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**Agenda for Quarterly Meeting on  
MDUFA V (FY 2023-2027) Performance  
November 20, 2025, 3:00 – 4:00 pm  
Teams**

**Welcome –**

**FDA MDUFA Performance — Actions through September 30, 2025**

- Report on performance goals for 4<sup>th</sup> Quarter FY 2025

**Guidance Development**

**Registration and Listing**

**Qualitative Update on Finances – 4<sup>th</sup> Quarter FY 2025**

- User fee receipts through the 4<sup>th</sup> Quarter FY2025
- Carry over balance

**Annual Hiring Goals Update**

**Reviewer to Manager Ratio**

**Return on Investment**

**Quality Management Update**

- Quality Management Annual Report
- Planning for FY 2026 audits
- Summary of FY 2025 audits (including deficiency audits) conducted
- Independent Assessment of Review Process Management

**Quarterly Update on  
Medical Device Performance Goals  
---- MDUFA V CDRH Performance Data ----  
Actions through 30 September 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***

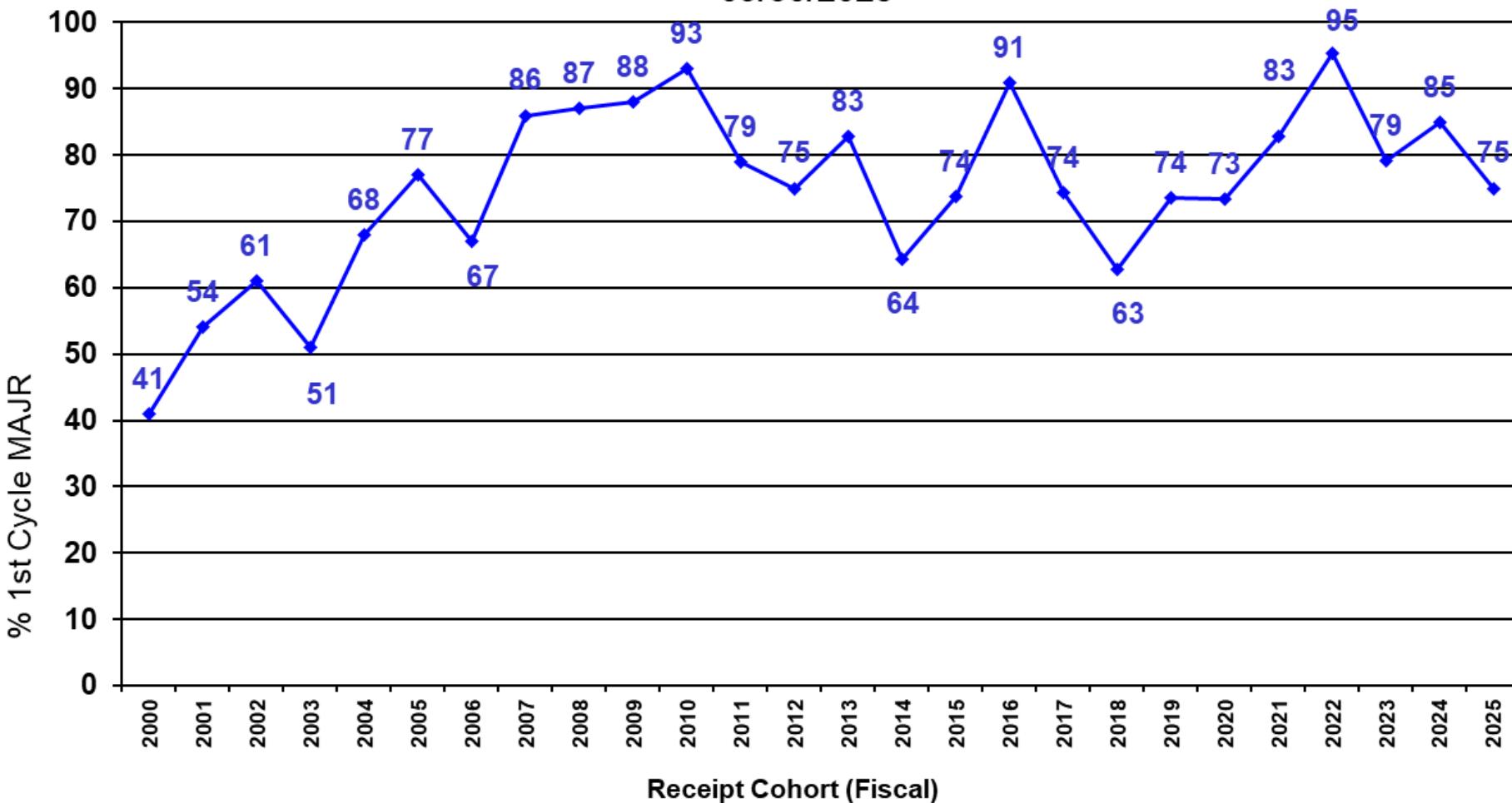
- OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
- OHT2: Office of Cardiovascular Devices
- OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
- OHT4: Office of Surgical and Infection Control Devices
- OHT5: Office of Neurological and Physical Medicine 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.**

# PMAs

## Q4FY2025

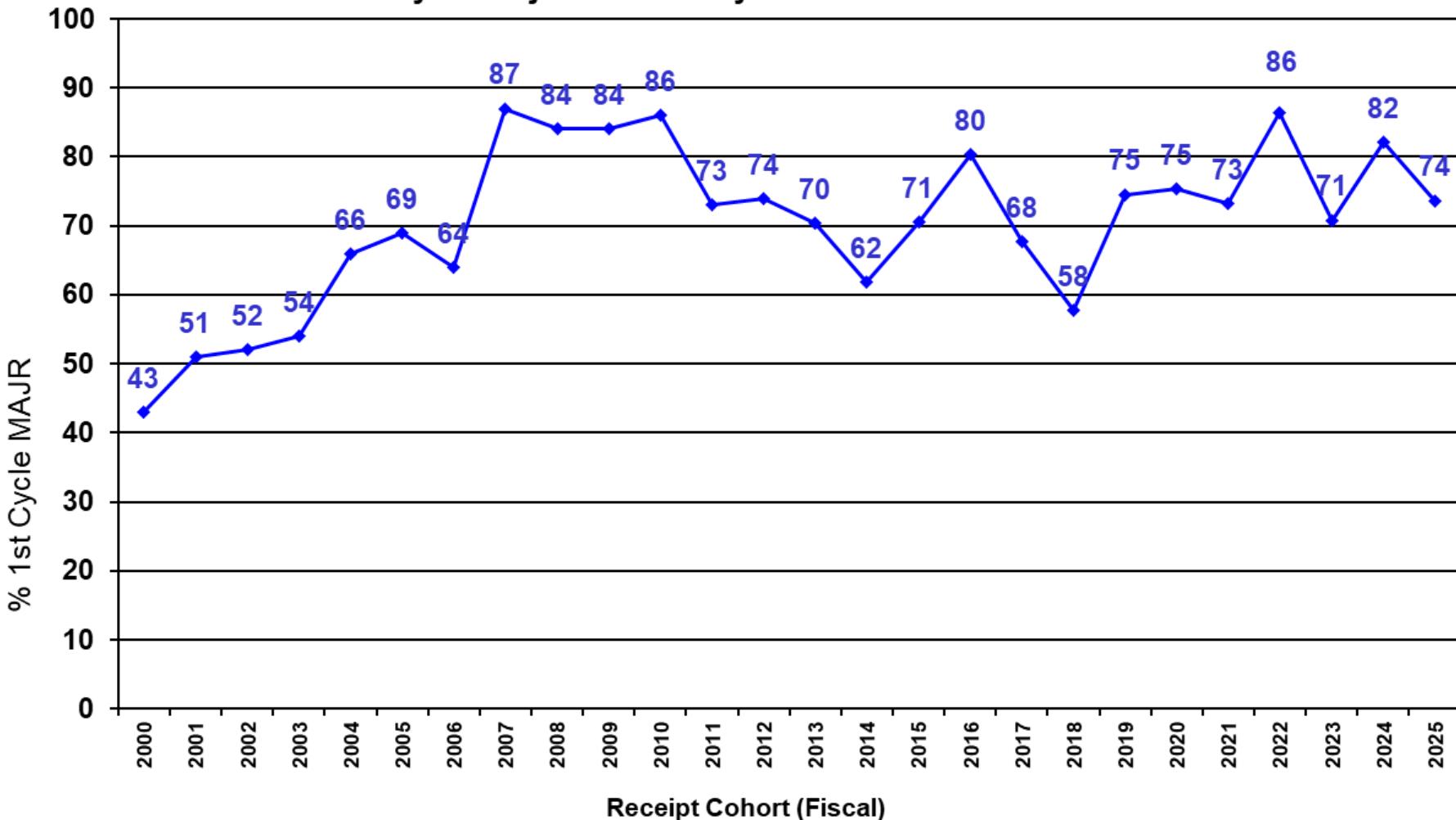
## PMA Originals Filed as of 06/30/2025: 1st Cycle Major Deficiency Rate as of 09/30/2025



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.

**PMA Originals and Panel track Supplements Filed as of 06/30/2025: 1st  
Cycle Major Deficiency Rate as of 09/30/2025**

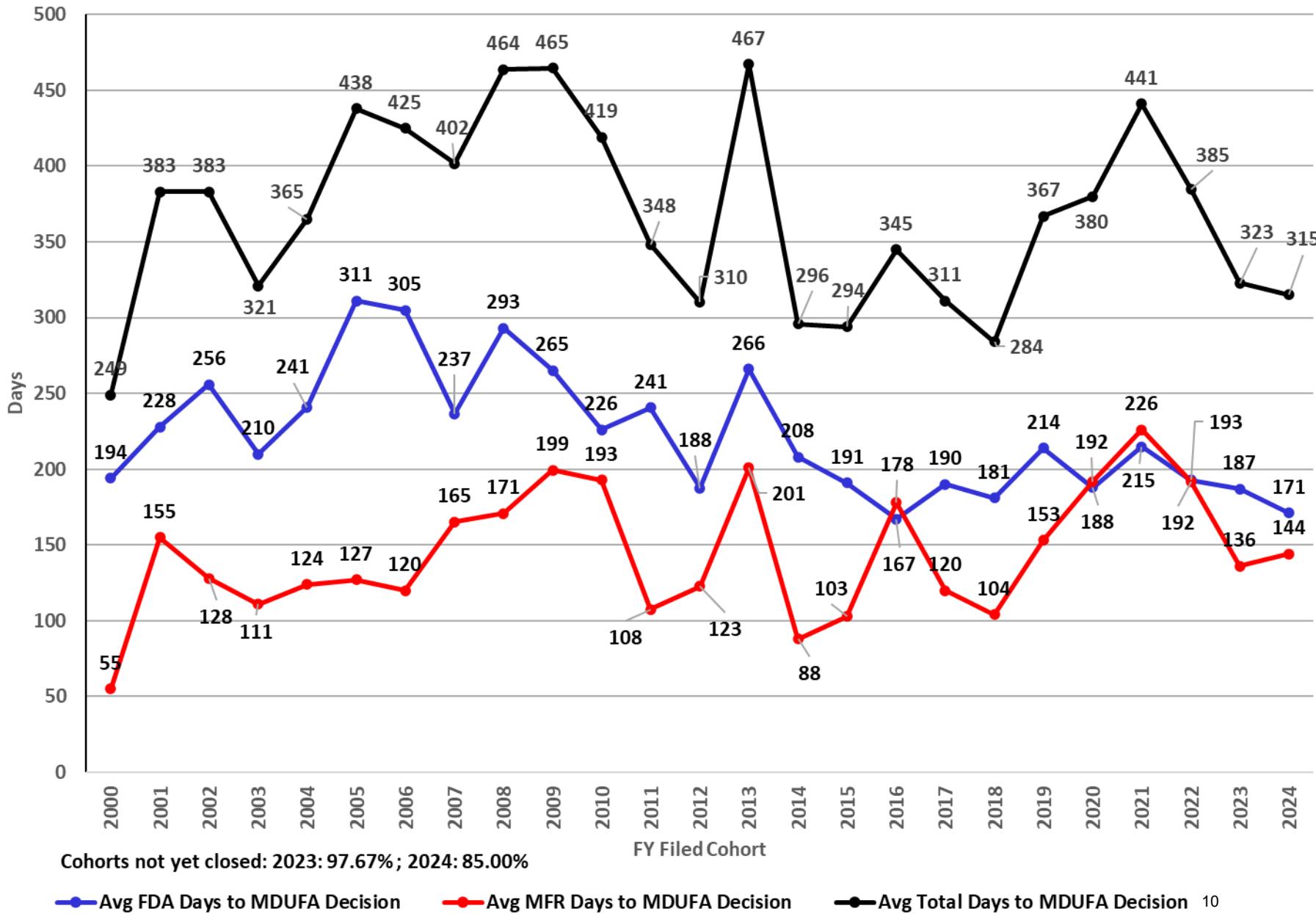


Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submission rec'd, accepted & filed as of 6/30/25.

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

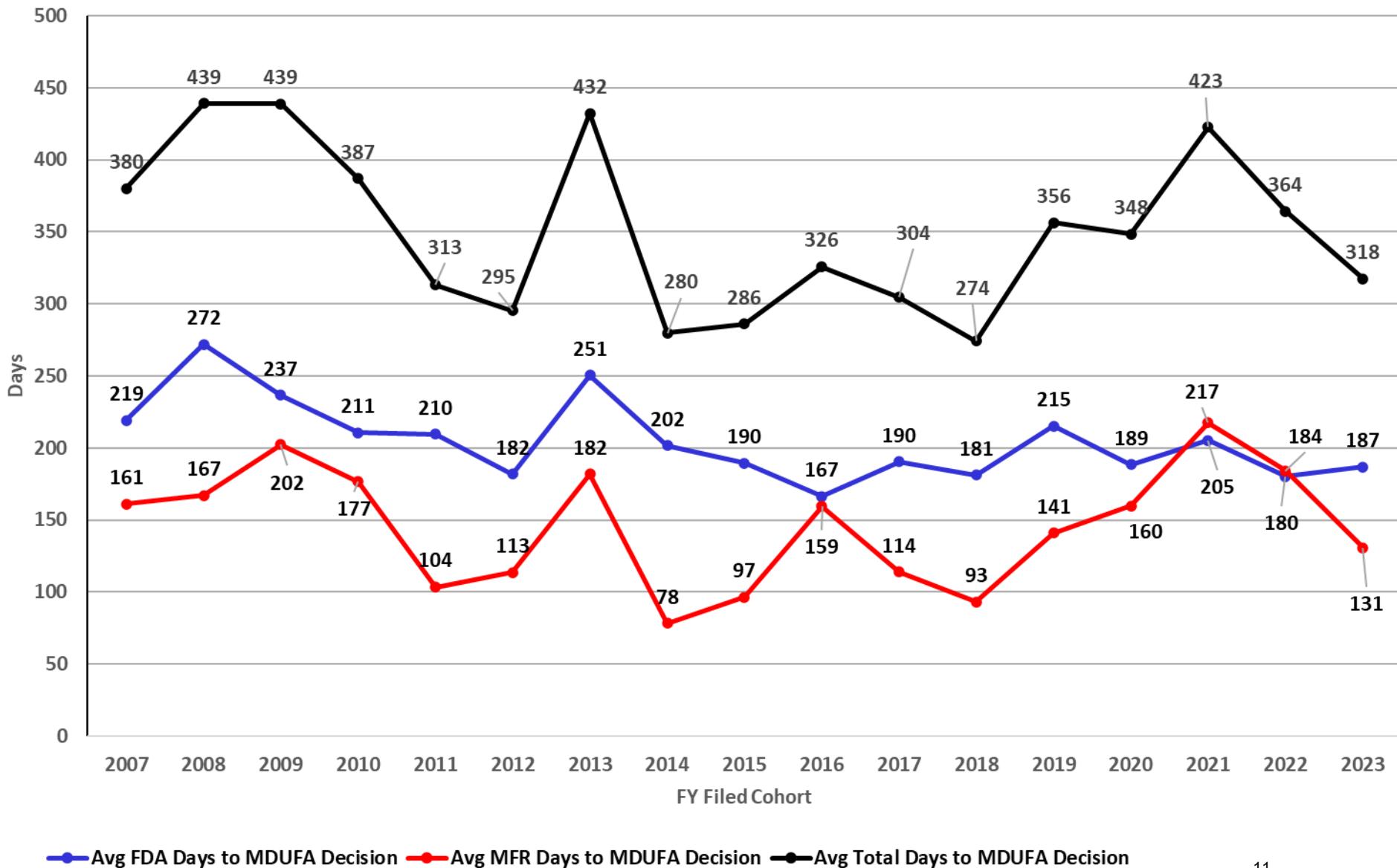
◆ % 1st Cycle MAJR PMAO/PTS

## PMA Originals Filed As Of 09/30/2025: Average Time to MDUFA Decision

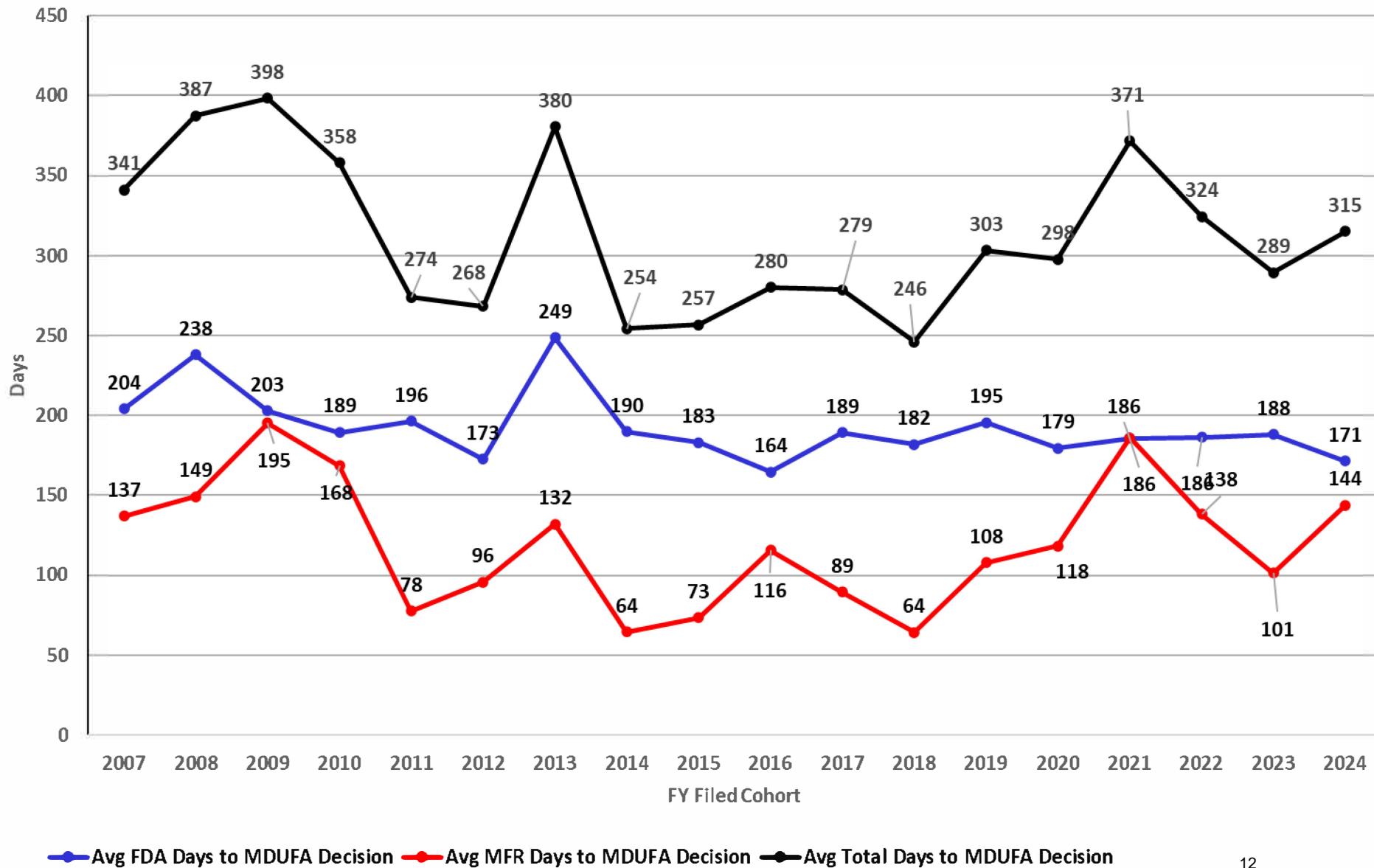


## PMA Originals Filed As Of 9/30/2025: Average Time to MDUFA Decision

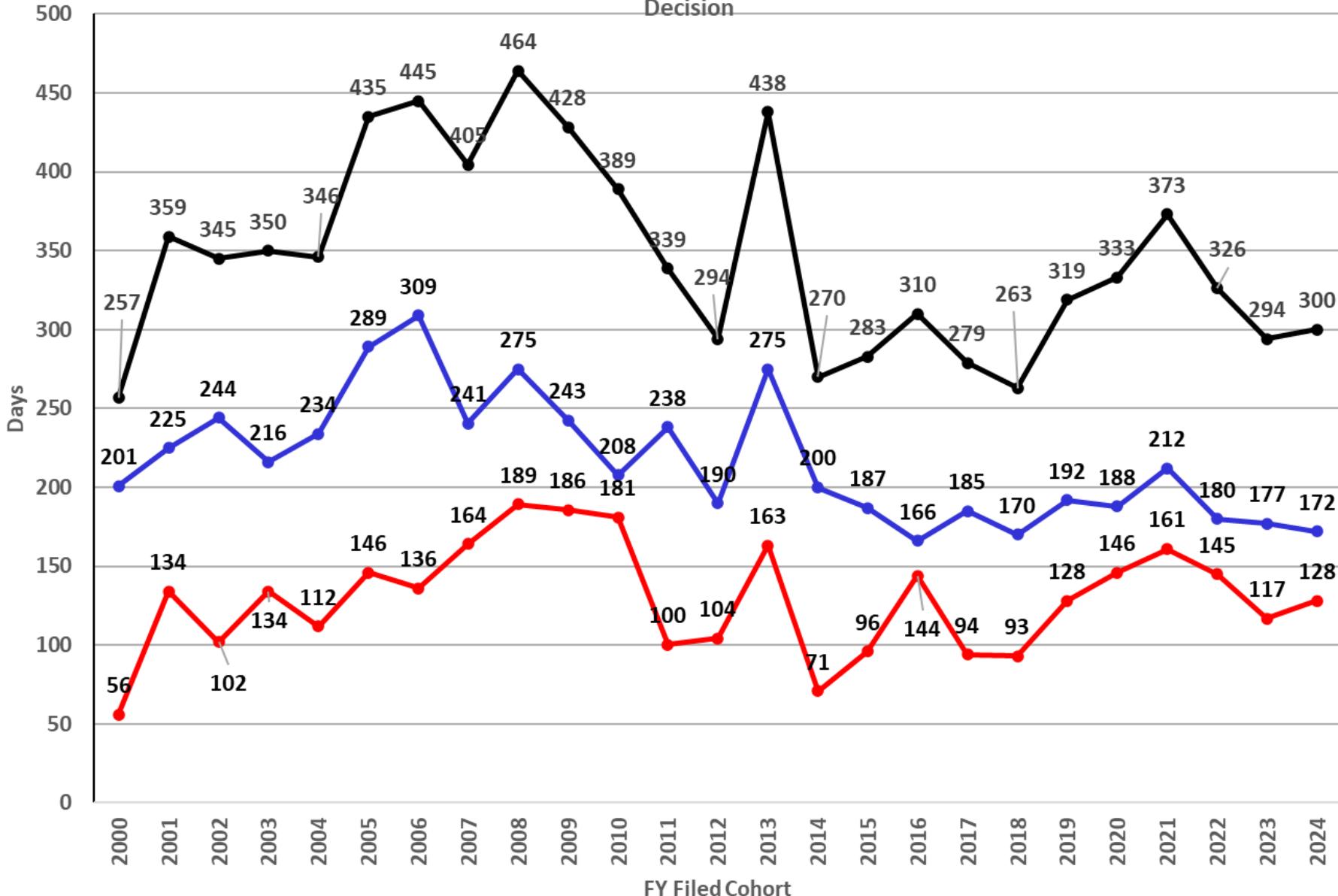
Comparison of Cohorts at 97.67% Closure



**PMA Originals Filed As Of 9/30/2025: Average Time to MDUFA Decision**  
**Comparison of Cohorts at 85.00% Closure**



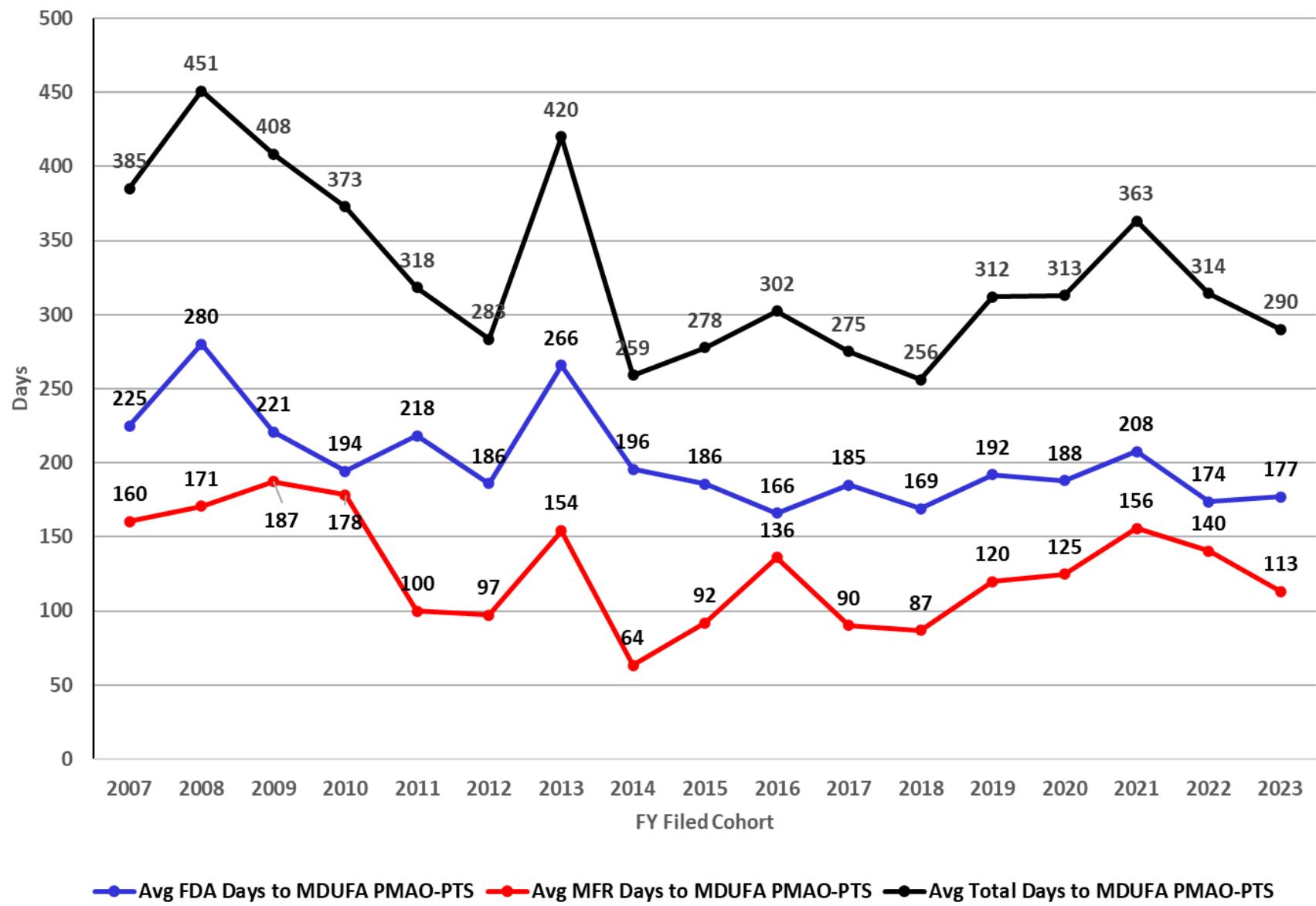
# PMA Originals and Panel Track Supplements Filed As Of 09/30/2025: Average Time to MDUFA Decision



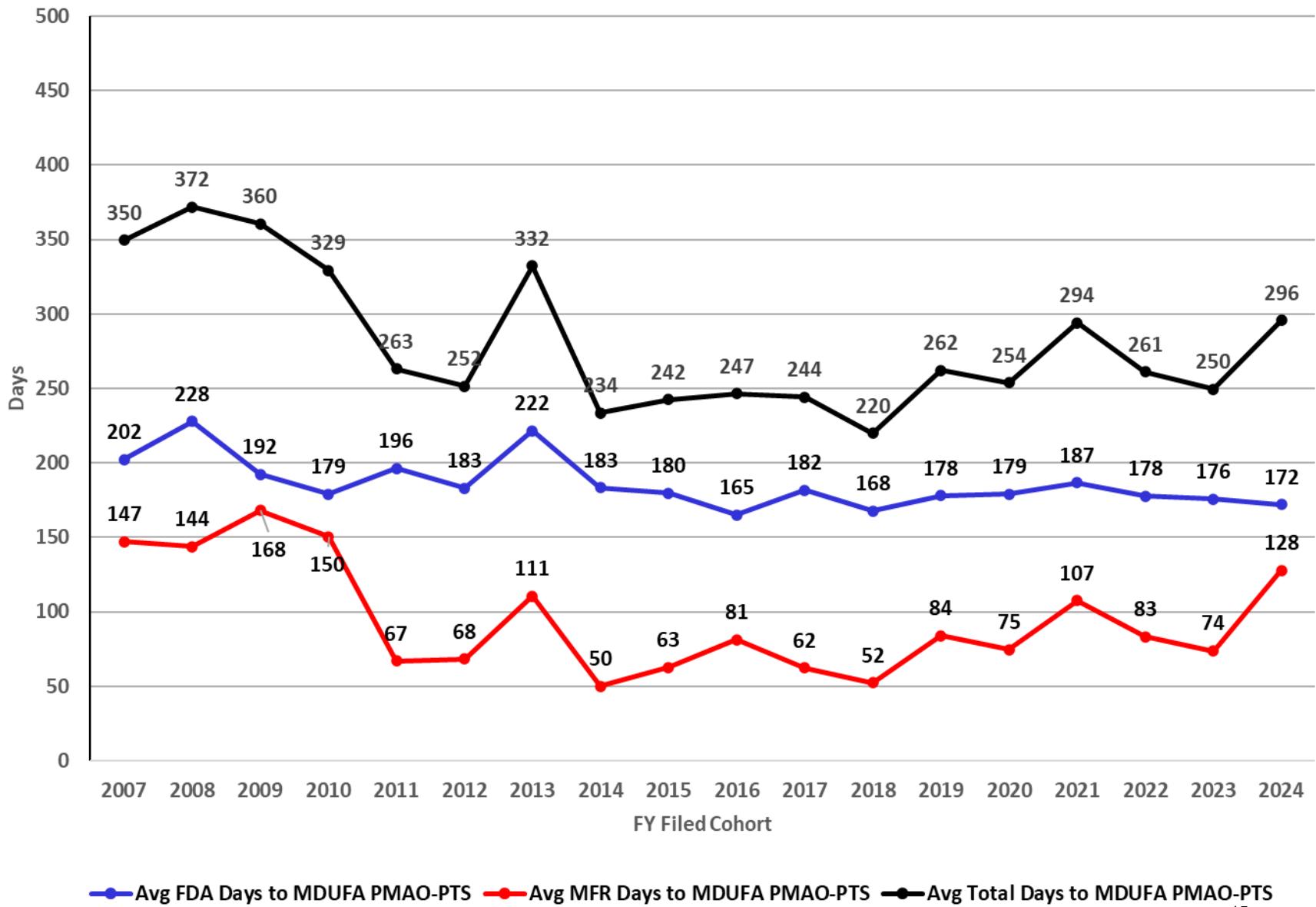
Cohorts not yet closed: 2023: 98.61%; 2024: 83.58%

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

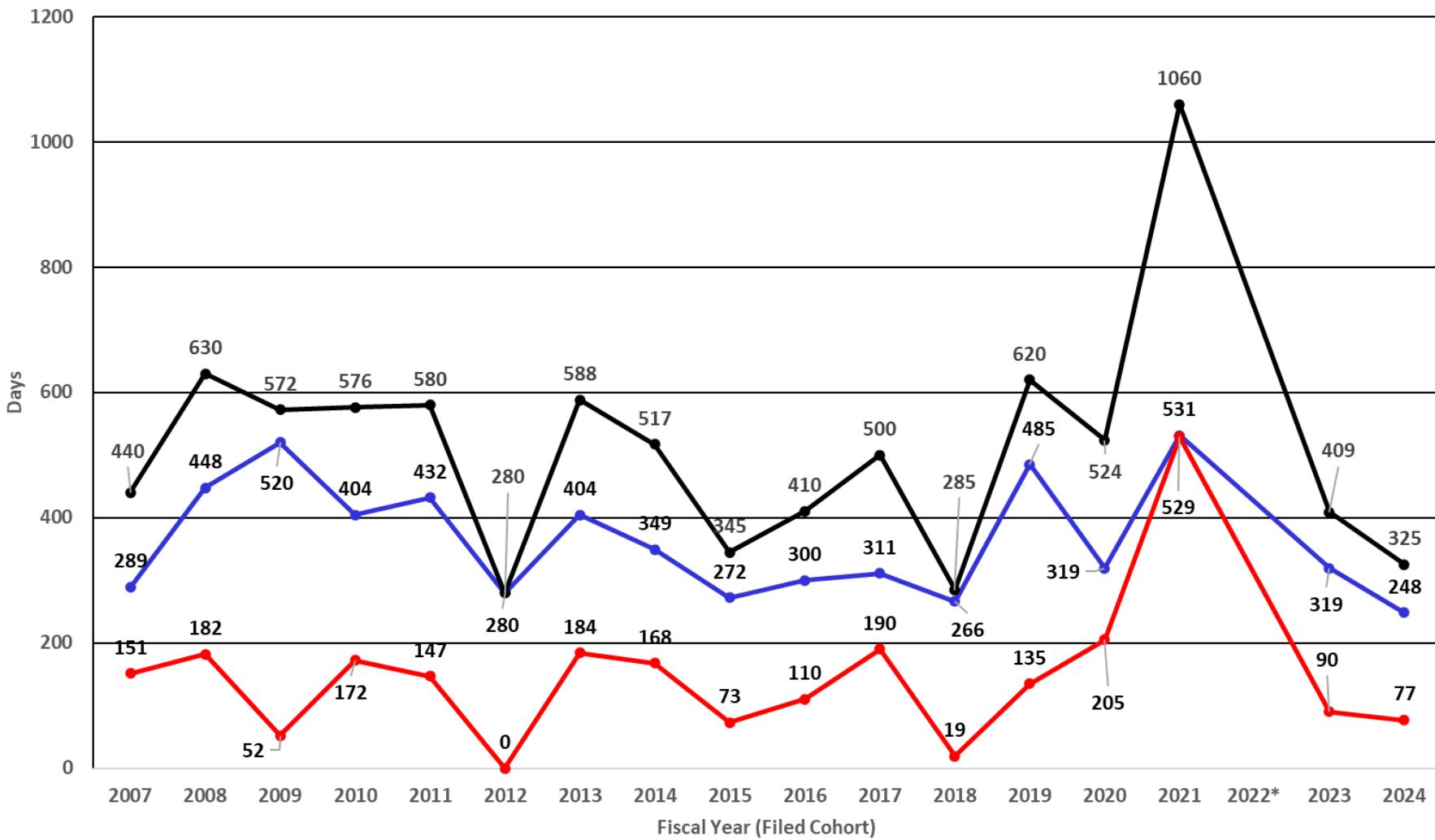
PMA Originals and Panel Track Supplements Filed as of 9/30/2025: Average Time to MDUFA Decision  
 Comparison of Cohorts at 98.61% Closure



PMA Originals and Panel Track Supplements Filed as of 9/30/2025: Average Time to MDUFA Decision  
 Comparison of Cohorts at 83.58% Closure



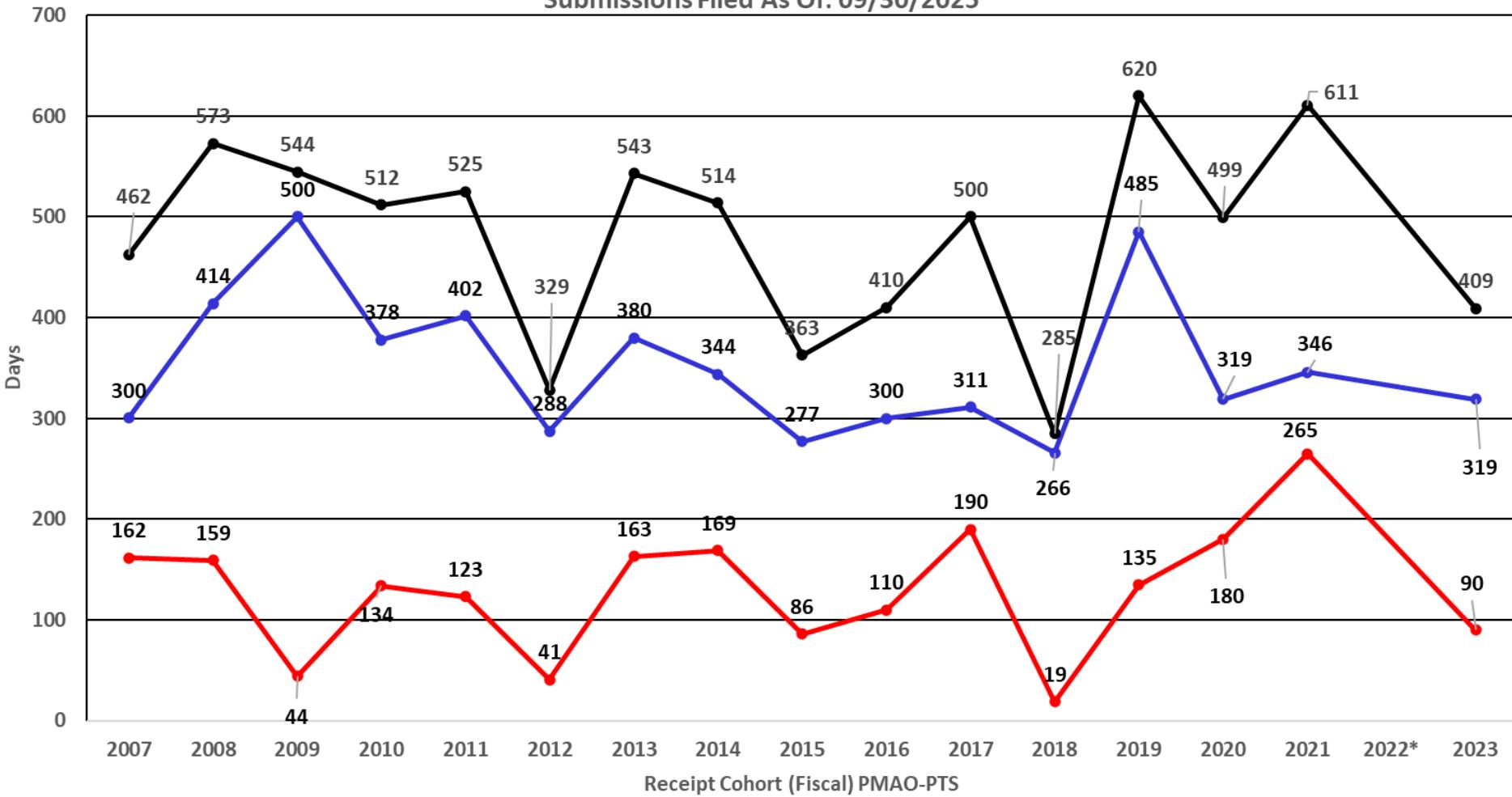
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of:  
09/30/2025



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: 09/30/2025

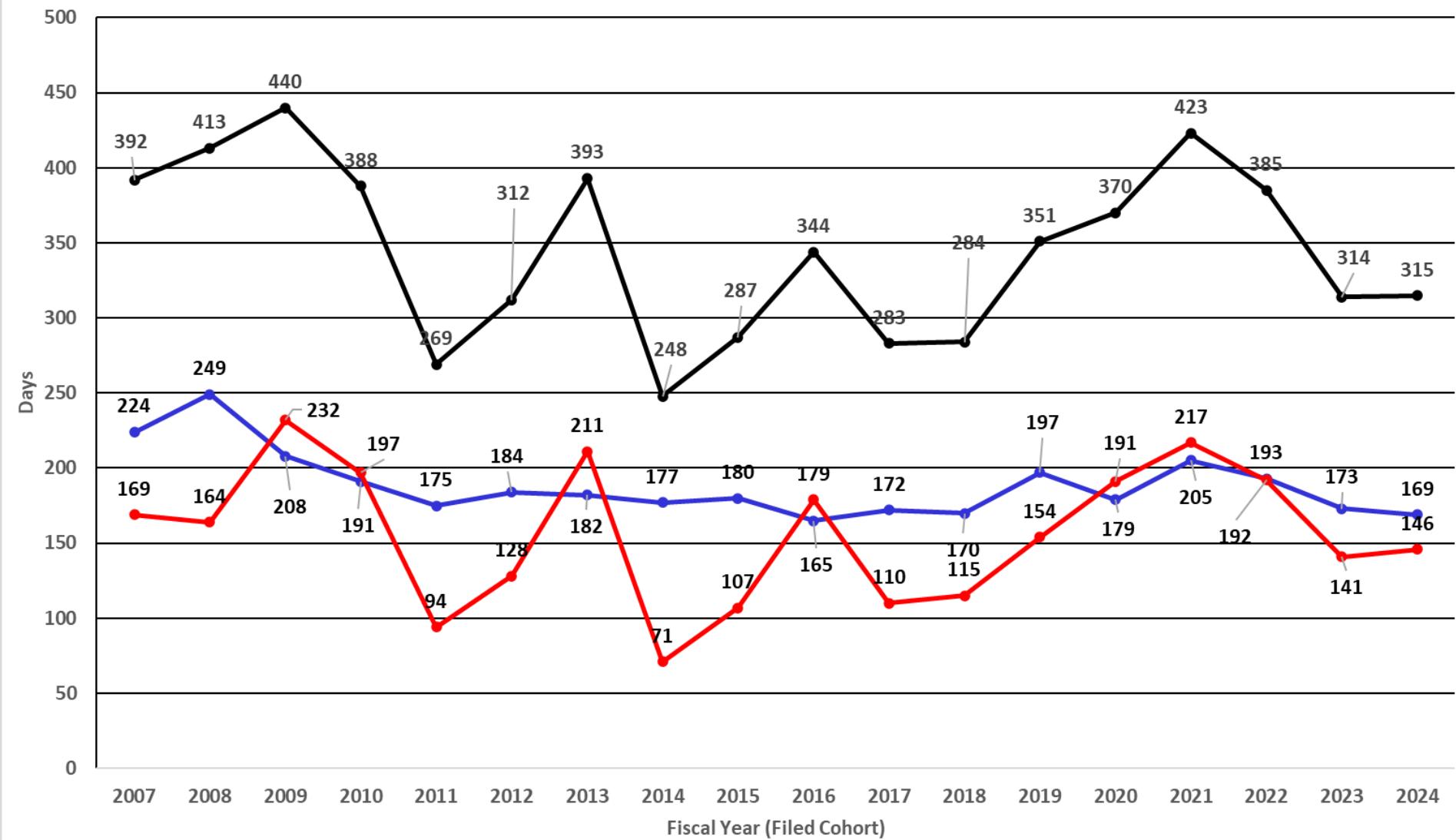


Numbers Closed/Filed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; 2012 = 2/2; 2013 = 17/17; 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/2; 2023 = 4/4

