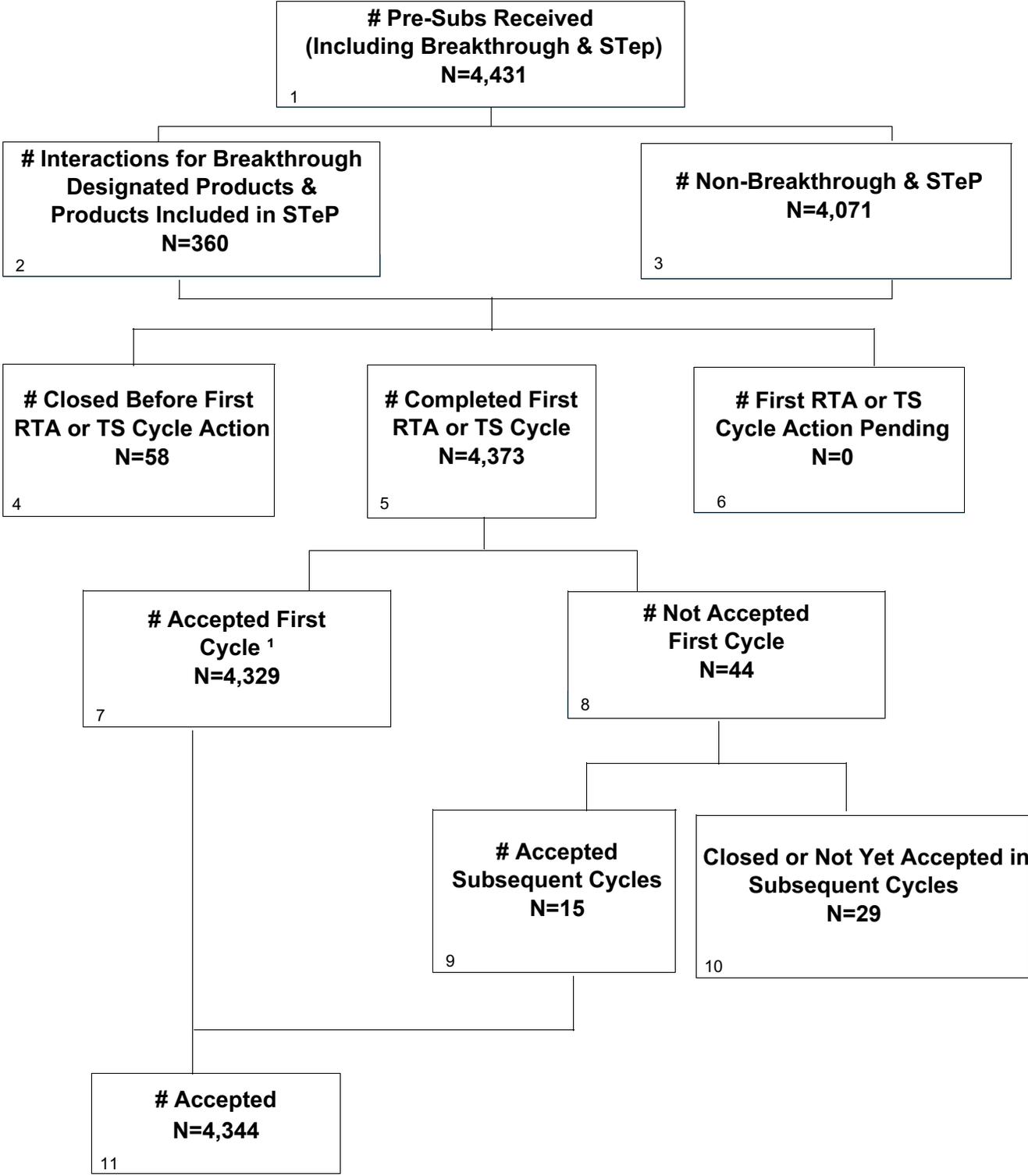
CDRH Pre-Sub - FY 2024 as of 12/31/25 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

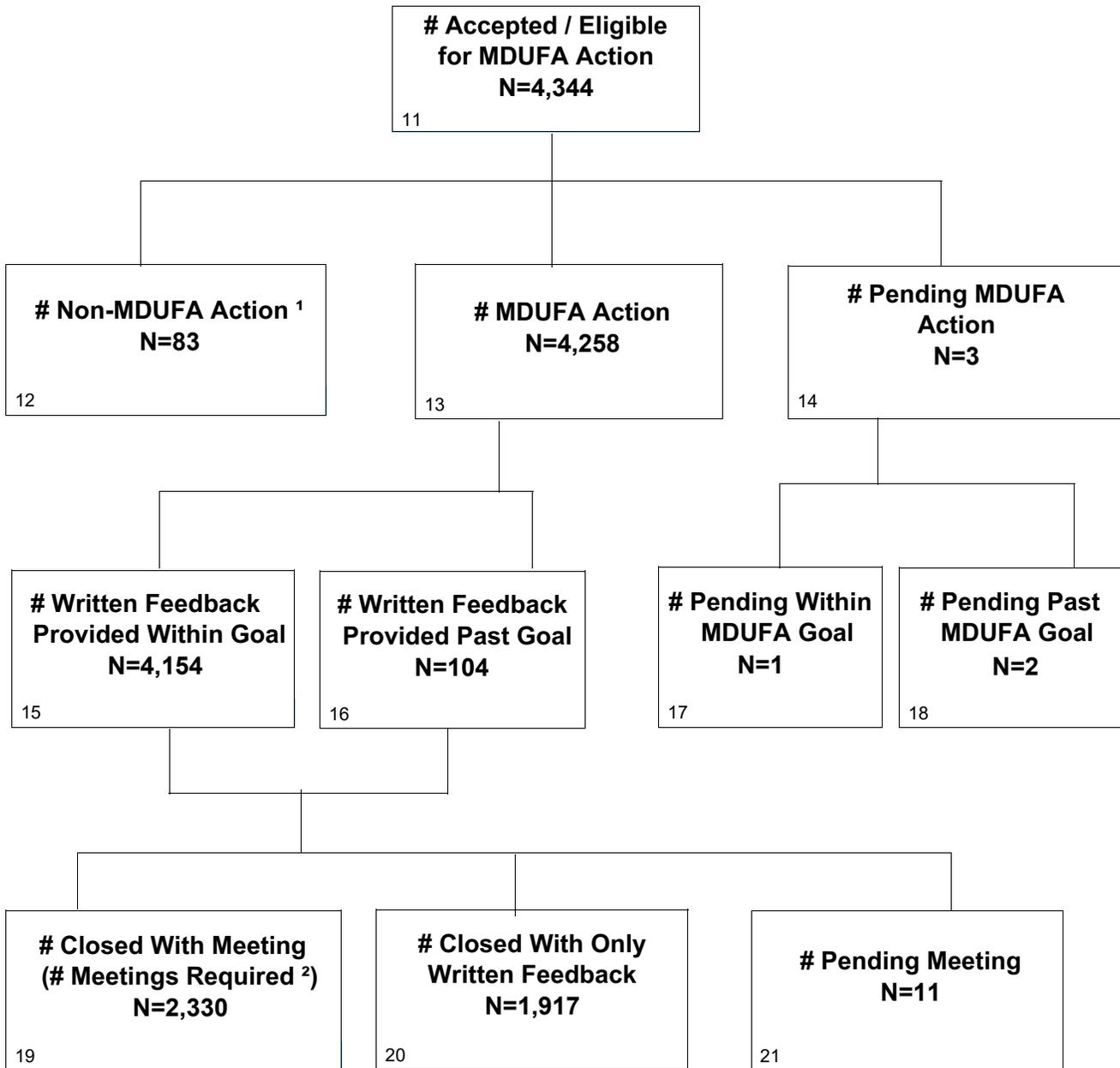
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2025 as of 12/31/25



1. This includes submissions accepted or passed TS on first cycle, submissions without a first cycle RTA or TS review, and those considered accepted upon receipt.

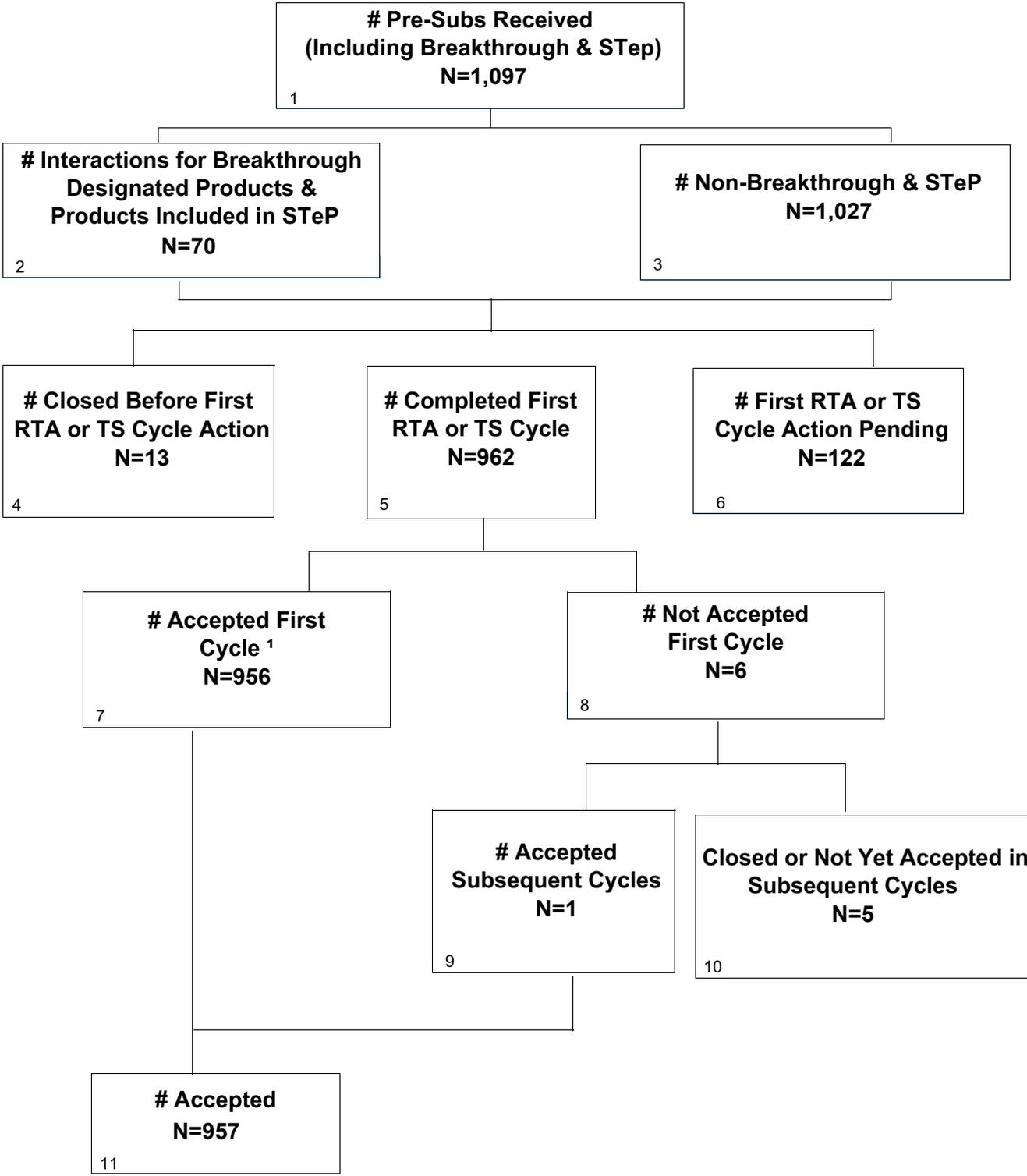
CDRH Pre-Sub - FY 2025 as of 12/31/25 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