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

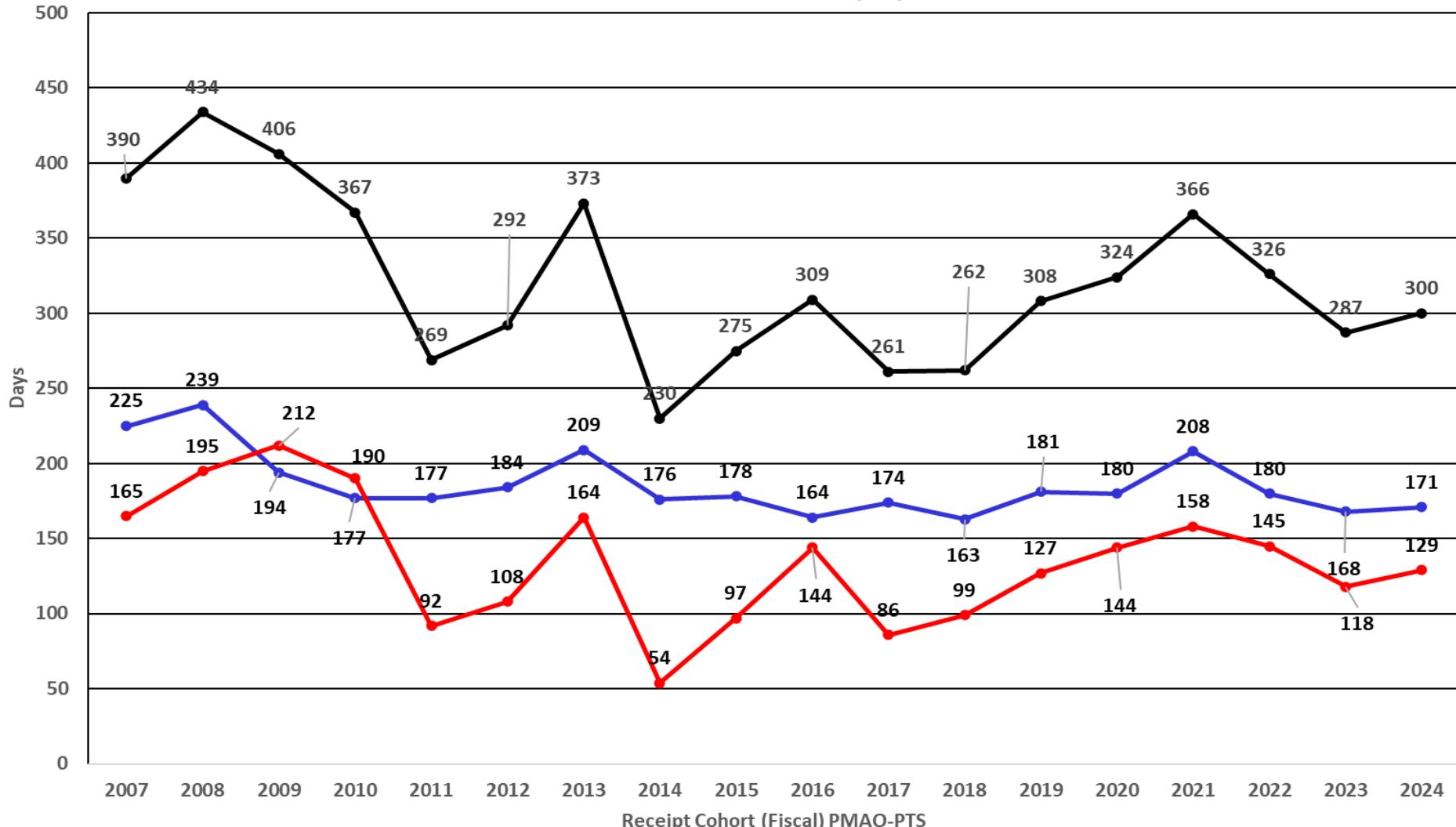
—●— Avg FDA Days to MDUFA Decision PMAO-PTS    —●— Avg MFR Days to MDUFA Decision PMAO-PTS    —●— Avg Total Days to MDUFA Decision PMAO-PTS

PMA Originals Without Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of:  
09/30/2025



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 = 38/39; 2024 = 33/39

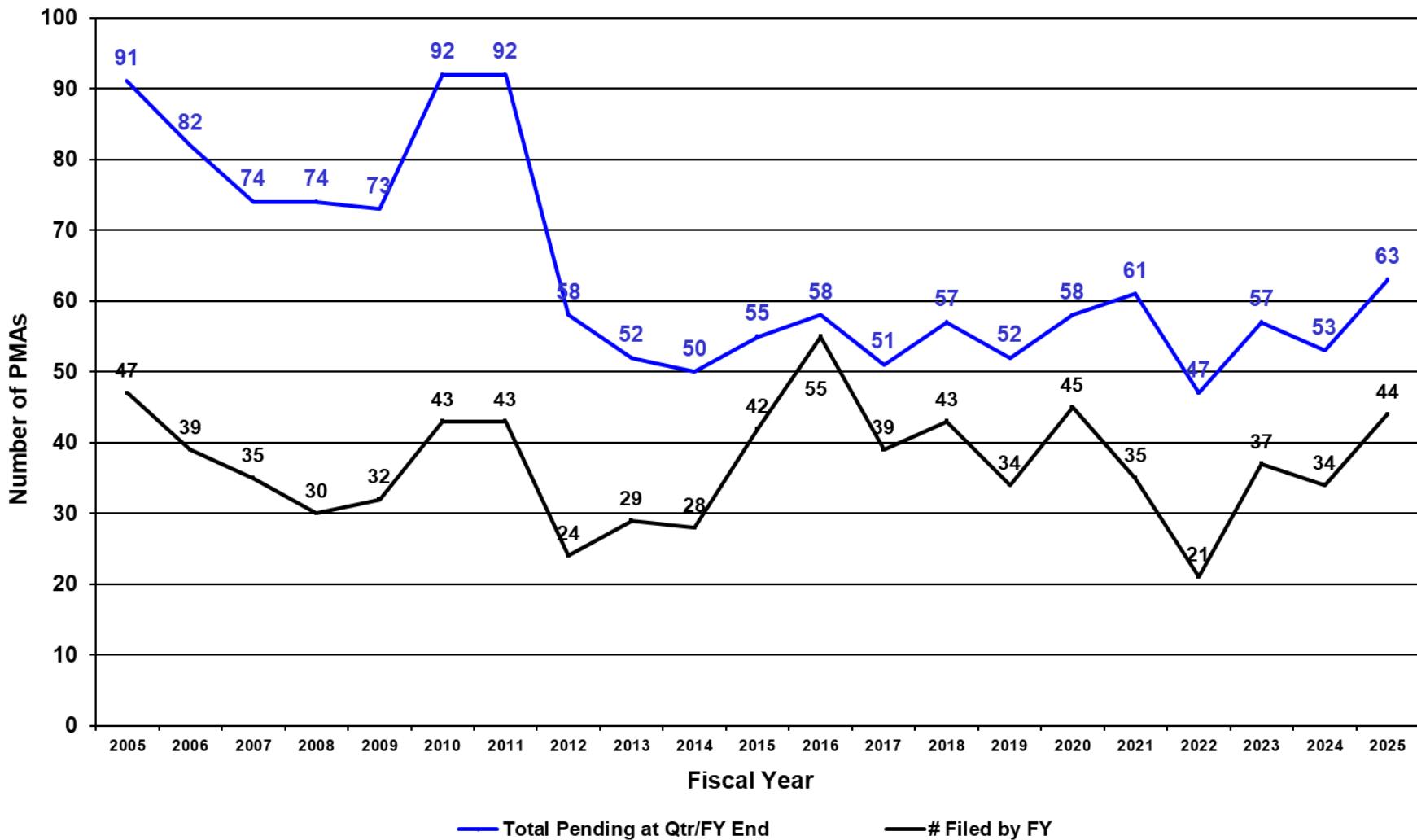
PMA Originals and Panel Track Supplements Without Panel Review: Average Time to MDUFA Decision  
for Submissions Filed As Of: 09/30/2025



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 = 67/68; 2024 = 55/64

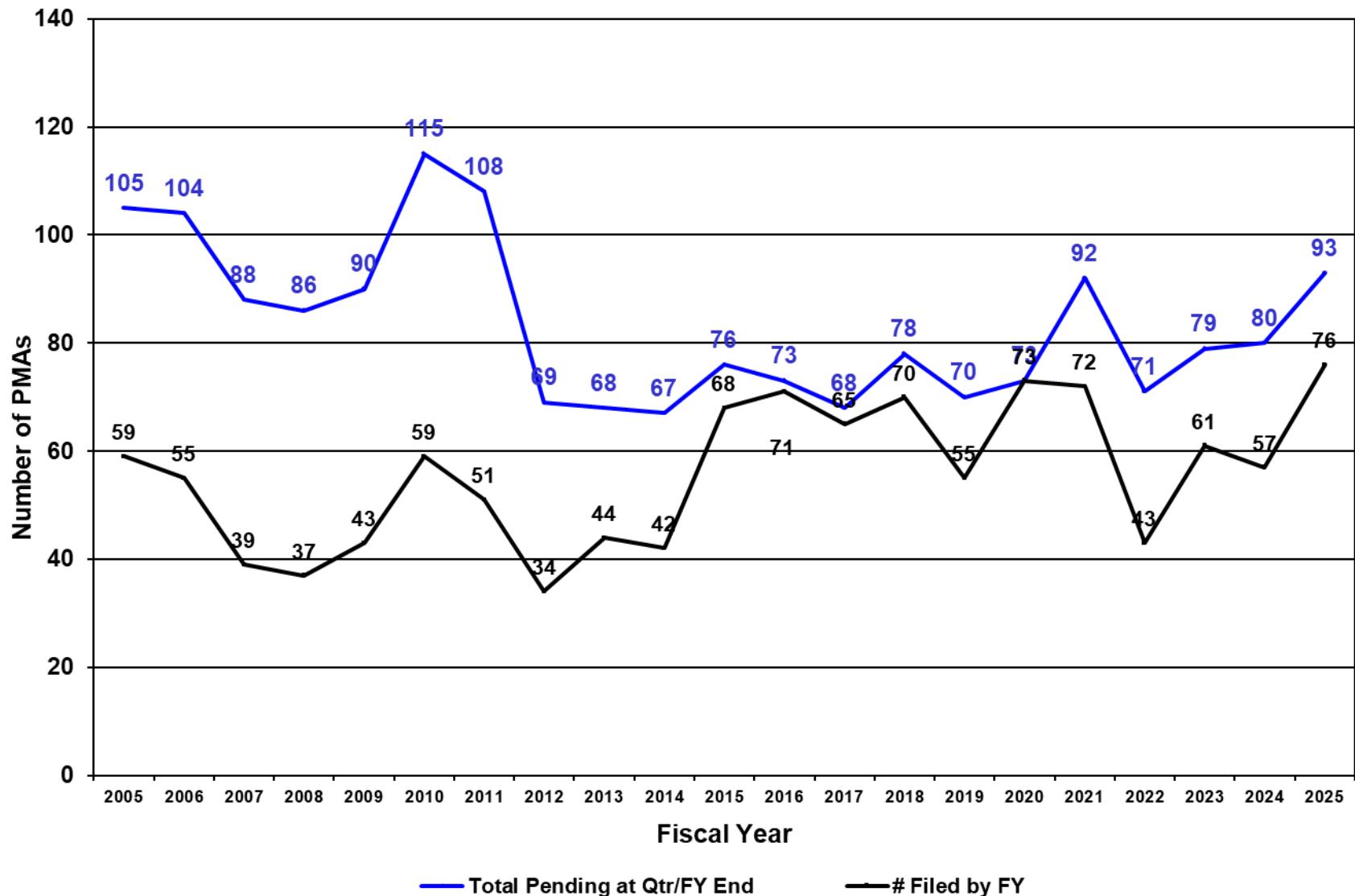
—●— Avg FDA Days to MDUFA Decision PMAO-PTS    —●— Avg MFR Days to MDUFA Decision PMAO-PTS    —●— Avg Total Days to MDUFA Decision PMAO-PTS

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



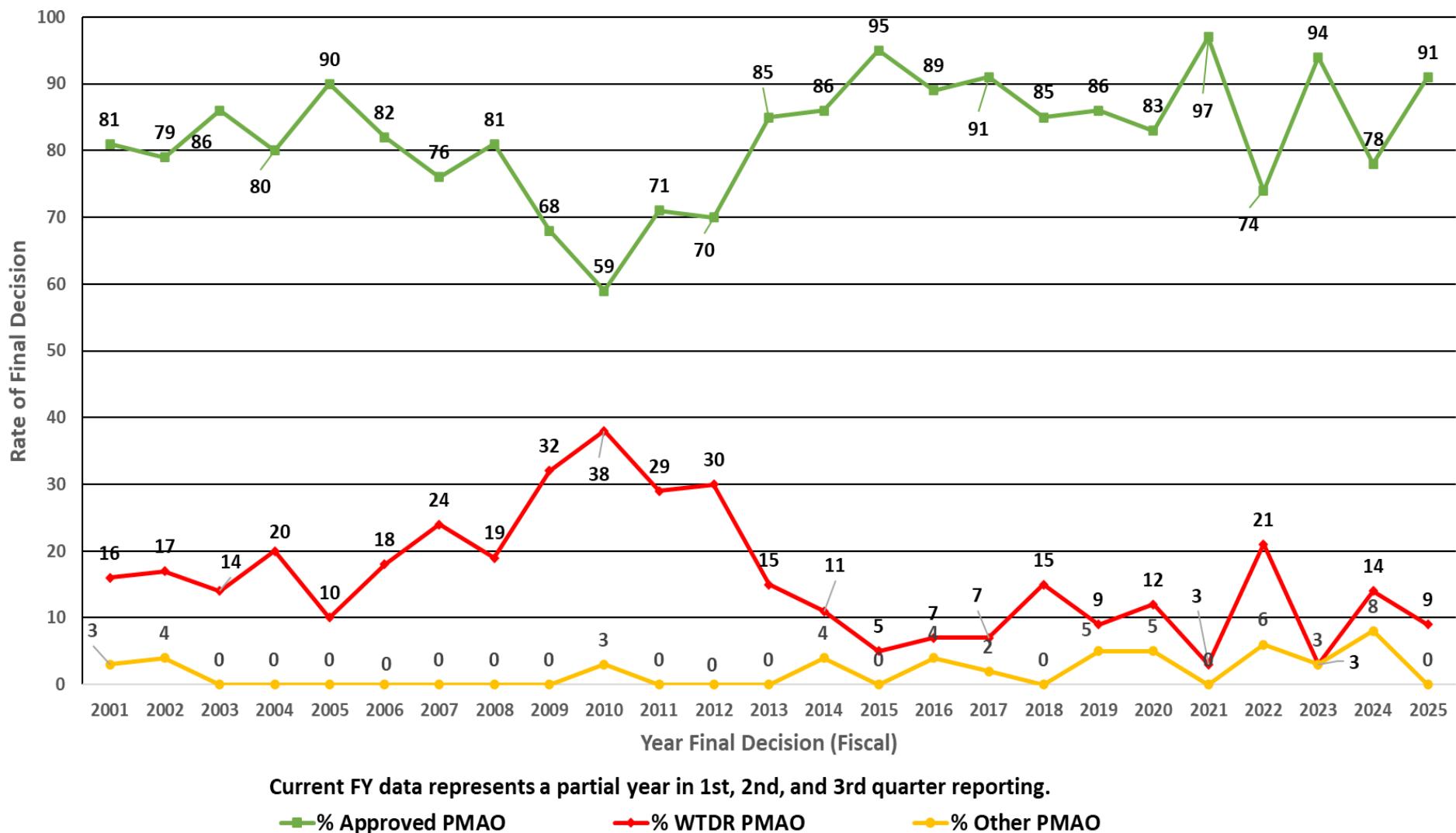
\*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

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



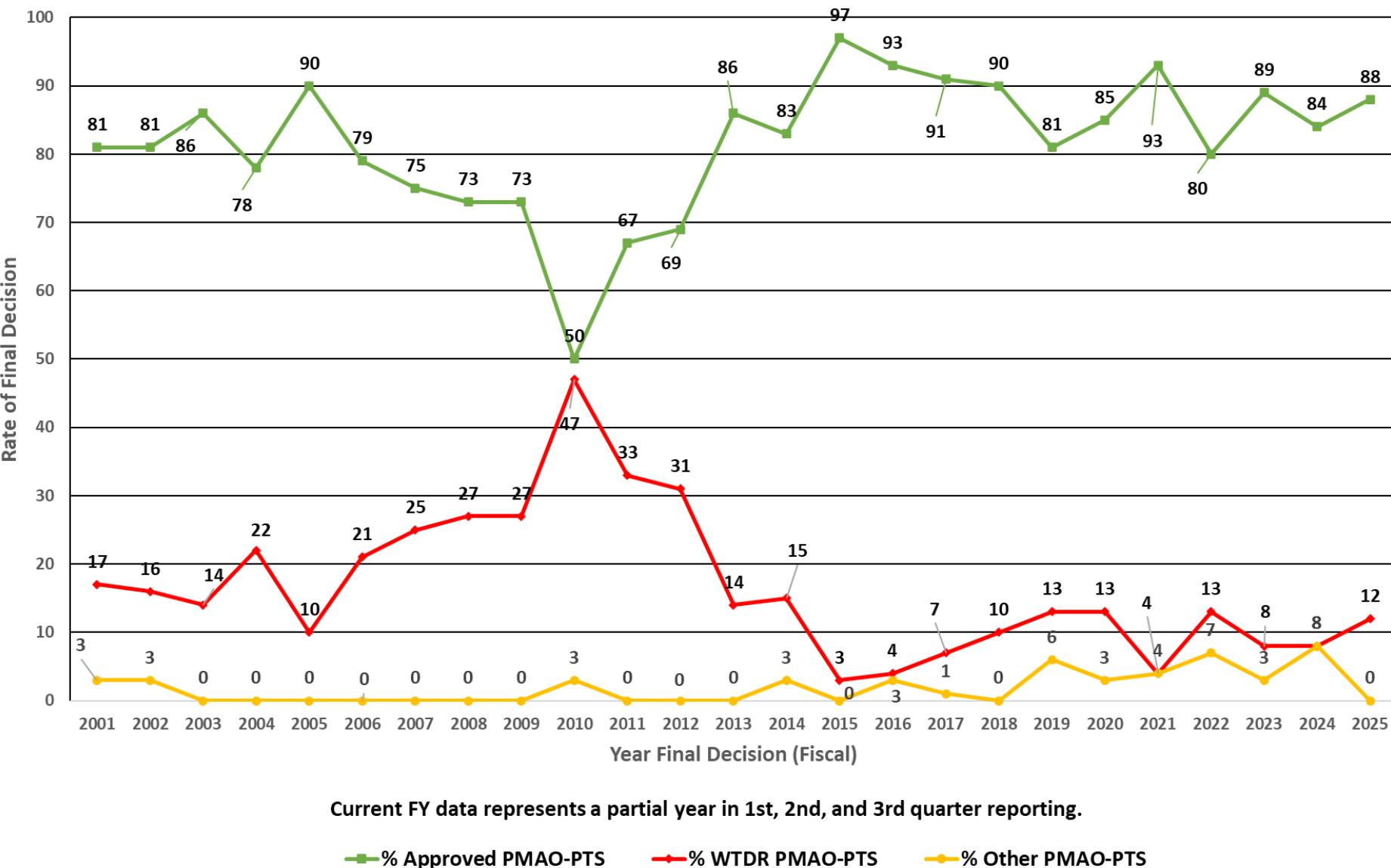
\*Original PMAs/PTS awaiting filing, MDUFA or final decision, under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

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



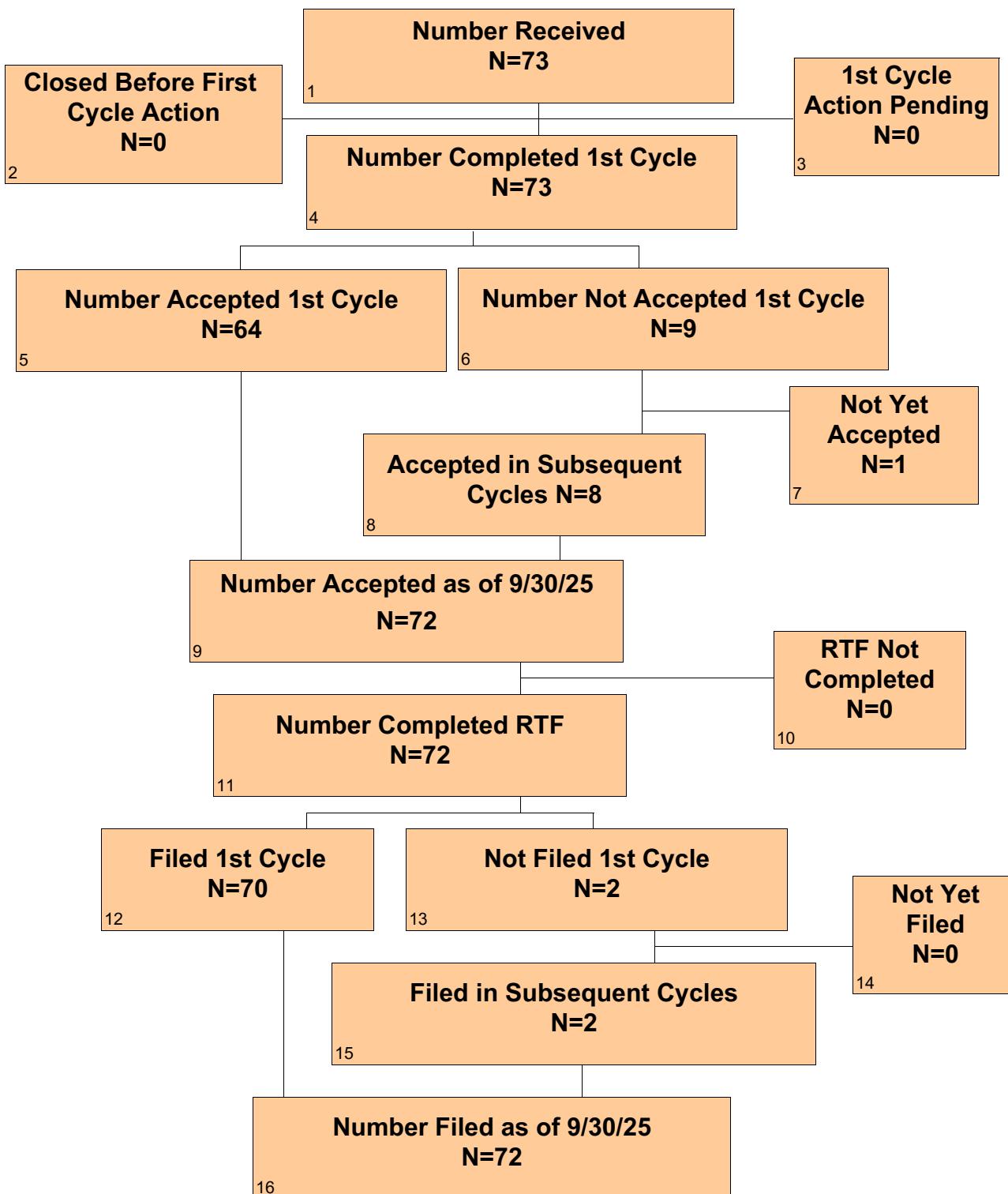
Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions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

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



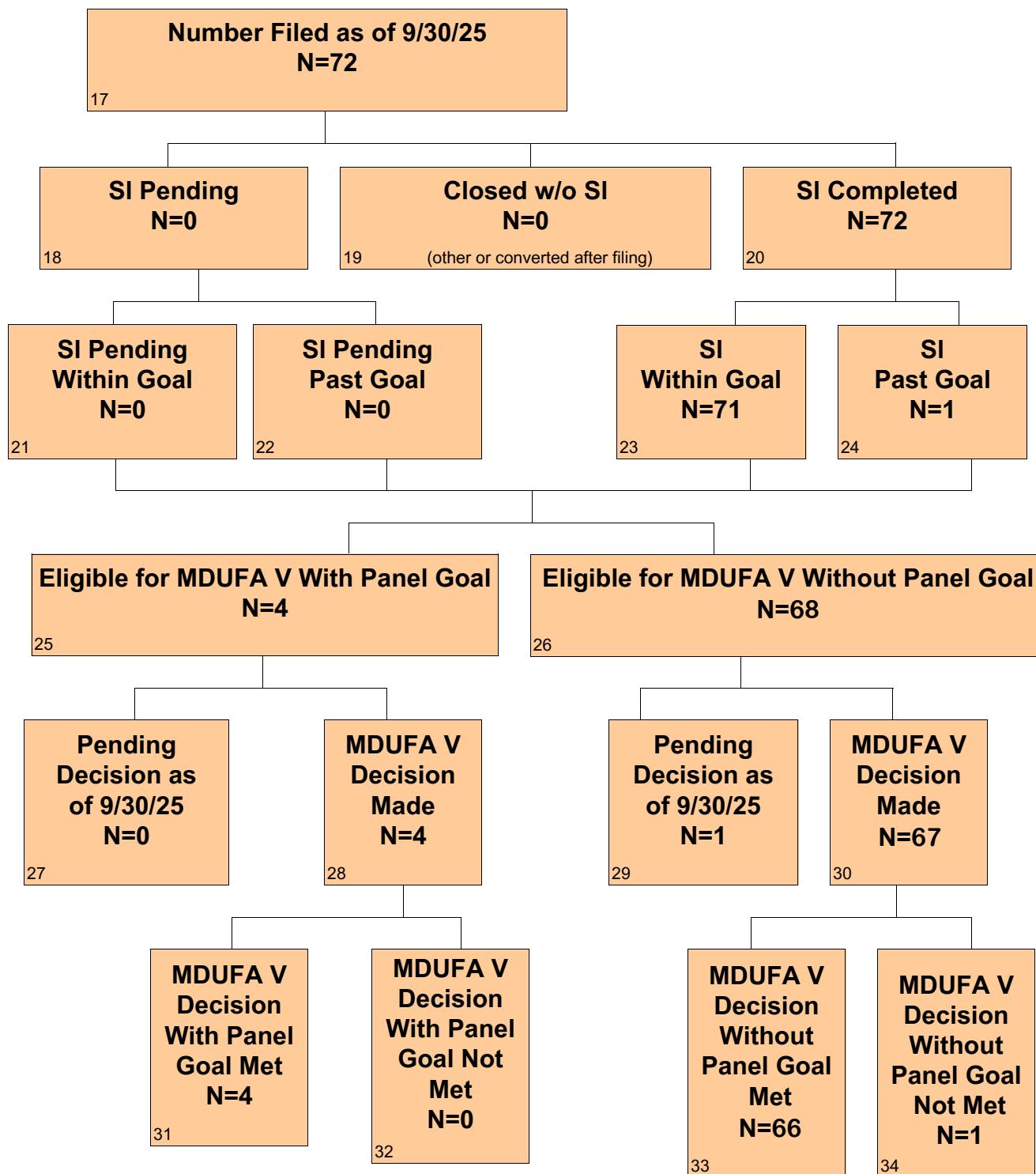
Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

# CDRH PMA Original and Panel Track Supplements - FY 2023 as of 9/30/25

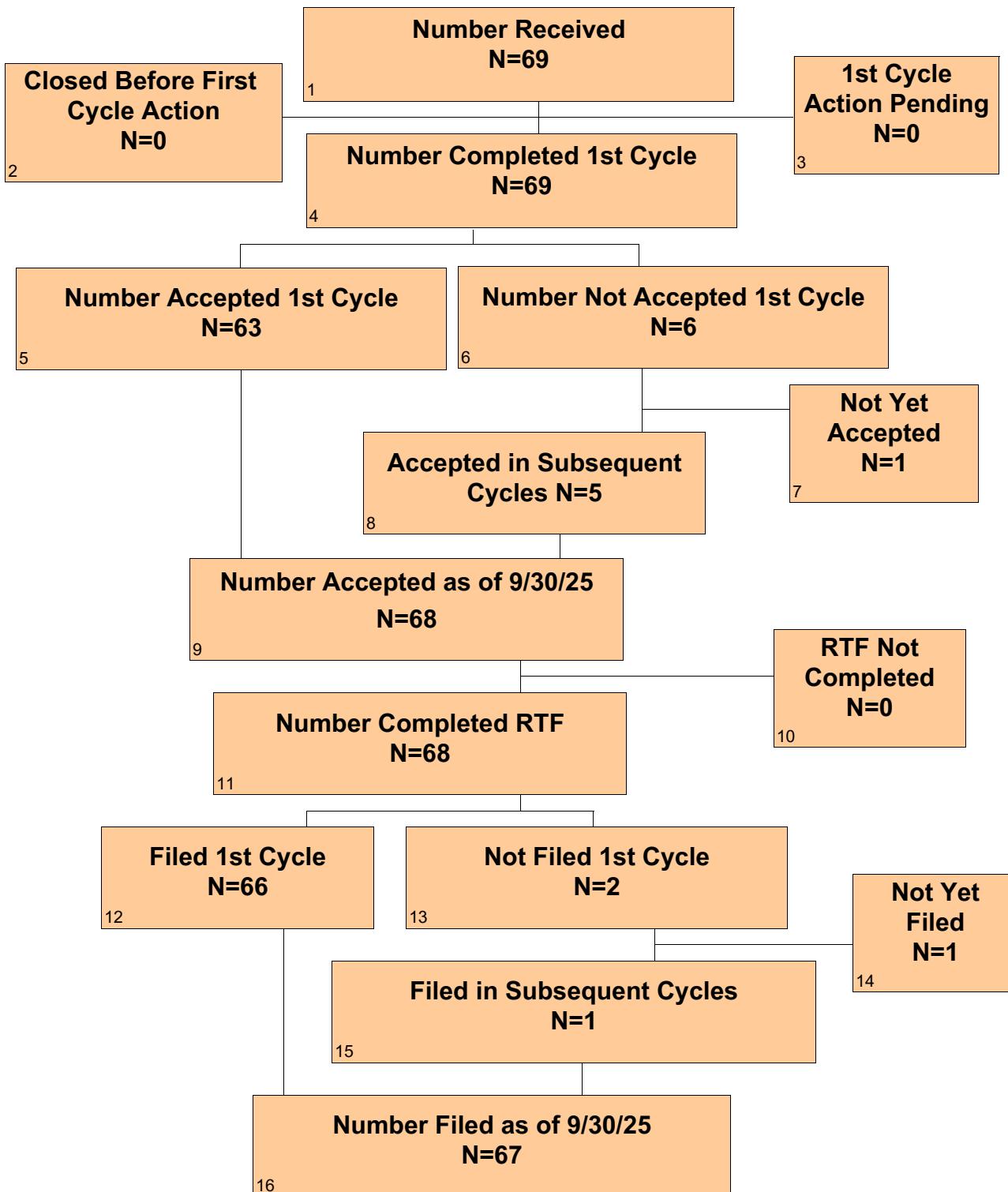


# CDRH PMA Original and Panel Track Supplements - FY 2023

## as of 9/30/25 Con't

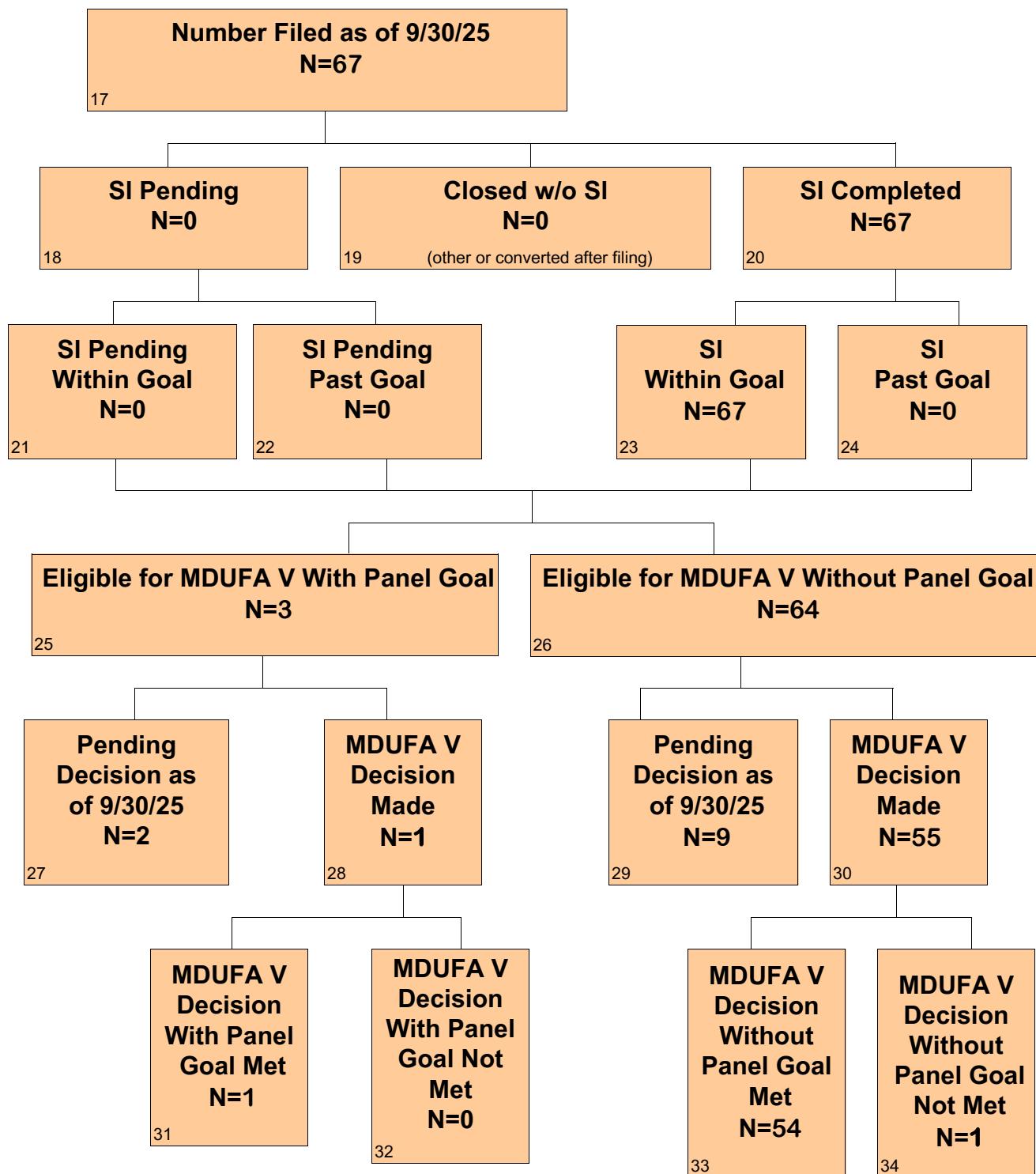


# CDRH PMA Original and Panel Track Supplements - FY 2024 as of 9/30/25

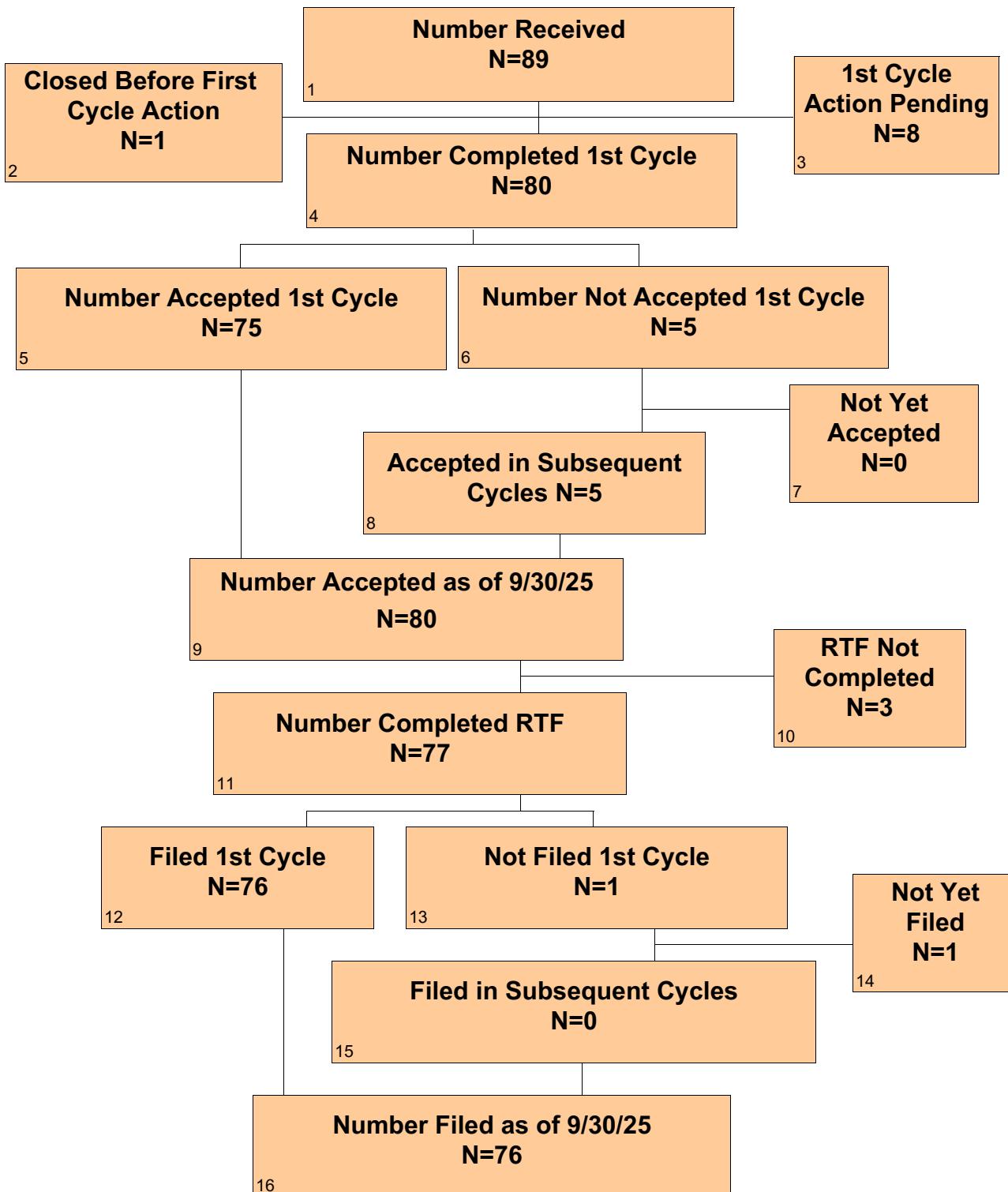


# CDRH PMA Original and Panel Track Supplements - FY 2024

## as of 9/30/25 Con't

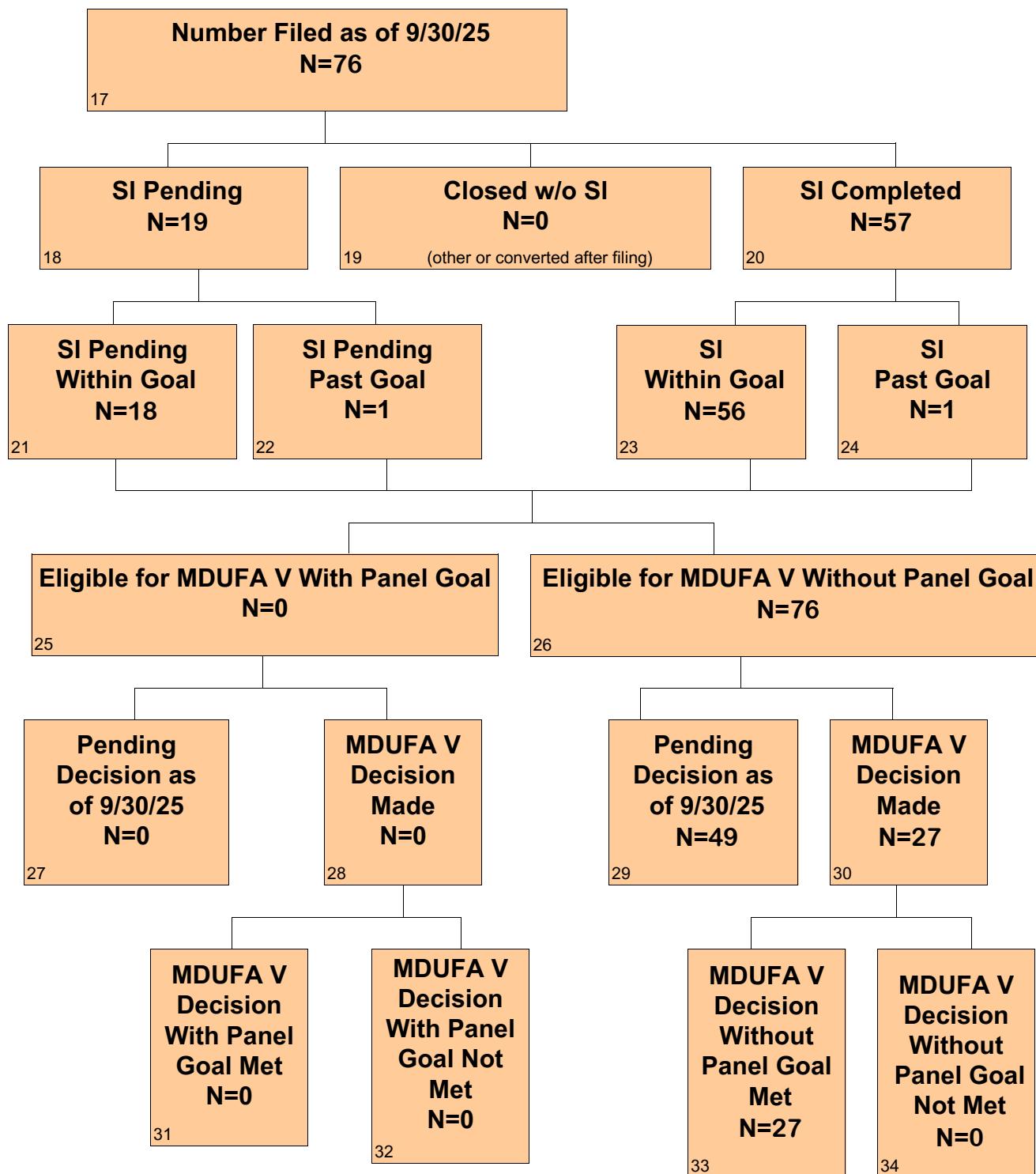


# CDRH PMA Original and Panel Track Supplements - FY 2025 as of 9/30/25



# CDRH PMA Original and Panel Track Supplements - FY 2025

## as of 9/30/25 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		
Number Closed Before First RTA Action	0	0	1		
Number Accepted First RTA Review	64	61	74		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	1		
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	8		
Number Not Accepted for Filing Review on First Cycle	9	6	5		
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	8.70%	6.25%		