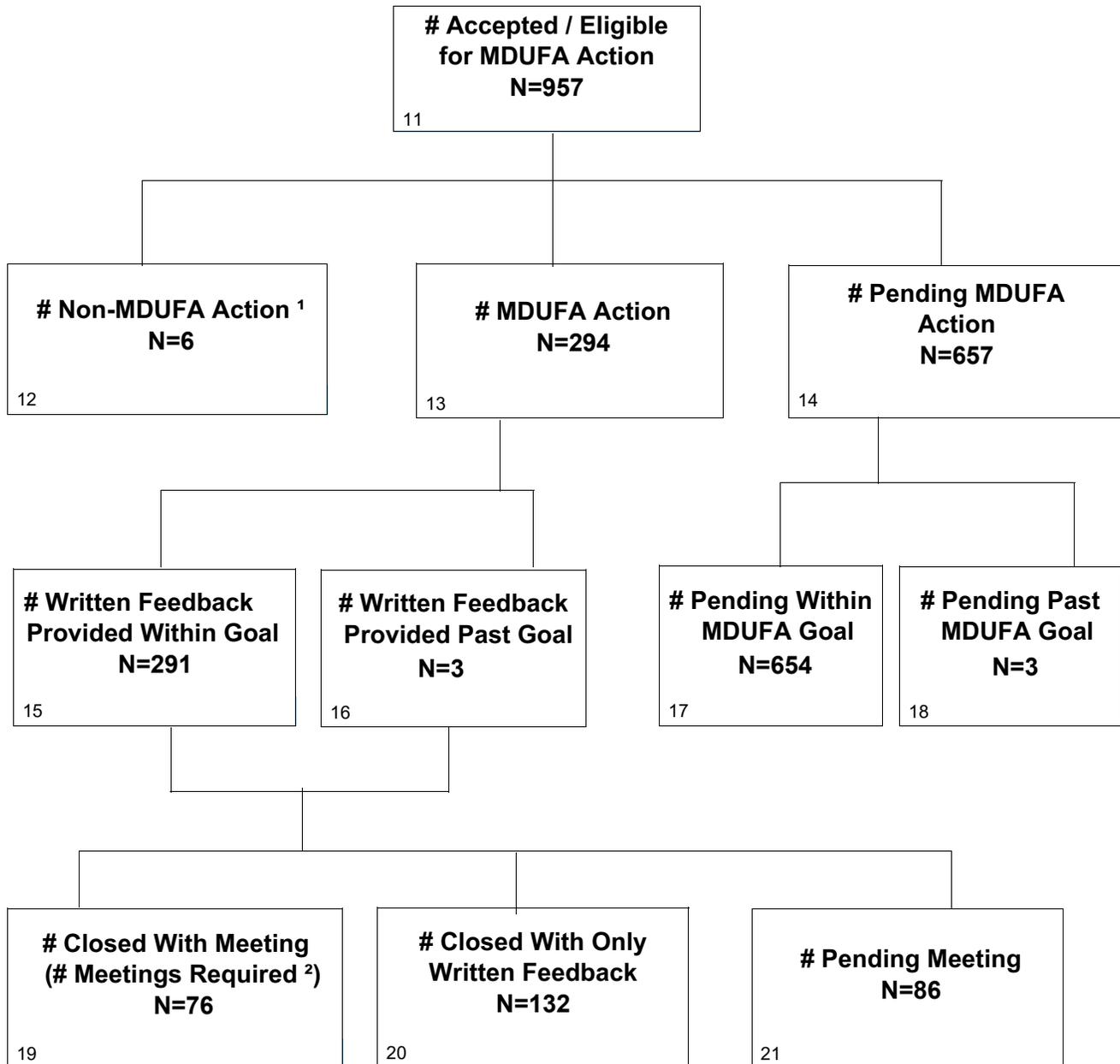
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2026 as of 12/31/25



1. This includes submissions accepted or passed TS on first cycle, submissions without a first cycle RTA or TS review, and those considered accepted upon receipt.

CDRH Pre-Sub - FY 2026 as of 12/31/25 Continued



1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

2. Number of meetings requested and then held after written feedback is provided.

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,843	4,140	4,431	1,097	
Interactions for Breakthrough Designated Products & Products Included in STeP	282	405	360	70	
Number Closed Before First RTA Action	39	27	58	13	
Number Accepted First RTA Cycle ¹	3,642	3,979	4,175	926	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	121	97	154	30	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	122	
Number Not Accepted First RTA Cycle	41	37	44	6	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.90%	1.01%	0.62%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, “Number Accepted First RTA Cycle” to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 CDRH - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	3,780	4,095	4,344	957	
Number with Non-MDUFA Action ³	58	69	83	6	
Number with MDUFA Action	3,721	4,025	4,258	294	
Written Feedback Provided Within Goal	3,679	3,972	4,154	291	
Number Pending MDUFA Action	1	1	3	657	
Pending MDUFA Action Past Goal	1	1	2	3	
Number in MDUFA Cohort (up to max 4300) ⁴	3,722	4,026	4,261	951	
Current Performance Percent Within Goal	98.84%	98.66%	97.51%	97.98%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 CDRH – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	3,721	4,025	4,258	294	
Average FDA Days to Written Feedback	62.20	62.25	61.86	54.37	
20th Percentile FDA Days to Written Feedback	56	56	56	43	
40th Percentile FDA Days to Written Feedback	64	64	64	53	
60th Percentile FDA Days to Written Feedback	68	67	67	62	
80th Percentile FDA Days to Written Feedback	70	70	70	68	
Maximum FDA Days to Written Feedback	141	245	307	81	

Table 9.4 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	136	130	153	39	
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.57	40.50	37.97	

Table 9.5 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	2,015	2,218	2,330	76	
Meeting Minutes Submitted Within 15 Days of Meeting	1,531	1,787	1,882	49	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	14	
Meeting Minutes Past 15 Days of Meeting	434	368	369	7	
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	63	79	6	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.98%	80.57%	80.77%	79.03%	

1. Number of meetings requested and then held after written feedback is provided.

Section 9 Pre-Sub Office Level Metrics

Table 9.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	444	492	522	110	
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27	23	5	
Number Closed Before First RTA Action	4	6	10	1	
Number Accepted First RTA Cycle ¹	411	461	490	93	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	20	20	10	4	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	11	
Number Not Accepted First RTA Cycle	9	5	12	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.03%	2.34%	1.02%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 OHT1 -Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	435	485	506	97	
Number with Non-MDUFA Action ³	12	12	15	0	
Number with MDUFA Action	423	473	488	22	
Written Feedback Provided Within Goal	410	460	472	21	
Number Pending MDUFA Action	0	0	3	75	
Pending MDUFA Action Past Goal	0	0	2	0	
Number in MDUFA Cohort (up to max 4300) ⁴	423	473	491	97	
Current Performance Percent Within Goal	96.93%	97.25%	96.33%	95.45%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

**Table 9.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	423	473	488	22	
Average FDA Days to Written Feedback	65.34	65.26	65.10	58.36	
20th Percentile FDA Days to Written Feedback	62	62	62	49	
40th Percentile FDA Days to Written Feedback	66	66	66	56	
60th Percentile FDA Days to Written Feedback	69	69	69	65	
80th Percentile FDA Days to Written Feedback	70	70	70	69	
Maximum FDA Days to Written Feedback	141	101	97	81	

**Table 9.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	30	23	20	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.70	42.00	37.00	

**Table 9.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	249	275	280	8	
Meeting Minutes Submitted Within 15 Days of Meeting	179	226	224	3	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	3	
Meeting Minutes Past 15 Days of Meeting	59	39	42	2	
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	10	14	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	82.18%	80.00%	60.00%	

1. Number of meetings requested and then held after written feedback is provided.

**Table 9.1 OHT2 - Office of Cardiovascular Devices
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	724	746	801	179	
Interactions for Breakthrough Designated Products & Products Included in STeP	73	84	78	11	
Number Closed Before First RTA Action	6	2	3	4	
Number Accepted First RTA Cycle ¹	701	727	761	159	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	13	14	36	3	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	13	
Number Not Accepted First RTA Cycle	4	3	1	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.40%	0.13%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	717	742	797	162	
Number with Non-MDUFA Action ³	4	4	4	1	
Number with MDUFA Action	712	737	793	43	
Written Feedback Provided Within Goal	697	716	753	42	
Number Pending MDUFA Action	1	1	0	118	
Pending MDUFA Action Past Goal	1	1	0	2	
Number in MDUFA Cohort (up to max 4300) ⁴	713	738	793	161	
Current Performance Percent Within Goal	97.76%	97.02%	94.96%	93.33%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT2 - Office of Cardiovascular Devices

MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	712	737	793	43	
Average FDA Days to Written Feedback	59.32	59.61	61.58	58.28	
20th Percentile FDA Days to Written Feedback	50	51	55	51	
40th Percentile FDA Days to Written Feedback	60	61	63	58	
60th Percentile FDA Days to Written Feedback	66	65	67	63	
80th Percentile FDA Days to Written Feedback	69	69	70	67	
Maximum FDA Days to Written Feedback	103	113	119	70	

Table 9.4 OHT2 - Office of Cardiovascular Devices

MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	33	21	40	13	
Average Days to Scheduling for Meetings Scheduled After Day 30	38.09	36.90	39.23	36.31	

Table 9.5 OHT2 - Office of Cardiovascular Devices

MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	406	424	430	10	
Meeting Minutes Submitted Within 15 Days of Meeting	308	318	315	6	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	
Meeting Minutes Past 15 Days of Meeting	91	90	96	1	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	16	19	2	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.86%	75.00%	73.26%	66.67%	

1. Number of meetings requested and then held after written feedback is provided.

**Table 9.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	461	510	558	160	
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63	54	5	
Number Closed Before First RTA Action	5	4	10	2	
Number Accepted First RTA Cycle ¹	438	484	520	143	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	12	11	14	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	14	
Number Not Accepted First RTA Cycle	6	11	14	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.32%	2.17%	2.55%	0.69%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	453	499	538	143	
Number with Non-MDUFA Action ³	10	11	8	1	
Number with MDUFA Action	443	488	530	38	
Written Feedback Provided Within Goal	439	485	524	37	
Number Pending MDUFA Action	0	0	0	104	
Pending MDUFA Action Past Goal	0	0	0	1	
Number in MDUFA Cohort (up to max 4300) ⁴	443	488	530	142	
Current Performance Percent Within Goal	99.10%	99.39%	98.87%	94.87%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

**Table 9.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	443	488	530	38	
Average FDA Days to Written Feedback	62.13	61.74	61.40	54.71	
20th Percentile FDA Days to Written Feedback	56	56	56	44	
40th Percentile FDA Days to Written Feedback	64	63	63	54	
60th Percentile FDA Days to Written Feedback	67	67	67	59	
80th Percentile FDA Days to Written Feedback	70	70	70	68	
Maximum FDA Days to Written Feedback	78	78	79	70	

**Table 9.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	12	12	15	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	42.67	43.50	39.93	39.00	

**Table 9.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	254	268	292	11	
Meeting Minutes Submitted Within 15 Days of Meeting	200	222	242	6	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	4	
Meeting Minutes Past 15 Days of Meeting	48	39	39	1	
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	7	11	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.74%	82.84%	82.88%	85.71%	