\*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		
Number Accepted	64	63	75		
Completed RTF	72	68	77		
Number Not Filed	2	2	1		
Rate of Submissions Not Filed	2.78%	2.94%	1.30%		

Table 1.3 CDRH - PMA Original and Panel-Track Supplements Substantive Interaction Performance 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	72	67	76		
SI Goal Met	71	67	56		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	18		
SI Pending Past Goal	0	0	1		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	98.61%	100.00%	96.55%		

**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	57		
Average Number of FDA Days to Substantive Interaction	87.42	89.13	86.70		
20th Percentile FDA Days to Substantive Interaction	86	88	86		
40th Percentile FDA Days to Substantive Interaction	88	89	88		
60th Percentile FDA Days to Substantive Interaction	90	90	89		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	91	153	102		

**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	76		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	67	55	27		
MDUFA Decision Goal Met	66	54	27		
PMAs Pending MDUFA Decision	1	9	49		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.51%	98.18%	100.00%		

**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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	1	0		
MDUFA Decision Goal Met	4	1	0		
PMAs Pending MDUFA Decision	0	2	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	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	67	55	27		
<b>Average FDA Days to MDUFA Decision</b>	168.43	170.71	169.67		
20th Percentile FDA Days to MDUFA Decision	171	175	168		
40th Percentile FDA Days to MDUFA Decision	178	178	177		
60th Percentile FDA Days to MDUFA Decision	180	180	178		
80th Percentile FDA Days to MDUFA Decision	180	180	180		
Maximum FDA Days to MDUFA Decision	271	228	180		
<b>Average Industry Days to MDUFA Decision</b>	118.27	128.89	41.00		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	39	51	0		
60th Percentile Industry Days to MDUFA Decision	98	122	44		
80th Percentile Industry Days to MDUFA Decision	277	264	87		
Maximum Industry Days to MDUFA Decision	362	368	168		
<b>Average Total Days to MDUFA Decision</b>	286.70	299.60	210.67		
20th Percentile Total Days to MDUFA Decision	179	188	177		
40th Percentile Total Days to MDUFA Decision	218	230	180		
60th Percentile Total Days to MDUFA Decision	281	301	214		
80th Percentile Total Days to MDUFA Decision	444	437	267		
Maximum Total Days to MDUFA Decision	536	537	345		

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	4	1	0		
<b>Average FDA Days to MDUFA Decision</b>	319.00	248.00	N/A		
20th Percentile FDA Days to MDUFA Decision	318	248	0		
40th Percentile FDA Days to MDUFA Decision	318	248	0		
60th Percentile FDA Days to MDUFA Decision	320	248	0		
80th Percentile FDA Days to MDUFA Decision	320	248	0		
Maximum FDA Days to MDUFA Decision	320	248	0		
<b>Average Industry Days to MDUFA Decision</b>	90.00	77.00	N/A		
20th Percentile Industry Days to MDUFA Decision	51	77	0		
40th Percentile Industry Days to MDUFA Decision	61	77	0		
60th Percentile Industry Days to MDUFA Decision	72	77	0		
80th Percentile Industry Days to MDUFA Decision	120	77	0		
Maximum Industry Days to MDUFA Decision	186	77	0		
<b>Average Total Days to MDUFA Decision</b>	409.00	325.00	N/A		
20th Percentile Total Days to MDUFA Decision	370	325	0		
40th Percentile Total Days to MDUFA Decision	381	325	0		
60th Percentile Total Days to MDUFA Decision	392	325	0		
80th Percentile Total Days to MDUFA Decision	439	325	0		
Maximum Total Days to MDUFA Decision	504	325	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	76		
Number with MDUFA Decision	67	55	27		
Number of Withdrawal	3	2	0		
Number of Not Approvable	12	7	2		
Number of Deleted	1	3	0		
Rate of Withdrawal	4.48%	3.64%	0.00%		
Rate of Not Approvable	17.91%	12.73%	7.41%		

**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		
Number With MDUFA Decision	4	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	0.00%	100.00%	N/A		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	1	0		
Mean FDA Days for Submissions that Missed the Goal	191.00	228.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	28.00	0.00	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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	8		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	5	2		
MDUFA Decision Goal Met	6	5	2		
PMAs Pending MDUFA Decision	0	0	6		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

\*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	13		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	8	7		
MDUFA Decision Goal Met	15	8	7		
PMAs Pending MDUFA Decision	0	2	6		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

\*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		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	3	6	6		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	6	1	1		
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	14.29%	14.29%		

\*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		
Number Accepted	3	6	6		
Completed RTF	8	7	7		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	12.50%	0.00%	0.00%		

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 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	7	7		
SI Goal Met	8	7	6		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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	6		
Average Number of FDA Days to Substantive Interaction	82.00	89.43	88.83		
20th Percentile FDA Days to Substantive Interaction	87	88	87		
40th Percentile FDA Days to Substantive Interaction	90	90	90		
60th Percentile FDA Days to Substantive Interaction	90	90	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	90	90	90		

**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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	8	7	7		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	7	2		
MDUFA Decision Goal Met	8	7	2		
PMAs Pending MDUFA Decision	0	0	5		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	8	7	2		
<b>Average FDA Days to MDUFA Decision</b>	138.00	180.00	177.50		
20th Percentile FDA Days to MDUFA Decision	90	180	177		
40th Percentile FDA Days to MDUFA Decision	157	180	177		
60th Percentile FDA Days to MDUFA Decision	179	180	178		
80th Percentile FDA Days to MDUFA Decision	180	180	178		
Maximum FDA Days to MDUFA Decision	180	180	179		
<b>Average Industry Days to MDUFA Decision</b>	217.75	145.43	92.00		
20th Percentile Industry Days to MDUFA Decision	65	65	66		
40th Percentile Industry Days to MDUFA Decision	247	102	83		
60th Percentile Industry Days to MDUFA Decision	295	148	101		
80th Percentile Industry Days to MDUFA Decision	337	236	118		
Maximum Industry Days to MDUFA Decision	362	311	136		
<b>Average Total Days to MDUFA Decision</b>	355.75	325.43	269.50		
20th Percentile Total Days to MDUFA Decision	245	245	242		
40th Percentile Total Days to MDUFA Decision	354	282	260		
60th Percentile Total Days to MDUFA Decision	456	328	279		
80th Percentile Total Days to MDUFA Decision	478	416	297		
Maximum Total Days to MDUFA Decision	536	491	315		

**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**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	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		
Number with MDUFA Decision	8	7	2		
Number of Withdrawal	1	0	0		
Number of Not Approvable	0	1	1		
Number of Deleted	1	0	0		
Rate of Withdrawal	12.50%	0.00%	0.00%		
Rate of Not Approvable	0.00%	14.29%	50.00%		

**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		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Number Closed Before First RTA Action	0	0	1		
Number Accepted First RTA Review	19	17	22		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	1		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	3		
Number Not Accepted for Filing Review on First Cycle	1	1	1		
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	5.00%	4.17%		

\*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		
Number Accepted	19	19	23		
Completed RTF	20	20	23		
Number Not Filed	0	1	1		
Rate of Submissions Not Filed	0.00%	5.00%	4.35%		

**Table 1.3 OHT2 - Office of Cardiovascular Devices**  
**PMA Original and Panel-Track Supplements Substantive Interaction Performance 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	20	20	22		
SI Goal Met	20	20	20		
SI Goal Not Met	0	0	1		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	95.24%		

**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	21		
Average Number of FDA Days to Substantive Interaction	88.25	88.20	88.71		
20th Percentile FDA Days to Substantive Interaction	86	87	88		
40th Percentile FDA Days to Substantive Interaction	90	89	89		
60th Percentile FDA Days to Substantive Interaction	90	90	90		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	90	90	102		

**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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	17	19	22		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	17	17	12		
MDUFA Decision Goal Met	17	16	12		
PMAs Pending MDUFA Decision	0	2	10		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	94.12%	100.00%		

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	17	17	12		
<b>Average FDA Days to MDUFA Decision</b>	177.65	179.12	177.50		
20th Percentile FDA Days to MDUFA Decision	172	177	177		
40th Percentile FDA Days to MDUFA Decision	177	178	178		
60th Percentile FDA Days to MDUFA Decision	180	180	180		
80th Percentile FDA Days to MDUFA Decision	180	180	180		
Maximum FDA Days to MDUFA Decision	271	228	180		
<b>Average Industry Days to MDUFA Decision</b>	64.29	54.18	33.25		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	23	0	0		
60th Percentile Industry Days to MDUFA Decision	47	25	11		
80th Percentile Industry Days to MDUFA Decision	113	50	68		
Maximum Industry Days to MDUFA Decision	271	357	168		
<b>Average Total Days to MDUFA Decision</b>	241.94	233.29	210.75		
20th Percentile Total Days to MDUFA Decision	176	178	179		
40th Percentile Total Days to MDUFA Decision	201	184	180		
60th Percentile Total Days to MDUFA Decision	236	204	188		
80th Percentile Total Days to MDUFA Decision	305	230	246		
Maximum Total Days to MDUFA Decision	442	537	345		

**Table 1.8 OHT2 - Office of Cardiovascular Devices  
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	3	1	0		
<b>Average FDA Days to MDUFA Decision</b>	319.33	248.00	N/A		
20th Percentile FDA Days to MDUFA Decision	319	248	0		
40th Percentile FDA Days to MDUFA Decision	320	248	0		
60th Percentile FDA Days to MDUFA Decision	320	248	0		
80th Percentile FDA Days to MDUFA Decision	320	248	0		
Maximum FDA Days to MDUFA Decision	320	248	0		
<b>Average Industry Days to MDUFA Decision</b>	58.00	77.00	N/A		
20th Percentile Industry Days to MDUFA Decision	47	77	0		
40th Percentile Industry Days to MDUFA Decision	54	77	0		
60th Percentile Industry Days to MDUFA Decision	61	77	0		
80th Percentile Industry Days to MDUFA Decision	68	77	0		
Maximum Industry Days to MDUFA Decision	76	77	0		
<b>Average Total Days to MDUFA Decision</b>	377.33	325.00	N/A		
20th Percentile Total Days to MDUFA Decision	366	325	0		
40th Percentile Total Days to MDUFA Decision	373	325	0		
60th Percentile Total Days to MDUFA Decision	381	325	0		
80th Percentile Total Days to MDUFA Decision	388	325	0		
Maximum Total Days to MDUFA Decision	396	325	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	22		
Number with MDUFA Decision	17	17	12		
Number of Withdrawal	1	0	0		
Number of Not Approvable	3	0	1		
Number of Deleted	0	0	0		
Rate of Withdrawal	5.88%	0.00%	0.00%		
Rate of Not Approvable	17.65%	0.00%	8.33%		

**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		
Number With MDUFA Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	1	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	0.00%	100.00%	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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	228.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	3	6	5		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	14.29%	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		
Number Accepted	3	6	5		
Completed RTF	3	7	5		
Number Not Filed	0	1	0		
Rate of Submissions Not Filed	0.00%	14.29%	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 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	3	6	5		
SI Goal Met	3	6	4		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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	4		
Average Number of FDA Days to Substantive Interaction	88.33	96.67	87.75		
20th Percentile FDA Days to Substantive Interaction	87	88	87		
40th Percentile FDA Days to Substantive Interaction	88	88	88		
60th Percentile FDA Days to Substantive Interaction	88	90	88		
80th Percentile FDA Days to Substantive Interaction	89	90	89		
Maximum FDA Days to Substantive Interaction	90	153	90		

**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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	3	6	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	4	0		
MDUFA Decision Goal Met	2	4	0		
PMAs Pending MDUFA Decision	0	2	5		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	66.67%	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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days				
Number of PMAs Filed	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	3	4	0		
<b>Average FDA Days to MDUFA Decision</b>	180.67	176.75	N/A		
20th Percentile FDA Days to MDUFA Decision	175	174	0		
40th Percentile FDA Days to MDUFA Decision	178	178	0		
60th Percentile FDA Days to MDUFA Decision	181	180	0		
80th Percentile FDA Days to MDUFA Decision	186	180	0		
Maximum FDA Days to MDUFA Decision	191	180	0		
<b>Average Industry Days to MDUFA Decision</b>	18.67	233.50	N/A		
20th Percentile Industry Days to MDUFA Decision	11	148	0		
40th Percentile Industry Days to MDUFA Decision	22	212	0		
60th Percentile Industry Days to MDUFA Decision	28	281	0		
80th Percentile Industry Days to MDUFA Decision	28	324	0		
Maximum Industry Days to MDUFA Decision	28	354	0		
<b>Average Total Days to MDUFA Decision</b>	199.33	410.25	N/A		
20th Percentile Total Days to MDUFA Decision	187	322	0		
40th Percentile Total Days to MDUFA Decision	196	383	0		
60th Percentile Total Days to MDUFA Decision	204	459	0		
80th Percentile Total Days to MDUFA Decision	211	503	0		
Maximum Total Days to MDUFA Decision	219	532	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**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	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		
Number with MDUFA Decision	3	4	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	N/A		
Rate of Not Approvable	33.33%	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		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	191.00	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	28.00	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	9	6	10		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	1		
Number Not Accepted for Filing Review on First Cycle	0	0	3		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%	23.08%		

\*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		
Number Accepted	9	6	10		
Completed RTF	9	6	12		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	0.00%	0.00%		

**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 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	9	6	12		
SI Goal Met	9	6	5		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	6		
SI Pending Past Goal	0	0	1		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	83.33%		

**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	5		
Average Number of FDA Days to Substantive Interaction	88.78	89.33	87.60		
20th Percentile FDA Days to Substantive Interaction	88	89	86		
40th Percentile FDA Days to Substantive Interaction	90	89	87		
60th Percentile FDA Days to Substantive Interaction	90	90	88		
80th Percentile FDA Days to Substantive Interaction	90	90	89		
Maximum FDA Days to Substantive Interaction	90	90	90		

**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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	9	4	12		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	8	4	2		
MDUFA Decision Goal Met	8	4	2		
PMAs Pending MDUFA Decision	1	0	10		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	8	4	2		
<b>Average FDA Days to MDUFA Decision</b>	179.00	156.25	178.50		
20th Percentile FDA Days to MDUFA Decision	178	141	178		
40th Percentile FDA Days to MDUFA Decision	179	177	178		
60th Percentile FDA Days to MDUFA Decision	180	179	179		
80th Percentile FDA Days to MDUFA Decision	180	180	179		
Maximum FDA Days to MDUFA Decision	180	180	180		
<b>Average Industry Days to MDUFA Decision</b>	60.38	281.50	64.50		
20th Percentile Industry Days to MDUFA Decision	0	233	37		
40th Percentile Industry Days to MDUFA Decision	32	351	55		
60th Percentile Industry Days to MDUFA Decision	53	353	74		
80th Percentile Industry Days to MDUFA Decision	64	358	92		
Maximum Industry Days to MDUFA Decision	264	365	110		
<b>Average Total Days to MDUFA Decision</b>	239.38	437.75	243.00		
20th Percentile Total Days to MDUFA Decision	179	367	215		
40th Percentile Total Days to MDUFA Decision	210	469	234		
60th Percentile Total Days to MDUFA Decision	233	515	252		
80th Percentile Total Days to MDUFA Decision	244	530	271		
Maximum Total Days to MDUFA Decision	444	530	290		

**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**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	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	12		
Number with MDUFA Decision	8	4	2		
Number of Withdrawal	0	0	0		
Number of Not Approvable	1	1	0		
Number of Deleted	0	1	0		
Rate of Withdrawal	0.00%	0.00%	0.00%		
Rate of Not Approvable	12.50%	25.00%	0.00%		

**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		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	5	6	5		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	1		
Number Not Accepted for Filing Review on First Cycle	1	1	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	16.67%	14.29%	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		
Number Accepted	5	6	5		
Completed RTF	6	7	5		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	0.00%	0.00%		

**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 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	7	5		
SI Goal Met	5	7	5		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	83.33%	100.00%	100.00%		

**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		
Average Number of FDA Days to Substantive Interaction	88.50	86.43	89.00		
20th Percentile FDA Days to Substantive Interaction	88	86	88		
40th Percentile FDA Days to Substantive Interaction	90	89	89		
60th Percentile FDA Days to Substantive Interaction	90	90	89		
80th Percentile FDA Days to Substantive Interaction	90	90	90		
Maximum FDA Days to Substantive Interaction	91	90	90		

**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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	6	7	5		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	6	1		
MDUFA Decision Goal Met	6	6	1		
PMAs Pending MDUFA Decision	0	1	4		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	6	6	1		
<b>Average FDA Days to MDUFA Decision</b>	175.33	162.83	180.00		
20th Percentile FDA Days to MDUFA Decision	179	176	180		
40th Percentile FDA Days to MDUFA Decision	180	177	180		
60th Percentile FDA Days to MDUFA Decision	180	178	180		
80th Percentile FDA Days to MDUFA Decision	180	178	180		
Maximum FDA Days to MDUFA Decision	180	180	180		
<b>Average Industry Days to MDUFA Decision</b>	55.17	96.67	88.00		
20th Percentile Industry Days to MDUFA Decision	0	36	88		
40th Percentile Industry Days to MDUFA Decision	37	71	88		
60th Percentile Industry Days to MDUFA Decision	71	104	88		
80th Percentile Industry Days to MDUFA Decision	101	120	88		
Maximum Industry Days to MDUFA Decision	122	249	88		
<b>Average Total Days to MDUFA Decision</b>	230.50	259.50	268.00		
20th Percentile Total Days to MDUFA Decision	180	214	268		
40th Percentile Total Days to MDUFA Decision	217	248	268		
60th Percentile Total Days to MDUFA Decision	251	280	268		
80th Percentile Total Days to MDUFA Decision	281	300	268		
Maximum Total Days to MDUFA Decision	301	337	268		

**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**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	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	5		
Number with MDUFA Decision	6	6	1		
Number of Withdrawal	0	1	0		
Number of Not Approvable	1	2	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	16.67%	0.00%		
Rate of Not Approvable	16.67%	33.33%	0.00%		

**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		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	4	3	4		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	1	0	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	20.00%	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		
Number Accepted	4	3	4		
Completed RTF	5	3	4		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	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 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	5	3	4		
SI Goal Met	5	3	2		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	2		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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	2		
Average Number of FDA Days to Substantive Interaction	85.40	88.00	83.50		
20th Percentile FDA Days to Substantive Interaction	84	87	81		
40th Percentile FDA Days to Substantive Interaction	86	87	83		
60th Percentile FDA Days to Substantive Interaction	87	88	84		
80th Percentile FDA Days to Substantive Interaction	88	89	86		
Maximum FDA Days to Substantive Interaction	88	90	88		

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

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	5	3	1		
<b>Average FDA Days to MDUFA Decision</b>	173.80	179.33	107.00		
20th Percentile FDA Days to MDUFA Decision	169	179	107		
40th Percentile FDA Days to MDUFA Decision	175	180	107		
60th Percentile FDA Days to MDUFA Decision	178	180	107		
80th Percentile FDA Days to MDUFA Decision	179	180	107		
Maximum FDA Days to MDUFA Decision	180	180	107		
<b>Average Industry Days to MDUFA Decision</b>	194.80	169.00	N/A		
20th Percentile Industry Days to MDUFA Decision	77	144	0		
40th Percentile Industry Days to MDUFA Decision	142	145	0		
60th Percentile Industry Days to MDUFA Decision	243	160	0		
80th Percentile Industry Days to MDUFA Decision	351	189	0		
Maximum Industry Days to MDUFA Decision	356	218	0		
<b>Average Total Days to MDUFA Decision</b>	368.60	348.33	107.00		
20th Percentile Total Days to MDUFA Decision	241	323	107		
40th Percentile Total Days to MDUFA Decision	309	324	107		
60th Percentile Total Days to MDUFA Decision	417	340	107		
80th Percentile Total Days to MDUFA Decision	530	369	107		
Maximum Total Days to MDUFA Decision	536	398	107		

**Table 1.8 OHT6 - Office of Orthopedic Devices  
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	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		
Number with MDUFA Decision	5	3	1		
Number of Withdrawal	0	0	0		
Number of Not Approvable	3	2	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	0.00%	0.00%		
Rate of Not Approvable	60.00%	66.67%	0.00%		

**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		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	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		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	21	14	22		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	3		
Number Not Accepted for Filing Review on First Cycle	0	2	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	12.50%	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		
Number Accepted	21	14	22		
Completed RTF	21	15	21		
Number Not Filed	1	0	0		
Rate of Submissions Not Filed	4.76%	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 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	15	21		
SI Goal Met	21	15	14		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	7		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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	14		
Average Number of FDA Days to Substantive Interaction	88.14	88.60	81.79		
20th Percentile FDA Days to Substantive Interaction	87	88	85		
40th Percentile FDA Days to Substantive Interaction	87	89	87		
60th Percentile FDA Days to Substantive Interaction	89	89	89		
80th Percentile FDA Days to Substantive Interaction	90	90	89		
Maximum FDA Days to Substantive Interaction	90	90	90		

**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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	20	15	21		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	20	13	9		
MDUFA Decision Goal Met	20	13	9		
PMAs Pending MDUFA Decision	0	2	12		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	20	13	9		
<b>Average FDA Days to MDUFA Decision</b>	163.30	158.62	161.33		
20th Percentile FDA Days to MDUFA Decision	136	137	146		
40th Percentile FDA Days to MDUFA Decision	178	174	168		
60th Percentile FDA Days to MDUFA Decision	179	180	178		
80th Percentile FDA Days to MDUFA Decision	180	180	178		
Maximum FDA Days to MDUFA Decision	180	180	180		
<b>Average Industry Days to MDUFA Decision</b>	162.25	126.62	34.11		
20th Percentile Industry Days to MDUFA Decision	0	12	0		
40th Percentile Industry Days to MDUFA Decision	68	48	0		
60th Percentile Industry Days to MDUFA Decision	236	88	36		
80th Percentile Industry Days to MDUFA Decision	322	290	73		
Maximum Industry Days to MDUFA Decision	354	368	112		
<b>Average Total Days to MDUFA Decision</b>	325.55	285.23	195.44		
20th Percentile Total Days to MDUFA Decision	179	191	156		
40th Percentile Total Days to MDUFA Decision	247	216	178		
60th Percentile Total Days to MDUFA Decision	364	252	200		
80th Percentile Total Days to MDUFA Decision	502	415	245		
Maximum Total Days to MDUFA Decision	534	532	290		

**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**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	1	0	0		
<b>Average FDA Days to MDUFA Decision</b>	318.00	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	318	0	0		
40th Percentile FDA Days to MDUFA Decision	318	0	0		
60th Percentile FDA Days to MDUFA Decision	318	0	0		
80th Percentile FDA Days to MDUFA Decision	318	0	0		
Maximum FDA Days to MDUFA Decision	318	0	0		
<b>Average Industry Days to MDUFA Decision</b>	186.00	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	186	0	0		
40th Percentile Industry Days to MDUFA Decision	186	0	0		
60th Percentile Industry Days to MDUFA Decision	186	0	0		
80th Percentile Industry Days to MDUFA Decision	186	0	0		
Maximum Industry Days to MDUFA Decision	186	0	0		
<b>Average Total Days to MDUFA Decision</b>	504.00	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	504	0	0		
40th Percentile Total Days to MDUFA Decision	504	0	0		
60th Percentile Total Days to MDUFA Decision	504	0	0		
80th Percentile Total Days to MDUFA Decision	504	0	0		
Maximum Total Days to MDUFA Decision	504	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	21		
Number with MDUFA Decision	20	13	9		
Number of Withdrawal	1	1	0		
Number of Not Approvable	3	1	0		
Number of Deleted	0	2	0		
Rate of Withdrawal	5.00%	7.69%	0.00%		
Rate of Not Approvable	15.00%	7.69%	0.00%		

**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		
Number With MDUFA Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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	8		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	5	2		
MDUFA Decision Goal Met	6	5	2		
PMAs Pending MDUFA Decision	0	0	6		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

\*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	13		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	8	7		
MDUFA Decision Goal Met	15	8	7		
PMAs Pending MDUFA Decision	0	2	6		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

\*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		
Number Closed Before First RTA Action	0	0	0		
Number Accepted First RTA Review	0	3	0		
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted for Filing Review on First Cycle	0	0	0		
Rate of Submissions Not Accepted for Filing Review on First Cycle	N/A	0.00%	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		
Number Accepted	0	3	0		
Completed RTF	0	3	0		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	N/A	0.00%	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 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	0	3	0		
SI Goal Met	0	3	0		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	N/A	100.00%	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		
Average Number of FDA Days to Substantive Interaction	N/A	89.33	N/A		
20th Percentile FDA Days to Substantive Interaction	0	89	0		
40th Percentile FDA Days to Substantive Interaction	0	90	0		
60th Percentile FDA Days to Substantive Interaction	0	90	0		
80th Percentile FDA Days to Substantive Interaction	0	90	0		
Maximum FDA Days to Substantive Interaction	0	90	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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	0	3	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	1	0		
MDUFA Decision Goal Met	0	1	0		
PMAs Pending MDUFA Decision	0	2	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	100.00%	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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days				
Number of PMAs Filed	0	0	0		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Goal Met	0	0	0		
PMAs Pending MDUFA Decision	0	0	0		
PMAs Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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**

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Number with MDUFA Decision	0	0	0		
<b>Average FDA Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile FDA Days to MDUFA Decision	0	0	0		
40th Percentile FDA Days to MDUFA Decision	0	0	0		
60th Percentile FDA Days to MDUFA Decision	0	0	0		
80th Percentile FDA Days to MDUFA Decision	0	0	0		
Maximum FDA Days to MDUFA Decision	0	0	0		
<b>Average Industry Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Industry Days to MDUFA Decision	0	0	0		
40th Percentile Industry Days to MDUFA Decision	0	0	0		
60th Percentile Industry Days to MDUFA Decision	0	0	0		
80th Percentile Industry Days to MDUFA Decision	0	0	0		
Maximum Industry Days to MDUFA Decision	0	0	0		
<b>Average Total Days to MDUFA Decision</b>	N/A	N/A	N/A		
20th Percentile Total Days to MDUFA Decision	0	0	0		
40th Percentile Total Days to MDUFA Decision	0	0	0		
60th Percentile Total Days to MDUFA Decision	0	0	0		
80th Percentile Total Days to MDUFA Decision	0	0	0		
Maximum Total Days to MDUFA Decision	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		
Number with MDUFA Decision	0	1	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	0.00%	N/A		
Rate of Not Approvable	N/A	0.00%	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		
Number With MDUFA Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A	N/A	N/A		
PMAs Pending MDUFA Decision	N/A	N/A	N/A		
PMAs Pending MDUFA Decision Past Goal	N/A	N/A	N/A		
Current Performance Percent Goal Met	N/A	N/A	N/A		

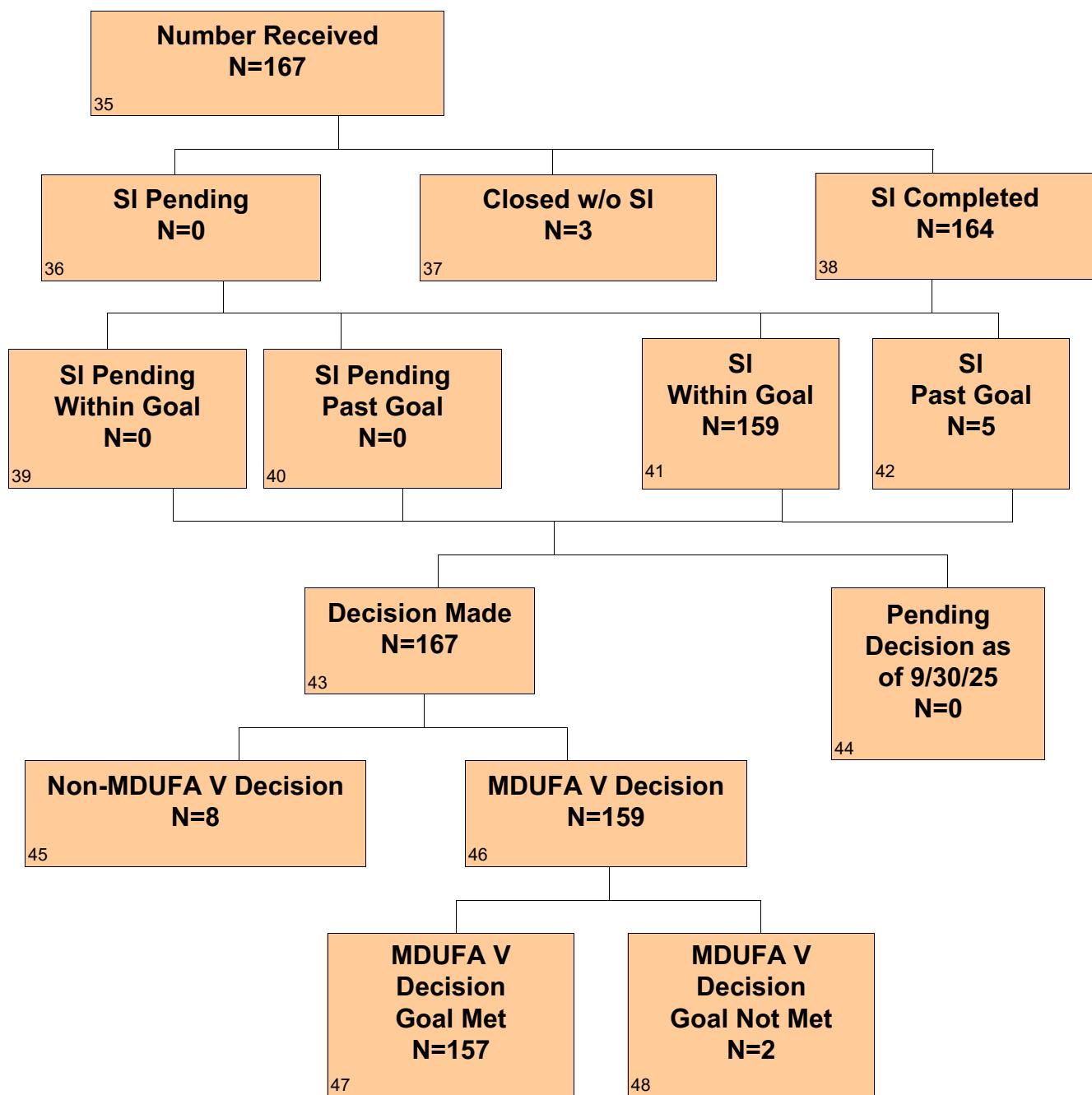
\*Includes submission that went to panel

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

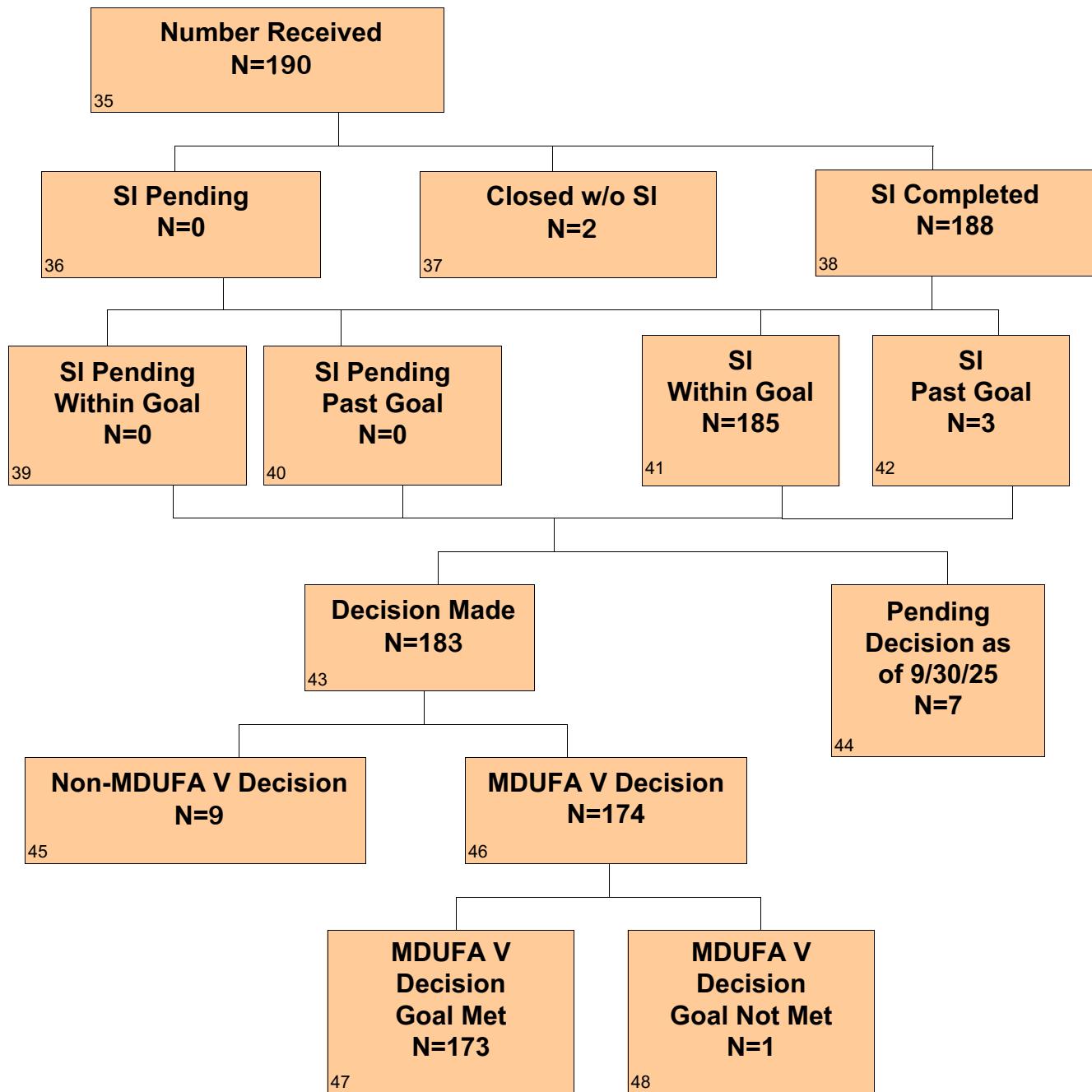
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Goal Met	N/A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

\*Includes submission that went to panel

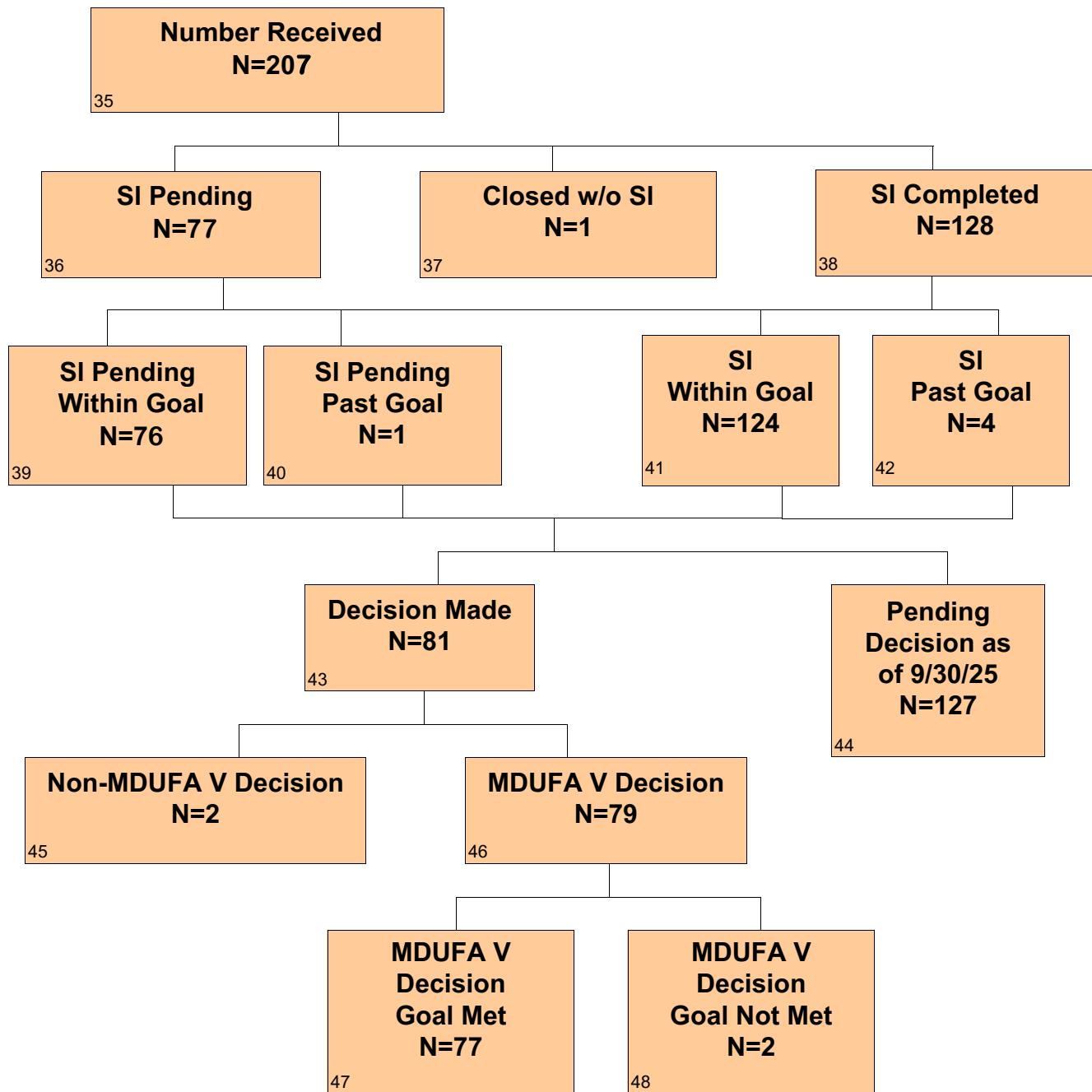
# CDRH PMA 180 Day Supplements - FY 2023 as of 9/30/25



# CDRH PMA 180 Day Supplements - FY 2024 as of 9/30/25



# CDRH PMA 180 Day Supplements - FY 2025 as of 9/30/25



## 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		
SI Goal Met	159	185	124		
SI Goal Not Met	5	3	4		
SI Pending Within Goal	0	0	76		
SI Pending Past Goal	0	0	1		
Closed Without SI	3	2	2		
Current SI Performance Percent Goal Met	96.95%	98.40%	96.12%		

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		
Non-MDUFA Decision	8	9	2		
MDUFA Decision	159	174	79		
MDUFA Decision Goal Met	157	173	77		
Supplements Pending MDUFA Decision	0	7	126		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	98.74%	99.43%	97.47%		

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		
Number with MDUFA Decision	159	174	79		
Number of Not Approvable	7	14	2		
Rate of Not Approvable	4.40%	8.05%	2.53%		

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		
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	184.50		
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	0.00		

## 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		
SI Goal Met	16	15	16		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	5		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Non-MDUFA Decision	1	2	0		
MDUFA Decision	15	13	6		
MDUFA Decision Goal Met	15	13	6		
Supplements Pending MDUFA Decision	0	0	15		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Number with MDUFA Decision	15	13	6		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	6.67%	7.69%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
SI Goal Met	55	80	42		
SI Goal Not Met	0	0	2		
SI Pending Within Goal	0	0	30		
SI Pending Past Goal	0	0	1		
Closed Without SI	1	1	2		
Current SI Performance Percent Goal Met	100.00%	100.00%	93.33%		

**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		
Non-MDUFA Decision	3	4	2		
MDUFA Decision	53	73	33		
MDUFA Decision Goal Met	53	73	32		
Supplements Pending MDUFA Decision	0	4	42		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	96.97%		

**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		
Number with MDUFA Decision	53	73	33		
Number of Not Approvable	1	11	0		
Rate of Not Approvable	1.89%	15.07%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	187.00		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00		

**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		
SI Goal Met	20	17	11		
SI Goal Not Met	1	0	1		
SI Pending Within Goal	0	0	7		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	95.24%	100.00%	91.67%		

**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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	21	17	10		
MDUFA Decision Goal Met	21	17	9		
Supplements Pending MDUFA Decision	0	0	9		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	90.00%		

**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		
Number with MDUFA Decision	21	17	10		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	182.00		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00		

**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		
SI Goal Met	8	12	7		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	6		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	8	11	4		
MDUFA Decision Goal Met	8	11	4		
Supplements Pending MDUFA Decision	0	0	9		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Number with MDUFA Decision	8	11	4		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
SI Goal Met	20	17	21		
SI Goal Not Met	3	3	1		
SI Pending Within Goal	0	0	9		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	86.96%	85.00%	95.45%		

**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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	23	19	14		
MDUFA Decision Goal Met	21	18	14		
Supplements Pending MDUFA Decision	0	1	17		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	91.30%	94.74%	100.00%		

**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		
Number with MDUFA Decision	23	19	14		
Number of Not Approvable	3	1	2		
Rate of Not Approvable	13.04%	5.26%	14.29%		

**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		
Mean FDA Days for Submissions that Missed the Goal	197.00	198.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	77.00	129.00	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		
SI Goal Met	6	5	8		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	3		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	6	5	3		
MDUFA Decision Goal Met	6	5	3		
Supplements Pending MDUFA Decision	0	0	8		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Number with MDUFA Decision	6	5	3		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
SI Goal Met	33	37	18		
SI Goal Not Met	1	0	0		
SI Pending Within Goal	0	0	16		
SI Pending Past Goal	0	0	0		
Closed Without SI	2	1	0		
Current SI Performance Percent Goal Met	97.06%	100.00%	100.00%		

**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		
Non-MDUFA Decision	4	2	0		
MDUFA Decision	32	34	9		
MDUFA Decision Goal Met	32	34	9		
Supplements Pending MDUFA Decision	0	2	25		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Number with MDUFA Decision	32	34	9		
Number of Not Approvable	2	1	0		
Rate of Not Approvable	6.25%	2.94%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
SI Goal Met	1	2	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	2	0		
MDUFA Decision Goal Met	1	2	0		
Supplements Pending MDUFA Decision	0	0	1		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	N/A		