1. Number of meetings requested and then held after written feedback is provided.

**Table 9.1 OHT4 - Office of Surgical and Infection Control Devices
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	379	463	533	146	
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35	33	4	
Number Closed Before First RTA Action	4	5	13	4	
Number Accepted First RTA Cycle ¹	359	436	485	117	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	9	14	32	6	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	19	
Number Not Accepted First RTA Cycle	7	8	3	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.87%	1.75%	0.58%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	371	455	519	123	
Number with Non-MDUFA Action ³	11	18	18	3	
Number with MDUFA Action	360	437	501	40	
Written Feedback Provided Within Goal	360	435	483	40	
Number Pending MDUFA Action	0	0	0	80	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300) ⁴	360	437	501	120	
Current Performance Percent Within Goal	100.00%	99.54%	96.41%	100.00%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

**Table 9.3 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	360	437	501	40	
Average FDA Days to Written Feedback	60.50	62.00	60.44	53.93	
20th Percentile FDA Days to Written Feedback	54	56	54	40	
40th Percentile FDA Days to Written Feedback	62	63	63	56	
60th Percentile FDA Days to Written Feedback	65	67	67	63	
80th Percentile FDA Days to Written Feedback	69	70	70	68	
Maximum FDA Days to Written Feedback	70	70	141	70	

**Table 9.4 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	14	15	15	8	
Average Days to Scheduling for Meetings Scheduled After Day 30	37.71	40.00	41.73	33.88	

**Table 9.5 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	206	234	281	13	
Meeting Minutes Submitted Within 15 Days of Meeting	159	183	223	9	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	
Meeting Minutes Past 15 Days of Meeting	39	47	46	3	
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	4	12	1	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.18%	78.21%	79.36%	69.23%	

1. Number of meetings requested and then held after written feedback is provided.

**Table 9.1 OHT5 - Office of Neurological and Physical Medicine Devices
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	397	428	470	133	
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42	37	22	
Number Closed Before First RTA Action	5	3	2	0	
Number Accepted First RTA Cycle ¹	371	406	434	104	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	17	10	24	8	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	18	
Number Not Accepted First RTA Cycle	4	9	10	3	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.12%	2.14%	2.61%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	390	421	460	113	
Number with Non-MDUFA Action ³	5	5	11	0	
Number with MDUFA Action	385	416	449	39	
Written Feedback Provided Within Goal	383	408	429	39	
Number Pending MDUFA Action	0	0	0	74	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300) ⁴	385	416	449	113	
Current Performance Percent Within Goal	99.48%	98.08%	95.55%	100.00%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

**Table 9.3 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	385	416	449	39	
Average FDA Days to Written Feedback	66.14	67.24	67.06	58.79	
20th Percentile FDA Days to Written Feedback	64	65	63	48	
40th Percentile FDA Days to Written Feedback	68	69	69	63	
60th Percentile FDA Days to Written Feedback	70	70	70	65	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	108	245	307	70	

Table 9.4 CDRH- OHT5 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	26	39	36	13	
Average Days to Scheduling for Meetings Scheduled After Day 30	39.04	39.26	39.00	43.08	

**Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	250	260	273	2	
Meeting Minutes Submitted Within 15 Days of Meeting	178	207	213	0	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	
Meeting Minutes Past 15 Days of Meeting	65	45	49	0	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	8	11	1	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.20%	79.62%	78.02%	0.00%	

1. Number of meetings requested and then held after written feedback is provided.

**Table 9.1 OHT6 - Office of Orthopedic Devices
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	289	294	299	59	
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79	57	9	
Number Closed Before First RTA Action	5	1	2	0	
Number Accepted First RTA Cycle ¹	270	286	288	52	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	10	7	7	1	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	6	
Number Not Accepted First RTA Cycle	4	0	2	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.41%	0.00%	0.67%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	282	293	296	53	
Number with Non-MDUFA Action ³	6	8	11	1	
Number with MDUFA Action	276	285	285	20	
Written Feedback Provided Within Goal	272	280	285	20	
Number Pending MDUFA Action	0	0	0	32	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300) ⁴	276	285	285	52	
Current Performance Percent Within Goal	98.55%	98.25%	100.00%	100.00%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT6 - Office of Orthopedic Devices

MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	276	285	285	20	
Average FDA Days to Written Feedback	58.46	56.93	58.58	47.60	
20th Percentile FDA Days to Written Feedback	45	43	45	37	
40th Percentile FDA Days to Written Feedback	58	57	60	43	
60th Percentile FDA Days to Written Feedback	65	64	65	52	
80th Percentile FDA Days to Written Feedback	69	68	69	63	
Maximum FDA Days to Written Feedback	97	92	70	70	

Table 9.4 CDRH- OHT6 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	4	2	5	0	
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50	39.40	N/A	

Table 9.5 OHT6 - Office of Orthopedic Devices

MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	124	129	139	5	
Meeting Minutes Submitted Within 15 Days of Meeting	91	103	117	5	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	
Meeting Minutes Past 15 Days of Meeting	29	17	20	0	
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	9	2	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.39%	79.84%	84.17%	100.00%	

1. Number of meetings requested and then held after written feedback is provided.

**Table 9.1 OHT7 - Office of In Vitro Diagnostics
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	880	921	908	227	
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60	66	11	
Number Closed Before First RTA Action	9	5	15	2	
Number Accepted First RTA Cycle ¹	833	900	865	190	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	35	15	28	6	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	29	
Number Not Accepted First RTA Cycle	3	1	0	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.11%	0.00%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	868	915	893	196	
Number with Non-MDUFA Action ³	7	11	9	0	
Number with MDUFA Action	861	904	884	76	
Written Feedback Provided Within Goal	857	903	882	76	
Number Pending MDUFA Action	0	0	0	120	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300) ⁴	861	904	884	196	
Current Performance Percent Within Goal	99.54%	99.89%	99.77%	100.00%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT7 - Office of In Vitro Diagnostics

MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	861	904	884	76	
Average FDA Days to Written Feedback	63.70	63.10	60.25	49.95	
20th Percentile FDA Days to Written Feedback	60	59	54	39	
40th Percentile FDA Days to Written Feedback	66	65	63	48	
60th Percentile FDA Days to Written Feedback	69	68	66	55	
80th Percentile FDA Days to Written Feedback	70	70	69	64	
Maximum FDA Days to Written Feedback	75	71	89	70	

Table 9.4 OHT7 - Office of In Vitro Diagnostics

MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	12	14	20	3	
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00	42.05	34.00	

Table 9.5 OHT7 - Office of In Vitro Diagnostics

MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	320	414	421	19	
Meeting Minutes Submitted Within 15 Days of Meeting	257	355	360	13	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	4	
Meeting Minutes Past 15 Days of Meeting	59	53	52	0	
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6	9	2	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.31%	85.75%	85.51%	86.67%	

1. Number of meetings requested and then held after written feedback is provided.

**Table 9.1 OHT8 - Office of Radiological Health
Pre-Sub Acceptance Review Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	269	286	340	83	
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15	12	3	
Number Closed Before First RTA Action	1	1	3	0	
Number Accepted First RTA Cycle ¹	259	279	332	68	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	5	6	3	2	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	12	
Number Not Accepted First RTA Cycle	4	0	2	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.49%	0.00%	0.59%	1.41%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

**Table 9.2 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Goals**

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	264	285	335	70	
Number with Non-MDUFA Action ³	3	0	7	0	
Number with MDUFA Action	261	285	328	16	
Written Feedback Provided Within Goal	261	285	326	16	
Number Pending MDUFA Action	0	0	0	54	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300) ⁴	261	285	328	70	
Current Performance Percent Within Goal	100.00%	100.00%	99.39%	100.00%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

**Table 9.3 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	261	285	328	16	
Average FDA Days to Written Feedback	60.57	60.68	60.75	57.31	
20th Percentile FDA Days to Written Feedback	55	55	55	50	
40th Percentile FDA Days to Written Feedback	60	62	62	57	
60th Percentile FDA Days to Written Feedback	64	65	65	61	
80th Percentile FDA Days to Written Feedback	67	69	69	65	
Maximum FDA Days to Written Feedback	70	70	85	70	

**Table 9.4 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)**

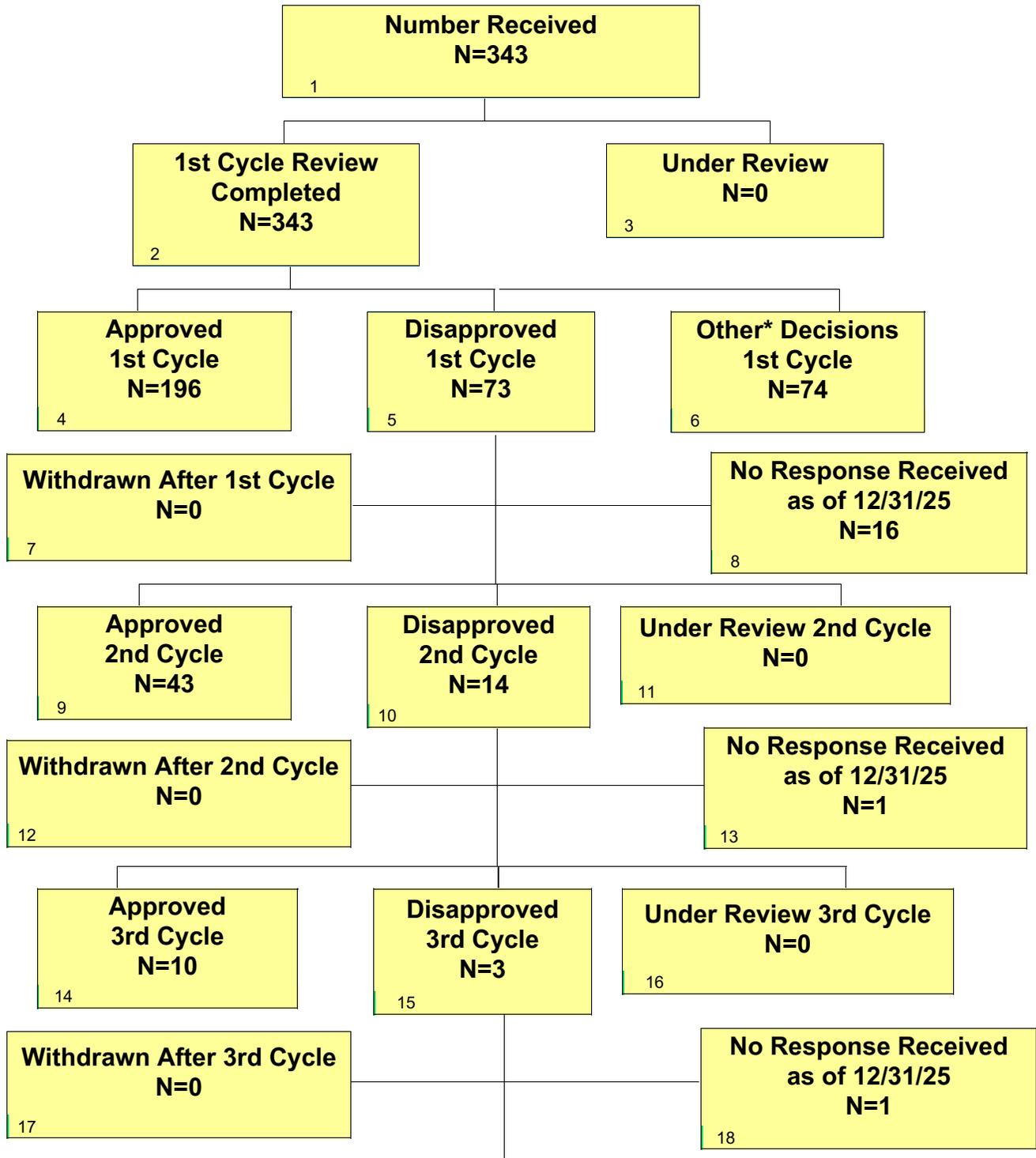
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4	2	0	
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25	60.50	N/A	