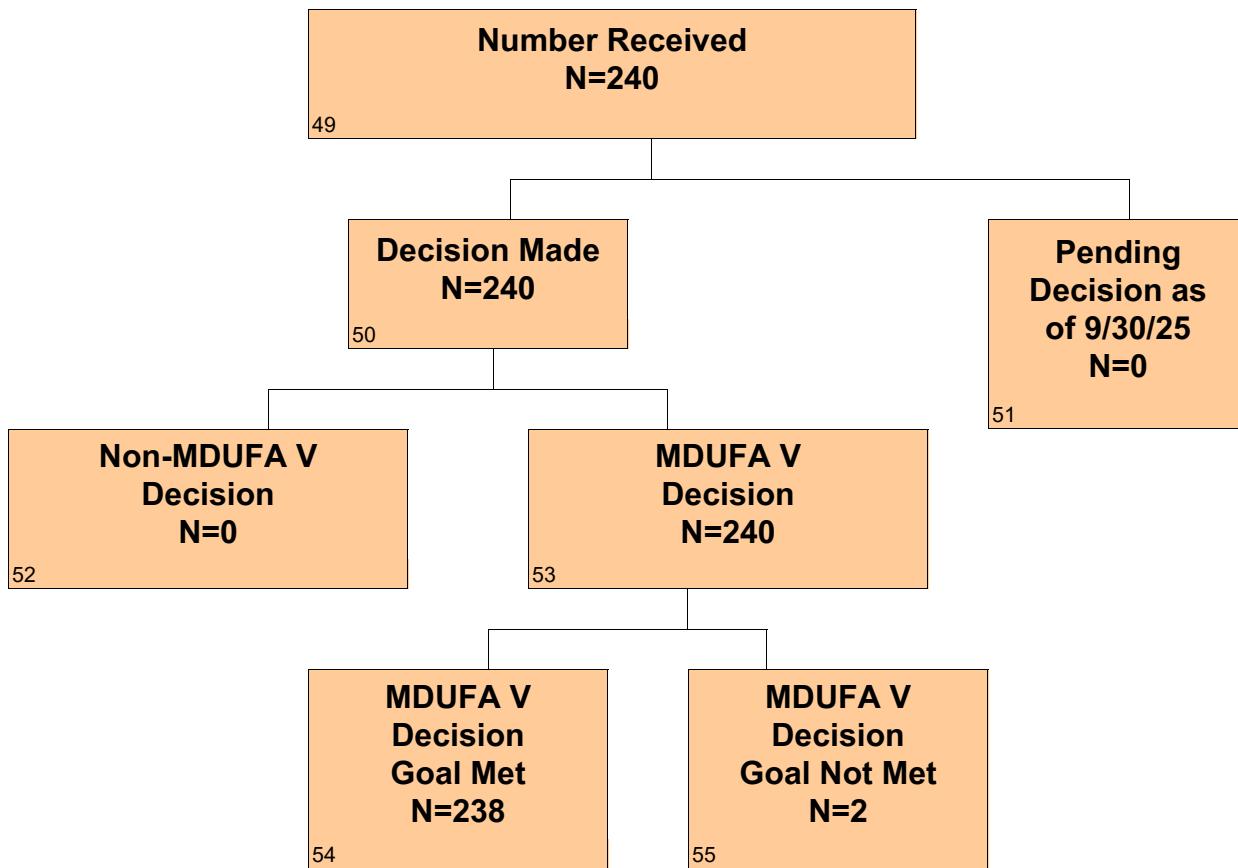
**Table 2.3 OHT8 - Office of Radiological Health**  
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

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

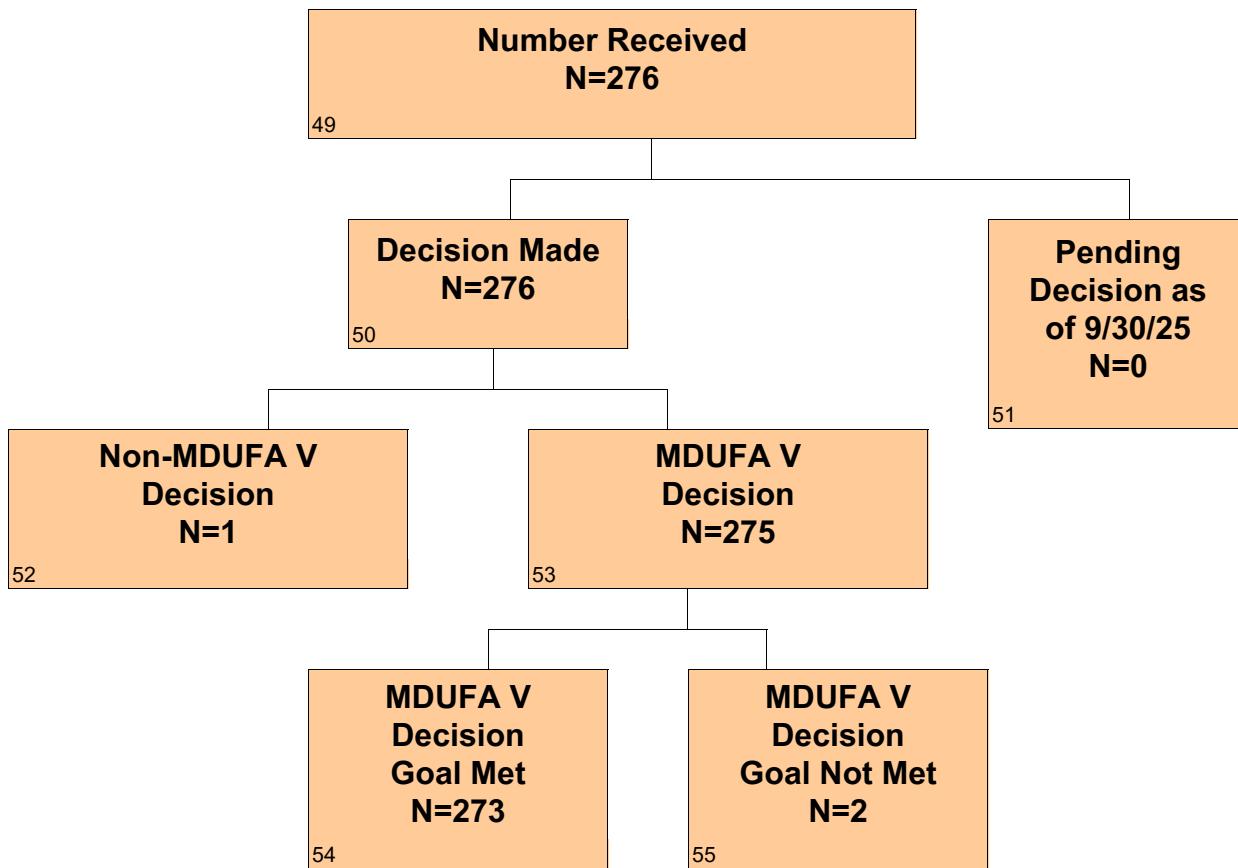
**Table 2.4 OHT8 - Office of Radiological Health**  
**PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

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

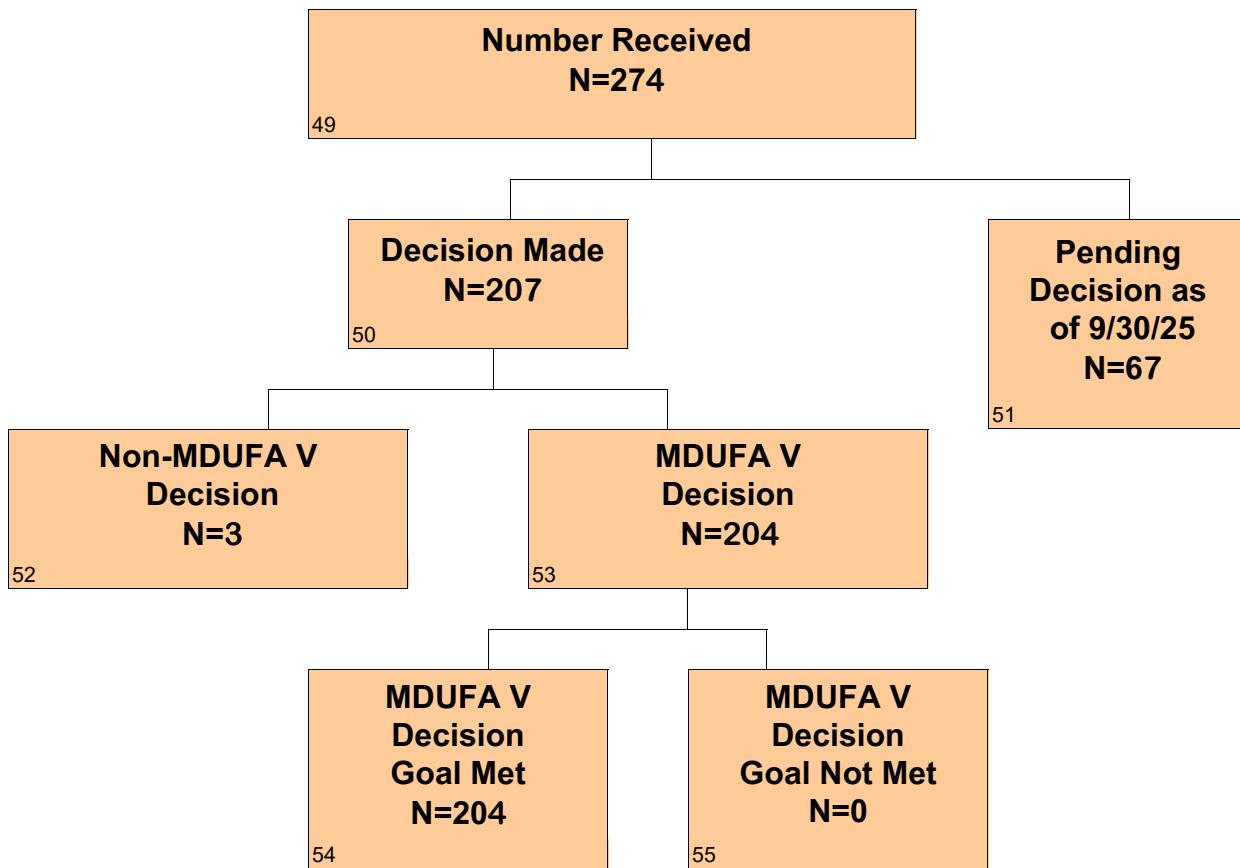
# CDRH PMA Real Time Supplements - FY 2023 as of 9/30/25



# CDRH PMA Real Time Supplements - FY 2024 as of 9/30/25



# CDRH PMA Real Time Supplements - FY 2025 as of 9/30/25



## 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		
Non-MDUFA Decision	0	1	3		
MDUFA Decision	240	275	204		
MDUFA Decision Goal Met	238	273	204		
Supplements Pending MDUFA Decision	0	0	67		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	99.17%	99.27%	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		
Number With MDUFA Decision	240	275	204		
Number of Not Approvable	11	10	17		
Rate of Not Approvable	4.58%	3.64%	8.33%		

**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	0		
Mean FDA Days for Submissions that Missed the Goal	109.50	119.50	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

### 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		
Non-MDUFA Decision	0	0	1		
MDUFA Decision	24	19	22		
MDUFA Decision Goal Met	24	19	22		
Supplements Pending MDUFA Decision	0	0	4		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

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		
Number With MDUFA Decision	24	19	22		
Number of Not Approvable	3	2	1		
Rate of Not Approvable	12.50%	10.53%	4.55%		

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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	0	0	1		
MDUFA Decision	136	142	96		
MDUFA Decision Goal Met	136	142	96		
Supplements Pending MDUFA Decision	0	0	28		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	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		
Number With MDUFA Decision	136	142	96		
Number of Not Approvable	4	1	12		
Rate of Not Approvable	2.94%	0.70%	12.50%		

**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	0		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	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		
Non-MDUFA Decision	0	1	0		
MDUFA Decision	19	22	13		
MDUFA Decision Goal Met	18	21	13		
Supplements Pending MDUFA Decision	0	0	4		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	94.74%	95.45%	100.00%		

**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		
Number With MDUFA Decision	19	22	13		
Number of Not Approvable	2	4	2		
Rate of Not Approvable	10.53%	18.18%	15.38%		

**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		
Mean FDA Days for Submissions that Missed the Goal	92.00	91.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	7	10	7		
MDUFA Decision Goal Met	7	10	7		
Supplements Pending MDUFA Decision	0	0	3		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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		
Number With MDUFA Decision	7	10	7		
Number of Not Approvable	2	1	1		
Rate of Not Approvable	28.57%	10.00%	14.29%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	16	37	40		
MDUFA Decision Goal Met	15	36	40		
Supplements Pending MDUFA Decision	0	0	10		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	93.75%	97.30%	100.00%		

**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		
Number With MDUFA Decision	16	37	40		
Number of Not Approvable	0	1	1		
Rate of Not Approvable	0.00%	2.70%	2.50%		

**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		
Mean FDA Days for Submissions that Missed the Goal	127.00	148.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	11	0		
MDUFA Decision Goal Met	4	11	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	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		
Number With MDUFA Decision	4	11	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	0	0	1		
MDUFA Decision	32	33	26		
MDUFA Decision Goal Met	32	33	26		
Supplements Pending MDUFA Decision	0	0	18		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	100.00%		

**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		
Number With MDUFA Decision	32	33	26		
Number of Not Approvable	0	1	0		
Rate of Not Approvable	0.00%	3.03%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	2	1	0		
MDUFA Decision Goal Met	2	1	0		
Supplements Pending MDUFA Decision	0	0	0		
Supplements Pending MDUFA Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	100.00%	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		
Number With MDUFA Decision	2	1	0		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0.00%	0.00%	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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A		

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

There were no pre-market reports received by FDA between October 1, 2024 and September 30, 2025.

## Section 5 PMA Annual General Metrics

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

PMA Submissions Received	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Premarket Report Submissions	0	1	2		
Original PMAs (Panel) - Breakthrough Device	3	0	0		
Original PMAs (No Panel) - Breakthrough Device	13	10	15		
Original PMAs (Panel) - Non-Breakthrough Device	1	1	0		
Original PMAs (No Panel) - Non-Breakthrough Device	27	31	36		
Panel-Tracked Supplements (Panel) - Breakthrough Device	0	0	0		
Panel-Tracked Supplements (No Panel) - Breakthrough Device	1	0	1		
Panel-Tracked Supplements (Panel) - Non-Breakthrough Device	0	2	0		
Panel-Tracked Supplements (No Panel) - Non-Breakthrough Device	28	25	37		
PMA Modules	79	90	97		
180-Day Supplements	167	190	207		
Real-Time Supplements	240	276	274		

Table 5.2 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Percent Cohorts Closed

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	72	67	76		
Number With a Decision (MDUFA or Non-MDUFA)	71	56	27		
% of FY Closed	98.61%	83.58%	35.53%		

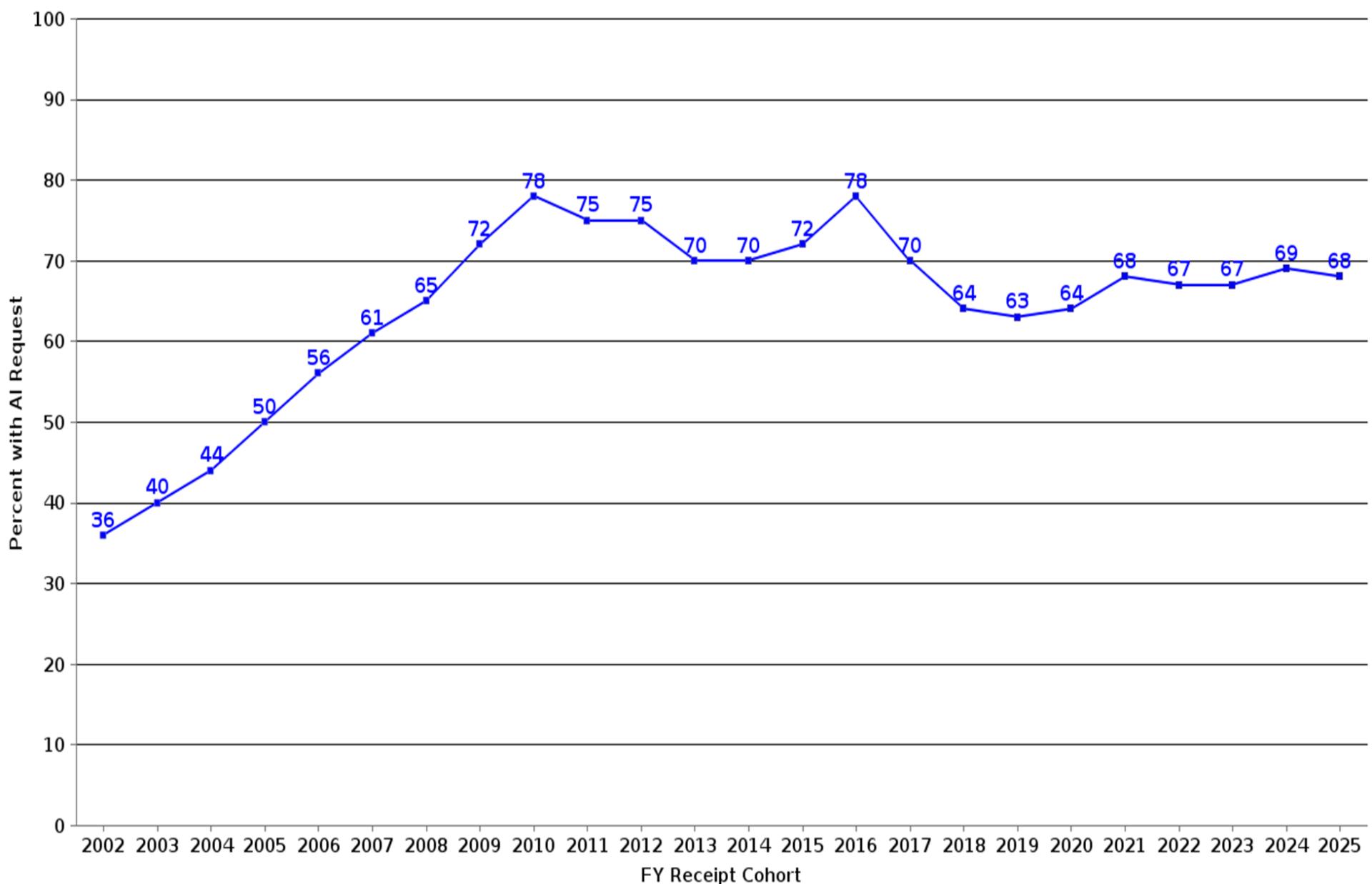
Table 5.3 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Three-Year Rolling Average Time to MDUFA V Decision

Performance Metric	FY 2023 3 Year Cohort 290 FDA Days	FY 2024 3 Year Cohort 290 FDA Days	FY 2025 3 Year Cohort 285 FDA Days	FY 2026 3 Year Cohort 285 FDA Days	FY 2027 3 Year Cohort 285 FDA Days
Number With a MDUFA Decision	180	167	152		
Number With a MDUFA Decision After Trimming the Upper and Lower 5%	162	151	138		
Three-year Rolling Average Total Time to MDUFA Decision	306.02	N/A	N/A		

510(k)s

Q4FY2025

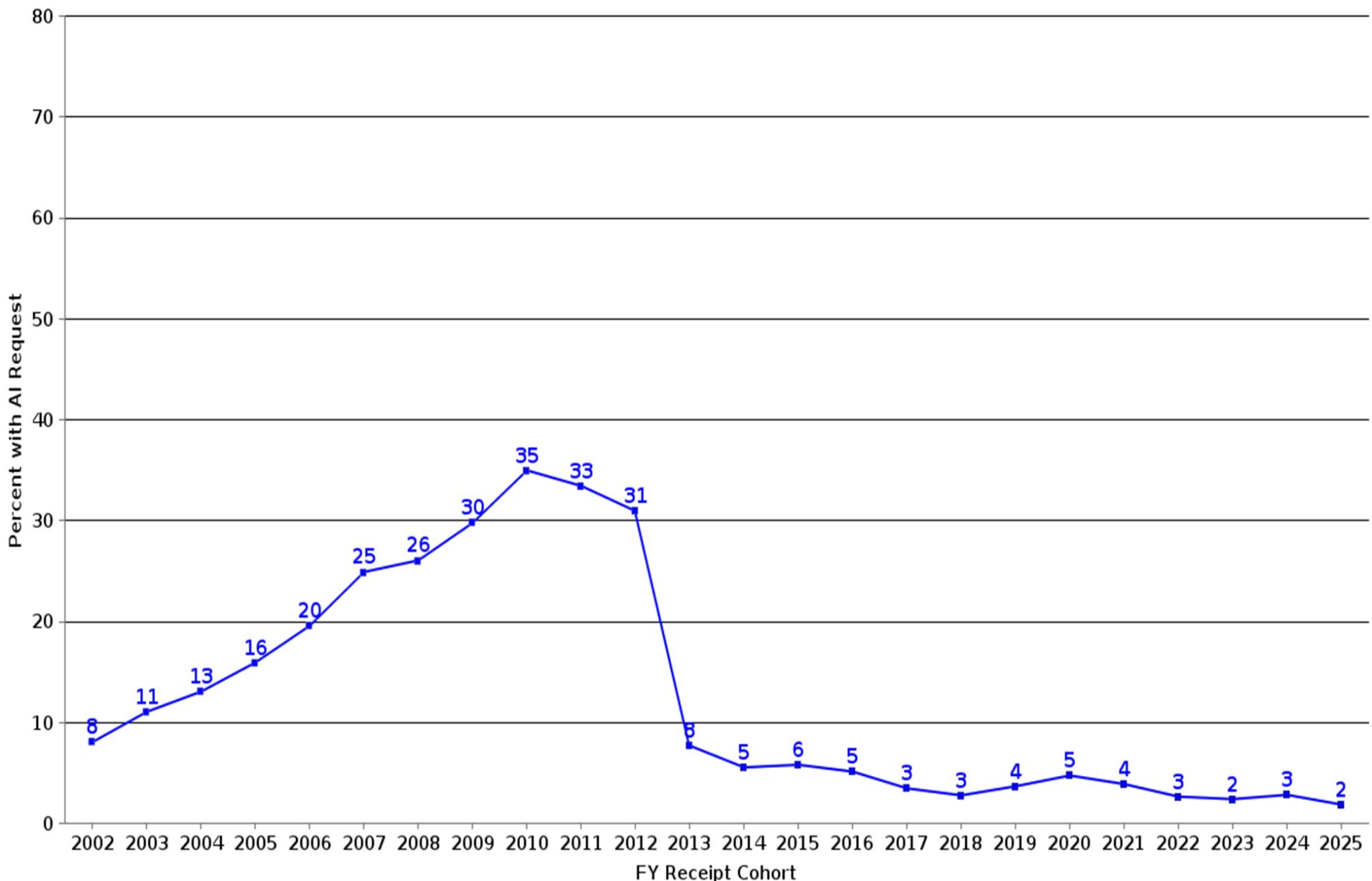
## Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 7/31/25

■ % with 1st Cycle AI Request

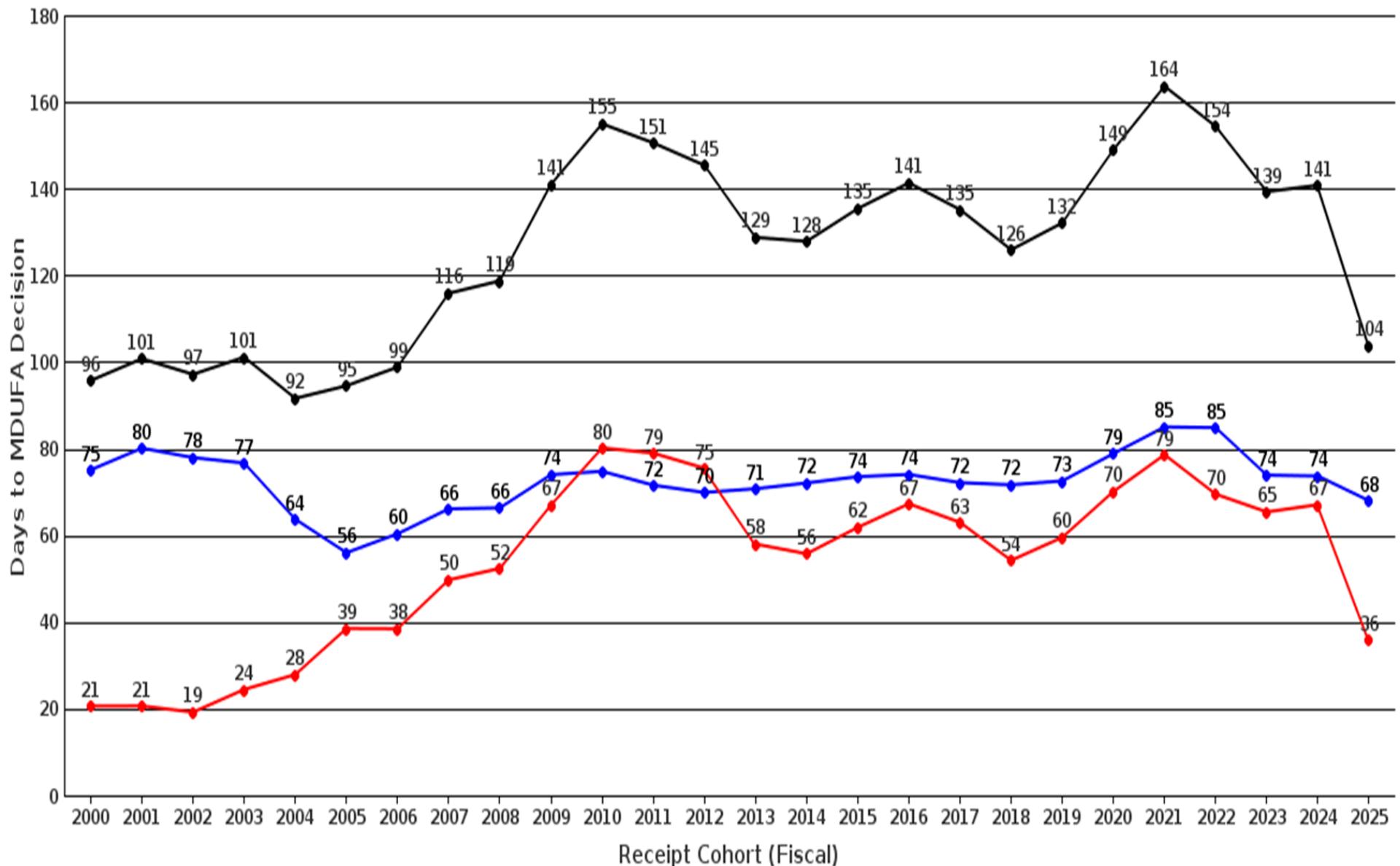
## Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 2/28/25

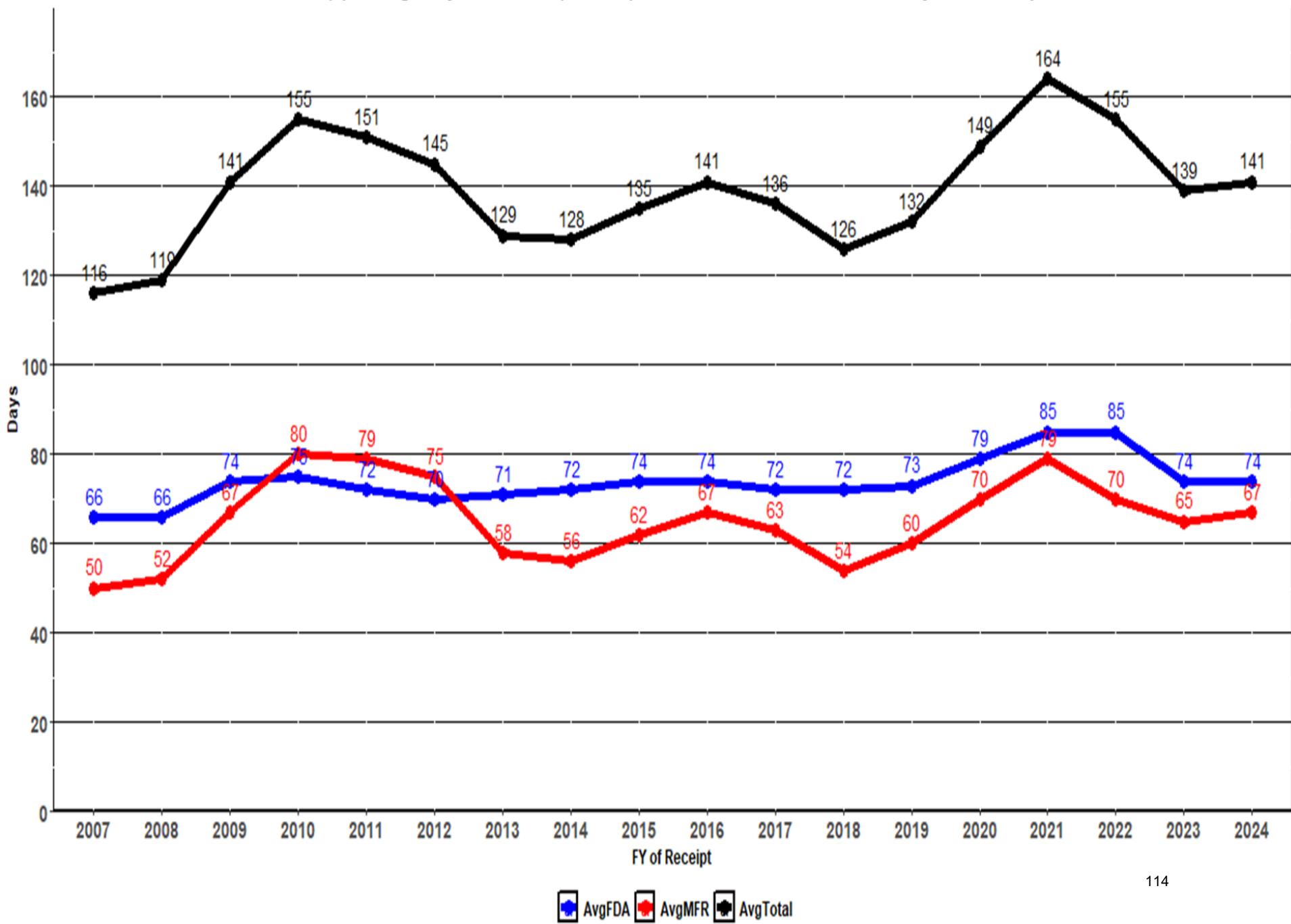
■ % with 2nd Cycle AI Request

## 510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 9/30/25

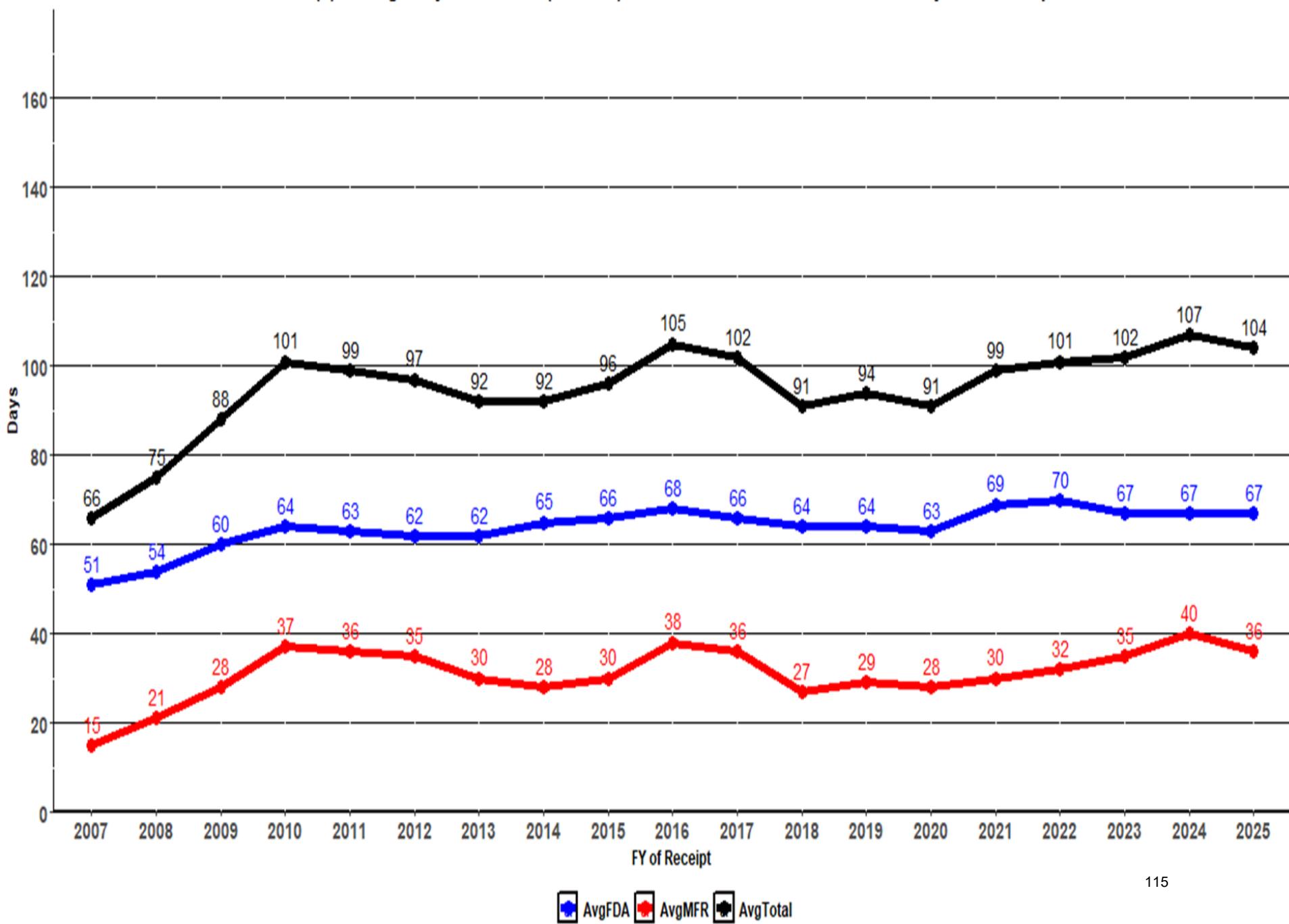


Cohorts not yet closed: 2021: 99.88%; 2022: 99.97%; 2023: 99.94%; 2024: 99%; 2025: 55.39%

## 510(k) Average Days to MDUFA (SE/NSE) Decision at 99 % Cohort Closure by FY of Receipt

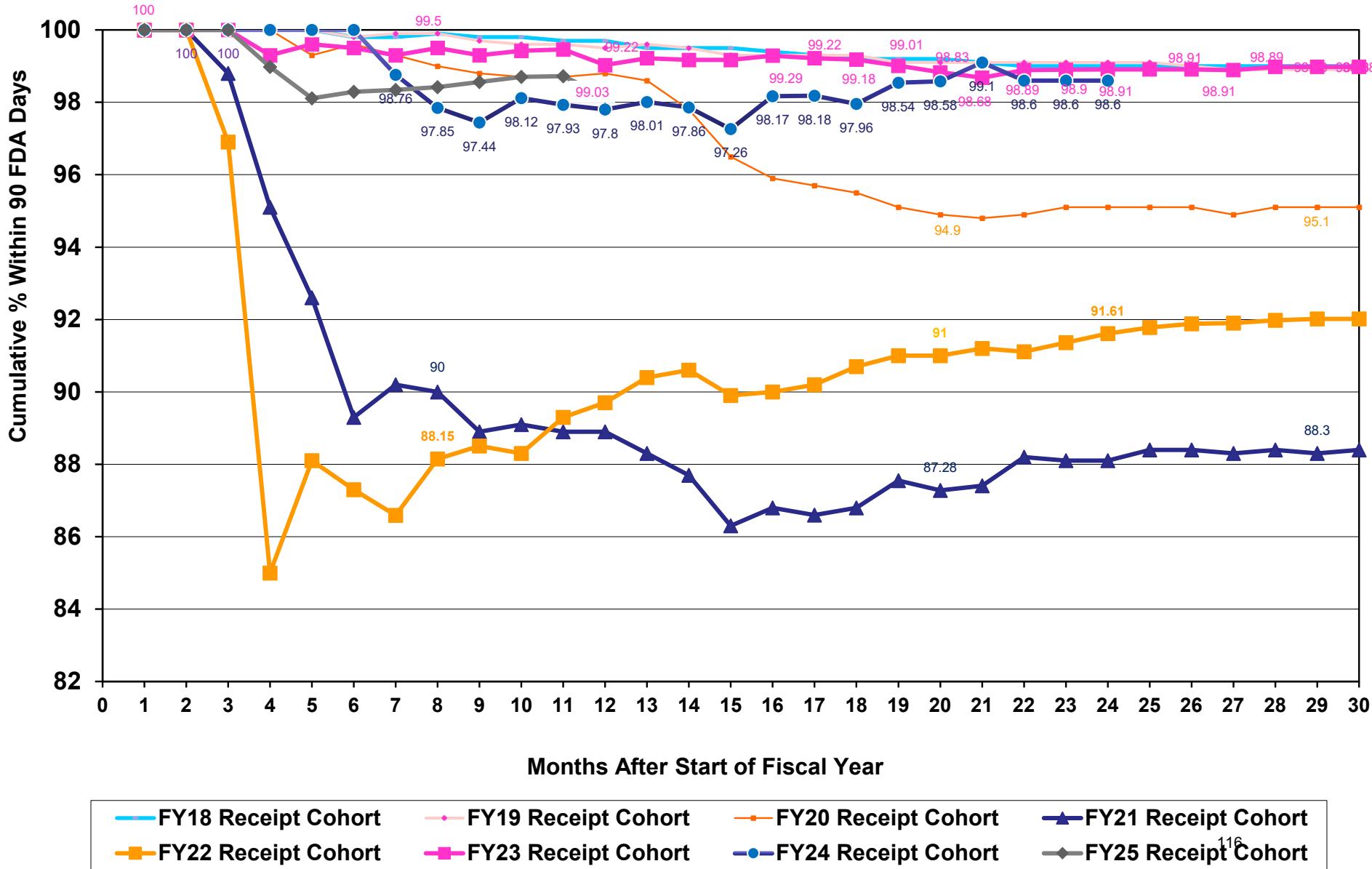


## 510(k) Average Days to MDUFA (SE/NSE) Decision at 55.39 % Cohort Closure by FY of Receipt

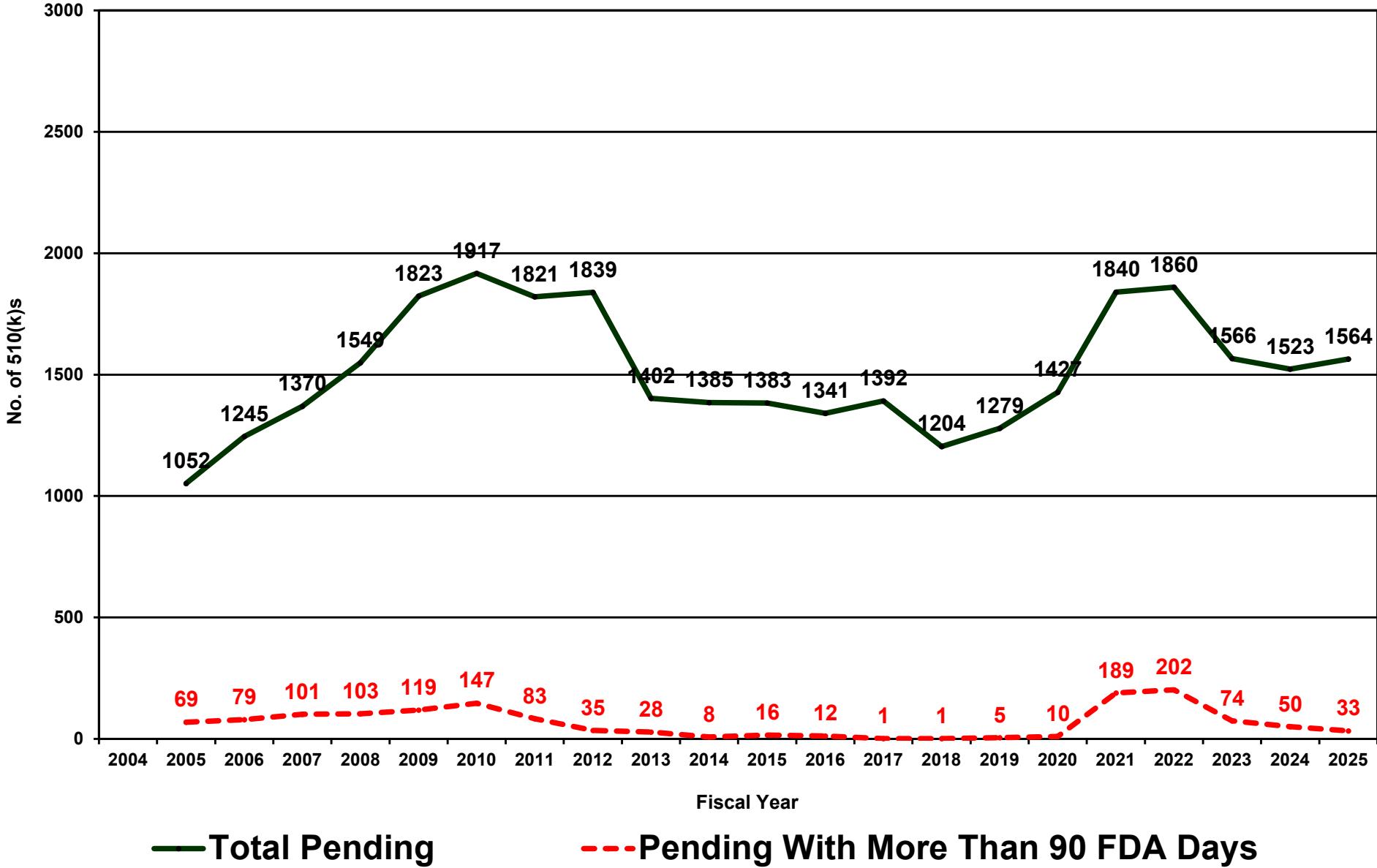


# Trend in 510(k) MDUFA Decision Goal Performance

## Comparison of FY18 – FY25 Receipt Cohorts

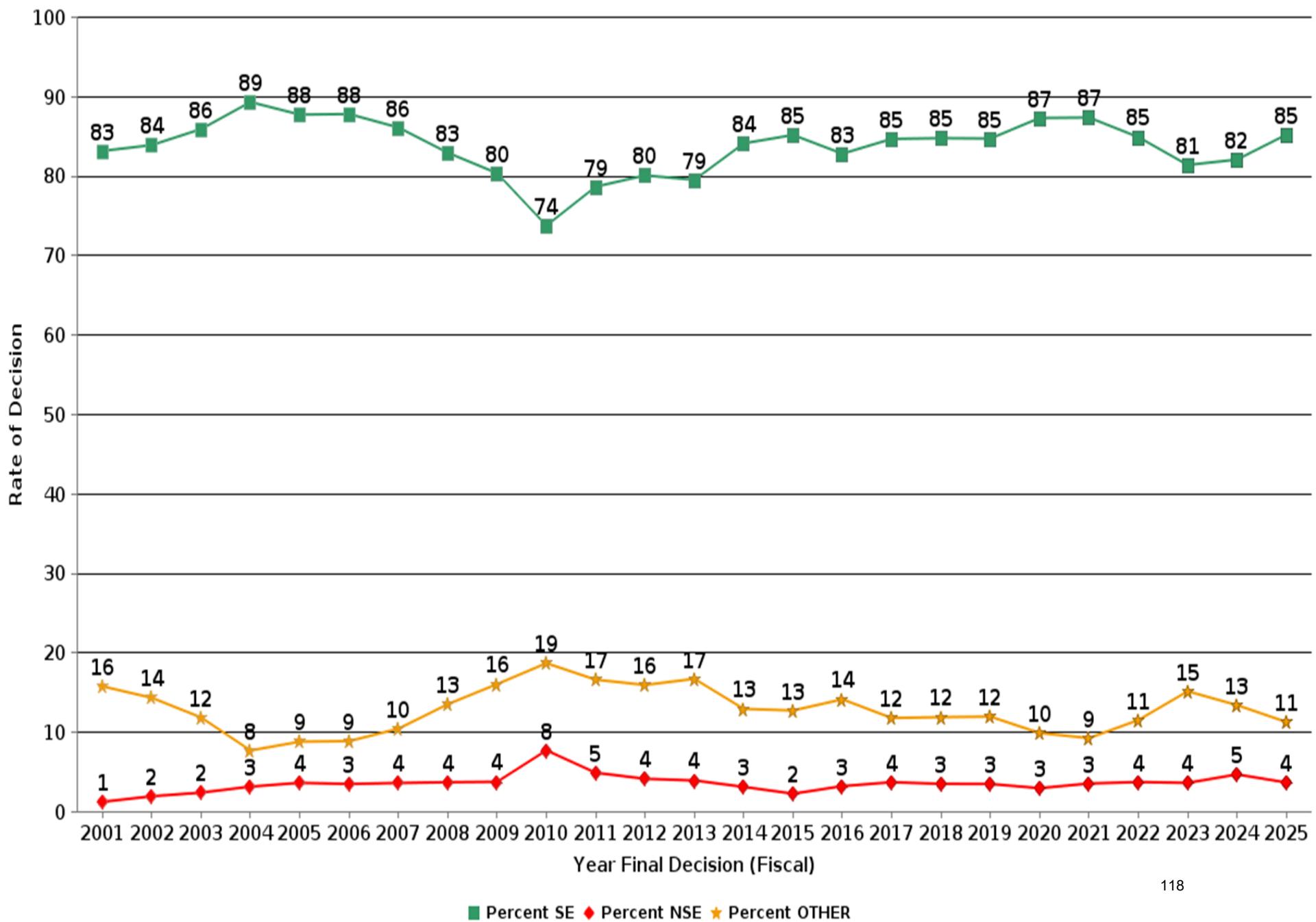


# 510(k)s Pending at End of Quarter/Year



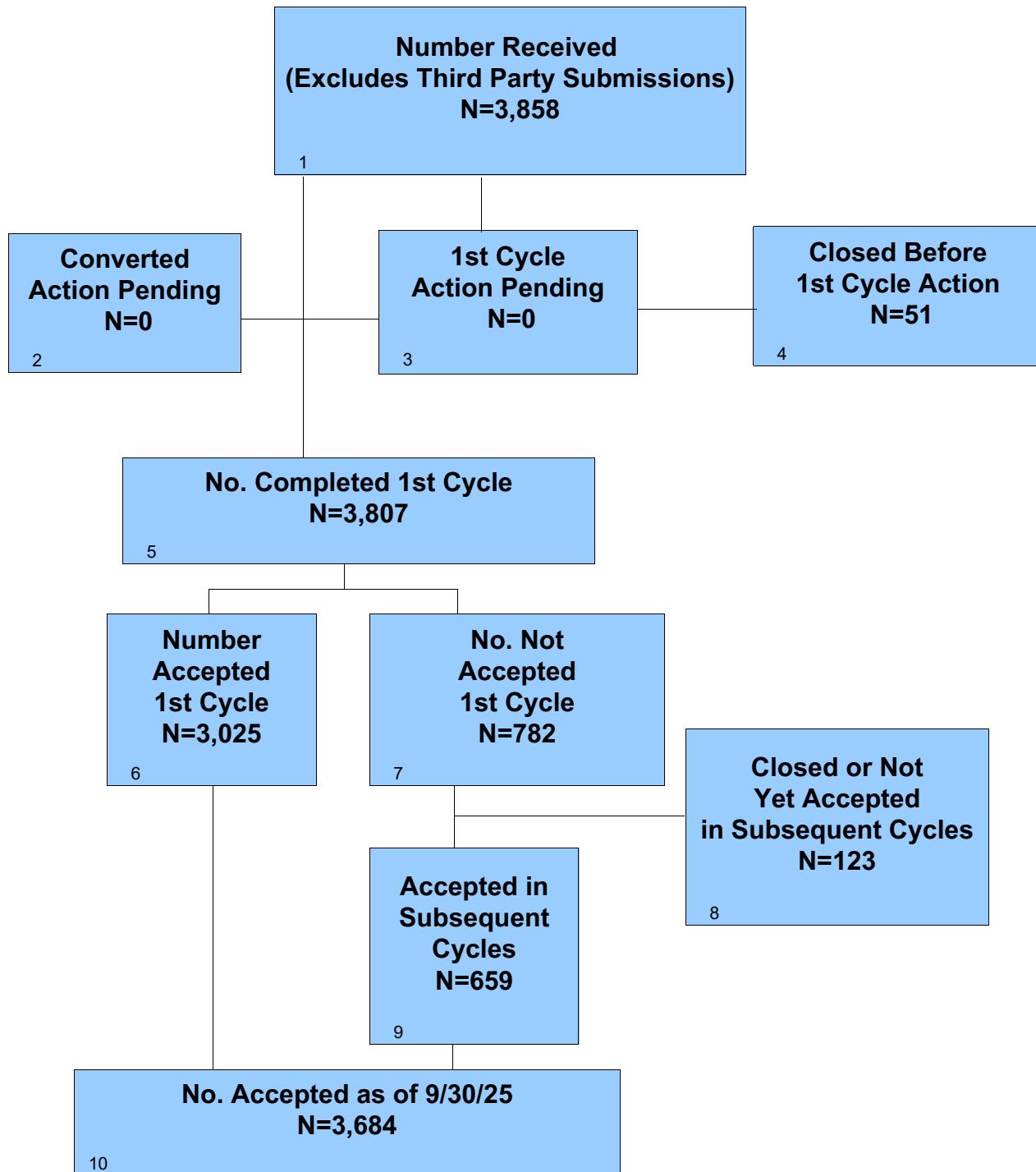
“Pending” means 510ks under review or on hold following a positive RTA decision (FY13 and later).