**Table 9.5 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	206	214	214	8	
Meeting Minutes Submitted Within 15 Days of Meeting	159	173	188	7	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	
Meeting Minutes Past 15 Days of Meeting	44	38	25	0	
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	3	1	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.18%	80.84%	87.85%	100.00%	

1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023 as of 12/31/25

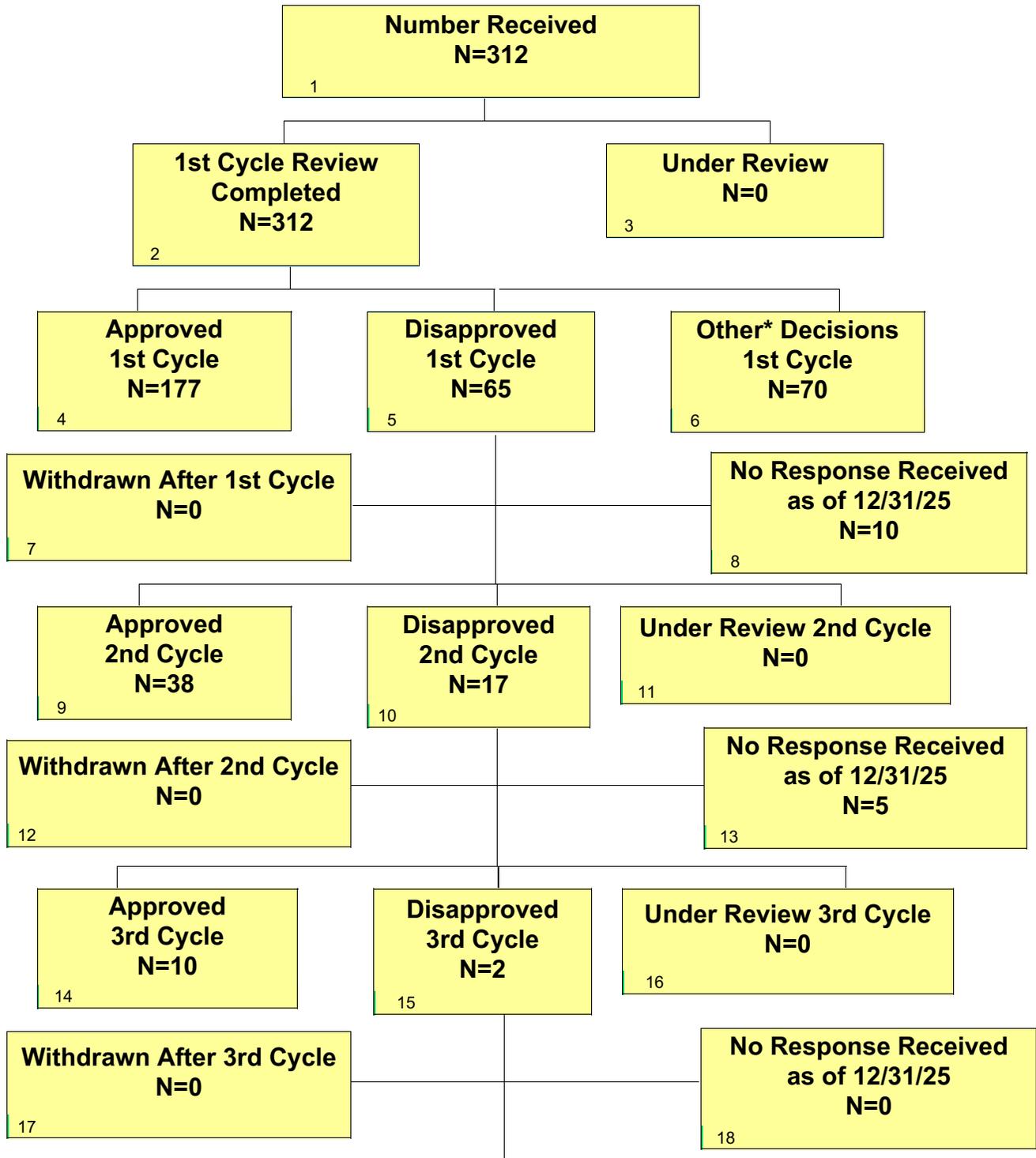


* Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).

CDRH IDEs - FY 2023 as of 12/31/25



CDRH IDEs - FY 2024 as of 12/31/25

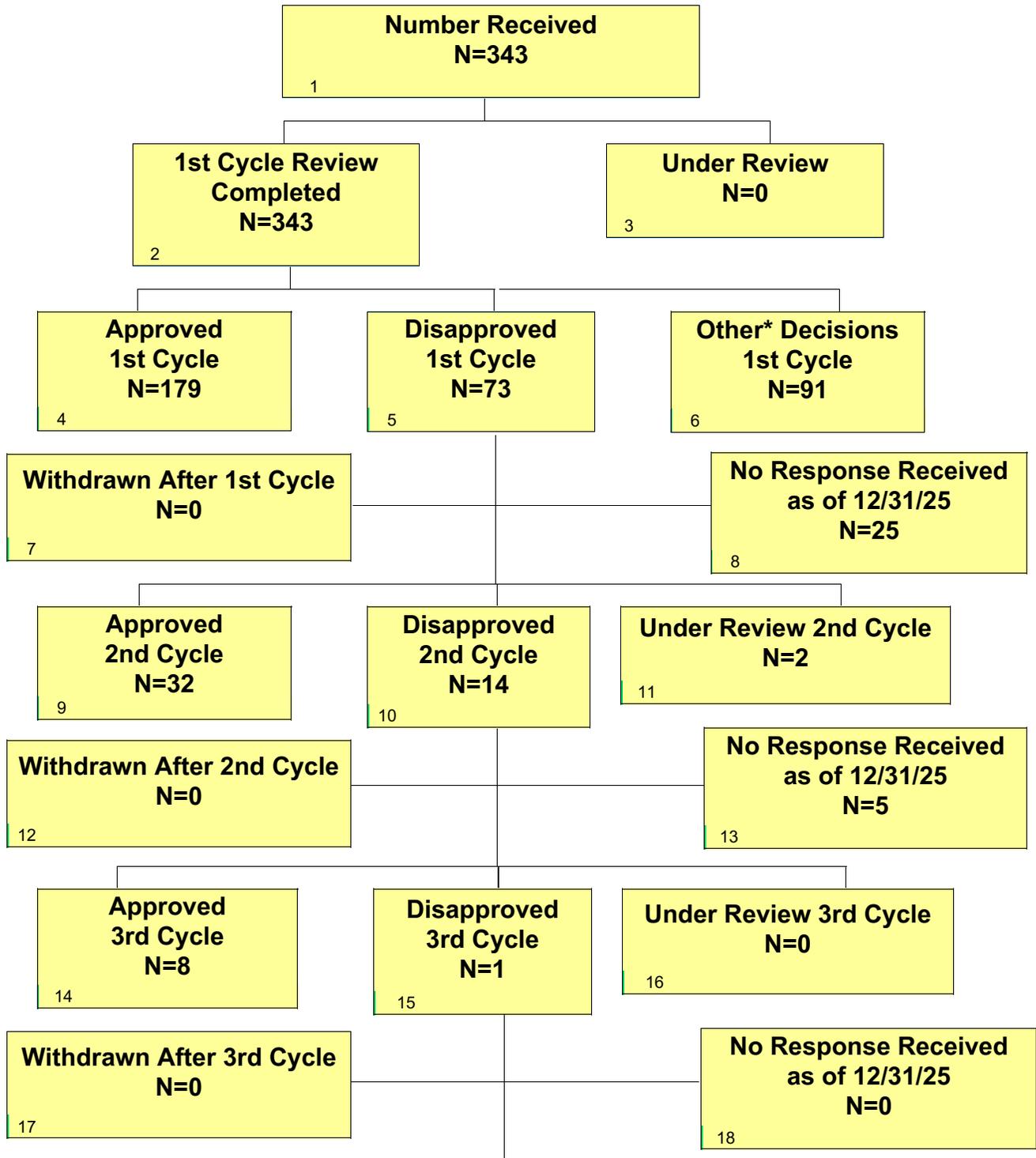


* Other decisions include withdrawn (N=10), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).