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

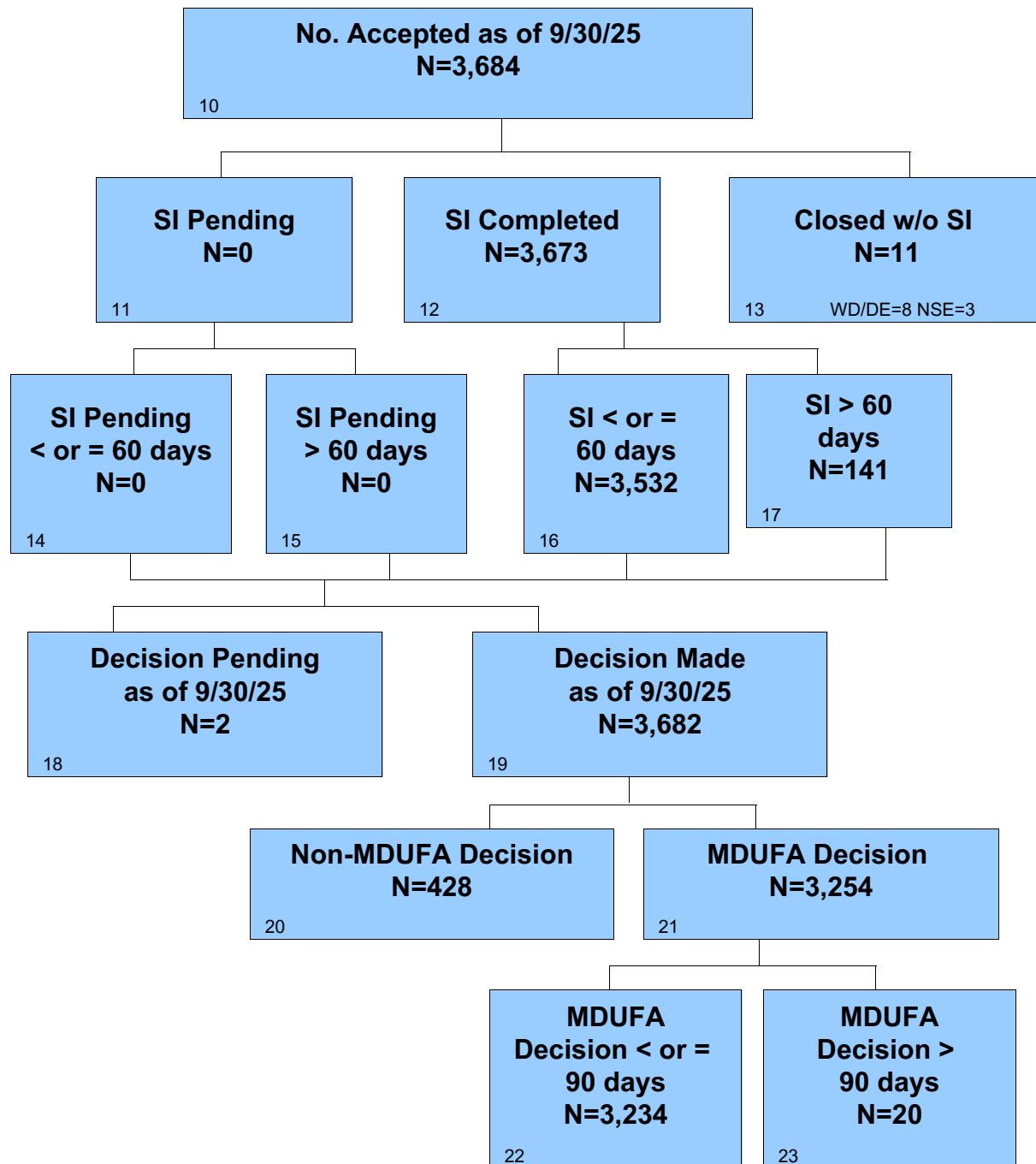


# CDRH 510(k)s - FY 2023

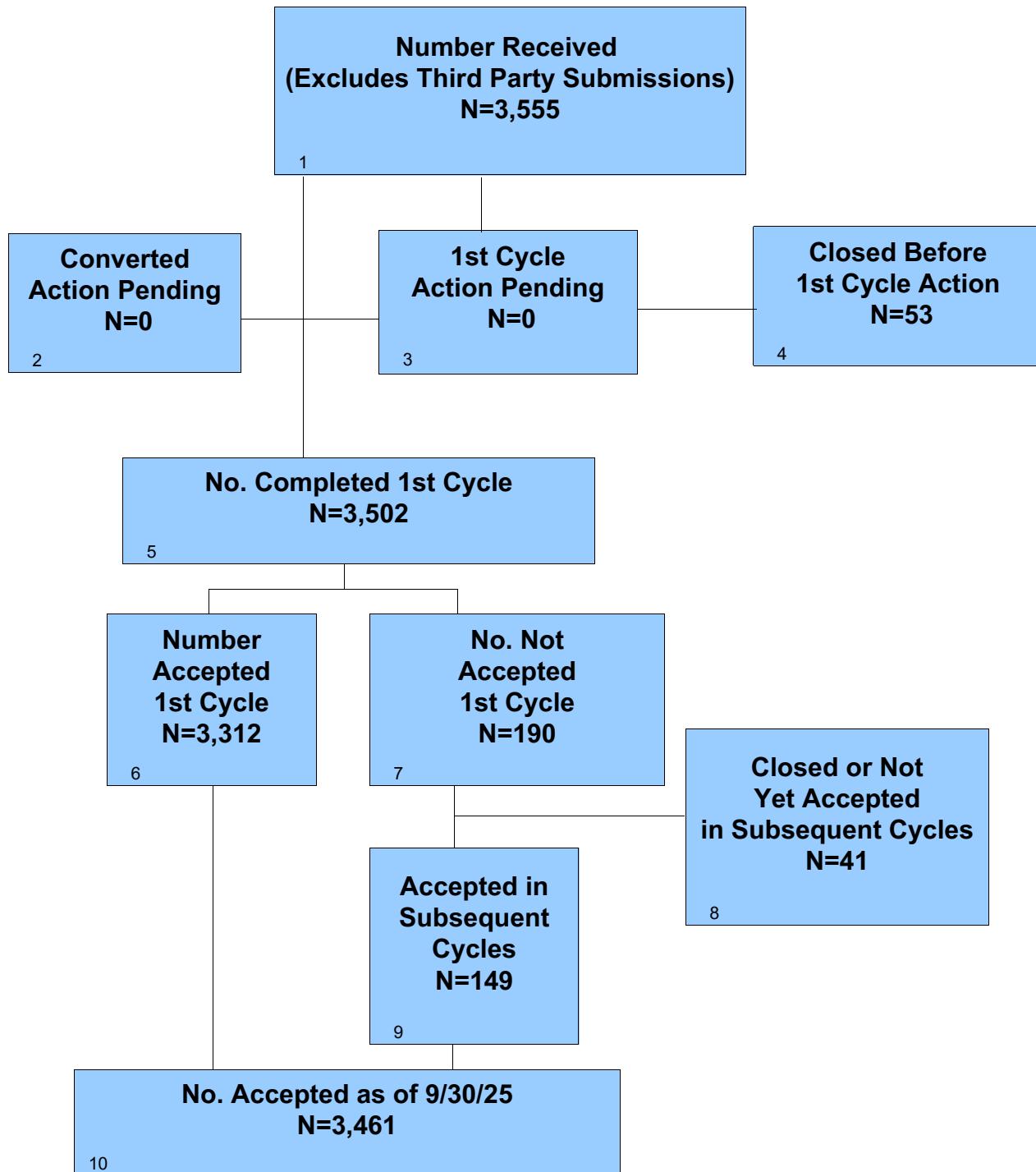
## as of 9/30/25



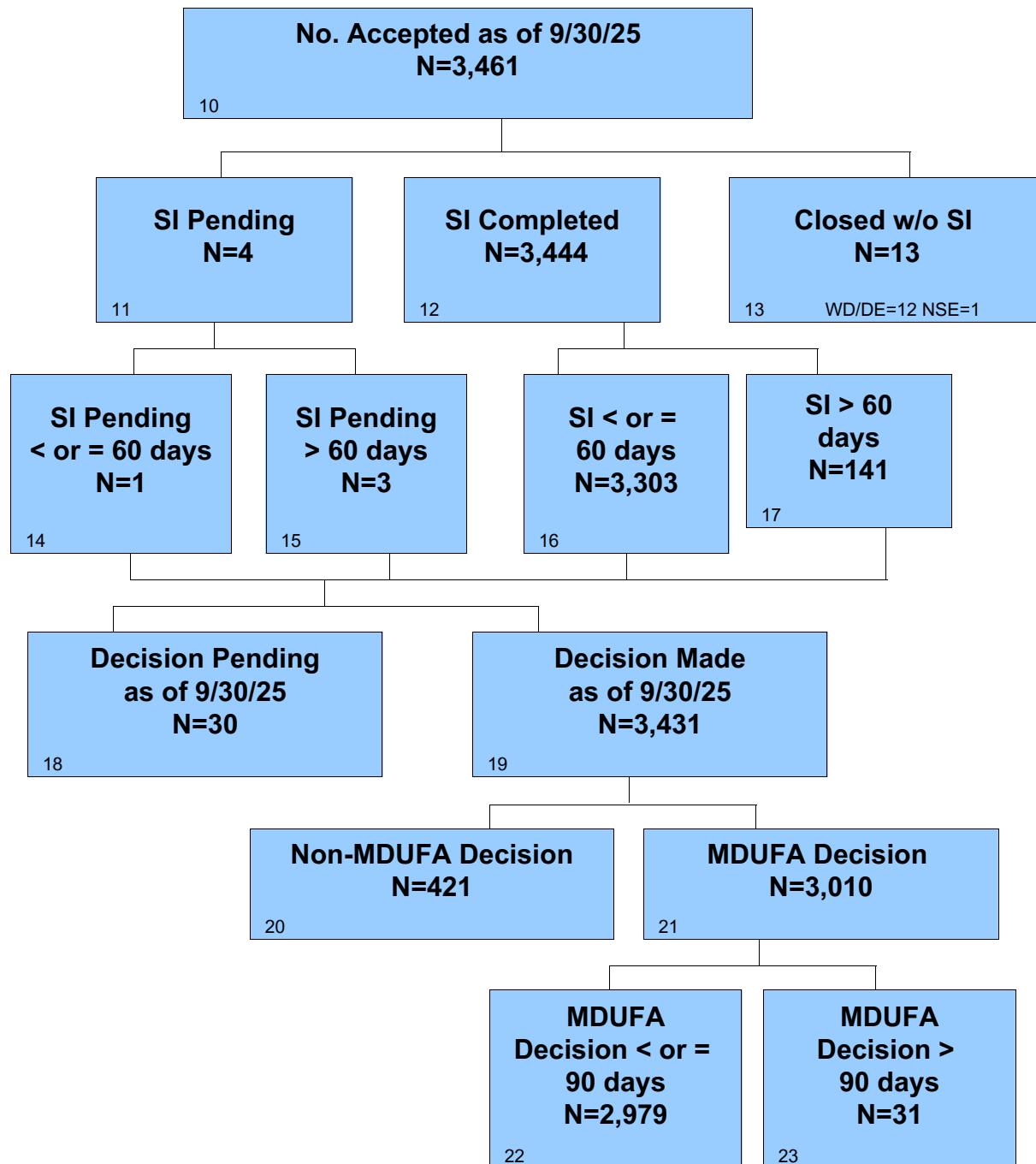
# CDRH 510(k)s - FY 2023 as of 9/30/25 Continued



# CDRH 510(k)s - FY 2024 as of 9/30/25

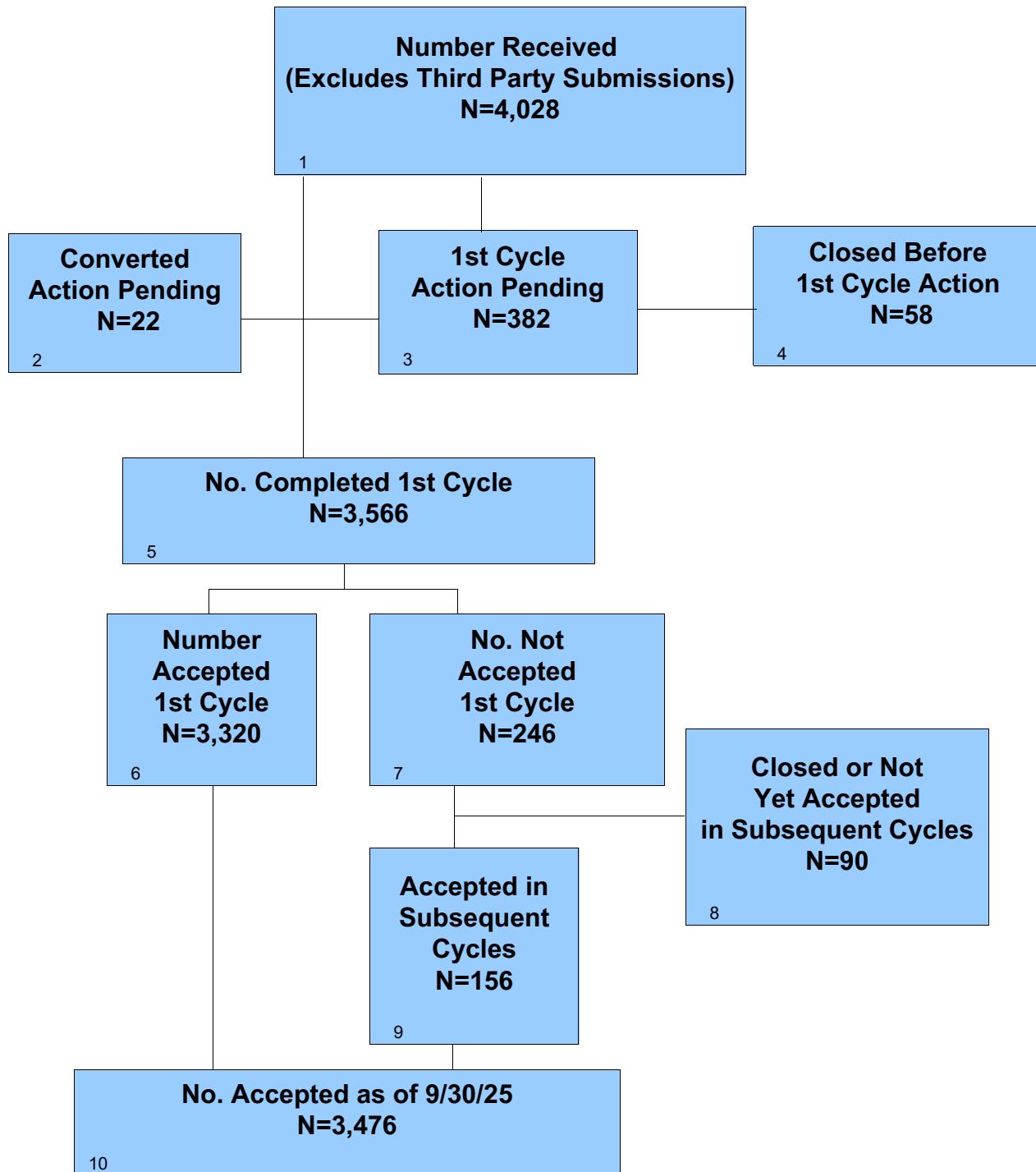


# CDRH 510(k)s - FY 2024 as of 9/30/25 Continued

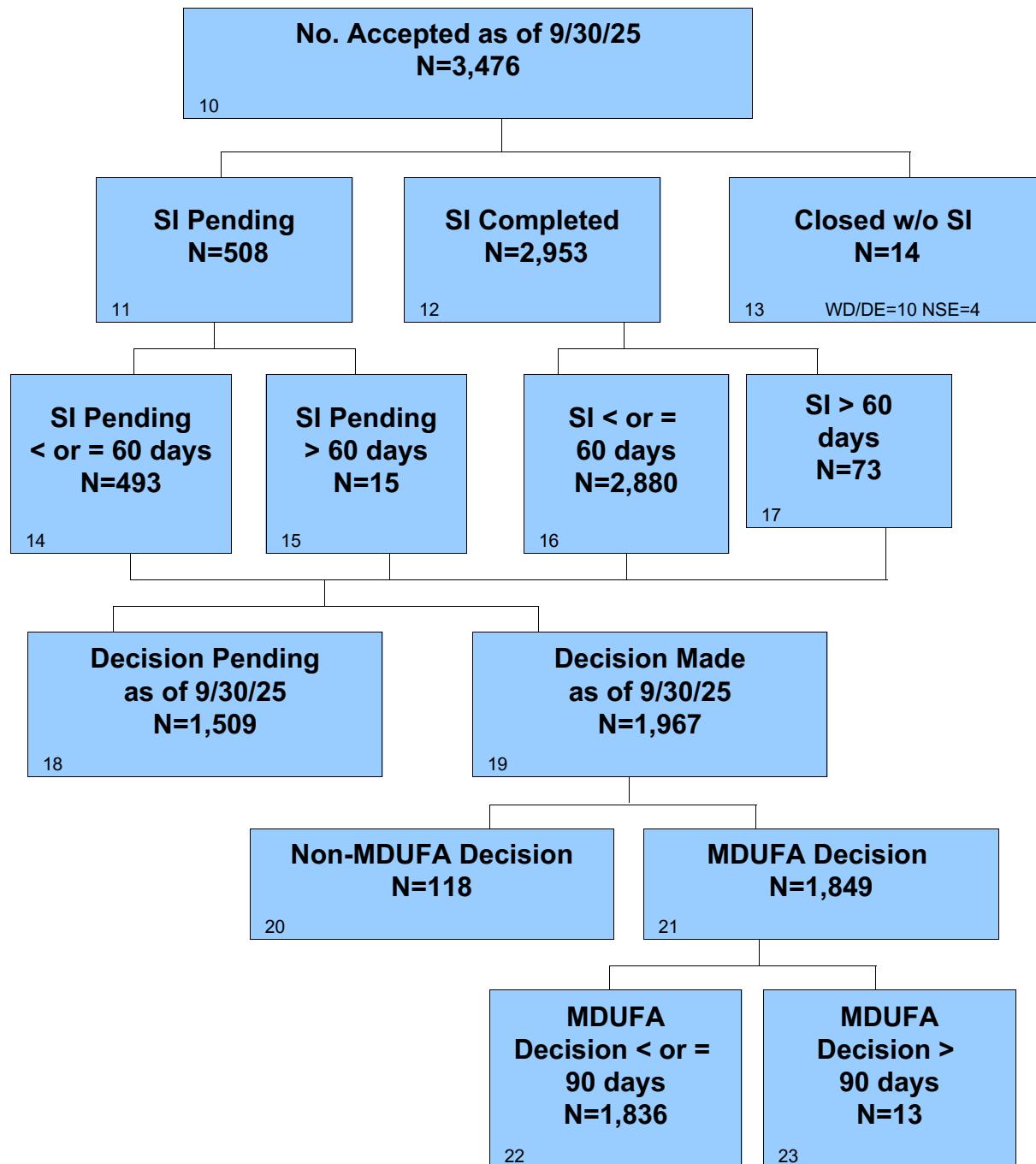


# CDRH 510(k)s - FY 2025

## as of 9/30/25



# CDRH 510(k)s - FY 2025 as of 9/30/25 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	3,858	3,555	4,028		
Closed Before First RTA or TS Action <sup>1</sup>	51	53	58		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	3,007	3,284	3,282		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	18	28	38		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	404		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	782	190	246		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	20.54%	5.43%	6.90%		

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 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	3,684	3,461	3,476		
Deleted or Withdrawn Prior to SI	8	12	10		
SI Within 60 FDA Days	3,532	3,303	2,880		
SI Over 60 FDA Days	141	141	73		
SI Pending Within 60 FDA Days	0	1	493		
SI Pending Over 60 FDA Days	0	3	15		
510(k)s NSE Without SI	3	1	4		
Current SI Performance Percent Within 60 FDA Days	96.08%	95.79%	96.90%		

**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	3,673	3,444	2,953		
Average Number of FDA Days to Substantive Interaction	52.70	52.47	52.00		
20th Percentile FDA Days to Substantive Interaction	48	48	45		
40th Percentile FDA Days to Substantive Interaction	57	57	56		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	212	95	175		

**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	3,684	3,461	3,476		
Non-MDUFA V Decision	428	421	118		
MDUFA V Decision (SE/NSE)	3,254	3,010	1,849		
MDUFA V Decision Within 90 FDA Days	3,234	2,979	1,836		
510(k)s Pending MDUFA V Decision	2	30	1,509		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	2	5	15		
Current Performance Percent Within 90 FDA Days	99.32%	98.81%	98.50%		

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

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
Average Review Cycles	1.67	1.69	1.52		
Number With MDUFA V Decision	3254	3010	1849		
<b>Average Number of FDA Days to MDUFA V Decision</b>	<b>74.81</b>	<b>74.62</b>	<b>69.04</b>		
20th Percentile FDA Days to MDUFA V Decision	57	57	37		
40th Percentile FDA Days to MDUFA V Decision	84	85	71		
60th Percentile FDA Days to MDUFA V Decision	88	88	87		
80th Percentile FDA Days to MDUFA V Decision	90	90	89		
Maximum FDA Days to MDUFA V Decision	276	203	234		
<b>Average Number of Industry Days to MDUFA V Decision</b>	<b>66.25</b>	<b>68.23</b>	<b>37.03</b>		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	14	18	0		
60th Percentile Industry Days to MDUFA V Decision	70	72	24		
80th Percentile Industry Days to MDUFA V Decision	152	155	76		
Maximum Industry Days to MDUFA V Decision	367	392	258		
<b>Average Number of Total Days to MDUFA V Decision</b>	<b>141.13</b>	<b>142.85</b>	<b>105.48</b>		
20th Percentile Total Days to MDUFA V Decision	59	58	42		
40th Percentile Total Days to MDUFA V Decision	97	100	84		
60th Percentile Total Days to MDUFA V Decision	155	157	108		
80th Percentile Total Days to MDUFA V Decision	238	241	161		
Maximum Total Days to MDUFA V Decision	517	546	348		

**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	3,684	3,461	3,476		
Number With MDUFA V Decision	3,254	3,010	1,849		
Number of SE Decision	3,107	2,871	1,808		
Number of NSE Decision	147	139	41		
Number of Withdrawal	225	228	74		
Number of Deleted	194	186	38		
Rate of SE Decision	95.48%	95.38%	97.78%		
Rate of NSE Decision	4.52%	4.62%	2.22%		
Rate of Withdrawal	6.11%	6.59%	2.13%		
Rate of Deleted	5.27%	5.37%	1.09%		

**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	20	31	13		
Mean FDA Days for Submissions that Missed the Goal	124.45	108.90	120.92		
Mean Industry Days for Submissions that Missed the Goal	129.15	138.45	63.85		

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days				
510(k)s Accepted	269	236	255		
Non-MDUFA V Decision	51	43	19		
MDUFA V Decision (SE/NSE)	218	190	137		
MDUFA V Decision Within 90 FDA Days	218	190	137		
510(k)s Pending MDUFA V Decision	0	3	99		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	593		
Closed Before First RTA or TS Action <sup>1</sup>	8	8	7		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	313	467	454		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	3	4	2		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	69		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	253	51	61		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	44.46%	9.77%	11.80%		

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	495		
Deleted or Withdrawn Prior to SI	2	2	3		
SI Within 60 FDA Days	425	427	409		
SI Over 60 FDA Days	105	84	13		
SI Pending Within 60 FDA Days	0	0	68		
SI Pending Over 60 FDA Days	0	0	1		
510(k)s NSE Without SI	1	0	0		
Current SI Performance Percent Within 60 FDA Days	80.04%	83.56%	96.69%		

**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	422		
Average Number of FDA Days to Substantive Interaction	56.90	55.87	54.09		
20th Percentile FDA Days to Substantive Interaction	55	53	50		
40th Percentile FDA Days to Substantive Interaction	58	57	56		
60th Percentile FDA Days to Substantive Interaction	60	59	58		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	212	80	79		

**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	495		
Non-MDUFA V Decision	84	67	26		
MDUFA V Decision (SE/NSE)	448	442	235		
MDUFA V Decision Within 90 FDA Days	439	436	234		
510(k)s Pending MDUFA V Decision	1	4	234		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	0	1		
Current Performance Percent Within 90 FDA Days	97.77%	98.64%	99.15%		

**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	1.66		
Number With MDUFA V Decision	448	442	235		
<b>Average Number of FDA Days to MDUFA V Decision</b>	82.79	82.25	76.21		
20th Percentile FDA Days to MDUFA V Decision	82	83	60		
40th Percentile FDA Days to MDUFA V Decision	88	87	86		
60th Percentile FDA Days to MDUFA V Decision	89	89	88		
80th Percentile FDA Days to MDUFA V Decision	90	90	90		
Maximum FDA Days to MDUFA V Decision	276	120	94		
<b>Average Number of Industry Days to MDUFA V Decision</b>	76.33	85.47	50.22		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	39	42	8		
60th Percentile Industry Days to MDUFA V Decision	87	104	45		
80th Percentile Industry Days to MDUFA V Decision	162	174	103		
Maximum Industry Days to MDUFA V Decision	353	392	207		
<b>Average Number of Total Days to MDUFA V Decision</b>	159.28	167.60	125.69		
20th Percentile Total Days to MDUFA V Decision	87	89	60		
40th Percentile Total Days to MDUFA V Decision	126	128	90		
60th Percentile Total Days to MDUFA V Decision	178	190	131		
80th Percentile Total Days to MDUFA V Decision	252	261	187		
Maximum Total Days to MDUFA V Decision	443	482	297		

**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	495		
Number With MDUFA V Decision	448	442	235		
Number of SE Decision	412	411	228		
Number of NSE Decision	36	31	7		
Number of Withdrawal	41	31	17		
Number of Deleted	42	35	8		
Rate of SE Decision	91.96%	92.99%	97.02%		
Rate of NSE Decision	8.04%	7.01%	2.98%		
Rate of Withdrawal	7.69%	6.04%	3.43%		
Rate of Deleted	7.88%	6.82%	1.62%		

**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	9	6	1		
Mean FDA Days for Submissions that Missed the Goal	148.78	102.67	94.00		
Mean Industry Days for Submissions that Missed the Goal	120.78	165.83	6.00		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	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	FY 2024	FY 2025	FY 2026	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		
Closed Before First RTA or TS Action <sup>1</sup>	8	6	7		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	332	354	326		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	1	6	5		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	44		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	38	12	35		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	10.24%	3.23%	9.56%		

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	355		
Deleted or Withdrawn Prior to SI	0	0	1		
SI Within 60 FDA Days	355	345	272		
SI Over 60 FDA Days	10	22	21		
SI Pending Within 60 FDA Days	0	0	57		
SI Pending Over 60 FDA Days	0	3	2		
510(k)s NSE Without SI	0	0	2		
Current SI Performance Percent Within 60 FDA Days	97.26%	93.24%	91.58%		

**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	293		
Average Number of FDA Days to Substantive Interaction	51.40	51.09	52.56		
20th Percentile FDA Days to Substantive Interaction	44	30	31		
40th Percentile FDA Days to Substantive Interaction	56	56	58		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	86	85	86		

**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	355		
Non-MDUFA V Decision	34	44	8		
MDUFA V Decision (SE/NSE)	331	319	170		
MDUFA V Decision Within 90 FDA Days	327	310	168		
510(k)s Pending MDUFA V Decision	0	7	177		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	5	3		
Current Performance Percent Within 90 FDA Days	98.79%	95.68%	97.11%		

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	1.76	1.62		
Number With MDUFA V Decision	331	319	170		
<b>Average Number of FDA Days to MDUFA V Decision</b>	73.39	72.93	69.42		
20th Percentile FDA Days to MDUFA V Decision	55	52	42		
40th Percentile FDA Days to MDUFA V Decision	84	83	62		
60th Percentile FDA Days to MDUFA V Decision	88	89	88		
80th Percentile FDA Days to MDUFA V Decision	90	90	90		
Maximum FDA Days to MDUFA V Decision	95	203	133		
<b>Average Number of Industry Days to MDUFA V Decision</b>	71.75	78.19	39.98		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	27	33	2		
60th Percentile Industry Days to MDUFA V Decision	78	92	34		
80th Percentile Industry Days to MDUFA V Decision	155	168	69		
Maximum Industry Days to MDUFA V Decision	360	360	258		
<b>Average Number of Total Days to MDUFA V Decision</b>	145.14	150.97	108.85		
20th Percentile Total Days to MDUFA V Decision	57	56	44		
40th Percentile Total Days to MDUFA V Decision	107	112	86		
60th Percentile Total Days to MDUFA V Decision	162	175	118		
80th Percentile Total Days to MDUFA V Decision	238	256	155		
Maximum Total Days to MDUFA V Decision	448	462	348		

**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	355		
Number With MDUFA V Decision	331	319	170		
Number of SE Decision	308	293	159		
Number of NSE Decision	23	26	11		
Number of Withdrawal	17	26	4		
Number of Deleted	17	16	4		
Rate of SE Decision	93.05%	91.85%	93.53%		
Rate of NSE Decision	6.95%	8.15%	6.47%		
Rate of Withdrawal	4.66%	7.03%	1.13%		
Rate of Deleted	4.66%	4.32%	1.13%		

**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	9	2		
Mean FDA Days for Submissions that Missed the Goal	92.75	124.44	112.50		
Mean Industry Days for Submissions that Missed the Goal	82.50	163.56	129.50		

**Table 6.8 OHT2 - Office of Cardiovascular Devices****LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	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	FY 2024	FY 2025	FY 2026	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	554		
Closed Before First RTA or TS Action <sup>1</sup>	5	11	8		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	389	417	470		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	2	1	3		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	47		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	81	16	26		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	17.16%	3.69%	5.21%		

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	430	488		
Deleted or Withdrawn Prior to SI	1	0	1		
SI Within 60 FDA Days	448	429	391		
SI Over 60 FDA Days	10	0	10		
SI Pending Within 60 FDA Days	0	0	83		
SI Pending Over 60 FDA Days	0	0	3		
510(k)s NSE Without SI	0	1	0		
Current SI Performance Percent Within 60 FDA Days	97.82%	99.77%	96.78%		

**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	429	401		
Average Number of FDA Days to Substantive Interaction	54.93	52.88	52.92		
20th Percentile FDA Days to Substantive Interaction	55	49	46		
40th Percentile FDA Days to Substantive Interaction	58	57	57		
60th Percentile FDA Days to Substantive Interaction	59	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	77	60	175		

**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	430	488		
Non-MDUFA V Decision	54	68	18		
MDUFA V Decision (SE/NSE)	405	359	234		
MDUFA V Decision Within 90 FDA Days	404	357	231		
510(k)s Pending MDUFA V Decision	0	3	236		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	3		
Current Performance Percent Within 90 FDA Days	99.75%	99.44%	97.47%		

**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	1.55		
Number With MDUFA V Decision	405	359	234		
<b>Average Number of FDA Days to MDUFA V Decision</b>	79.93	76.52	70.20		
20th Percentile FDA Days to MDUFA V Decision	79	58	34		
40th Percentile FDA Days to MDUFA V Decision	88	87	74		
60th Percentile FDA Days to MDUFA V Decision	89	89	88		
80th Percentile FDA Days to MDUFA V Decision	90	90	90		
Maximum FDA Days to MDUFA V Decision	93	160	147		
<b>Average Number of Industry Days to MDUFA V Decision</b>	85.37	81.97	43.88		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	48	41	0		
60th Percentile Industry Days to MDUFA V Decision	106	105	31		
80th Percentile Industry Days to MDUFA V Decision	172	169	95		
Maximum Industry Days to MDUFA V Decision	354	349	251		
<b>Average Number of Total Days to MDUFA V Decision</b>	165.30	158.65	113.01		
20th Percentile Total Days to MDUFA V Decision	87	68	34		
40th Percentile Total Days to MDUFA V Decision	133	123	88		
60th Percentile Total Days to MDUFA V Decision	193	192	119		
80th Percentile Total Days to MDUFA V Decision	260	257	181		
Maximum Total Days to MDUFA V Decision	443	438	286		

**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	430	488		
Number With MDUFA V Decision	405	359	234		
Number of SE Decision	378	331	231		
Number of NSE Decision	27	28	3		
Number of Withdrawal	24	38	10		
Number of Deleted	29	28	5		
Rate of SE Decision	93.33%	92.20%	98.72%		
Rate of NSE Decision	6.67%	7.80%	1.28%		
Rate of Withdrawal	5.23%	8.84%	2.05%		
Rate of Deleted	6.32%	6.51%	1.02%		

**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	3		
Mean FDA Days for Submissions that Missed the Goal	93.00	125.50	112.33		
Mean Industry Days for Submissions that Missed the Goal	192.00	51.50	58.67		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	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	FY 2024	FY 2025	FY 2026	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	653		
Closed Before First RTA or TS Action <sup>1</sup>	10	6	7		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	558	561	515		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	1	12	21		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	68		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	140	35	42		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	20.03%	5.76%	7.27%		

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	559		
Deleted or Withdrawn Prior to SI	1	5	1		
SI Within 60 FDA Days	671	580	447		
SI Over 60 FDA Days	5	14	18		
SI Pending Within 60 FDA Days	0	0	89		
SI Pending Over 60 FDA Days	0	0	3		
510(k)s NSE Without SI	0	0	1		
Current SI Performance Percent Within 60 FDA Days	99.26%	97.64%	95.31%		

**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	465		
Average Number of FDA Days to Substantive Interaction	52.62	52.84	52.69		
20th Percentile FDA Days to Substantive Interaction	49	50	49		
40th Percentile FDA Days to Substantive Interaction	56	57	57		
60th Percentile FDA Days to Substantive Interaction	58	58	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	122	66	105		

**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	559		
Non-MDUFA V Decision	89	82	18		
MDUFA V Decision (SE/NSE)	588	511	299		
MDUFA V Decision Within 90 FDA Days	586	506	295		
510(k)s Pending MDUFA V Decision	0	6	242		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	1		
Current Performance Percent Within 90 FDA Days	99.66%	99.02%	98.33%		

**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	1.60	1.44		
Number With MDUFA V Decision	588	511	299		
<b>Average Number of FDA Days to MDUFA V Decision</b>	75.12	74.36	70.19		
20th Percentile FDA Days to MDUFA V Decision	58	57	32		
40th Percentile FDA Days to MDUFA V Decision	83	84	76		
60th Percentile FDA Days to MDUFA V Decision	87	88	87		
80th Percentile FDA Days to MDUFA V Decision	89	90	89		
Maximum FDA Days to MDUFA V Decision	101	95	234		
<b>Average Number of Industry Days to MDUFA V Decision</b>	56.52	51.78	29.97		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	47	39	11		
80th Percentile Industry Days to MDUFA V Decision	124	118	55		
Maximum Industry Days to MDUFA V Decision	359	360	210		
<b>Average Number of Total Days to MDUFA V Decision</b>	131.74	126.03	99.92		
20th Percentile Total Days to MDUFA V Decision	60	58	32		
40th Percentile Total Days to MDUFA V Decision	88	90	83		
60th Percentile Total Days to MDUFA V Decision	128	124	96		
80th Percentile Total Days to MDUFA V Decision	211	204	144		
Maximum Total Days to MDUFA V Decision	449	448	300		

**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	559		
Number With MDUFA V Decision	588	511	299		
Number of SE Decision	571	504	291		
Number of NSE Decision	17	7	8		
Number of Withdrawal	52	40	10		
Number of Deleted	36	41	7		
Rate of SE Decision	97.11%	98.63%	97.32%		
Rate of NSE Decision	2.89%	1.37%	2.68%		
Rate of Withdrawal	7.68%	6.68%	1.79%		
Rate of Deleted	5.32%	6.84%	1.25%		

**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		
Mean FDA Days for Submissions that Missed the Goal	96.50	92.20	157.25		
Mean Industry Days for Submissions that Missed the Goal	59.50	118.60	14.00		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	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	FY 2024	FY 2025	FY 2026	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	403		
Closed Before First RTA or TS Action <sup>1</sup>	3	3	8		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	214	275	311		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	1	1	6		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	47		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	96	27	31		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	30.87%	8.91%	8.91%		

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	337		
Deleted or Withdrawn Prior to SI	0	0	1		
SI Within 60 FDA Days	287	281	285		
SI Over 60 FDA Days	11	19	6		
SI Pending Within 60 FDA Days	0	0	38		
SI Pending Over 60 FDA Days	0	0	6		
510(k)s NSE Without SI	0	0	1		
Current SI Performance Percent Within 60 FDA Days	96.31%	93.67%	95.64%		

**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	291		
Average Number of FDA Days to Substantive Interaction	54.67	54.90	51.71		
20th Percentile FDA Days to Substantive Interaction	56	53	39		
40th Percentile FDA Days to Substantive Interaction	58	58	57		
60th Percentile FDA Days to Substantive Interaction	60	59	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	80	95	67		

**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	337		
Non-MDUFA V Decision	34	31	9		
MDUFA V Decision (SE/NSE)	263	266	178		
MDUFA V Decision Within 90 FDA Days	259	257	176		
510(k)s Pending MDUFA V Decision	1	3	150		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1	0	7		
Current Performance Percent Within 90 FDA Days	98.11%	96.62%	95.14%		

**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	1.61		
Number With MDUFA V Decision	263	266	178		
<b>Average Number of FDA Days to MDUFA V Decision</b>	77.86	78.45	70.06		
20th Percentile FDA Days to MDUFA V Decision	59	61	47		
40th Percentile FDA Days to MDUFA V Decision	87	87	72		
60th Percentile FDA Days to MDUFA V Decision	89	89	88		
80th Percentile FDA Days to MDUFA V Decision	90	90	90		
Maximum FDA Days to MDUFA V Decision	150	126	99		
<b>Average Number of Industry Days to MDUFA V Decision</b>	76.22	77.20	36.66		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	35	35	2		
60th Percentile Industry Days to MDUFA V Decision	90	91	27		
80th Percentile Industry Days to MDUFA V Decision	168	157	72		
Maximum Industry Days to MDUFA V Decision	367	268	224		
<b>Average Number of Total Days to MDUFA V Decision</b>	154.53	155.97	106.17		
20th Percentile Total Days to MDUFA V Decision	61	82	49		
40th Percentile Total Days to MDUFA V Decision	118	124	89		
60th Percentile Total Days to MDUFA V Decision	175	181	111		
80th Percentile Total Days to MDUFA V Decision	254	239	158		
Maximum Total Days to MDUFA V Decision	517	458	270		