CDRH IDEs - FY 2024 as of 12/31/25

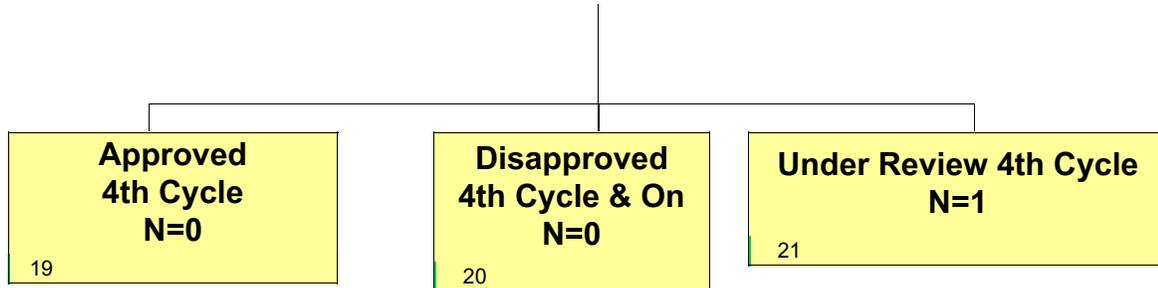


CDRH IDEs - FY 2025 as of 12/31/25

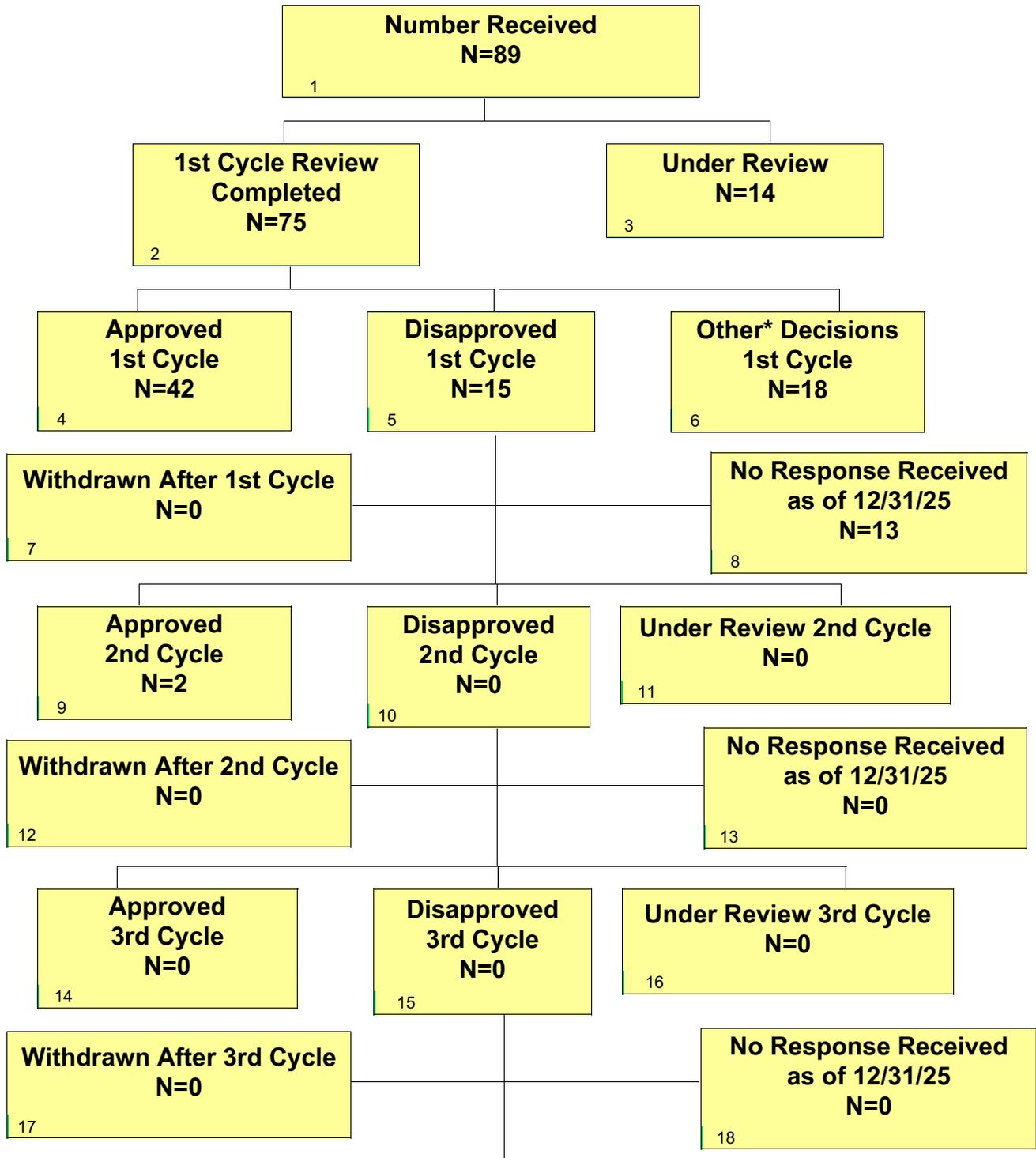


* Other decisions include withdrawn (N=13), withdrawn and converted (N=46), RTA (N=0), nonsignificant risk device (N=24), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=7), Basic Physiological Research (N=0).

CDRH IDEs - FY 2025 as of 12/31/25

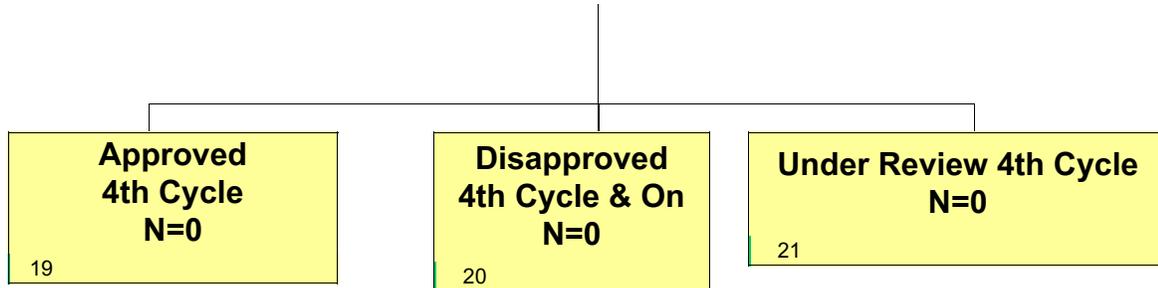


CDRH IDEs - FY 2026 as of 12/31/25



* Other decisions include withdrawn (N=4), withdrawn and converted (N=12), RTA (N=0), nonsignificant risk device (N=2), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=0), Basic Physiological Research (N=0).

CDRH IDEs - FY 2026 as of 12/31/25



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	343	312	343	89	
Average Number of Cycles to IDE Approval or Conditional Approval	1.28	1.28	1.22	1.05	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.28	0.28	0.22	0.05	

Section 10 IDE - Office Level Metric

**Table 10.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	42	32	25	10	
Average Number of Cycles to IDE Approval or Conditional Approval	1.39	1.21	1.56	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.39	0.21	0.56	0.00	

**Table 10.1 OHT2 - Office of Cardiovascular Devices
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	82	69	22	
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.40	1.36	1.20	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.40	0.36	0.20	

**Table 10.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	36	41	45	9	
Average Number of Cycles to IDE Approval or Conditional Approval	1.31	1.31	1.15	1.20	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.31	0.31	0.15	0.20	

**Table 10.1 OHT4 - Office of Surgical and Infection Control Devices
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	37	17	44	11	
Average Number of Cycles to IDE Approval or Conditional Approval	1.13	1.00	1.04	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.13	0.00	0.04	0.00	

**Table 10.1 OHT5 - Office of Neurological and Physical Medicine Devices
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	63	85	15	
Average Number of Cycles to IDE Approval or Conditional Approval	1.24	1.41	1.18	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.24	0.41	0.18	0.00	

**Table 10.1 OHT6 - Office of Orthopedic Devices
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	26	23	17	2	
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.27	1.67	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.27	0.67	0.00	

**Table 10.1 OHT7 - Office of In Vitro Diagnostics
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	46	43	51	16	
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00	0.00	0.00	

**Table 10.1 OHT8 - Office of Radiological Health
IDE MDUFA V Decision Performance Goal**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	8	11	7	4	
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.25	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.25	0.00	0.00	

Section 11 CLIA Waiver Annual Metrics

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

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.

Section 13 TAP Center Level Metrics

Table 13.1 CDRH - TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		31	81	14	
Closed before Teleconference		0	0	0	
Teleconferences Held		31	81	10	
Teleconferences Held Within 14 Days		30	78	8	
Teleconferences Pending		0	0	4	
Teleconferences Pending Over 14 Days		0	0	1	
Current Performance Percent Within 14 Days		96.77%	96.30%	72.73%	

Table 13.2 CDRH - TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	12	3	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		3	12	2	
Written Feedback Provided Within 21 Days		3	10	0	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		100.00%	83.33%	0.00%	

Table 13.3 CDRH - TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		44	67	20	
Closed before Written Feedback		0	1	0	
Written Feedback Provided		44	66	16	
Written Feedback Provided Within 40 Days		44	64	14	
Written Feedback Pending		0	0	4	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	96.97%	87.50%	

TAP Pilot Enrollment Data

Table 13.4 - TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		47	54	13	
Enrollment Requests Accepted		40	49	7	
Enrollment Requests Not Accepted		7	4	5	
Enrollment Requests Withdrawn Before Decision		0	1	0	
Enrollment Requests Pending		0	0	1	

Section 13 TAP Documents - Office Level Metric

**Table 13.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	2	1	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	2	1	
Teleconferences Held Within 14 Days		0	2	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	0.00%	

**Table 13.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	2	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	0.00%	

**Table 13.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

**Table 13.4 - OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP Pilot Enrollment Data**

Table 13.4 - TAP Pilot Enrollment Data	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	2	0	
Enrollment Requests Accepted		0	2	0	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

**Table 13.1 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		21	34	3	
Closed before Teleconference		0	0	0	
Teleconferences Held		21	34	2	
Teleconferences Held Within 14 Days		20	32	2	
Teleconferences Pending		0	0	1	
Teleconferences Pending Over 14 Days		0	0	1	
Current Performance Percent Within 14 Days		95.24%	94.12%	66.67%	

**Table 13.2 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		3	6	2	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		3	6	2	
Written Feedback Provided Within 21 Days		3	4	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		100.00%	66.67%	0.00%	

**Table 13.3 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		34	39	13	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		34	39	11	
Written Feedback Provided Within 40 Days		34	39	9	
Written Feedback Pending		0	0	2	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	100.00%	81.82%	

**Table 13.4 - OHT2 - Office of Cardiovascular Devices
TAP Pilot Enrollment Data**

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		21	14	4	
Enrollment Requests Accepted		16	13	2	
Enrollment Requests Not Accepted		5	1	2	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

**Table 13.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0	0	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	0	0	
Teleconferences Held Within 14 Days		0	0	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	N/A	N/A	

**Table 13.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

**Table 13.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

**Table 13.4 - OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP Pilot Enrollment Data**

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		1	2	1	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		1	2	1	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

**Table 13.1 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0	0	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	0	0	
Teleconferences Held Within 14 Days		0	0	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	N/A	N/A	

**Table 13.2 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

**Table 13.3 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

**Table 13.4 - OHT4 - Office of Surgical and Infection Control Devices
TAP Pilot Enrollment Data**

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	0	0	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

**Table 13.1 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		10	35	9	
Closed before Teleconference		0	0	0	
Teleconferences Held		10	35	7	
Teleconferences Held Within 14 Days		10	34	6	
Teleconferences Pending		0	0	2	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		100.00%	97.14%	85.71%	

**Table 13.2 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	6	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	6	0	
Written Feedback Provided Within 21 Days		0	6	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	100.00%	N/A	

**Table 13.3 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		10	21	3	
Closed before Written Feedback		0	1	0	
Written Feedback Provided		10	20	2	
Written Feedback Provided Within 40 Days		10	18	2	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	90.00%	100.00%	

**Table 13.4 - OHT5 - Office of Neurological and Physical Medicine Devices
TAP Pilot Enrollment Data**

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		25	12	4	
Enrollment Requests Accepted		24	12	2	
Enrollment Requests Not Accepted		1	0	1	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	1	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

**Table 13.1 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	9	1	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	9	0	
Teleconferences Held Within 14 Days		0	9	0	
Teleconferences Pending		0	0	1	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	N/A	

**Table 13.2 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	1	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

**Table 13.3 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	4	4	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	4	3	
Written Feedback Provided Within 40 Days		0	4	3	
Written Feedback Pending		0	0	1	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	100.00%	100.00%	

**Table 13.4 - OHT6 - Office of Orthopedic Devices
TAP Pilot Enrollment Data**

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	15	2	
Enrollment Requests Accepted		0	15	1	
Enrollment Requests Not Accepted		0	0	1	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

**Table 13.1 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0	0	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	0	0	
Teleconferences Held Within 14 Days		0	0	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	N/A	N/A	

**Table 13.2 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

**Table 13.3 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

**Table 13.4 - OHT7 - Office of In Vitro Diagnostics
TAP Pilot Enrollment Data**

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	0	0	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

**Table 13.1 OHT8 - Office of Radiological Health
TAP MDUFA V Teleconference Engagement Performance Goal**

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	1	0	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	1	0	
Teleconferences Held Within 14 Days		0	1	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	N/A	

**Table 13.2 OHT8 - Office of Radiological Health
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal**

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

**Table 13.3 OHT8 - Office of Radiological Health
TAP MDUFA V Written Feedback (Other) Performance Goal**

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	3	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	3	0	
Written Feedback Provided Within 40 Days		0	3	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	100.00%	N/A	

**Table 13.4 - OHT8 - Office of Radiological Health
TAP Pilot Enrollment Data**

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	9	2	
Enrollment Requests Accepted		0	7	2	
Enrollment Requests Not Accepted		0	1	0	
Enrollment Requests Withdrawn Before Decision		0	1	0	
Enrollment Requests Pending*		0	0	0	

* Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

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	Number Closed Before First RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a First Cycle 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 First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review on First Cycle	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 on First Cycle	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 Originals 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	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 and Panel Track Supplements Substantive Interaction Performance Goal - 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 Metric – 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 and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal - 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 Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.6 and Tables 1.6.x**PMA Originals and Panel Track Supplements (With Panel Review) MDUFA V Decision Performance Goal - 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 Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.7 and Tables 1.7.x**PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions**

#	Measure	Description
1	Number With MDUFA 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 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 Originals and Panel Track Supplements (With Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number With MDUFA 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 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) MDUFA V Performance Metric – Rates of Withdrawal, Not Approvable and Deleted - 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 decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	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 Withdrawal	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 Originals and Panel Track Supplements (With Panel Review) Performance Metric – Rate of Withdrawal, Not Approvable and Deleted - 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 Withdrawal	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 Withdrawal	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 1.11 and Tables 1.11.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Submissions Missing Performance Goal - 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 of FDA days to MDUFA decision exceeding number of goal 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 the Goal	Mean industry days for submissions that missed the goal (line 1).