**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	337		
Number With MDUFA V Decision	263	266	178		
Number of SE Decision	245	246	172		
Number of NSE Decision	18	20	6		
Number of Withdrawal	10	10	6		
Number of Deleted	21	20	3		
Rate of SE Decision	93.16%	92.48%	96.63%		
Rate of NSE Decision	6.84%	7.52%	3.37%		
Rate of Withdrawal	3.36%	3.33%	1.78%		
Rate of Deleted	7.05%	6.67%	0.89%		

**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	4	9	2		
Mean FDA Days for Submissions that Missed the Goal	123.25	103.11	95.00		
Mean Industry Days for Submissions that Missed the Goal	213.75	125.44	128.50		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	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	FY 2024	FY 2025	FY 2026	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	615		
Closed Before First RTA or TS Action <sup>1</sup>	6	4	7		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	517	535	514		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	3	0	1		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	71		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	93	24	22		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	15.17%	4.29%	4.10%		

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	532		
Deleted or Withdrawn Prior to SI	1	2	1		
SI Within 60 FDA Days	604	551	449		
SI Over 60 FDA Days	0	0	2		
SI Pending Within 60 FDA Days	0	1	80		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	99.56%		

**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	551	451		
Average Number of FDA Days to Substantive Interaction	49.84	50.05	48.59		
20th Percentile FDA Days to Substantive Interaction	30	30	29		
40th Percentile FDA Days to Substantive Interaction	56	56	55		
60th Percentile FDA Days to Substantive Interaction	58	58	58		
80th Percentile FDA Days to Substantive Interaction	60	60	59		
Maximum FDA Days to Substantive Interaction	60	60	61		

**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	532		
Non-MDUFA V Decision	51	53	12		
MDUFA V Decision (SE/NSE)	554	497	337		
MDUFA V Decision Within 90 FDA Days	554	497	336		
510(k)s Pending MDUFA V Decision	0	4	183		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	99.70%		

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	1.32		
Number With MDUFA V Decision	554	497	337		
<b>Average Number of FDA Days to MDUFA V Decision</b>	65.77	65.58	58.39		
20th Percentile FDA Days to MDUFA V Decision	30	30	28		
40th Percentile FDA Days to MDUFA V Decision	59	60	55		
60th Percentile FDA Days to MDUFA V Decision	85	85	73		
80th Percentile FDA Days to MDUFA V Decision	89	88	88		
Maximum FDA Days to MDUFA V Decision	90	90	97		
<b>Average Number of Industry Days to MDUFA V Decision</b>	42.82	44.31	20.09		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	18	12	0		
80th Percentile Industry Days to MDUFA V Decision	92	109	28		
Maximum Industry Days to MDUFA V Decision	354	344	182		
<b>Average Number of Total Days to MDUFA V Decision</b>	108.59	110.09	78.13		
20th Percentile Total Days to MDUFA V Decision	30	30	28		
40th Percentile Total Days to MDUFA V Decision	60	60	55		
60th Percentile Total Days to MDUFA V Decision	98	98	81		
80th Percentile Total Days to MDUFA V Decision	179	188	116		
Maximum Total Days to MDUFA V Decision	443	546	272		

**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	532		
Number With MDUFA V Decision	554	497	337		
Number of SE Decision	544	489	335		
Number of NSE Decision	10	8	2		
Number of Withdrawal	37	37	6		
Number of Deleted	12	16	5		
Rate of SE Decision	98.19%	98.39%	99.41%		
Rate of NSE Decision	1.81%	1.61%	0.59%		
Rate of Withdrawal	6.12%	6.68%	1.13%		
Rate of Deleted	1.98%	2.89%	0.94%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	97.00		
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	76.00		

**Table 6.8 OHT6 - Office of Orthopedic Devices****LDT 510(k) MDUFA V Decision Metric**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	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	FY 2024	FY 2025	FY 2026	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		
Closed Before First RTA or TS Action <sup>1</sup>	7	13	8		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	243	228	247		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	5	4	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	17		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	40	13	13		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	13.89%	5.31%	5.00%		

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	256		
Deleted or Withdrawn Prior to SI	3	0	2		
SI Within 60 FDA Days	266	239	228		
SI Over 60 FDA Days	0	1	2		
SI Pending Within 60 FDA Days	0	0	24		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	2	0	0		
Current SI Performance Percent Within 60 FDA Days	99.25%	99.58%	99.13%		

**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	230		
Average Number of FDA Days to Substantive Interaction	52.54	51.18	51.27		
20th Percentile FDA Days to Substantive Interaction	47	43	43		
40th Percentile FDA Days to Substantive Interaction	56	55	56		
60th Percentile FDA Days to Substantive Interaction	58	58	58		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	60	81	67		

**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	256		
Non-MDUFA V Decision	51	43	19		
MDUFA V Decision (SE/NSE)	220	194	137		
MDUFA V Decision Within 90 FDA Days	220	194	137		
510(k)s Pending MDUFA V Decision	0	3	100		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	1.31		
Number With MDUFA V Decision	220	194	137		
<b>Average Number of FDA Days to MDUFA V Decision</b>	76.25	74.84	68.49		
20th Percentile FDA Days to MDUFA V Decision	59	53	30		
40th Percentile FDA Days to MDUFA V Decision	87	87	80		
60th Percentile FDA Days to MDUFA V Decision	89	89	88		
80th Percentile FDA Days to MDUFA V Decision	90	90	90		
Maximum FDA Days to MDUFA V Decision	90	90	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	80.81	81.33	34.66		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	5	0		
60th Percentile Industry Days to MDUFA V Decision	119	110	0		
80th Percentile Industry Days to MDUFA V Decision	177	174	83		
Maximum Industry Days to MDUFA V Decision	361	361	209		
<b>Average Number of Total Days to MDUFA V Decision</b>	157.05	156.17	102.55		
20th Percentile Total Days to MDUFA V Decision	60	60	30		
40th Percentile Total Days to MDUFA V Decision	90	90	83		
60th Percentile Total Days to MDUFA V Decision	205	199	90		
80th Percentile Total Days to MDUFA V Decision	265	260	172		
Maximum Total Days to MDUFA V Decision	451	451	268		

**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	256		
Number With MDUFA V Decision	220	194	137		
Number of SE Decision	211	186	134		
Number of NSE Decision	9	8	3		
Number of Withdrawal	28	22	15		
Number of Deleted	23	21	4		
Rate of SE Decision	95.91%	95.88%	97.81%		
Rate of NSE Decision	4.09%	4.12%	2.19%		
Rate of Withdrawal	10.33%	9.17%	5.86%		
Rate of Deleted	8.49%	8.75%	1.56%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days				
510(k)s Accepted	2	4	1		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	2	4	0		
MDUFA V Decision Within 90 FDA Days	2	4	0		
510(k)s Pending MDUFA V Decision	0	0	1		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days				
510(k)s Accepted	269	236	255		
Non-MDUFA V Decision	51	43	19		
MDUFA V Decision (SE/NSE)	218	190	137		
MDUFA V Decision Within 90 FDA Days	218	190	137		
510(k)s Pending MDUFA V Decision	0	3	99		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	508		
Closed Before First RTA or TS Action <sup>1</sup>	4	2	6		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	441	447	445		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	2	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	41		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	41	12	16		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	8.47%	2.61%	3.47%		

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 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	454		
Deleted or Withdrawn Prior to SI	0	3	0		
SI Within 60 FDA Days	476	451	399		
SI Over 60 FDA Days	0	1	1		
SI Pending Within 60 FDA Days	0	0	54		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	0	0		
Current SI Performance Percent Within 60 FDA Days	100.00%	99.78%	99.75%		

**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	400		
Average Number of FDA Days to Substantive Interaction	49.51	50.89	52.15		
20th Percentile FDA Days to Substantive Interaction	35	46	48		
40th Percentile FDA Days to Substantive Interaction	53	55	56		
60th Percentile FDA Days to Substantive Interaction	57	58	58		
80th Percentile FDA Days to Substantive Interaction	59	59	60		
Maximum FDA Days to Substantive Interaction	60	61	61		

**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	454		
Non-MDUFA V Decision	31	33	8		
MDUFA V Decision (SE/NSE)	445	422	259		
MDUFA V Decision Within 90 FDA Days	445	422	259		
510(k)s Pending MDUFA V Decision	0	0	187		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	1.71		
Number With MDUFA V Decision	445	422	259		
<b>Average Number of FDA Days to MDUFA V Decision</b>	71.52	74.77	73.34		
20th Percentile FDA Days to MDUFA V Decision	52	57	56		
40th Percentile FDA Days to MDUFA V Decision	79	84	81		
60th Percentile FDA Days to MDUFA V Decision	86	88	87		
80th Percentile FDA Days to MDUFA V Decision	89	89	89		
Maximum FDA Days to MDUFA V Decision	90	90	90		
<b>Average Number of Industry Days to MDUFA V Decision</b>	63.50	67.37	48.64		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	24	31	18		
60th Percentile Industry Days to MDUFA V Decision	62	71	49		
80th Percentile Industry Days to MDUFA V Decision	138	144	90		
Maximum Industry Days to MDUFA V Decision	182	226	181		
<b>Average Number of Total Days to MDUFA V Decision</b>	135.03	141.93	121.22		
20th Percentile Total Days to MDUFA V Decision	56	66	60		
40th Percentile Total Days to MDUFA V Decision	107	114	102		
60th Percentile Total Days to MDUFA V Decision	146	156	128		
80th Percentile Total Days to MDUFA V Decision	222	219	174		
Maximum Total Days to MDUFA V Decision	272	304	269		

**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	454		
Number With MDUFA V Decision	445	422	259		
Number of SE Decision	438	411	258		
Number of NSE Decision	7	11	1		
Number of Withdrawal	16	24	6		
Number of Deleted	14	9	2		
Rate of SE Decision	98.43%	97.39%	99.61%		
Rate of NSE Decision	1.57%	2.61%	0.39%		
Rate of Withdrawal	3.36%	5.27%	1.32%		
Rate of Deleted	2.94%	1.98%	0.44%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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	FY 2024	FY 2025	FY 2026	FY 2027
	95% Within 90 FDA Days				
510(k)s Accepted	N/A	N/A	N/A		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	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		
Non-MDUFA V Decision	N/A	N/A	N/A		
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A		
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A		

## Section 7 510(k) Annual General Metrics

Table 7.1 CDRH - 510(k) Annual General Metrics - 510(k)s Received by Type

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted	3,761	3,529	3,543		
Number of Traditional Submissions	3,107	2,940	2,955		
Number of Special Submissions	526	479	479		
Number of Abbreviated Submissions	51	42	42		
Average Number of Days to Accept/Refuse to Accept	11.53	10.84	10.85		
Number of Third Party Submissions	77	68	67		

Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal

Performance Metrics	FY 2023 128 Days	FY 2024 124 Days	FY 2025 112 Days	FY 2026 112/108 Days <sup>1</sup>	FY 2027 112/108 Days <sup>1,2</sup>
Number Accepted	3,761	3,529	3,543		
Currently Under Review	2	31	1,526		
Number With Non-MDUFA V Decision	437	427	122		
Number With MDUFA V Decision	3,322	3,071	1,895		
Percent of Cohort Closed	99.94%	99.00%	55.39%		
Number With MDUFA Decision (CDRH+CBER) Within a 99% Closed Cohort With Provisions <sup>3</sup>	3,110	2,975	N/A		
Average Total Time to MDUFA V Decision	127.18	139.28	N/A		

1 If FDA's 510(k) decision goal, the FDA/Industry 510(k) Shared Outcome Total Time to Decision goal, FDA's PMA decision goal, and the FDA/Industry PMA Shared Outcome Total Time to Decision goal are met for FY 2023, and fee revenue above the annual total revenue amount is provided in FY 2026 and FY 2027 to support performance improvements, the 510(k) Shared Outcome Total Time to Decision goal will be adjusted to 108 days for FY 2026 and FY 2027.

2 If FDA's 510(k) decision goal, the FDA/Industry 510(k) Shared Outcome Total Time to Decision goal, FDA's PMA decision goal, and the FDA/Industry PMA Shared Outcome Total Time to Decision goal are met in FY 2024, and fee revenues above the annual total revenue amount are provided in FY 2027 to support performance improvements, the 510(k) Shared Outcome Total Time to Decision goal will be adjusted to 108 days for FY 2027.

3 The Average Total Time to Decision for 510(k) submissions is calculated as the average of Total Times to Decision for 510(k) submissions within a 99% closed cohort, with the following provisions:

In FY2023, the cohort excludes submissions with any one hold greater than 180-days and excluding the highest 5% of Total Time to Decision on the remaining cohort.

In FY 2024-2027, the cohort excludes the highest 2% and lowest 2% of values and includes all 510(k)s with a MDUFA decision.

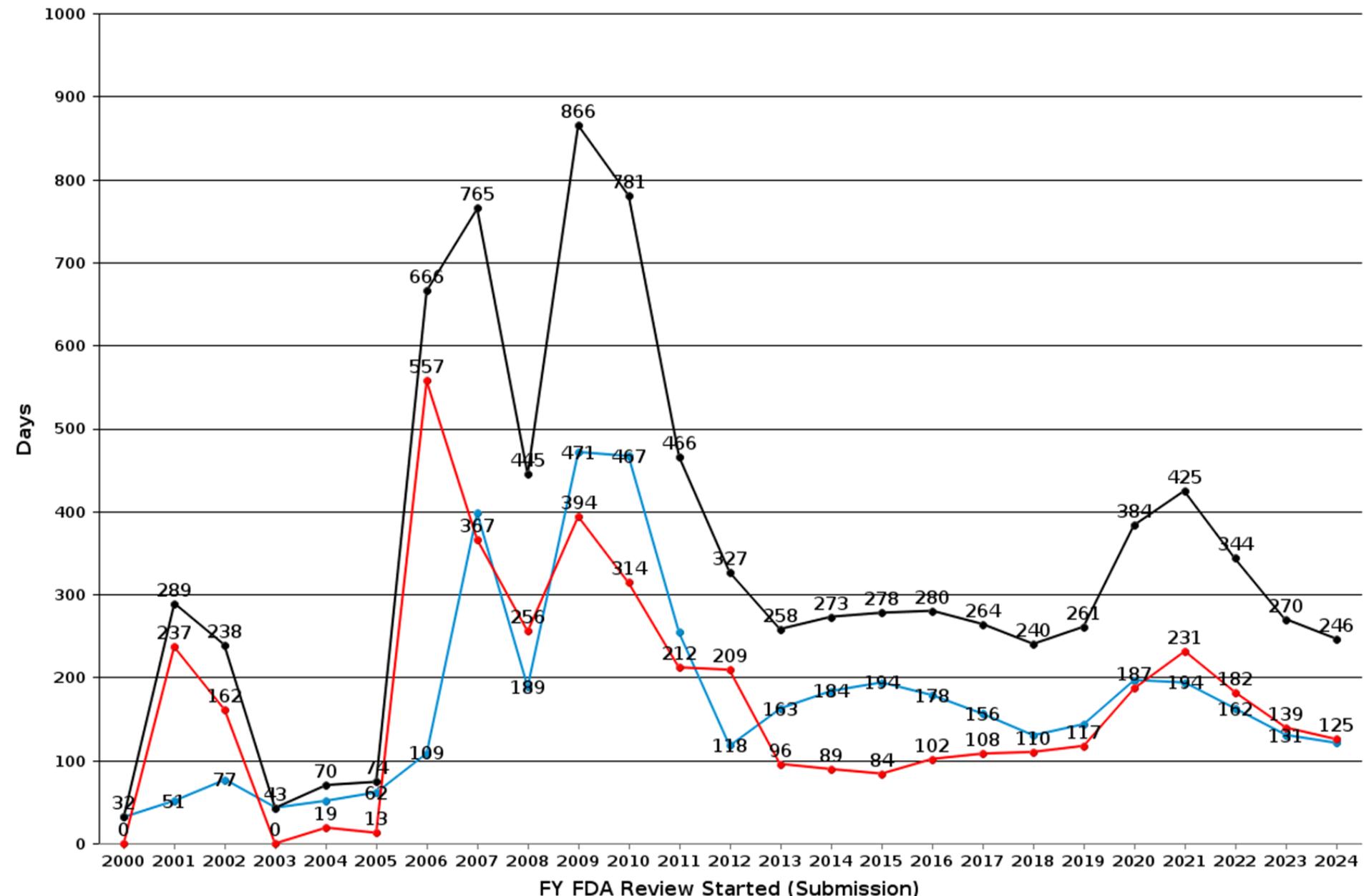
Table 7.3 CDRH - 510(k) Third Party Performance

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Third Party Submissions	77	68	67		
90th Percentile FDA Days to MDUFA V Decision	60	45	62		

De Novos

Q4FY2025

### De Novo Average Days to MDUFA Decision as of: 9/30/25



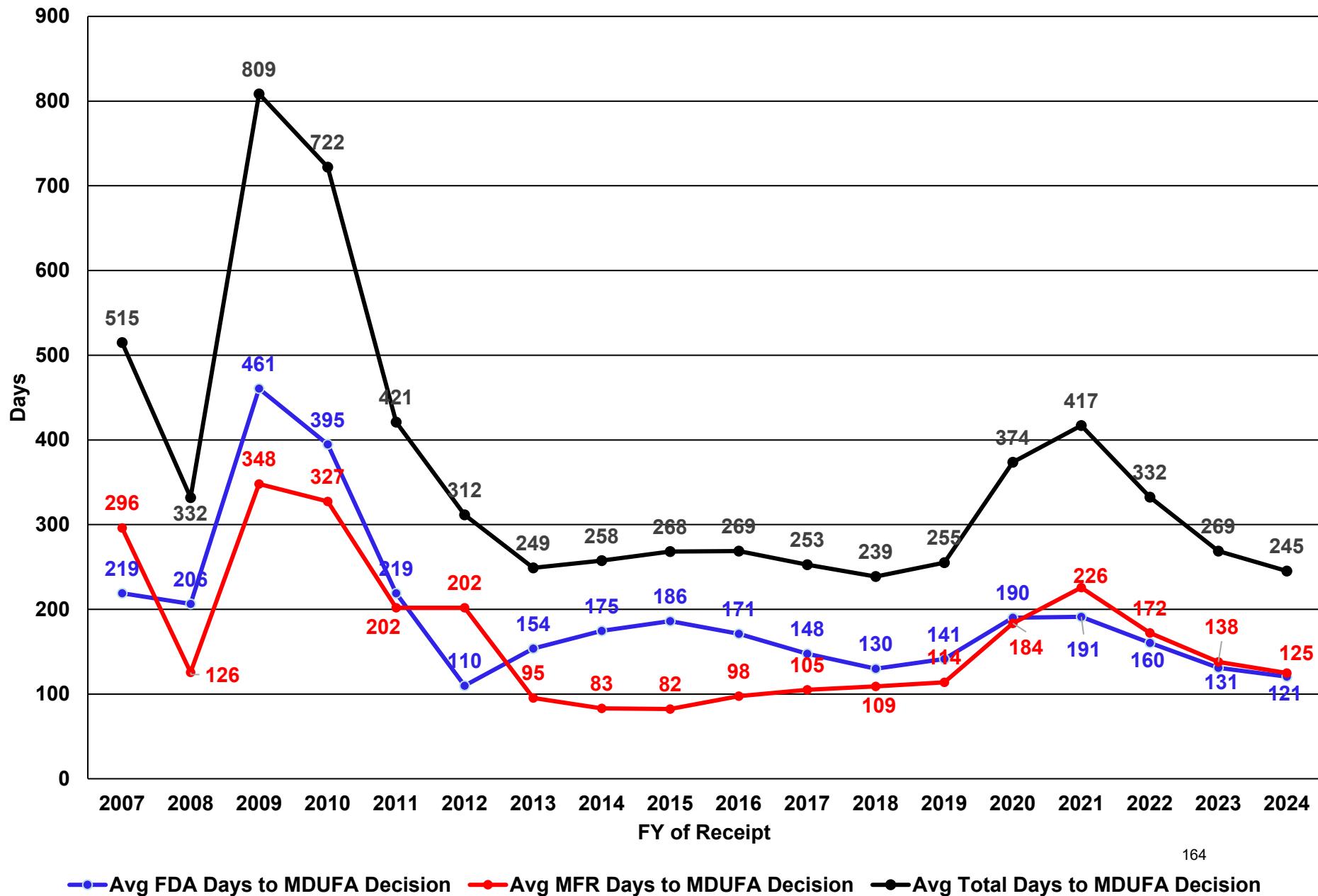
Cohorts not yet closed: 2024: 98.6%

163

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

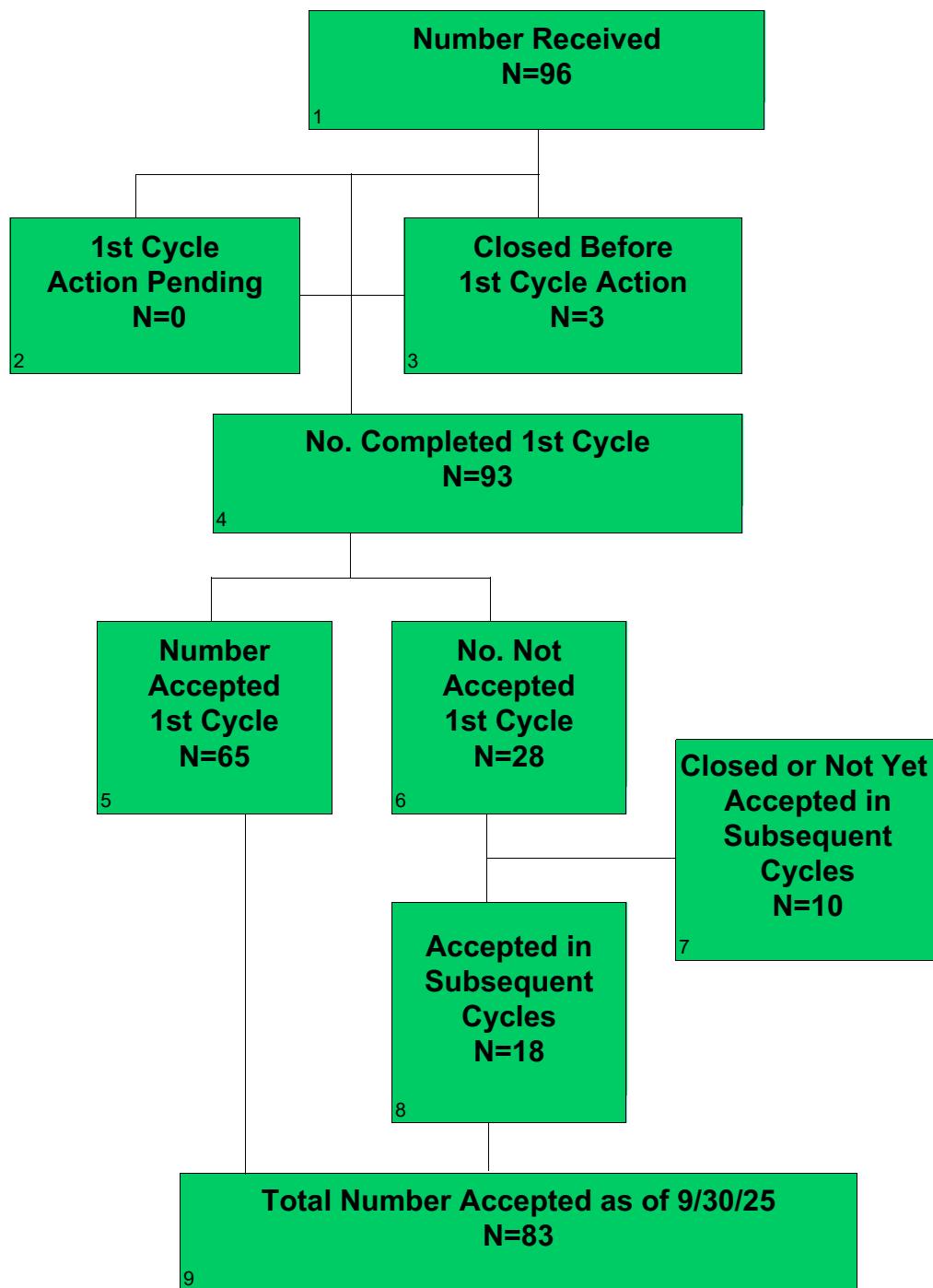
# Average Time to MDUFA Decision: De Novos

(98.6% closure comparison)

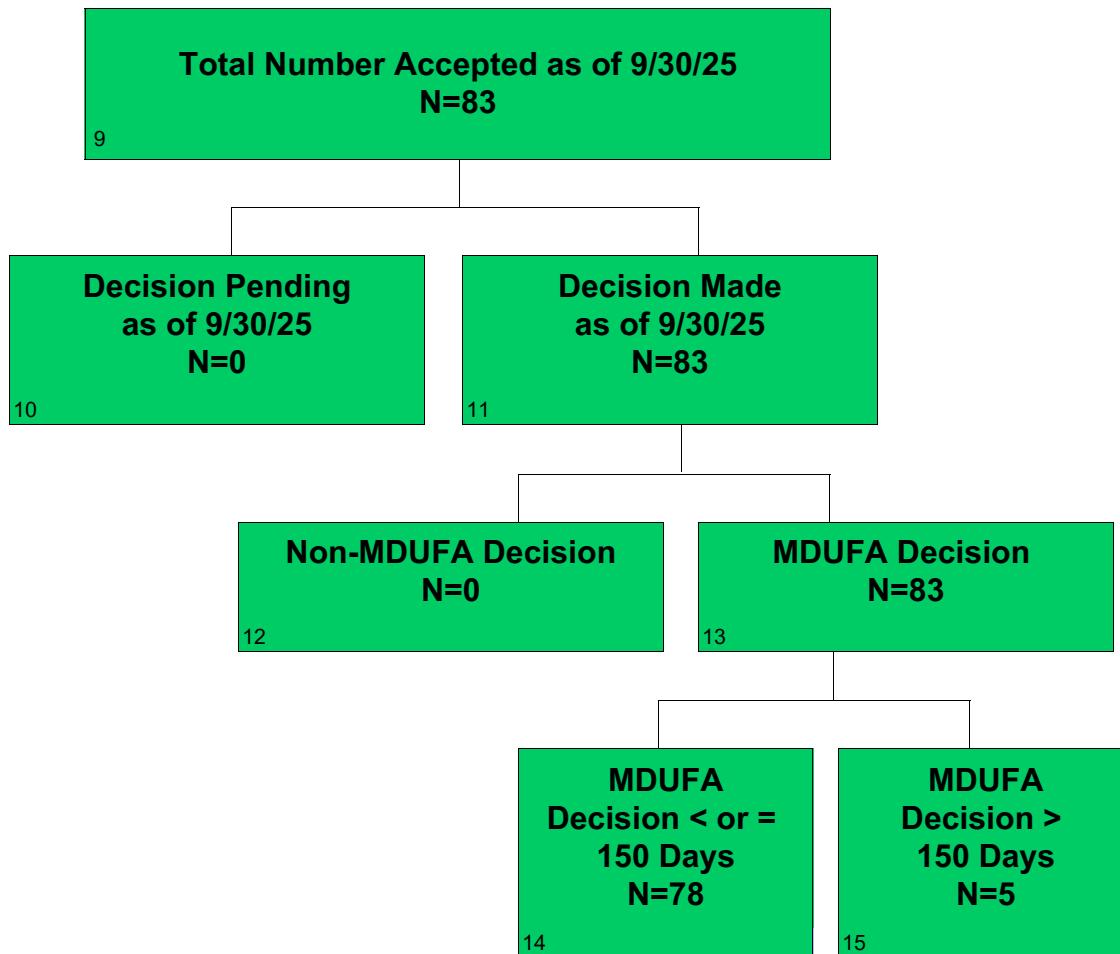


# CDRH De Novo - FY 2023

## as of 9/30/25

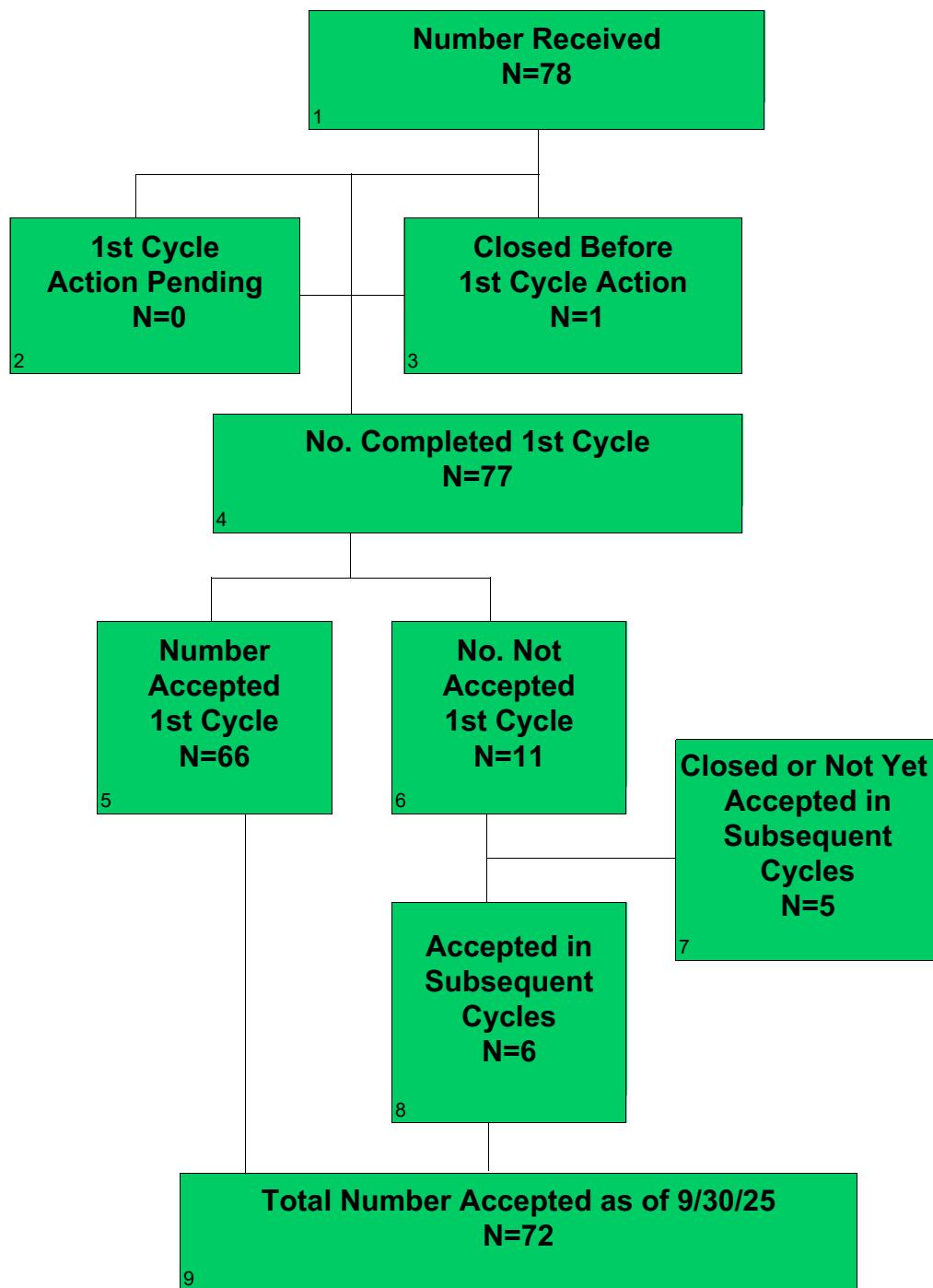


# CDRH De Novo - FY 2023 as of 9/30/25 Continued

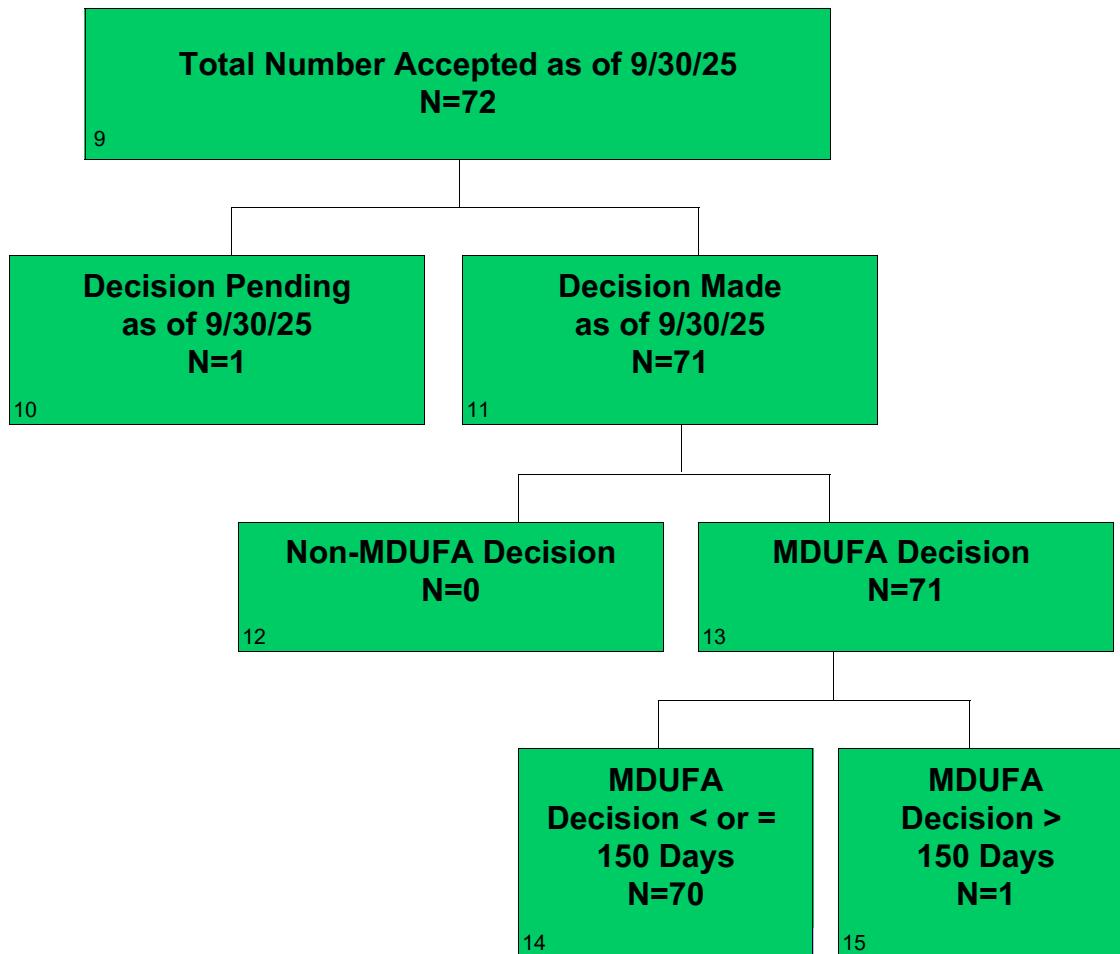


# CDRH De Novo - FY 2024

## as of 9/30/25

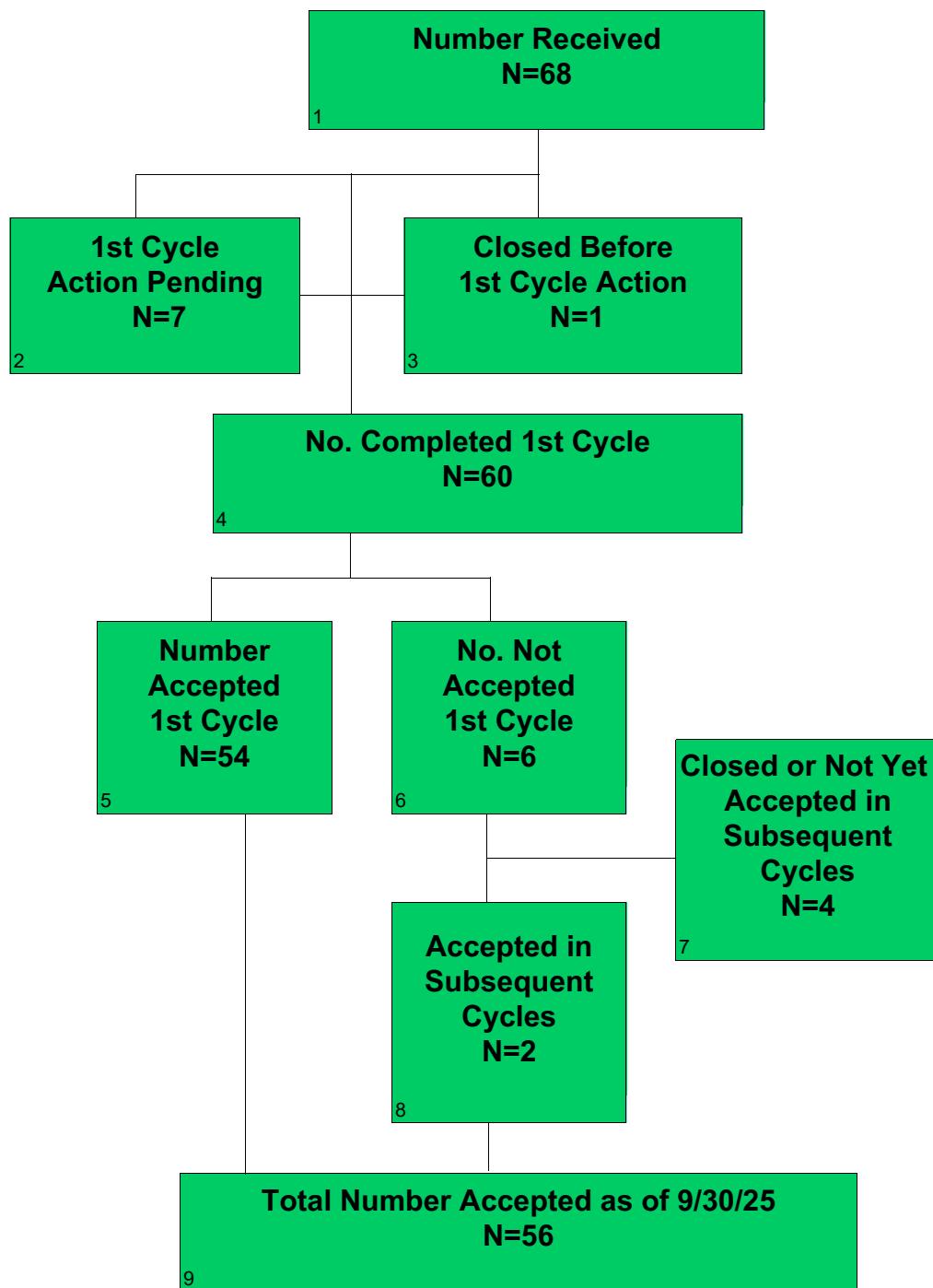


# CDRH De Novo - FY 2024 as of 9/30/25 Continued

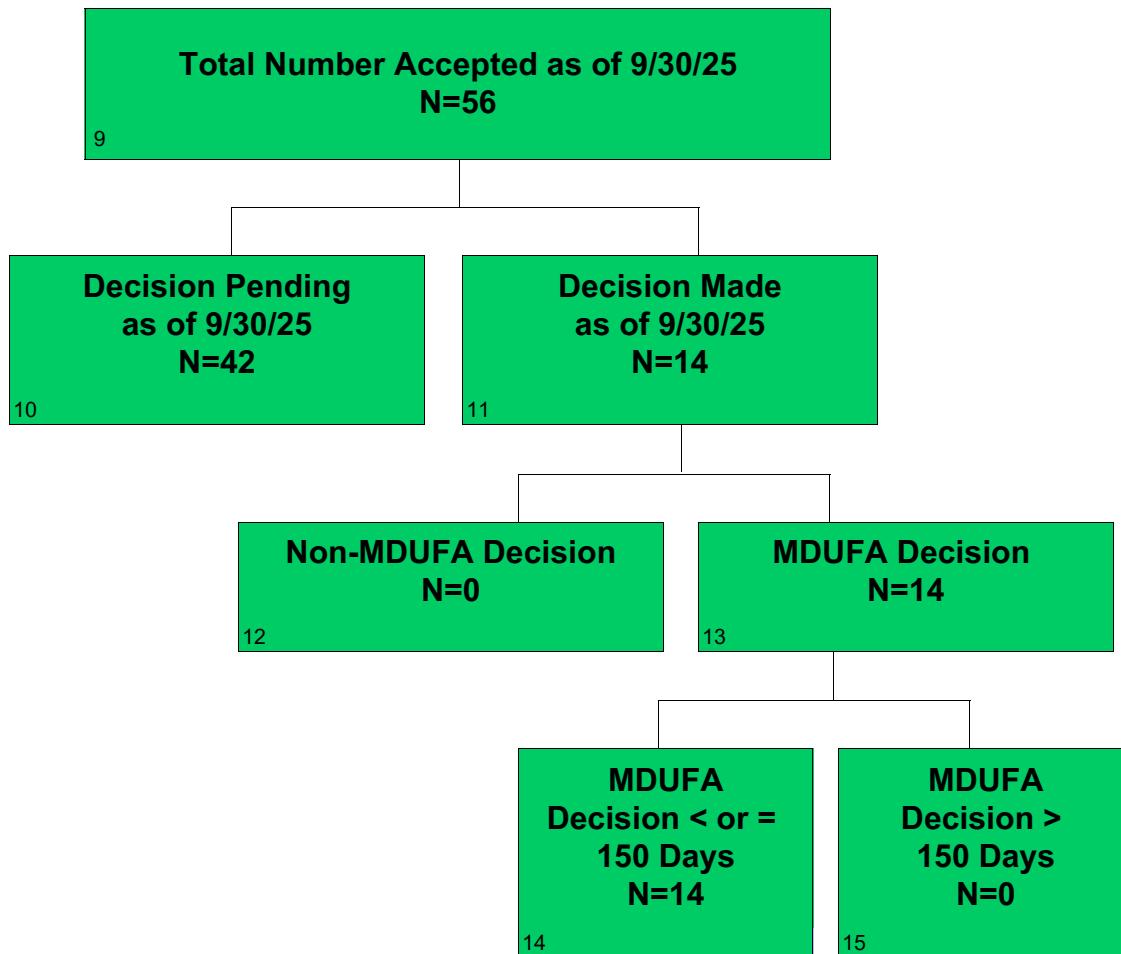


# CDRH De Novo - FY 2025

## as of 9/30/25



# CDRH De Novo - FY 2025 as of 9/30/25 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		
Closed Before First RTA or TS Action	3	1	1		
Number Accepted or Passed TS on First Cycle	65	66	54		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	7		
Number Not Accepted or Failed TS on First Cycle	28	11	6		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	14.29%	10.00%		

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 (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	56		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	83	71	14		
MDUFA Decision Within 150 FDA Days	78	70	14		
De Novos Pending MDUFA Decision	0	1	42		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	93.98%	98.59%	100.00%		