Table 1.12 and Tables 1.12.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Submissions Missing Performance Goal - 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 decision exceeding number of goal 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 the Goal	Mean industry days for submissions that missed the goal (line 1).

**Tables 1.13 and Tables 1.13.x LDT PMA Originals and Panel-Track Supplements MDUFA V Metric*
- 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 Decision	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decision	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA 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 MDUFA V Metric* - 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 Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA 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 Goal – 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 V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA Decision	Supplements received (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements Pending MDUFA Decision	Number of supplements received (line 1) that do not have a MDUFA decision or a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA 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 MDUFA V Performance Metric – 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 MDUFA V Performance Metric – Submissions Missing Performance Goal – 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 V 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 PMA Real Time Supplements MDUFA V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) within goal.
5	Supplements Pending MDUFA Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA decision and are not closed with a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 3.2 and Tables 3.2.x PMA Real Time Supplements MDUFA V Performance Metric – 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

**PMA Real Time PMA Supplements MDUFA V Performance Metric –
Submissions Missing Performance Goal – 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 a MDUFA Decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number With a 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 V decision and 5% of submissions with the highest number of Total Days to MDUFA V 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 V 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 First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an “RTA Accepted” (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1 st 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15 th day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a “Not Accepted” (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (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 passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent 510k definitions.
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 awaiting SI and where 60 days have elapsed.
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 received an SI (line 3 and line 4), the number of submissions that missed the SI goal or are awaiting SI after 60 days as of quarter end (line 6), and the number of submissions that were found NSE without 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 RTA accepted or passed TS 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 V Decision Performance Goal– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA Decision	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA Decisions (line 3) and pending submissions that have missed the MDUFA goal (line 6).

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA V 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 Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA V 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 V decision.

Table 6.6 and Tables 6.6.x**510(k) MDUFA V Performance Metric - Rates 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 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 V 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 Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of LDT submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA Decision over 90 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA decision within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA Decision (line 3) and pending LDT submissions that already missed the MDUFA goal (line 6).

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA V 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 Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA V decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA Decision within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA Decision (line 3) and pending non-LDT IVD submissions that already missed 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/TS 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 decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Currently Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA V decision and the 2% of submissions with the highest number of Total Days to MDUFA decision.
7	Average Total Time to MDUFA 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 Decision	The 90 th percentile of FDA days to MDUFA decision on 3 rd Party 510(k) submissions received in this fiscal year

Section 8 De Novo MDUFA V 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 First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1 st 15 days of the first RTA/TS review cycle. Decision codes are RTAN, RTAS, RTAW and TSRN) decision in the first RTA review cycle. An RTAN/TSRN decision is automatically recorded by CTS at the end of day 15 of RTA/TS review, if no other RTA/TS decision is made. This RTA/TS decision means that the 510(k) is deemed accepted/deemed to have passed Technical Screening. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (see box 5 in flowchart).
5	Number Without a RTA or TS Review and <= 15 Days Since Date Received	Number Received (line 1) that are still in the first RTA /TS review cycle and have not yet reached the 15 th day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).

Tables 8.2 and Tables 8.2.x De Novo MDUFA V Decision Performance Goal– Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent De Novo definitions.
2	Non-MDUFA Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA V Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already have missed the MDUFA goal (line 6).

Table 8.3 and Tables 8.3.x De Novo Time to MDUFA V 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 decision (line 2).
2	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA 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 decision.

Table 8.4 and Tables 8.4.x**De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA V Decisions	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA 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 submissions with MDUFA decision made beyond 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 V Decision Metrics – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA V Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA V Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA V Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA V Decision over 150 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA V review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA Decisions (line 3) and pending LDT submissions that have missed the MDUFA goal (line 6).

Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA V 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 Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA 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 Decisions (line 3) and pending non-LDT IVD submissions that have missed 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	Number of De Novo submissions accepted in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept/Technical Screening	Average number of days in the first RTA/TS review cycle

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 received in this fiscal year (includes Q-Sub types tracked as Pre-Sub Meeting, Pre-Sub Written Feedback, Breakthrough Interaction, and STeP Interaction).
2	Interactions for Breakthrough Designated Products & Products Included in STeP	Number of Breakthrough Interactions and STeP Interactions received in this fiscal year (excludes submissions tracked as Pre-Sub Meeting and Pre-Sub Written Feedback).
3	Number Closed Before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
4	Number Accepted First RTA Cycle	Number Received (line 1) that had “RTA Accepted” (RTAA) decision in the first RTA review cycle entered by reviewer and submissions considered accepted upon receipt
5	Number Without First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that had a “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. The data contained in this row should be combined with the data in the row above, “Number Accepted First RTA Cycle” to determine the total number of submissions accepted on the first RTA cycle.
6	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
7	Number Not Accepted First RTA Cycle	Number of submissions received in this fiscal year (line 1) that had a “Refuse to accept” (RTA1) decision in the first RTA review cycle.
8	Rate of Submissions Not Accepted for Review on First RTA Cycle	Number Not Accepted First RTA Cycle (line 7) expressed as a percentage of the sum of the Number Accepted First RTA Cycle (line 4), Number Without First Cycle RTA Review and > 15 Days Since Date Received (line 5), and Number Not Accepted First RTA Cycle (line 7).

Table 9.2 and Tables 9.2.x MDUFA V Pre-Sub Performance Goals – Definitions

#	Measure	Description
1	Number Accepted / Eligible for MDUFA Action	Number of submissions that passed via the RTA process as of quarter end date and Breakthrough/STeP Interactions
2	Number with Non-MDUFA Action	Number of submissions accepted (line 1) and closed with a non-MDUFA action (WTDR, JPND, JTRX, CLLR). Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.
3	Number with MDUFA Action	Number of submissions accepted (line 1) with a MDUFA action (EMAL, EMFB).
4	Written Feedback Provided Within Goal	Number of submissions with a MDUFA action (line 3) made by the MDUFA review goal (day 70 or 5 days prior to the meeting, whichever is sooner).
5	Number Pending MDUFA Action	Number of submissions accepted (line 1) still under review and pending feedback.
6	Pending MDUFA Action Past Goal	Number of submissions pending a MDUFA action (line 5) that have already missed the MDUFA review goal.
7	Number in MDUFA Cohort (up to max 4300)	<p>Number of submissions accepted with a MDUFA action (line 3) plus the number of submissions accepted and pending a MDUFA action (line 5).</p> <p>If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027.</p> <p>If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027.</p> <p>If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.</p>
8	Current Performance Percent Within Goal	Number of submissions with MDUFA actions made by the MDUFA review goal (line 4) expressed as a percentage of the sum of the number of submissions with a MDUFA action (line 3) and the number of submissions pending a MDUFA action and already passed the MDUFA review goal (line 6).

Table 9.3 and Tables 9.3.x**MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort) – Definitions**

#	Measure	Description
1	Number with Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA V 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 V 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 V 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 V 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 V 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 V 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 V Decision EMAL or EMFB (line 1).

Table 9.4 and Tables 9.4.x**MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort) - 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**MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort) - Definitions**

#	Measure	Description
1	Number of Meetings Required	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date. Number of meetings requested and then held after written feedback is provided.
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 V Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 150 FDA Days	Number of submissions with MDUFA V decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA V Decision for more than 150 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA V Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.4 CLIA Waiver (with Panel Review) MDUFA V Decision Performance Goals) – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 320 FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V 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 V Decision - Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V 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 V Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA V 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 V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 180 FDA Days	Number of submissions with MDUFA V decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 180 FDA days	Number of submissions pending MDUFA V Decision for more than 180 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA V Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA V Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA V 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 V Decisions	Number of submissions closed with non-MDUFA V decisions.
3	MDUFA V Decisions	Number of submissions closed with MDUFA V decisions.
4	MDUFA V Decisions within 320FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V 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 V Decision – Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision, and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V 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 13 Total Product Life Cycle Advisory Program (TAP)

Table 13.1 TAP Teleconference Engagement Performance Goal – Definitions

#	Measure	Description
1	Teleconferences Requested	Number of Teleconferences requested
2	Closed before Teleconference	Number of Teleconferences Requested (line 1) that were closed with a final decision before Teleconference Held (e.g., “Withdrawn by Sponsor/Applicant” (WTDR))
3	Teleconferences Held	Number of Teleconferences Requested (line 1) that had a final decision (e.g., “Teleconference Held” (TCON))
4	Teleconferences Held Within 14 Days	Number of Teleconferences Requested (line 1) that had a final decision (e.g., “Teleconference Held” (TCON)) within 14 days
5	Teleconferences Pending	Number of Teleconferences Requested (line 1) that are under review without a final decision
6	Teleconferences Pending Over 14 Days	Number of Teleconferences Requested (line 1) that are under review without a final decision and where 14 days have elapsed.
7	Current Performance Percent Within 14 Days	Number of Teleconferences Held Within 14 Days (line 4) expressed as a percentage of the sum of the Teleconferences Held (line 3) and Teleconferences Pending Over 14 Days (line 6)

Table 13.2 TAP Written Feedback (Biocompatibility/Sterility) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on Biocompatibility and Sterility topics(s)
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 21 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 21 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 21 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 21 days have elapsed.
7	Current Performance Percent Within 21 Days	Number of Written Feedback Provided Within 21 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 21 Days (line 6)

Table 13.3 TAP Written Feedback (Other) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on topics(s) other than Biocompatibility and Sterility
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 40 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 40 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 40 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 40 days have elapsed.
7	Current Performance Percent Within 40 Days	Number of Written Feedback Provided Within 40 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 40 Days (line 6)

Table 13.4 TAP Pilot Enrollment Data– Definitions

#	Measure	Description
1	Enrollment Requests Received	Number of TAP Pilot Enrollment Requests received in the fiscal year.
2	Enrollment Requests Accepted	Number of TAP Pilot Enrollment Requests accepted in the fiscal year.
3	Enrollment Requests Not Accepted	Number of TAP Pilot Enrollment Requests not accepted in the fiscal year.
4	Enrollment Requests Pending	Number of TAP Pilot Enrollment Requests still under review.

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 31 December 2025**

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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0	1	1	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	3	0	1	1	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	0.00%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0	1	1	
Number Accepted	3	0	1	1	
Completed RTF	3	0	1	1	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	N/A	0.00%	0.00%	

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

Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	3	0	1	1	
SI Goal Met	3	0	1	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	N/A	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	3	0	1	0	
Average Number of FDA Days to Substantive Interaction	88.33	0.00	90.00	0.00	
20th Percentile FDA Days to Substantive Interaction	87	0	90	0.00	
40th Percentile FDA Days to Substantive Interaction	88	0	90	0.00	
60th Percentile FDA Days to Substantive Interaction	88	0	90	0.00	
80th Percentile FDA Days to Substantive Interaction	89	0	90	0.00	
Maximum FDA Days to Substantive Interaction	90	0	90	0.00	

Table 1.5 CBER - PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	3	0	1	1	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	3	0	1	0	
MDUFA V Decision Goal Met	3	0	1	0	
PMAs Pending MDUFA V Decision	0	0	0	1	
PMAs Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	N/A	100.00%	N/A	

Table 1.6 CBER - PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days				
Number of PMAs Filed	0	0	0	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	0	0	0	0	
MDUFA V Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA V Decision	0	0	0	0	
PMAs Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	3	0	1	0	
Average FDA Days to MDUFA V Decision	177.00	0.00	142.00	0.00	
20th Percentile FDA Days to MDUFA V Decision	175	0	142	0	
40th Percentile FDA Days to MDUFA V Decision	178	0	142	0	
60th Percentile FDA Days to MDUFA V Decision	179	0	142	0	
80th Percentile FDA Days to MDUFA V Decision	180	0	142	0	
Maximum FDA Days to MDUFA V Decision	180	0	142	0	
Average Industry Days to MDUFA V Decision	0.00	0.00	62.00	0.00	
20th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
60th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
80th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
Maximum Industry Days to MDUFA V Decision	0	0	62	0	
Average Total Days to MDUFA V Decision	177.00	0.00	204.00	0.00	
20th Percentile Total Days to MDUFA V Decision	175	0	204	0	
40th Percentile Total Days to MDUFA V Decision	178	0	204	0	
60th Percentile Total Days to MDUFA V Decision	179	0	204	0	
80th Percentile Total Days to MDUFA V Decision	180	0	204	0	
Maximum Total Days to MDUFA V Decision	180	0	204	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	0	0	0	0	
Average FDA Days to MDUFA V Decision	0.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
40th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
60th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
80th Percentile FDA Days to MDUFA V Decision	0	0	0	0	
Maximum FDA Days to MDUFA V Decision	0	0	0	0	
Average Industry Days to MDUFA V Decision	0.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
80th Percentile Industry Days to MDUFA V Decision	0.00	0.00	0	0	
Maximum Industry Days to MDUFA V Decision	0	0	0	0	
Average Total Days to MDUFA V Decision	0	0	0.00	0.00	
20th Percentile Total Days to MDUFA V Decision	0	0	0	0	
40th Percentile Total Days to MDUFA V Decision	0	0	0	0	
60th Percentile Total Days to MDUFA V Decision	0	0	0	0	
80th Percentile Total Days to MDUFA V Decision	0	0	0	0	
Maximum Total Days to MDUFA V Decision	0	0	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	0	1	1	
Number with MDUFA V Decision	3	0	1	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	N/A	0.00%	N/A	
Rate of Not Approvable	0.00%	N/A	0.00%	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0	0	
Number With MDUFA V Decision	0	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	N/A	N/A	N/A	N/A	
Rate of Not Approvable	N/A	N/A	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	0	0	0	0	
MDUFA V Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA V Decision	0	0	0	0	
PMAs Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	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 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	0	0	0	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	0	0	0	0	
MDUFA V Decision Goal Met	0	0	0	0	
PMAs Pending MDUFA V Decision	0	0	0	0	
PMAs Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	N/A	N/A	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 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 90 FDA Days				
Eligible for SI	4	5	8	0	
SI Goal Met	2	5	8	0	
SI Goal Not Met	2	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%	N/A	

Table 2.2 CBER - PMA 180-Day Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 180 FDA Days				
Supplements Received	4	5	8	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	4	5	6	0	
MDUFA V Decision Goal Met	3	5	6	0	
Supplements Pending MDUFA V Decision	0	0	2	0	
Supplements Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	75.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	8	0	
Number with MDUFA V Decision	4	5	6	0	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	25.00%	20.00%	0.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	206.00	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	121.00	N/A	N/A	N/A	

Section 3 PMA Real-Time Supplements - Center Level Metric

Table 3.1 CBER - PMA Real-Time Supplements MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	3	2	2	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	3	2	2	0	
MDUFA V Decision Goal Met	3	2	2	0	
Supplements Pending MDUFA V Decision	0	0	0	0	
Supplements Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2	2	0	
Number With MDUFA V Decision	3	2	2	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	0%	0%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	41	33	52	11	
Closed Before First RTA or TS Action ¹	0	4	2	0	
Number Accepted or Passed TS on First Cycle ²	30	25	40	5	
Number Without a RTA or TS Review and > 15 Days Since Date Received ³	0	0	1	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received ¹	0	0	0	2	
Number Not Accepted or Failed TS on First Cycle ²	11	4	9	4	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle ²	26.83%	13.79%	18.00%	44.44%	

1. Includes converted submissions that have not yet or did not receive a first cycle RTA or TS action.

2. Excludes converted submissions that have not yet received a first cycle RTA or TS action.

3. The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 6.2 CBER - 510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% SI Within 60 FDA Days				
Eligible for SI	39	29	45	9	
Deleted or Withdrawn Prior to SI	0	0	0	0	
SI Within 60 FDA Days	37	29	44	0	
SI Over 60 FDA Days	2	0	1	0	
SI Pending Within 60 FDA Days	0	0	0	0	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	94.87%	100.00%	97.78%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	39	29	45	0	
Average Number of FDA Days to Substantive Interaction	55.53	56.79	51.64	0.00	
20th Percentile FDA Days to Substantive Interaction	51	56	46	0	
40th Percentile FDA Days to Substantive Interaction	56	57	57	0	
60th Percentile FDA Days to Substantive Interaction	59	58	59	0	
80th Percentile FDA Days to Substantive Interaction	60	60	60	0	
Maximum FDA Days to Substantive Interaction	90	60	62	0	

Table 6.4 CBER - 510(k) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	39	29	45	9	
Non-MDUFA V Decision	3	3	2	0	
MDUFA V Decision (SE/NSE)	36	26	32	0	
MDUFA V Decision Within 90 FDA Days	36	26	32	0	
510(k)s Pending MDUFA V Decision	0	0	11	9	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.33	1.54	1.47	0.00	
Number With MDUFA V Decision	36	26	32	0	
Average Number of FDA Days to MDUFA V Decision	77.33	80.08	68.96	0.00	
20th Percentile FDA Days to MDUFA V Decision	69	73	28	0	
40th Percentile FDA Days to MDUFA V Decision	84	86	77	0	
60th Percentile FDA Days to MDUFA V Decision	89	87	85	0	
80th Percentile FDA Days to MDUFA V Decision	90	89	88	0	
Maximum FDA Days to MDUFA V Decision	90	90	90	0	
Average Number of Industry Days to MDUFA V Decision	48.92	82.12	41.09	0.00	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	0	102	29	0	
80th Percentile Industry Days to MDUFA V Decision	115	180	73	0	
Maximum Industry Days to MDUFA V Decision	315	207	193	0	
Average Number of Total Days to MDUFA V Decision	126.25	162.19	110.06	0.00	
20th Percentile Total Days to MDUFA V Decision	81	79	34	0	
40th Percentile Total Days to MDUFA V Decision	88	90	84	0	
60th Percentile Total Days to MDUFA V Decision	90	188	111	0	
80th Percentile Total Days to MDUFA V Decision	90	266	161	0	
Maximum Total Days to MDUFA V Decision	375	288	269	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	39	29	45	9	
Number With MDUFA V Decision	36	26	32	0	
Number of SE Decision	35	20	28	0	
Number of NSE Decision	1	6	4	0	
Number of Withdrawal	2	1	1	0	
Number of Deleted	1	2	1	0	
Rate of SE Decision	97.22%	76.92%	87.50%	N/A	
Rate of NSE Decision	2.78%	23.08%	12.50%	N/A	
Rate of Withdrawal	5.13%	3.45%	2.22%	N/A	
Rate of Deleted	2.56%	6.90%	2.22%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

Table 6.8 CBER - LDT 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	0	0	0	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision (SE/NSE)	0	0	0	0	
MDUFA V Decision Within 90 FDA Days	0	0	0	0	
510(k)s Pending MDUFA V Decision	0	0	0	0	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	

Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	7	4	3	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision (SE/NSE)	7	4	3	0	
MDUFA V Decision Within 90 FDA Days	7	4	3	0	
510(k)s Pending MDUFA V Decision	0	0	0	0	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	N/A	

Section 8 De Novo Center Level Metrics

Table 8.1 CBER - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	1	0	1	0	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	0	0	1	0	
Number Without a RTA or TS Review and > 15 Days Since Date Received ¹	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	1	0	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%	N/A	0.00%	N/A	

1.The data contained in this row should be combined with the data in the row above, “Number Accepted or Passed TS on First Cycle”, to determine the total number of submissions accepted or passed on the first RTA or TS cycle.

Table 8.2 CBER - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	1	0	1	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	1	0	0	0	
MDUFA Decision Within 150 FDA Days	1	0	0	0	
De Novos Pending MDUFA Decision	0	0	1	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	N/A	N/A	N/A	

Table 8.3 CBER - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00	0.00	0.00	0.00	
Number With MDUFA Decision	1	0	0	0	
Average FDA Days to MDUFA Decision	75.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA Decision	75	0	0	0	
40th Percentile FDA Days to MDUFA Decision	75	0	0	0	
60th Percentile FDA Days to MDUFA Decision	75	0	0	0	
80th Percentile FDA Days to MDUFA Decision	75	0	0	0	
Maximum FDA Days to MDUFA Decision	75	0	0	0	
Average Industry Days to MDUFA Decision	177.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA Decision	177	0	0	0	
40th Percentile Industry Days to MDUFA Decision	177	0	0	0	
60th Percentile Industry Days to MDUFA Decision	177	0	0	0	
80th Percentile Industry Days to MDUFA Decision	177	0	0	0	
Maximum Industry Days to MDUFA Decision	177	0	0	0	
Average Total Days to MDUFA Decision	252.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA Decision	252	0	0	0	
40th Percentile Total Days to MDUFA Decision	252	0	0	0	
60th Percentile Total Days to MDUFA Decision	252	0	0	0	
80th Percentile Total Days to MDUFA Decision	252	0	0	0	
Maximum Total Days to MDUFA Decision	252	0	0	0	

Table 8.4 CBER - De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	1	0	
Number With MDUFA Decision	1	0	0	0	
Number With Granted Decision	0	0	0	0	
Number With Declined Decision	1	0	0	0	
Number of Withdrawal	0	0	0	0	
Number of Deleted	0	0	0	0	
Rate of Granted Decision	0.00%	N/A	N/A	N/A	
Rate of Declined Decision	100.00%	N/A	N/A	N/A	
Rate of Withdrawal	0.00%	N/A	N/A	N/A	
Rate of Deleted	0.00%	N/A	N/A	N/A	

Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	

Table 8.6 CBER - LDT De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Table 8.7 CBER - Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	0	0	0	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	0	0	0	0	
MDUFA Decision Within 150 FDA Days	0	0	0	0	
De Novos Pending MDUFA Decision	0	0	0	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	68	62	75	20	
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1	4	1	
Number Closed Before First RTA Action	7	1	1	1	
Number Accepted First RTA Cycle ¹	59	60	74	15	
Number Without First Cycle RTA Review and > 15 Days Since Date Received ²	2	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	4	
Number Not Accepted First RTA Cycle	0	1	0	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	1.64%	0.00%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

2. The data contained in this row should be combined with the data in the row above, "Number Accepted First RTA Cycle" to determine the total number of submissions accepted on the first RTA cycle.