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	1.59	1.57		
Number With MDUFA Decision	83	71	14		
<b>Average FDA Days to MDUFA Decision</b>	<b>130.60</b>	<b>120.99</b>	<b>130.86</b>		
20th Percentile FDA Days to MDUFA Decision	75	75	116		
40th Percentile FDA Days to MDUFA Decision	148	131	149		
60th Percentile FDA Days to MDUFA Decision	150	149	150		
80th Percentile FDA Days to MDUFA Decision	150	150	150		
Maximum FDA Days to MDUFA Decision	251	151	150		
<b>Average Industry Days to MDUFA Decision</b>	<b>139.47</b>	<b>125.45</b>	<b>98.07</b>		
20th Percentile Industry Days to MDUFA Decision	72	32	19		
40th Percentile Industry Days to MDUFA Decision	152	141	83		
60th Percentile Industry Days to MDUFA Decision	178	177	124		
80th Percentile Industry Days to MDUFA Decision	181	180	167		
Maximum Industry Days to MDUFA Decision	350	185	189		
<b>Average Total Days to MDUFA Decision</b>	<b>270.07</b>	<b>246.44</b>	<b>228.93</b>		
20th Percentile Total Days to MDUFA Decision	214	175	169		
40th Percentile Total Days to MDUFA Decision	256	255	231		
60th Percentile Total Days to MDUFA Decision	303	283	247		
80th Percentile Total Days to MDUFA Decision	329	327	272		
Maximum Total Days to MDUFA Decision	437	330	301		

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	56		
Number With MDUFA Decision	83	71	14		
Number With Granted Decision	37	29	8		
Number With Declined Decision	18	18	2		
Number of Withdrawal	17	12	1		
Number of Deleted	11	12	3		
Rate of Granted Decision	44.58%	40.85%	57.14%		
Rate of Declined Decision	21.69%	25.35%	14.29%		
Rate of Withdrawal	20.48%	16.90%	7.14%		
Rate of Deleted	13.25%	16.90%	21.43%		

**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	0		
Mean FDA Days for Submissions that Missed the Goal	194.80	151.00	N/A		
Mean Industry Days for Submissions that Missed the Goal	111.20	150.00	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Within 150 FDA Days	1	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	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	9		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	18	4		
MDUFA Decision Within 150 FDA Days	19	18	4		
De Novos Pending MDUFA Decision	0	0	5		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**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	56		
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	12.23	11.44	11.80		

## 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		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	6	10	5		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	2		
Number Not Accepted or Failed TS on First Cycle	6	3	3		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	23.08%	37.50%		

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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	12	1		
MDUFA Decision Within 150 FDA Days	8	11	1		
De Novos Pending MDUFA Decision	0	0	6		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	72.73%	91.67%	100.00%		

**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	1.00		
Number With MDUFA Decision	11	12	1		
<b>Average FDA Days to MDUFA Decision</b>	<b>130.82</b>	<b>118.42</b>	<b>150.00</b>		
20th Percentile FDA Days to MDUFA Decision	73	73	150		
40th Percentile FDA Days to MDUFA Decision	75	109	150		
60th Percentile FDA Days to MDUFA Decision	150	148	150		
80th Percentile FDA Days to MDUFA Decision	178	150	150		
Maximum FDA Days to MDUFA Decision	251	151	150		
<b>Average Industry Days to MDUFA Decision</b>	<b>137.45</b>	<b>131.75</b>	<b>N/A</b>		
20th Percentile Industry Days to MDUFA Decision	81	125	0		
40th Percentile Industry Days to MDUFA Decision	152	137	0		
60th Percentile Industry Days to MDUFA Decision	178	166	0		
80th Percentile Industry Days to MDUFA Decision	182	181	0		
Maximum Industry Days to MDUFA Decision	189	181	0		
<b>Average Total Days to MDUFA Decision</b>	<b>268.27</b>	<b>250.17</b>	<b>150.00</b>		
20th Percentile Total Days to MDUFA Decision	231	222	150		
40th Percentile Total Days to MDUFA Decision	255	261	150		
60th Percentile Total Days to MDUFA Decision	262	284	150		
80th Percentile Total Days to MDUFA Decision	328	321	150		
Maximum Total Days to MDUFA Decision	343	328	150		

**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		
Number With MDUFA Decision	11	12	1		
Number With Granted Decision	5	3	1		
Number With Declined Decision	1	4	0		
Number of Withdrawal	1	3	0		
Number of Deleted	4	2	0		
Rate of Granted Decision	45.45%	25.00%	100.00%		
Rate of Declined Decision	9.09%	33.33%	0.00%		
Rate of Withdrawal	9.09%	25.00%	0.00%		
Rate of Deleted	36.36%	16.67%	0.00%		

**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	0		
Mean FDA Days for Submissions That Missed the Goal	206.67	151.00	N/A		
Mean Industry Days for Submissions That Missed the Goal	122.33	150.00	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	10	4	3		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted or Failed TS on First Cycle	2	0	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	16.67%	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	3		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	10	4	1		
MDUFA Decision Within 150 FDA Days	10	4	1		
De Novos Pending MDUFA Decision	0	0	2		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**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		
Number With MDUFA Decision	10	4	1		
<b>Average FDA Days to MDUFA Decision</b>	<b>137.10</b>	<b>149.75</b>	<b>60.00</b>		
20th Percentile FDA Days to MDUFA Decision	140	150	60		
40th Percentile FDA Days to MDUFA Decision	150	150	60		
60th Percentile FDA Days to MDUFA Decision	150	150	60		
80th Percentile FDA Days to MDUFA Decision	150	150	60		
Maximum FDA Days to MDUFA Decision	150	150	60		
<b>Average Industry Days to MDUFA Decision</b>	<b>114.40</b>	<b>114.50</b>	<b>182.00</b>		
20th Percentile Industry Days to MDUFA Decision	47	61	182		
40th Percentile Industry Days to MDUFA Decision	90	116	182		
60th Percentile Industry Days to MDUFA Decision	178	162	182		
80th Percentile Industry Days to MDUFA Decision	180	178	182		
Maximum Industry Days to MDUFA Decision	183	180	182		
<b>Average Total Days to MDUFA Decision</b>	<b>251.50</b>	<b>264.25</b>	<b>242.00</b>		
20th Percentile Total Days to MDUFA Decision	197	210	242		
40th Percentile Total Days to MDUFA Decision	238	266	242		
60th Percentile Total Days to MDUFA Decision	267	312	242		
80th Percentile Total Days to MDUFA Decision	328	328	242		
Maximum Total Days to MDUFA Decision	329	330	242		

**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	3		
Number With MDUFA Decision	10	4	1		
Number With Granted Decision	6	3	0		
Number With Declined Decision	3	1	0		
Number of Withdrawal	0	0	0		
Number of Deleted	1	0	1		
Rate of Granted Decision	60.00%	75.00%	0.00%		
Rate of Declined Decision	30.00%	25.00%	0.00%		
Rate of Withdrawal	0.00%	0.00%	0.00%		
Rate of Deleted	10.00%	0.00%	100.00%		

**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		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	9	7	9		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	2		
Number Not Accepted or Failed TS on First Cycle	2	1	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%	12.50%	10.00%		

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	9		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	11	7	1		
MDUFA Decision Within 150 FDA Days	11	7	1		
De Novos Pending MDUFA Decision	0	1	8		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**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	1.86	2.00		
Number With MDUFA Decision	11	7	1		
<b>Average FDA Days to MDUFA Decision</b>	<b>128.45</b>	<b>130.14</b>	<b>149.00</b>		
20th Percentile FDA Days to MDUFA Decision	74	106	149		
40th Percentile FDA Days to MDUFA Decision	148	146	149		
60th Percentile FDA Days to MDUFA Decision	150	149	149		
80th Percentile FDA Days to MDUFA Decision	150	149	149		
Maximum FDA Days to MDUFA Decision	150	150	149		
<b>Average Industry Days to MDUFA Decision</b>	<b>122.73</b>	<b>157.29</b>	<b>125.00</b>		
20th Percentile Industry Days to MDUFA Decision	83	148	125		
40th Percentile Industry Days to MDUFA Decision	124	178	125		
60th Percentile Industry Days to MDUFA Decision	163	180	125		
80th Percentile Industry Days to MDUFA Decision	180	181	125		
Maximum Industry Days to MDUFA Decision	214	183	125		
<b>Average Total Days to MDUFA Decision</b>	<b>251.18</b>	<b>287.43</b>	<b>274.00</b>		
20th Percentile Total Days to MDUFA Decision	231	261	274		
40th Percentile Total Days to MDUFA Decision	247	281	274		
60th Percentile Total Days to MDUFA Decision	274	311	274		
80th Percentile Total Days to MDUFA Decision	293	327	274		
Maximum Total Days to MDUFA Decision	330	329	274		

**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	9		
Number With MDUFA Decision	11	7	1		
Number With Granted Decision	7	2	0		
Number With Declined Decision	1	2	1		
Number of Withdrawal	1	2	0		
Number of Deleted	2	1	0		
Rate of Granted Decision	63.64%	28.57%	0.00%		
Rate of Declined Decision	9.09%	28.57%	100.00%		
Rate of Withdrawal	9.09%	28.57%	0.00%		
Rate of Deleted	18.18%	14.29%	0.00%		

**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		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	11	11	5		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	9	3	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	45.00%	21.43%	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	15	12	1		
MDUFA Decision Within 150 FDA Days	13	12	1		
De Novos Pending MDUFA Decision	0	0	4		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	86.67%	100.00%	100.00%		

**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	1.00		
Number With MDUFA Decision	15	12	1		
<b>Average FDA Days to MDUFA Decision</b>	<b>126.87</b>	<b>119.92</b>	<b>74.00</b>		
20th Percentile FDA Days to MDUFA Decision	75	74	74		
40th Percentile FDA Days to MDUFA Decision	143	117	74		
60th Percentile FDA Days to MDUFA Decision	148	150	74		
80th Percentile FDA Days to MDUFA Decision	150	150	74		
Maximum FDA Days to MDUFA Decision	203	150	74		
<b>Average Industry Days to MDUFA Decision</b>	<b>134.87</b>	<b>129.00</b>	<b>189.00</b>		
20th Percentile Industry Days to MDUFA Decision	80	29	189		
40th Percentile Industry Days to MDUFA Decision	156	165	189		
60th Percentile Industry Days to MDUFA Decision	180	174	189		
80th Percentile Industry Days to MDUFA Decision	181	179	189		
Maximum Industry Days to MDUFA Decision	198	185	189		
<b>Average Total Days to MDUFA Decision</b>	<b>261.73</b>	<b>248.92</b>	<b>263.00</b>		
20th Percentile Total Days to MDUFA Decision	228	164	263		
40th Percentile Total Days to MDUFA Decision	254	247	263		
60th Percentile Total Days to MDUFA Decision	302	319	263		
80th Percentile Total Days to MDUFA Decision	329	326	263		
Maximum Total Days to MDUFA Decision	346	330	263		

**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		
Number With MDUFA Decision	15	12	1		
Number With Granted Decision	7	7	0		
Number With Declined Decision	2	2	0		
Number of Withdrawal	5	2	0		
Number of Deleted	1	1	1		
Rate of Granted Decision	46.67%	58.33%	0.00%		
Rate of Declined Decision	13.33%	16.67%	0.00%		
Rate of Withdrawal	33.33%	16.67%	0.00%		
Rate of Deleted	6.67%	8.33%	100.00%		

**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		
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	94.50	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Closed Before First RTA or TS Action	1	0	0		
Number Accepted or Passed TS on First Cycle	5	11	14		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted or Failed TS on First Cycle	4	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	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 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	14		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	9	12	5		
MDUFA Decision Within 150 FDA Days	9	12	5		
De Novos Pending MDUFA Decision	0	0	9		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**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	1.60		
Number With MDUFA Decision	9	12	5		
<b>Average FDA Days to MDUFA Decision</b>	<b>141.44</b>	<b>118.92</b>	<b>150.00</b>		
20th Percentile FDA Days to MDUFA Decision	149	76	150		
40th Percentile FDA Days to MDUFA Decision	150	109	150		
60th Percentile FDA Days to MDUFA Decision	150	148	150		
80th Percentile FDA Days to MDUFA Decision	150	150	150		
Maximum FDA Days to MDUFA Decision	150	150	150		
<b>Average Industry Days to MDUFA Decision</b>	<b>145.56</b>	<b>110.58</b>	<b>33.60</b>		
20th Percentile Industry Days to MDUFA Decision	112	6	0		
40th Percentile Industry Days to MDUFA Decision	154	111	19		
60th Percentile Industry Days to MDUFA Decision	172	176	42		
80th Percentile Industry Days to MDUFA Decision	182	179	62		
Maximum Industry Days to MDUFA Decision	231	183	79		
<b>Average Total Days to MDUFA Decision</b>	<b>287.00</b>	<b>229.50</b>	<b>183.60</b>		
20th Percentile Total Days to MDUFA Decision	237	105	150		
40th Percentile Total Days to MDUFA Decision	300	255	169		
60th Percentile Total Days to MDUFA Decision	313	263	192		
80th Percentile Total Days to MDUFA Decision	326	326	212		
Maximum Total Days to MDUFA Decision	381	328	229		

**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	14		
Number With MDUFA Decision	9	12	5		
Number With Granted Decision	3	3	4		
Number With Declined Decision	5	6	1		
Number of Withdrawal	0	1	0		
Number of Deleted	1	2	0		
Rate of Granted Decision	33.33%	25.00%	80.00%		
Rate of Declined Decision	55.56%	50.00%	20.00%		
Rate of Withdrawal	0.00%	8.33%	0.00%		
Rate of Deleted	11.11%	16.67%	0.00%		

**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		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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	7		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	3	2	6		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	0	0	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	0.00%	14.29%		

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	6		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	3	2	1		
MDUFA Decision Within 150 FDA Days	3	2	1		
De Novos Pending MDUFA Decision	0	0	5		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**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	1.00		
Number With MDUFA Decision	3	2	1		
<b>Average FDA Days to MDUFA Decision</b>	149.00	111.50	57.00		
20th Percentile FDA Days to MDUFA Decision	148	88	57		
40th Percentile FDA Days to MDUFA Decision	149	104	57		
60th Percentile FDA Days to MDUFA Decision	149	119	57		
80th Percentile FDA Days to MDUFA Decision	150	135	57		
Maximum FDA Days to MDUFA Decision	150	150	57		
<b>Average Industry Days to MDUFA Decision</b>	119.33	180.00	181.00		
20th Percentile Industry Days to MDUFA Decision	71	179	181		
40th Percentile Industry Days to MDUFA Decision	142	180	181		
60th Percentile Industry Days to MDUFA Decision	178	180	181		
80th Percentile Industry Days to MDUFA Decision	179	181	181		
Maximum Industry Days to MDUFA Decision	180	181	181		
<b>Average Total Days to MDUFA Decision</b>	268.33	291.50	238.00		
20th Percentile Total Days to MDUFA Decision	220	269	238		
40th Percentile Total Days to MDUFA Decision	292	284	238		
60th Percentile Total Days to MDUFA Decision	328	299	238		
80th Percentile Total Days to MDUFA Decision	329	314	238		
Maximum Total Days to MDUFA Decision	329	329	238		

**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	6		
Number With MDUFA Decision	3	2	1		
Number With Granted Decision	2	1	0		
Number With Declined Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Deleted	0	1	1		
Rate of Granted Decision	66.67%	50.00%	0.00%		
Rate of Declined Decision	33.33%	0.00%	0.00%		
Rate of Withdrawal	0.00%	0.00%	0.00%		
Rate of Deleted	0.00%	50.00%	100.00%		

**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		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A	N/A	N/A		
Current Performance Percent Within 150 FDA Days	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	12		
Closed Before First RTA or TS Action	1	1	1		
Number Accepted or Passed TS on First Cycle	17	17	9		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	1		
Number Not Accepted or Failed TS on First Cycle	5	2	1		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	10.53%	10.00%		

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	9		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	20	18	4		
MDUFA Decision Within 150 FDA Days	20	18	4		
De Novos Pending MDUFA Decision	0	0	5		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**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	2.00		
Number With MDUFA Decision	20	18	4		
<b>Average FDA Days to MDUFA Decision</b>	<b>127.95</b>	<b>116.61</b>	<b>148.00</b>		
20th Percentile FDA Days to MDUFA Decision	85	73	147		
40th Percentile FDA Days to MDUFA Decision	140	113	149		
60th Percentile FDA Days to MDUFA Decision	149	148	149		
80th Percentile FDA Days to MDUFA Decision	150	150	149		
Maximum FDA Days to MDUFA Decision	150	150	150		
<b>Average Industry Days to MDUFA Decision</b>	<b>167.85</b>	<b>114.33</b>	<b>132.00</b>		
20th Percentile Industry Days to MDUFA Decision	139	16	112		
40th Percentile Industry Days to MDUFA Decision	175	101	127		
60th Percentile Industry Days to MDUFA Decision	179	175	146		
80th Percentile Industry Days to MDUFA Decision	182	181	154		
Maximum Industry Days to MDUFA Decision	350	185	157		
<b>Average Total Days to MDUFA Decision</b>	<b>295.80</b>	<b>230.94</b>	<b>280.00</b>		
20th Percentile Total Days to MDUFA Decision	252	155	261		
40th Percentile Total Days to MDUFA Decision	299	235	276		
60th Percentile Total Days to MDUFA Decision	328	256	295		
80th Percentile Total Days to MDUFA Decision	330	322	301		
Maximum Total Days to MDUFA Decision	437	329	301		

**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	9		
Number With MDUFA Decision	20	18	4		
Number With Granted Decision	5	9	3		
Number With Declined Decision	5	2	0		
Number of Withdrawal	9	3	1		
Number of Deleted	1	4	0		
Rate of Granted Decision	25.00%	50.00%	75.00%		
Rate of Declined Decision	25.00%	11.11%	0.00%		
Rate of Withdrawal	45.00%	16.67%	25.00%		
Rate of Deleted	5.00%	22.22%	0.00%		

**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		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Within 150 FDA Days	1	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	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	9		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	19	18	4		
MDUFA Decision Within 150 FDA Days	19	18	4		
De Novos Pending MDUFA Decision	0	0	5		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%		

**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		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	4	4	3		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	0	1	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	20.00%	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 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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	4	4	0		
MDUFA Decision Within 150 FDA Days	4	4	0		
De Novos Pending MDUFA Decision	0	0	3		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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	N/A		
Number With MDUFA Decision	4	4	0		
<b>Average FDA Days to MDUFA Decision</b>	<b>108.75</b>	<b>117.75</b>	<b>N/A</b>		
20th Percentile FDA Days to MDUFA Decision	70	95	0		
40th Percentile FDA Days to MDUFA Decision	89	115	0		
60th Percentile FDA Days to MDUFA Decision	133	133	0		
80th Percentile FDA Days to MDUFA Decision	149	143	0		
Maximum FDA Days to MDUFA Decision	150	149	0		
<b>Average Industry Days to MDUFA Decision</b>	<b>130.50</b>	<b>118.50</b>	<b>N/A</b>		
20th Percentile Industry Days to MDUFA Decision	83	70	0		
40th Percentile Industry Days to MDUFA Decision	132	129	0		
60th Percentile Industry Days to MDUFA Decision	169	164	0		
80th Percentile Industry Days to MDUFA Decision	186	178	0		
Maximum Industry Days to MDUFA Decision	193	181	0		
<b>Average Total Days to MDUFA Decision</b>	<b>239.25</b>	<b>236.25</b>	<b>N/A</b>		
20th Percentile Total Days to MDUFA Decision	190	197	0		
40th Percentile Total Days to MDUFA Decision	258	257	0		
60th Percentile Total Days to MDUFA Decision	265	264	0		
80th Percentile Total Days to MDUFA Decision	297	286	0		
Maximum Total Days to MDUFA Decision	343	315	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		
Number With MDUFA Decision	4	4	0		
Number With Granted Decision	2	1	0		
Number With Declined Decision	0	1	0		
Number of Withdrawal	1	1	0		
Number of Deleted	1	1	0		
Rate of Granted Decision	50.00%	25.00%	N/A		
Rate of Declined Decision	0.00%	25.00%	N/A		
Rate of Withdrawal	25.00%	25.00%	N/A		
Rate of Deleted	25.00%	25.00%	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		
Mean FDA Days for Submissions That Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions That Missed the Goal	N/A	N/A	N/A		

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

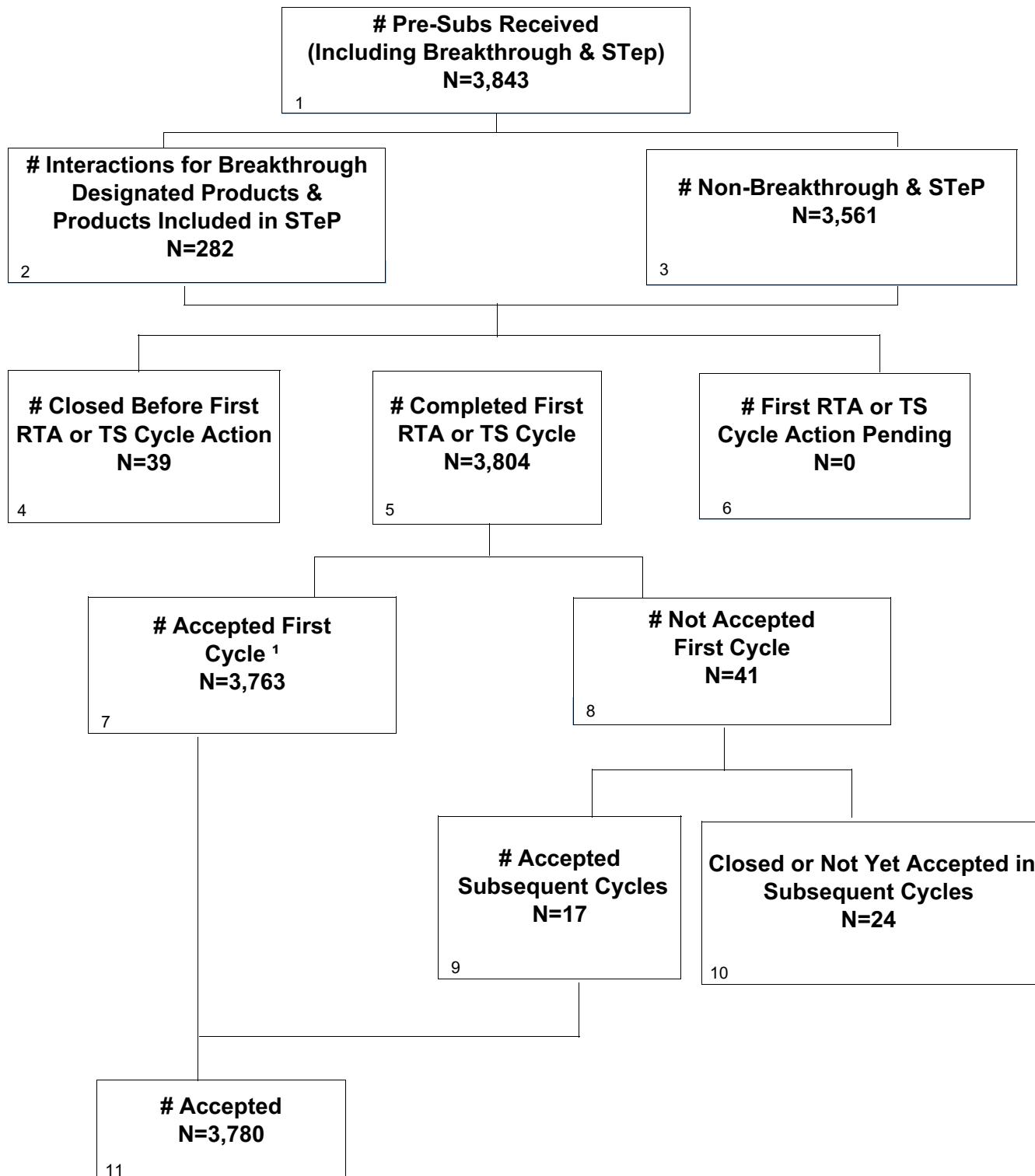
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A		
Non-MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision	N/A	N/A	N/A		
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A		
De Novos Pending MDUFA Decision	N/A	N/A	N/A		
De Novos Pending MDUFA Decision Over 150 FDA Days	N/A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

# CDRH Pre-Sub - FY 2023

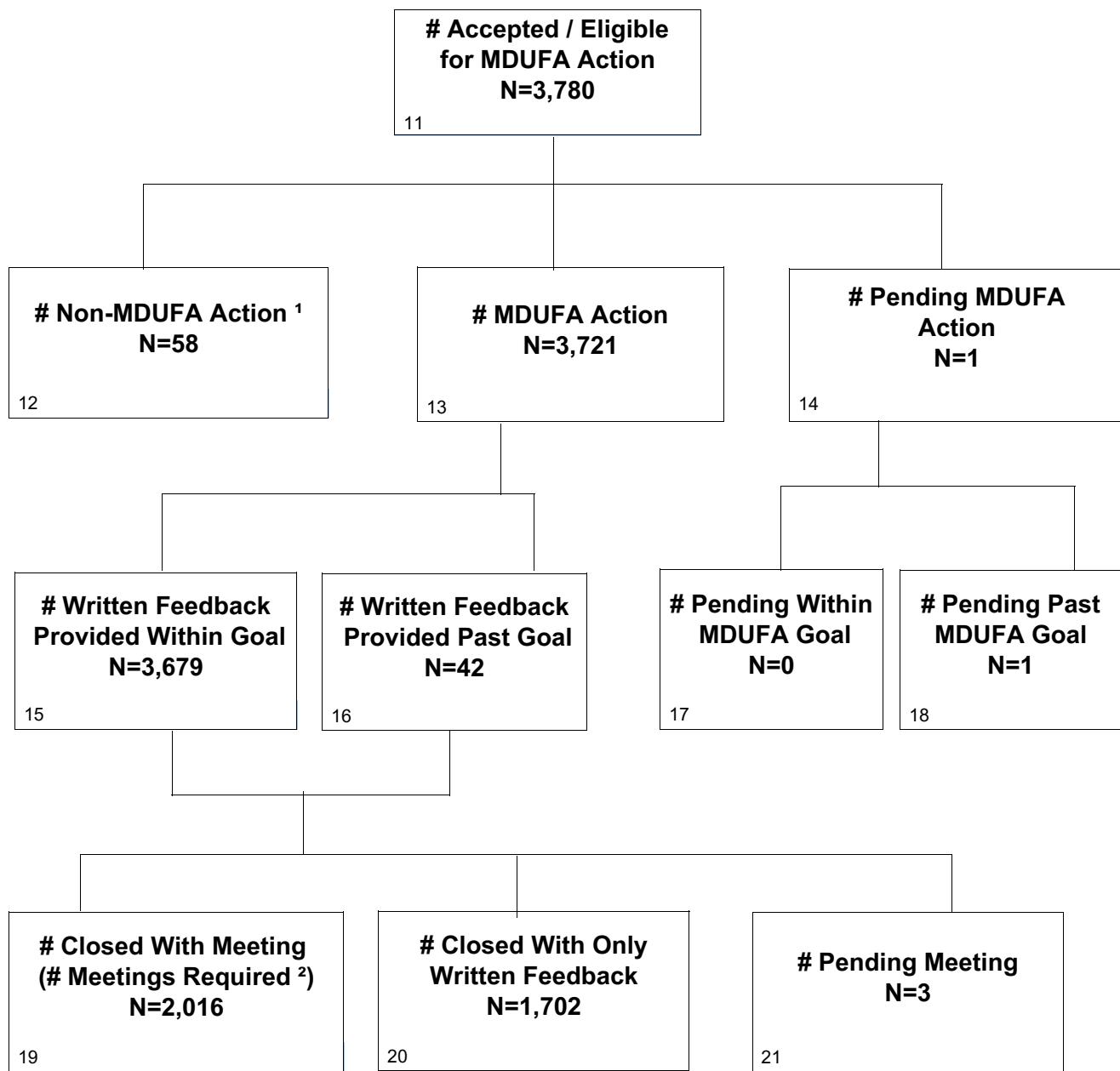
## as of 9/30/25



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 9/30/25 Continued

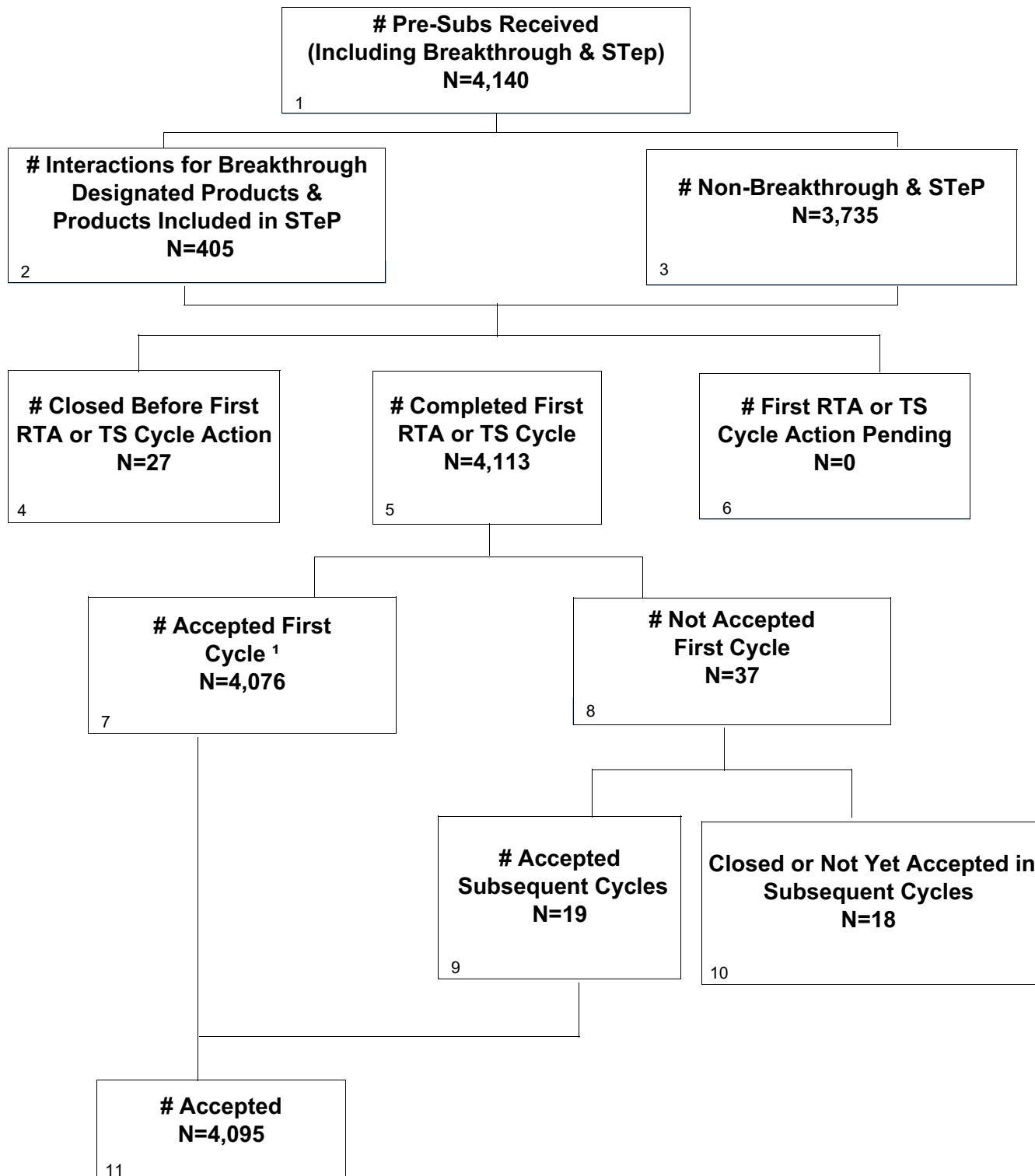


1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

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

# CDRH Pre-Sub - FY 2024

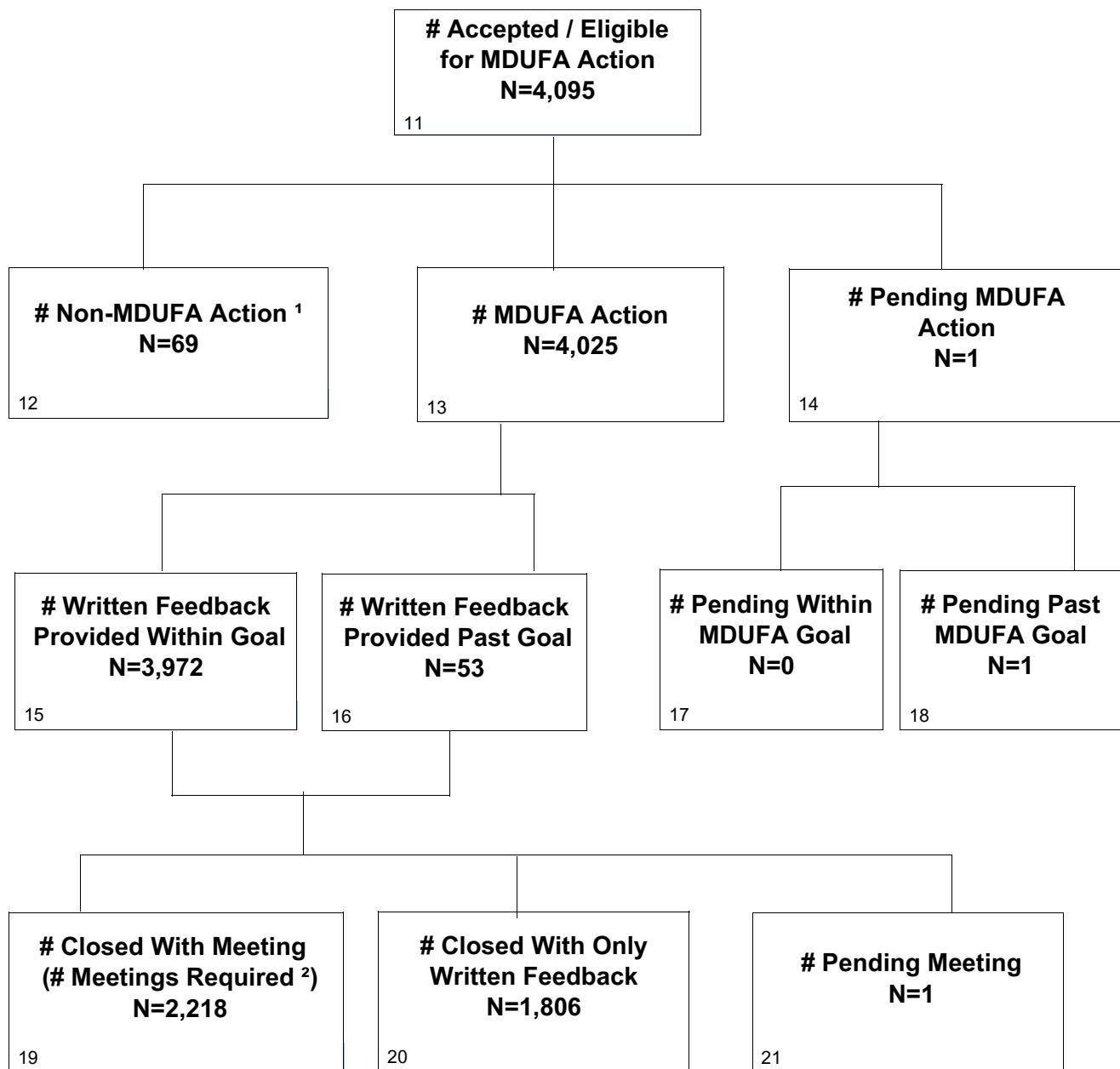
## as of 9/30/25



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 9/30/25 Continued

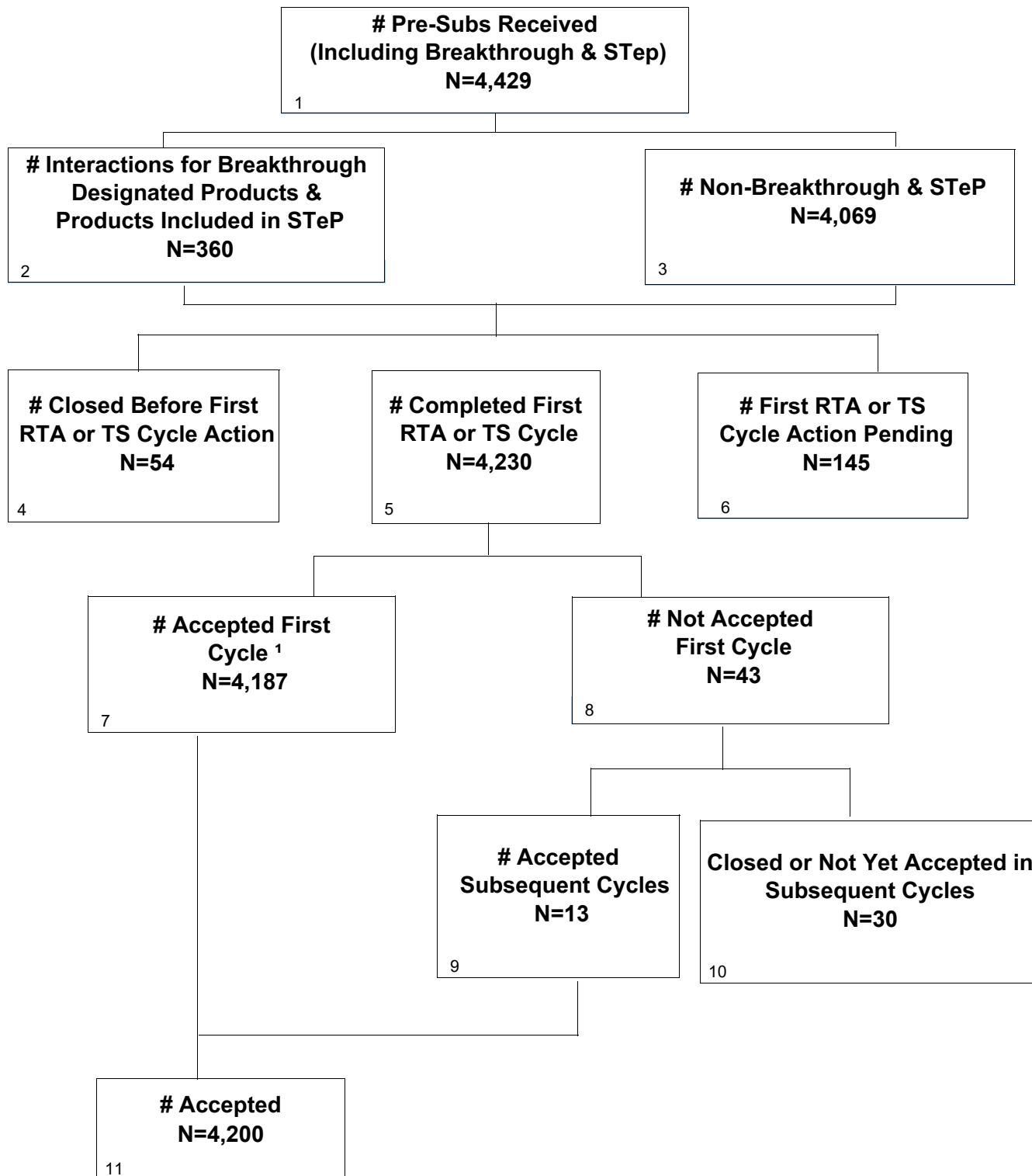


1. Non-MDUFA actions include Pre-Subs that are withdrawn at request of applicant, closed due to lack of applicant response, or is not a device subject to a CDRH lead review.