Table 9.2 CBER - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal ¹	FY 2024 90% / 80% Within MDUFA Goal ²	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	61	61	74	15	
Number with Non-MDUFA Action ³	3	0	0	0	
Number with MDUFA Action	58	61	74	3	
Written Feedback Provided Within Goal	55	61	74	3	
Number Pending MDUFA Action	0	0	0	12	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300) ⁴	58	61	74	15	
Current Performance Percent Within Goal	94.83%	100.00%	100.00%	100.00%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

3. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 CBER – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	58	61	74	3	
Average FDA Days to Written Feedback	59.38	60.79	60.30	48.00	
20th Percentile FDA Days to Written Feedback	55	54	55	39	
40th Percentile FDA Days to Written Feedback	60	61	59	51	
60th Percentile FDA Days to Written Feedback	64	65	65	58	
80th Percentile FDA Days to Written Feedback	69	69	68	59	
Maximum FDA Days to Written Feedback	72	70	70	60	

Table 9.4 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	0	0	0	0	
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00	0.00	0.00	

Table 9.5 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required ¹	24	31	26	1	
Meeting Minutes Submitted Within 15 Days of Meeting	21	26	22	1	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	
Meeting Minutes Past 15 Days of Meeting	3	5	4	0	
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0	0	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	83.87%	84.62%	100.00%	

1. Number of meetings requested and then held after written feedback is provided.

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	20	15	10	4	
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.07	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.06	0.00	0.00	

CBER – Annual General Metric Report for BLA/BLA Resubmissions
****Annual Metrics and Goals will be reported in the Annual Report****

Medical Devices

Guidance Documents

Pursuant to the MDUFA V Commitment Letter,¹ the table below includes all FDA guidance documents issued in FY 2026 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 V Commitment Letter are indicated as such.² 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).³ Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for FY 2026.

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2026

#	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	Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome	10/22/2025	Yes	Yes	Section 3002 of the 21st Century Cures Act	No
2	Q1	Quality Management System Information for Certain Premarket Submission Reviews www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-management-system-information-certain-premarket-submission-reviews	10/27/2025	Yes	No	N/A	A-List
3	Q1	Menstrual Products - Performance Testing and Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/menstrual-products-performance-testing-and-labeling-recommendations	10/28/2025	Yes	No	No	A-List
4	Q1	Cross-Center Master Files: Where to Submit www.fda.gov/regulatory-information/search-fda-guidance-documents/cross-center-master-files-where-submit	11/25/2025	Yes	No	N/A	No
5	Q1	⁴ eCopy Program for Medical Device Submissions	12/03/2025	Yes	No	N/A	No

¹ www.fda.gov/media/158308/download.

² CDRH provides the annotation of “yes” for guidance’s that are substantially related to the process. CDRH provides the annotation of “no” for guidance’s that contain a minimal amount of guidance related to the process.

³ [CDRH Proposed Guidance Development | FDA](#)

⁴ This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)

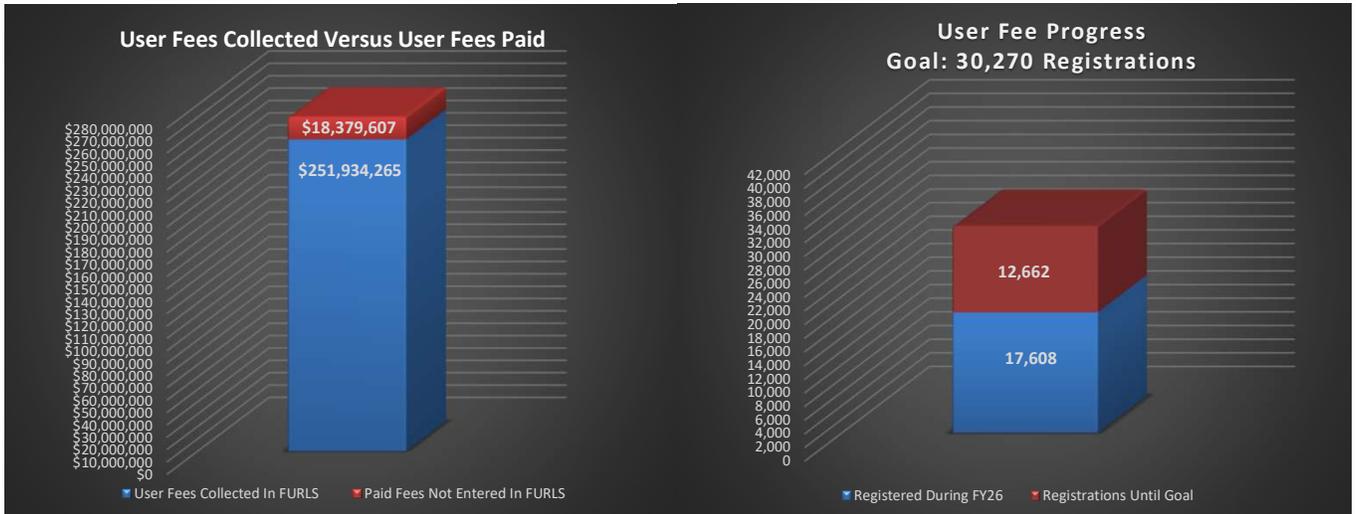
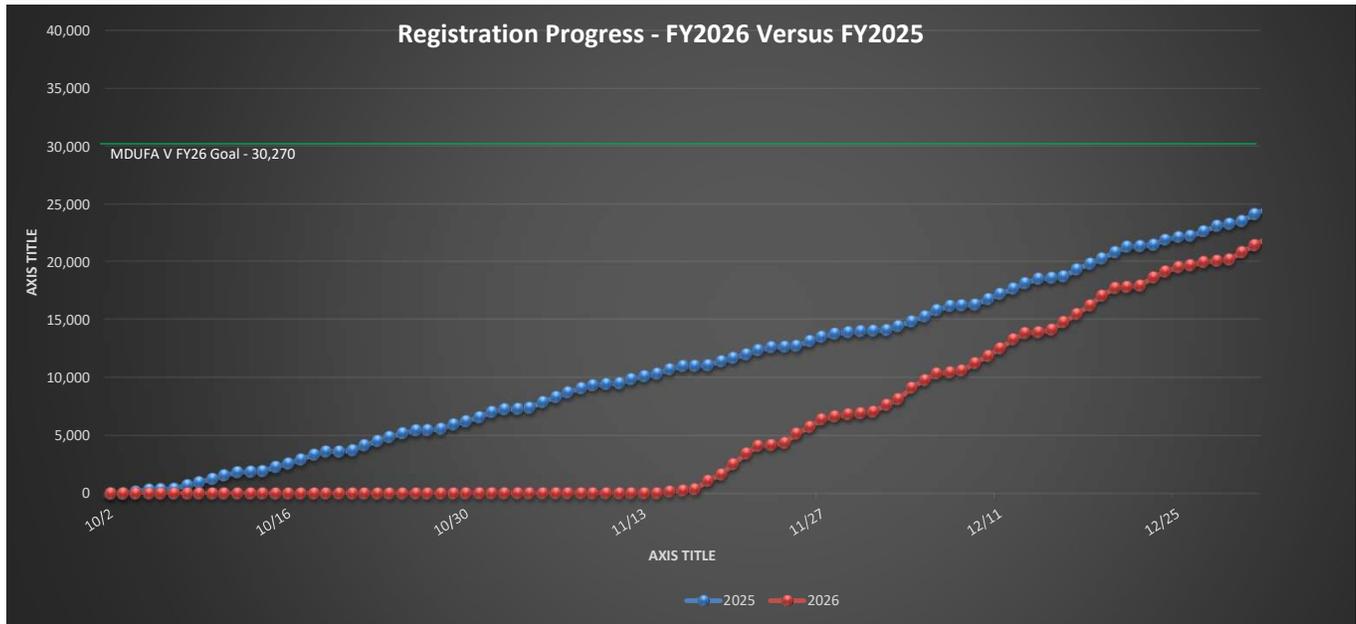
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
		www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions					
6	Q1	Study of Sex Differences in the Clinical Evaluation of Medical Products www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products	12/15/2025	Yes	No	N/A	No
7	Q1	Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices	12/15/2025	Yes	No	N/A	No
8	Q1	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices	12/18/2025	Yes	Yes	Section 3629 of the Food and Drug Omnibus Reform Act (FDORA) & MDUFA V Commitment Letter V.F.	A-List
9	Q1	Processes and Practices Applicable to Bioresearch Monitoring Inspections www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	12/19/2025	Yes	Yes	Section 3612 of the Food and Drug Omnibus Reform Act (FDORA)	No

Registrations and Listings

MDUFA V Registrations - 1st Quarter Summary FY2026*

Current Active Registrations by Type	FY26 Q1			FY25 Year End Active Totals			FY26 vs End FY25
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	4842	9066	13908	6,499	12,045	18,544	75.00%
Contract Manufacturer	893	1676	2569	1,267	2,101	3,368	76.28%
Contract Sterilizer	72	154	226	77	181	258	87.60%
Specification Developer	998	425	1423	1,579	551	2,130	66.81%
Reprocessor of Single Use Devices	15	4	19	23	4	27	70.37%
U.S. Manufacturer of Export Only Devices	57		57	113	0	113	50.44%
Repackager/Relabeler	684	123	807	1,057	189	1,246	64.77%
Remanufacturer	7	4	11	15	8	23	47.83%
Foreign Exporter/Private Label Distributor	0	717	717		1,064	1,064	67.39%
Initial Importer	2131	0	2131	3,063		3,063	69.57%
Unknown	0	0	0	0	0	0	0.00%
Total:	9699	12169	21868	13,693	16,143	29,836	73.29%

*Data is current as of 12/31/2025



Medical Device User Fee Collections

Q1 FY 2026 Medical Device User Fee Collections as of December 31, 2025 Excludes Unearned Revenue					
	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$249,083,159	\$0	\$249,083,159		
Application Fees	\$24,116,762	-\$21,723	\$24,095,039		
Total	\$273,199,920	-\$21,723	\$273,178,197	\$478,165,880	57%
Medical Device User Fee Collection History Excludes Unearned Revenue, Includes Refunds					
	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
MD I	\$21,620,549	\$26,281,779	\$31,738,775	\$34,425,417	\$28,031,569
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
MD II	\$47,794,823	\$56,962,602	\$63,699,312	\$69,720,145	\$65,324,184
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
MD III	\$101,306,430	\$122,346,416	\$136,098,825	\$147,165,318	\$137,782,995
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
MD IV	\$193,896,895	\$208,692,116	\$215,697,178	\$275,338,627	\$269,130,850
	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
MD V	\$322,347,363	\$340,209,427	\$411,483,643	\$273,178,197	

Number of Discretionary Fee Waivers or Reductions

MDUFA V Commitment Letter - VI. Performance Reports

2.12. Number of discretionary fee waivers or reductions granted by type of submission^{1/}

CDRH Data 1st Quarter FY 2026 by Submission type	# Waived	# Reduced
Full Fee applications^{2/}	0	0
PMA	0	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	3
De Novo Classification	0	19
180-Day Supplements	1	3
Real-Time Supplements	0	8
510(k)s	14	369
30-day Notices /135 day supplements*	4	17
513(g)s	0	5
PMA Annual Report		
Total	19	424

^{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. Counts are cumulative for the Fiscal Year.

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

*135-day supplements were initially received and paid as 30-day notices; totals are combinations of both cohorts