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

# CDRH Pre-Sub - FY 2025

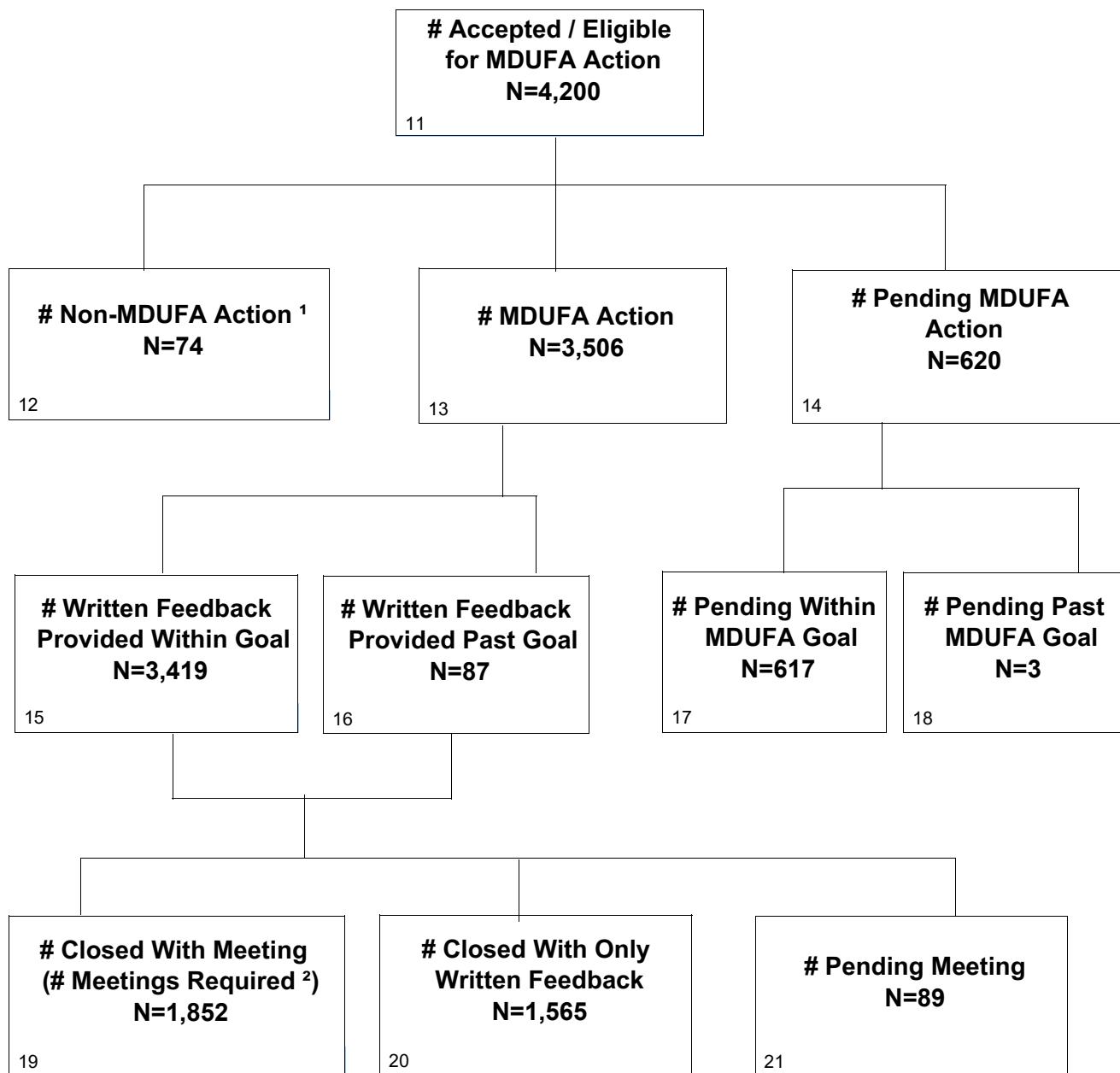
## as of 9/30/25



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 9/30/25 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	4,429		
Interactions for Breakthrough Designated Products & Products Included in STeP	282	405	360		
Number Closed Before First RTA Action	39	27	54		
Number Accepted First RTA Cycle <sup>1</sup>	3,642	3,979	4,042		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	121	97	145		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	145		
Number Not Accepted First RTA Cycle	41	37	43		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.90%	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 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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	4,200		
Number with Non-MDUFA Action <sup>3</sup>	58	69	74		
Number with MDUFA Action	3,721	4,025	3,506		
Written Feedback Provided Within Goal	3,679	3,972	3,419		
Number Pending MDUFA Action	1	1	620		
Pending MDUFA Action Past Goal	1	1	3		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	3,722	4,026	4,126		
Current Performance Percent Within Goal	98.84%	98.66%	97.44%		

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	3,506		
Average FDA Days to Written Feedback	62.20	62.25	61.33		
20th Percentile FDA Days to Written Feedback	56	56	55		
40th Percentile FDA Days to Written Feedback	64	64	63		
60th Percentile FDA Days to Written Feedback	68	67	67		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	141	245	141		

**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	129		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.57	41.05		

**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 <sup>1</sup>	2,015	2,218	1,852		
Meeting Minutes Submitted Within 15 Days of Meeting	1,531	1,787	1,449		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	69		
Meeting Minutes Past 15 Days of Meeting	434	368	273		
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	63	61		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.98%	80.57%	81.27%		

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	521		
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27	23		
Number Closed Before First RTA Action	4	6	9		
Number Accepted First RTA Cycle <sup>1</sup>	411	461	470		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	20	20	9		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	21		
Number Not Accepted First RTA Cycle	9	5	12		
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.03%	2.44%		

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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	484	
Number with Non-MDUFA Action <sup>3</sup>	12	12	12		
Number with MDUFA Action	423	473	393		
Written Feedback Provided Within Goal	410	460	379		
Number Pending MDUFA Action	0	0	79		
Pending MDUFA Action Past Goal	0	0	1		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	423	473	472		
Current Performance Percent Within Goal	96.93%	97.25%	96.19%		

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	393		
Average FDA Days to Written Feedback	65.34	65.26	64.83		
20th Percentile FDA Days to Written Feedback	62	62	62		
40th Percentile FDA Days to Written Feedback	66	66	66		
60th Percentile FDA Days to Written Feedback	69	69	69		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	141	101	91		

**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	18		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.70	42.17		

**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 <sup>1</sup>	249	275	215		
Meeting Minutes Submitted Within 15 Days of Meeting	179	226	155		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	11		
Meeting Minutes Past 15 Days of Meeting	59	39	36		
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	10	13		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	82.18%	75.98%		

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	800		
Interactions for Breakthrough Designated Products & Products Included in STeP	73	84	78		
Number Closed Before First RTA Action	6	2	3		
Number Accepted First RTA Cycle <sup>1</sup>	701	727	742		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	13	14	33		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	21		
Number Not Accepted First RTA Cycle	4	3	1		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.40%	0.13%		

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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	775		
Number with Non-MDUFA Action <sup>3</sup>	4	4	4		
Number with MDUFA Action	712	737	636		
Written Feedback Provided Within Goal	697	716	604		
Number Pending MDUFA Action	1	1	135		
Pending MDUFA Action Past Goal	1	1	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	713	738	771		
Current Performance Percent Within Goal	97.76%	97.02%	94.97%		

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	636		
Average FDA Days to Written Feedback	59.32	59.61	61.13		
20th Percentile FDA Days to Written Feedback	50	51	54		
40th Percentile FDA Days to Written Feedback	60	61	63		
60th Percentile FDA Days to Written Feedback	66	65	67		
80th Percentile FDA Days to Written Feedback	69	69	70		
Maximum FDA Days to Written Feedback	103	113	119		

**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	33		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.09	36.90	40.61		

**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 <sup>1</sup>	406	424	348		
Meeting Minutes Submitted Within 15 Days of Meeting	308	318	257		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	12		
Meeting Minutes Past 15 Days of Meeting	91	90	65		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	16	14		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.86%	75.00%	76.49%		

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	462	510	560		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63	54		
Number Closed Before First RTA Action	5	4	9		
Number Accepted First RTA Cycle <sup>1</sup>	439	484	505		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	12	11	14		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	18		
Number Not Accepted First RTA Cycle	6	11	14		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.31%	2.17%	2.63%		

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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	454	499	523		
Number with Non-MDUFA Action <sup>3</sup>	10	11	7		
Number with MDUFA Action	444	488	445		
Written Feedback Provided Within Goal	440	485	439		
Number Pending MDUFA Action	0	0	71		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	444	488	516		
Current Performance Percent Within Goal	99.10%	99.39%	98.65%		

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	444	488	445		
Average FDA Days to Written Feedback	62.14	61.74	61.13		
20th Percentile FDA Days to Written Feedback	56	56	55		
40th Percentile FDA Days to Written Feedback	64	63	63		
60th Percentile FDA Days to Written Feedback	67	67	67		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	78	78	79		

**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	13	12	13		
Average Days to Scheduling for Meetings Scheduled After Day 30	41.85	43.50	41.23		

**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 <sup>1</sup>	255	268	233		
Meeting Minutes Submitted Within 15 Days of Meeting	200	222	184		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	11		
Meeting Minutes Past 15 Days of Meeting	49	39	31		
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	7	7		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.43%	82.84%	82.88%		

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		
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35	33		
Number Closed Before First RTA Action	4	5	11		
Number Accepted First RTA Cycle <sup>1</sup>	359	436	464		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	9	14	31		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	24		
Number Not Accepted First RTA Cycle	7	8	3		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.87%	1.75%	0.60%		

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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	497		
Number with Non-MDUFA Action <sup>3</sup>	11	18	17		
Number with MDUFA Action	360	437	424		
Written Feedback Provided Within Goal	360	435	409		
Number Pending MDUFA Action	0	0	56		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	360	437	480		
Current Performance Percent Within Goal	100.00%	99.54%	96.46%		

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	424		
Average FDA Days to Written Feedback	60.50	62.00	59.67		
20th Percentile FDA Days to Written Feedback	54	56	51		
40th Percentile FDA Days to Written Feedback	62	63	62		
60th Percentile FDA Days to Written Feedback	65	67	66		
80th Percentile FDA Days to Written Feedback	69	70	69		
Maximum FDA Days to Written Feedback	70	70	141		

**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	11		
Average Days to Scheduling for Meetings Scheduled After Day 30	37.71	40.00	41.55		

**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 <sup>1</sup>	206	234	226		
Meeting Minutes Submitted Within 15 Days of Meeting	159	183	171		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	10		
Meeting Minutes Past 15 Days of Meeting	39	47	35		
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	4	10		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.18%	78.21%	79.17%		

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	396	428	470		
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42	37		
Number Closed Before First RTA Action	5	3	2		
Number Accepted First RTA Cycle <sup>1</sup>	370	406	422		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	17	10	22		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	15		
Number Not Accepted First RTA Cycle	4	9	9		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.12%	1.99%		

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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	389	421	445		
Number with Non-MDUFA Action <sup>3</sup>	5	5	9		
Number with MDUFA Action	384	416	353		
Written Feedback Provided Within Goal	382	408	337		
Number Pending MDUFA Action	0	0	83		
Pending MDUFA Action Past Goal	0	0	2		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	384	416	436		
Current Performance Percent Within Goal	99.48%	98.08%	94.93%		

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	384	416	353		
Average FDA Days to Written Feedback	66.14	67.24	65.84		
20th Percentile FDA Days to Written Feedback	64	65	63		
40th Percentile FDA Days to Written Feedback	68	69	69		
60th Percentile FDA Days to Written Feedback	70	70	70		
80th Percentile FDA Days to Written Feedback	70	70	70		
Maximum FDA Days to Written Feedback	108	245	127		

**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	25	39	29		
Average Days to Scheduling for Meetings Scheduled After Day 30	39.32	39.26	38.66		

**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 <sup>1</sup>	249	260	202		
Meeting Minutes Submitted Within 15 Days of Meeting	178	207	159		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	3		
Meeting Minutes Past 15 Days of Meeting	64	45	32		
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	8	8		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.49%	79.62%	79.90%		

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	297		
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79	57		
Number Closed Before First RTA Action	5	1	2		
Number Accepted First RTA Cycle <sup>1</sup>	270	286	280		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	10	7	6		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	7		
Number Not Accepted First RTA Cycle	4	0	2		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.41%	0.00%	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 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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	287		
Number with Non-MDUFA Action <sup>3</sup>	6	8	10		
Number with MDUFA Action	276	285	241		
Written Feedback Provided Within Goal	272	280	241		
Number Pending MDUFA Action	0	0	36		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	276	285	277		
Current Performance Percent Within Goal	98.55%	98.25%	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	241		
Average FDA Days to Written Feedback	58.46	56.93	58.02		
20th Percentile FDA Days to Written Feedback	45	43	44		
40th Percentile FDA Days to Written Feedback	58	57	58		
60th Percentile FDA Days to Written Feedback	65	64	65		
80th Percentile FDA Days to Written Feedback	69	68	69		
Maximum FDA Days to Written Feedback	97	92	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		
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50	39.40		

**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 <sup>1</sup>	124	129	112		
Meeting Minutes Submitted Within 15 Days of Meeting	91	103	88		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	5		
Meeting Minutes Past 15 Days of Meeting	29	17	17		
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	9	2		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.39%	79.84%	82.24%		

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		
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60	66		
Number Closed Before First RTA Action	9	5	15		
Number Accepted First RTA Cycle <sup>1</sup>	833	900	837		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	35	15	27		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	29		
Number Not Accepted First RTA Cycle	3	1	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.11%	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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	864		
Number with Non-MDUFA Action <sup>3</sup>	7	11	9		
Number with MDUFA Action	861	904	748		
Written Feedback Provided Within Goal	857	903	746		
Number Pending MDUFA Action	0	0	107		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	861	904	855		
Current Performance Percent Within Goal	99.54%	99.89%	99.73%		

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	748		
Average FDA Days to Written Feedback	63.70	63.10	59.94		
20th Percentile FDA Days to Written Feedback	60	59	54		
40th Percentile FDA Days to Written Feedback	66	65	63		
60th Percentile FDA Days to Written Feedback	69	68	66		
80th Percentile FDA Days to Written Feedback	70	70	69		
Maximum FDA Days to Written Feedback	75	71	89		

**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	18		
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00	42.50		

**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 <sup>1</sup>	320	414	342		
Meeting Minutes Submitted Within 15 Days of Meeting	257	355	287		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	11		
Meeting Minutes Past 15 Days of Meeting	59	53	38		
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6	6		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.31%	85.75%	86.71%		

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		
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15	12		
Number Closed Before First RTA Action	1	1	3		
Number Accepted First RTA Cycle <sup>1</sup>	259	279	322		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	5	6	3		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	10		
Number Not Accepted First RTA Cycle	4	0	2		
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.49%	0.00%	0.61%		

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 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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	325		
Number with Non-MDUFA Action <sup>3</sup>	3	0	6		
Number with MDUFA Action	261	285	266		
Written Feedback Provided Within Goal	261	285	264		
Number Pending MDUFA Action	0	0	53		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	261	285	319		
Current Performance Percent Within Goal	100.00%	100.00%	99.25%		

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	266		
Average FDA Days to Written Feedback	60.57	60.68	60.55		
20th Percentile FDA Days to Written Feedback	55	55	55		
40th Percentile FDA Days to Written Feedback	60	62	62		
60th Percentile FDA Days to Written Feedback	64	65	65		
80th Percentile FDA Days to Written Feedback	67	69	69		
Maximum FDA Days to Written Feedback	70	70	85		

**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		
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25	60.50		

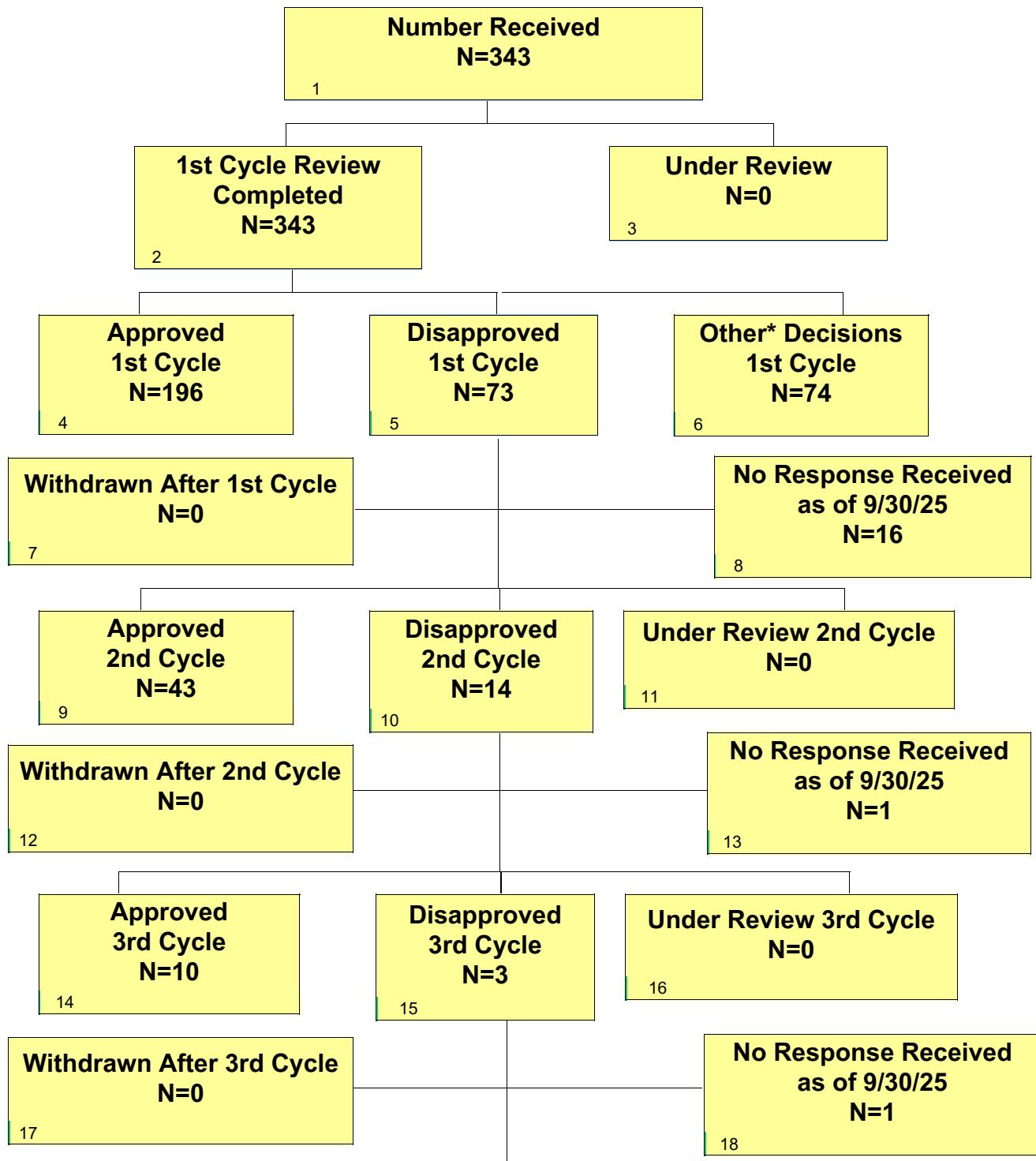
**Table 9.5 OHT8 - Office of Radiological Health****MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required <sup>1</sup>	206	214	174		
Meeting Minutes Submitted Within 15 Days of Meeting	159	173	148		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	6		
Meeting Minutes Past 15 Days of Meeting	44	38	19		
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	3	1		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.18%	80.84%	88.10%		

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

# CDRH IDEs - FY 2023

## as of 9/30/25

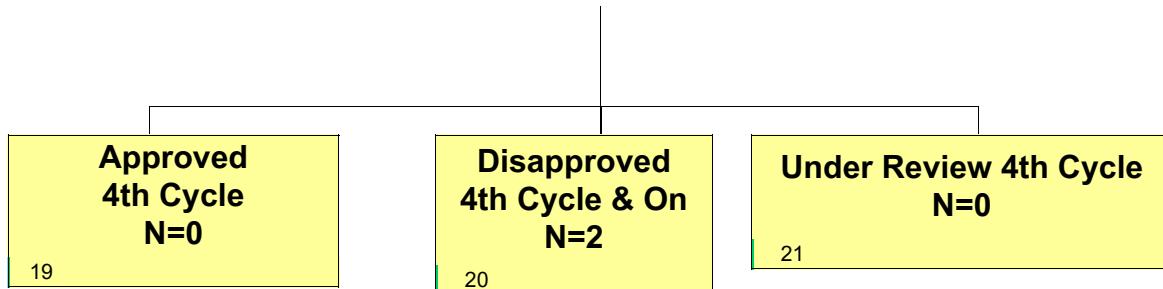


\* Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).

# CDRH IDEs - FY 2023

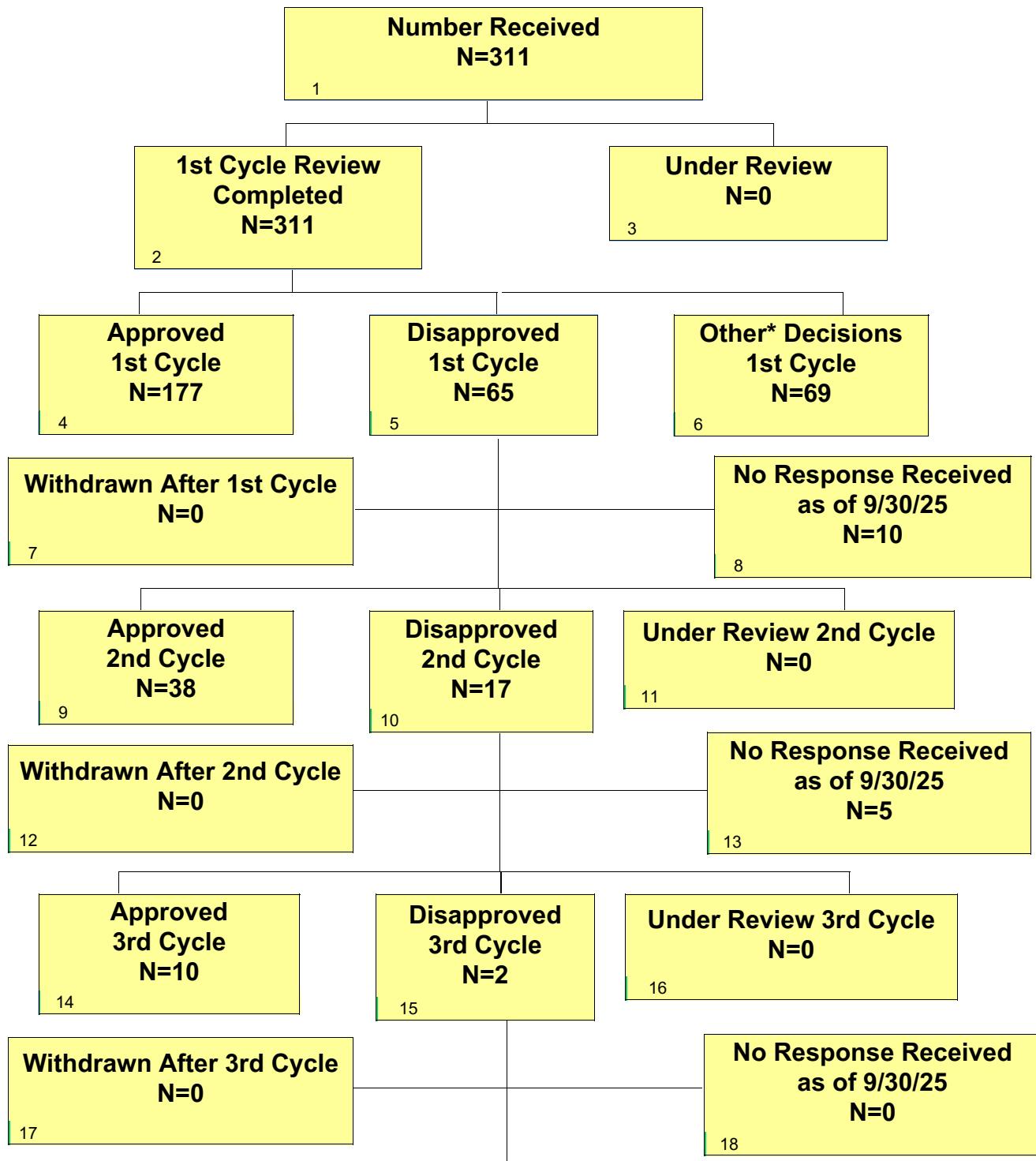
## as of 9/30/25

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# CDRH IDEs - FY 2024

## as of 9/30/25

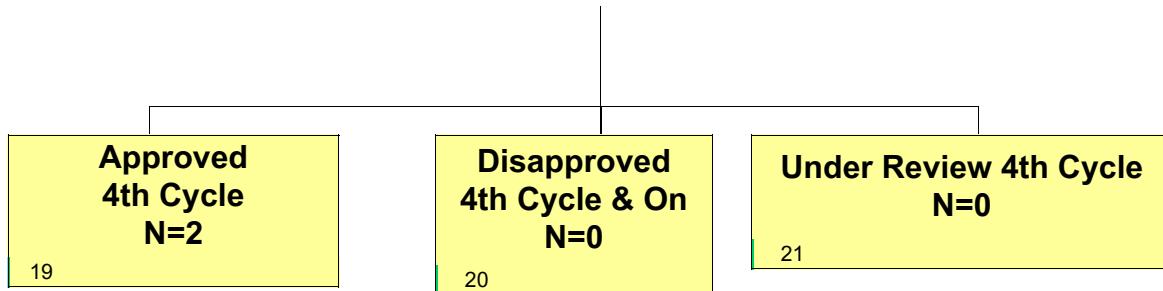


\* Other decisions include withdrawn (N=9), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).

# CDRH IDEs - FY 2024

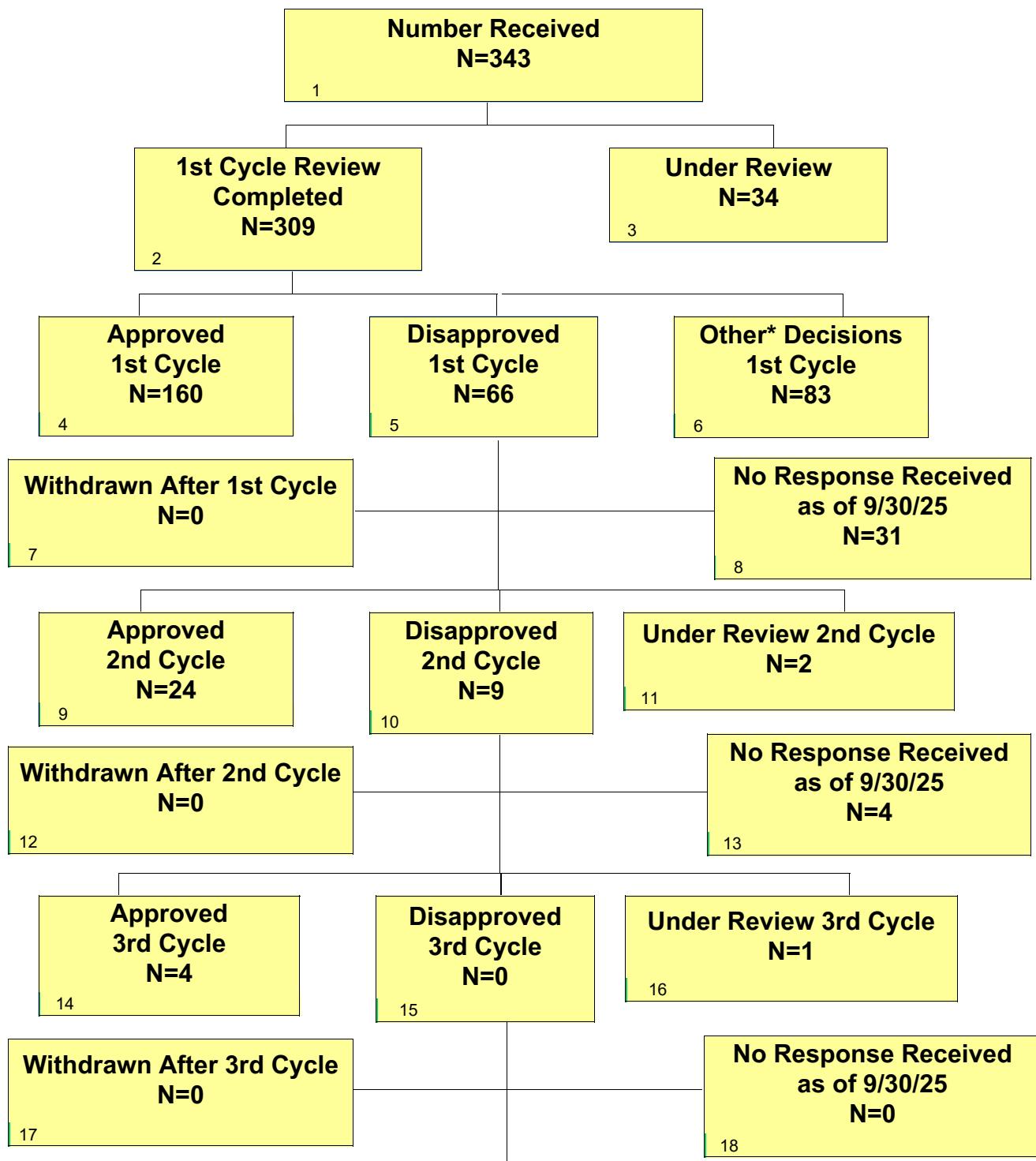
## as of 9/30/25

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# CDRH IDEs - FY 2025

## as of 9/30/25

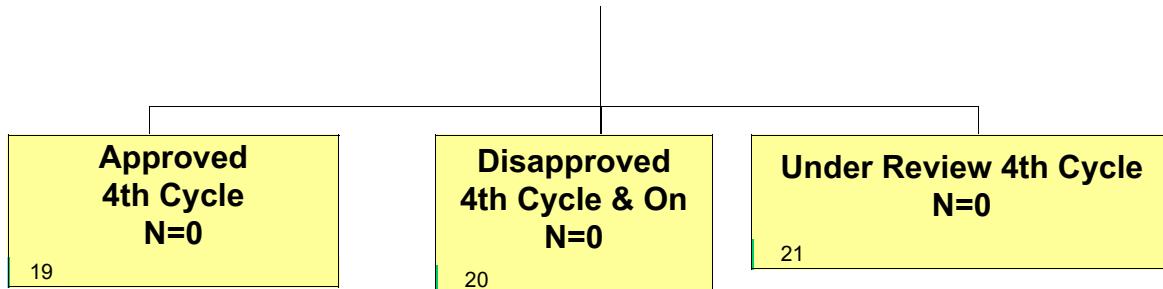


\* Other decisions include withdrawn (N=12), withdrawn and converted (N=42), RTA (N=0), nonsignificant risk device (N=21), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=7), Basic Physiological Research (N=0).

# CDRH IDEs - FY 2025

## as of 9/30/25

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## 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	311	343		
Average Number of Cycles to IDE Approval or Conditional Approval	1.28	1.28	1.17		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.28	0.28	0.17		

## 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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.39	1.21	1.44		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.39	0.21	0.44		

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	81	69		
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.40	1.27		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.40	0.27		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.31	1.31	1.14		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.31	0.31	0.14		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.13	1.00	1.04		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.13	0.00	0.04		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.24	1.41	1.09		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.24	0.41	0.09		

**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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.27	1.55		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.27	0.55		

**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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.25	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.25	0.00		

## Section 11 CLIA Waiver Annual Metrics

**Table 11.1.CDRH – CLIA Waiver Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% SI within 90 FDA days				
Eligible for SI	3	9 (12)		5	
Withdrawn prior to SI	1	0 (1)		1	
SI within 90 FDA days	1	9 (10)		1	
SI over 90 FDA days	1	0 (1)		0	
SI pending within 90 FDA days	0	0 (0)		3	
SI pending over 90 FDA days	0	0 (0)		0	
Denial without SI	0	0 (0)		0	
Current SI Performance Percent within 90 FDA days	N/A*	90.91%		N/A*	

\* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

**Table 11.2.CDRH – CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	2	9	1		
Average number of FDA days to Substantive Interaction	60.50	65.22	90.00		
20th Percentile FDA days to Substantive Interaction	37	31	90		
40th Percentile FDA days to Substantive Interaction	53	86	90		
60th Percentile FDA days to Substantive Interaction	68	87	90		
80th Percentile FDA days to Substantive Interaction	84	89	90		
Maximum FDA days to Substantive Interaction	99	90	90		

**Table 11.3.CDRH – CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
	90% Within 150 FDA Days				
Eligible for MDUFA V Decisions	3	9 (12)	5		
Non-MDUFA V Decisions	0	0 (0)	0		
MDUFA V Decisions	3	9 (12)	2		
MDUFA V Decisions within 150 FDA Days	3	9 (12)	2		
CLIA Waiver Applications pending MDUFA V Decision	0	0 (0)	3		
CLIA Waiver Applications pending MDUFA V Decision over 150 FDA days	0	0 (0)	0		
Current Performance Percent within 150 FDA Days	N/A*	100.00%	N/A*		

\* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

**Table 11.4.CDRH – CLIA Waiver with Panel Review MDUFA Decision Performance Goals**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
	90% Within 320 FDA Days				
Eligible for MDUFA V Decisions	0	0	0		
Non-MDUFA V Decisions	0	0	0		
MDUFA V Decisions	0	0	0		
MDUFA V Decisions within 320 FDA Days	0	0	0		
CLIA Waiver Applications pending MDUFA V Decision	0	0	0		
CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	0	0	0		
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*		

\* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

**Table 11.5.CDRH – CLIA Waiver (without Panel Review) Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA decision	3	9	2		
Average FDA days to MDUFA V decision	59.67	93.56	68.00		
20th Percentile FDA days to MDUFA V decision	18	31	55		
40th Percentile FDA days to MDUFA V decision	21	91	64		
60th Percentile FDA days to MDUFA V decision	46	138	72		
80th Percentile FDA days to MDUFA V decision	94	146	81		
Maximum FDA days to MDUFA V decision	142	149	90		
Average Industry days to MDUFA V decision	0.00	28.33	88.50		
20th Percentile Industry days to MDUFA V decision	0	0	35		
40th Percentile Industry days to MDUFA V decision	0	0	71		
60th Percentile Industry days to MDUFA V decision	0	0	106		
80th Percentile Industry days to MDUFA V decision	0	15	142		
Maximum Industry days to MDUFA V decision	0	217	177		
Average Total days to MDUFA V decision	59.67	121.89	156.50		
20th Percentile Total days to MDUFA V decision	18	31	90		
40th Percentile Total days to MDUFA V decision	21	91	134		
60th Percentile Total days to MDUFA V decision	46	138	179		
80th Percentile Total days to MDUFA V decision	94	161	223		
Maximum Total days to MDUFA V decision	142	366	267		

**Table 11.6.CDRH – CLIA Waiver (with Panel Review) Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA decision	0	0	0		
Average FDA days to MDUFA V decision	0.00	0.00	0.00		
20th Percentile FDA days to MDUFA V decision	0	0	0		
40th Percentile FDA days to MDUFA V decision	0	0	0		
60th Percentile FDA days to MDUFA V decision	0	0	0		
80th Percentile FDA days to MDUFA V decision	0	0	0		
Maximum FDA days to MDUFA V decision	0	0	0		
Average Industry days to MDUFA V decision	0.00	0.00	0.00		
20th Percentile Industry days to MDUFA V decision	0	0	0		
40th Percentile Industry days to MDUFA V decision	0	0	0		
60th Percentile Industry days to MDUFA V decision	0	0	0		
80th Percentile Industry days to MDUFA V decision	0	0	0		
Maximum Industry days to MDUFA V decision	0	0	0		
Average Total days to MDUFA V decision	0.00	0.00	0.00		
20th Percentile Total days to MDUFA V decision	0	0	0		
40th Percentile Total days to MDUFA V decision	0	0	0		
60th Percentile Total days to MDUFA V decision	0	0	0		
80th Percentile Total days to MDUFA V decision	0	0	0		
Maximum Total days to MDUFA V decision	0	0	0		

## Section 12 DUAL (510(k) and CLIA Waiver) Annual Metrics

Table 12.1 CDRH – DUAL (510(k) and CLIA Waiver) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% SI within 90 FDA days				
Eligible for SI	15	13	20		
Withdrawn prior to SI	0	0	0		
SI within 90 FDA days	15	13	14		
SI over 90 FDA days	0	0	0		
SI pending within 90 FDA days	0	0	6		
SI pending over 90 FDA days	0	0	0		
Denial without SI	0	0	0		
Current SI Performance Percent within 90 FDA days*	100.00%	100.00%	100.00%		

\* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.2.CDRH –DUAL (510(k) and CLIA Waiver)Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	15	13	14		
Average number of FDA days to Substantive Interaction	82.87	86.08	85.79		
20th Percentile FDA days to Substantive Interaction	76	86	83		
40th Percentile FDA days to Substantive Interaction	86	88	87		
60th Percentile FDA days to Substantive Interaction	90	89	89		
80th Percentile FDA days to Substantive Interaction	90	90	90		
Maximum FDA days to Substantive Interaction	90	90	90		

**Table 12.3.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
	90% Within 180 FDA Days				
Eligible for MDUFA V Decision	15	13	20		
Non-MDUFA V Decisions	0	1	0		
MDUFA V Decisions	15	13	7		
MDUFA V Decisions within 180 FDA Days	15	13	7		
CLIA Waiver Applications pending MDUFA V Decision	0	0	13		
CLIA Waiver Applications pending MDUFA V Decision over 180 FDA days	0	0	0		
Current Performance Percent within 180 FDA Days*	100.00%	100.00%	100.00%		

\* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

**Table 12.4.CDRH – DUAL (510(k) and CLIA Waiver) (with panel review) MDUFA Decision Performance Goals**

<b>Performance Metric</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>
	90% Within 320 FDA Days				
Eligible for MDUFA V Decision	0	0	0		
Non-MDUFA V Decisions	0	0	0		
MDUFA V Decisions	0	0	0		
MDUFA V Decisions within 320 FDA Days	0	0	0		
CLIA Waiver Applications pending MDUFA V Decision	0	0	0		
CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	0	0	0		
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*		

\* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA V commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.5.CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V decision	15	13	7		
Average FDA days to MDUFA V decision	146.13	161.00	169.00		
20th Percentile FDA days to MDUFA V decision	90	146	167		
40th Percentile FDA days to MDUFA V decision	163	178	175		
60th Percentile FDA days to MDUFA V decision	177	180	176		
80th Percentile FDA days to MDUFA V decision	179	180	178		
Maximum FDA days to MDUFA V decision	180	180	179		
Average Industry days to MDUFA V decision	137.33	96.46	17.71		
20th Percentile Industry days to MDUFA V decision	83	0	0		
40th Percentile Industry days to MDUFA V decision	155	33	0		
60th Percentile Industry days to MDUFA V decision	176	161	2		
80th Percentile Industry days to MDUFA V decision	179	177	23		
Maximum Industry days to MDUFA V decision	202	180	93		
Average Total days to MDUFA V decision	283.47	257.46	186.71		
20th Percentile Total days to MDUFA V decision	221	180	167		
40th Percentile Total days to MDUFA V decision	258	210	175		
60th Percentile Total days to MDUFA V decision	335	273	179		
80th Percentile Total days to MDUFA V decision	355	356	199		
Maximum Total days to MDUFA V decision	360	360	272		

**Table 12.6.CDRH – DUAL (510(k) and CLIA Waiver) (with Panel Review) Time to MDUFA Decision**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V decision	0	0	0		
Average FDA days to MDUFA V decision	0.00	0.00	0.00		
20th Percentile FDA days to MDUFA V decision	0	0	0		
40th Percentile FDA days to MDUFA V decision	0	0	0		
60th Percentile FDA days to MDUFA V decision	0	0	0		
80th Percentile FDA days to MDUFA V decision	0	0	0		
Maximum FDA days to MDUFA V decision	0	0	0		
Average Industry days to MDUFA V decision	0.00	0.00	0.00		
20th Percentile Industry days to MDUFA V decision	0	0	0		
40th Percentile Industry days to MDUFA V decision	0	0	0		
60th Percentile Industry days to MDUFA V decision	0	0	0		
80th Percentile Industry days to MDUFA V decision	0	0	0		
Maximum Industry days to MDUFA V decision	0	0	0		
Average Total days to MDUFA V decision	0.00	0.00	0.00		
20th Percentile Total days to MDUFA V decision	0	0	0		
40th Percentile Total days to MDUFA V decision	0	0	0		
60th Percentile Total days to MDUFA V decision	0	0	0		
80th Percentile Total days to MDUFA V decision	0	0	0		
Maximum Total days to MDUFA V decision	0	0	0		

## 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		
Closed before Teleconference		0	0		
Teleconferences Held		31	74		
Teleconferences Held Within 14 Days		30	72		
Teleconferences Pending		0	7		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		96.77%	97.30%		

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		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	12		
Written Feedback Provided Within 21 Days		3	10		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	83.33%		

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		
Closed before Written Feedback		0	1		
Written Feedback Provided		44	58		
Written Feedback Provided Within 40 Days		44	57		
Written Feedback Pending		0	8		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	98.28%		

## 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		
Enrollment Requests Accepted		40	49		
Enrollment Requests Not Accepted		7	4		
Enrollment Requests Pending		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		
Closed before Teleconference		0	0		
Teleconferences Held		0	1		
Teleconferences Held Within 14 Days		0	1		
Teleconferences Pending		0	1		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		N/A	100.00%		

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		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	N/A		

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		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		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		
Enrollment Requests Accepted		0	2		
Enrollment Requests Not Accepted		0	0		
Enrollment Requests Pending		0	0		

**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		
Closed before Teleconference		0	0		
Teleconferences Held		21	29		
Teleconferences Held Within 14 Days		20	28		
Teleconferences Pending		0	5		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		95.24%	96.55%		

**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		
Closed before Written Feedback		0	0		
Written Feedback Provided		3	6		
Written Feedback Provided Within 21 Days		3	4		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		100.00%	66.67%		

**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		
Closed before Written Feedback		0	0		
Written Feedback Provided		34	37		
Written Feedback Provided Within 40 Days		34	37		
Written Feedback Pending		0	2		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	100.00%		

**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		
Enrollment Requests Accepted		16	13		
Enrollment Requests Not Accepted		5	1		
Enrollment Requests Pending		0	0		

**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		
Closed before Teleconference		0	0		
Teleconferences Held		0	0		
Teleconferences Held Within 14 Days		0	0		
Teleconferences Pending		0	0		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		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		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 21 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		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		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	0		
Written Feedback Provided Within 40 Days		0	0		
Written Feedback Pending		0	0		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		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		25	2		
Enrollment Requests Accepted		24	0		
Enrollment Requests Not Accepted		1	2		
Enrollment Requests Pending		0	0		

**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	
Closed before Teleconference			0	0	
Teleconferences Held			0	0	
Teleconferences Held Within 14 Days			0	0	
Teleconferences Pending			0	0	
Teleconferences Pending Over 14 Days			0	0	
Current Performance Percent Within 14 Days		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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	0	
Written Feedback Provided Within 21 Days			0	0	
Written Feedback Pending			0	0	
Written Feedback Pending Over 21 Days			0	0	
Current Performance Percent Within 21 Days		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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	0	
Written Feedback Provided Within 40 Days			0	0	
Written Feedback Pending			0	0	
Written Feedback Pending Over 40 Days			0	0	
Current Performance Percent Within 40 Days		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	
Enrollment Requests Accepted			0	0	
Enrollment Requests Not Accepted			0	0	
Enrollment Requests Pending			0	0	

**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		
Closed before Teleconference		0	0		
Teleconferences Held		10	34		
Teleconferences Held Within 14 Days		10	33		
Teleconferences Pending		0	1		
Teleconferences Pending Over 14 Days		0	0		
Current Performance Percent Within 14 Days		100.00%	97.06%		

**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		
Closed before Written Feedback		0	0		
Written Feedback Provided		0	6		
Written Feedback Provided Within 21 Days		0	6		
Written Feedback Pending		0	0		
Written Feedback Pending Over 21 Days		0	0		
Current Performance Percent Within 21 Days		N/A	100.00%		

**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		
Closed before Written Feedback		0	1		
Written Feedback Provided		10	16		
Written Feedback Provided Within 40 Days		10	15		
Written Feedback Pending		0	4		
Written Feedback Pending Over 40 Days		0	0		
Current Performance Percent Within 40 Days		100.00%	93.75%		

**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		
Enrollment Requests Accepted		24	12		
Enrollment Requests Not Accepted		1	0		
Enrollment Requests Pending		0	0		

**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	
Closed before Teleconference			0	0	
Teleconferences Held			0	9	
Teleconferences Held Within 14 Days			0	9	
Teleconferences Pending			0	0	
Teleconferences Pending Over 14 Days			0	0	
Current Performance Percent Within 14 Days		N/A	100.00%		

**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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	0	
Written Feedback Provided Within 21 Days			0	0	
Written Feedback Pending			0	0	
Written Feedback Pending Over 21 Days			0	0	
Current Performance Percent Within 21 Days		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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	4	
Written Feedback Provided Within 40 Days			0	4	
Written Feedback Pending			0	0	
Written Feedback Pending Over 40 Days			0	0	
Current Performance Percent Within 40 Days		N/A	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	
Enrollment Requests Accepted			0	15	
Enrollment Requests Not Accepted			0	0	
Enrollment Requests Pending			0	0	

**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	
Closed before Teleconference			0	0	
Teleconferences Held			0	0	
Teleconferences Held Within 14 Days			0	0	
Teleconferences Pending			0	0	
Teleconferences Pending Over 14 Days			0	0	
Current Performance Percent Within 14 Days		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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	0	
Written Feedback Provided Within 21 Days			0	0	
Written Feedback Pending			0	0	
Written Feedback Pending Over 21 Days			0	0	
Current Performance Percent Within 21 Days		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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	0	
Written Feedback Provided Within 40 Days			0	0	
Written Feedback Pending			0	0	
Written Feedback Pending Over 40 Days			0	0	
Current Performance Percent Within 40 Days		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	
Enrollment Requests Accepted			0	0	
Enrollment Requests Not Accepted			0	0	
Enrollment Requests Pending			0	0	

**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	
Closed before Teleconference			0	0	
Teleconferences Held			0	1	
Teleconferences Held Within 14 Days			0	1	
Teleconferences Pending			0	0	
Teleconferences Pending Over 14 Days			0	0	
Current Performance Percent Within 14 Days		N/A	100.00%		

**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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	0	
Written Feedback Provided Within 21 Days			0	0	
Written Feedback Pending			0	0	
Written Feedback Pending Over 21 Days			0	0	
Current Performance Percent Within 21 Days		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	
Closed before Written Feedback			0	0	
Written Feedback Provided			0	1	
Written Feedback Provided Within 40 Days			0	1	
Written Feedback Pending			0	2	
Written Feedback Pending Over 40 Days			0	0	
Current Performance Percent Within 40 Days		N/A	100.00%		

**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	
Enrollment Requests Accepted			0	7	
Enrollment Requests Not Accepted			0	1	
Enrollment Requests Pending			0	1	

## 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 <sup>th</sup> Percentile FDA Days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA Days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA Days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA Days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA Days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 1.5 and Tables 1.5.x PMA Originals 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.8 and Tables 1.8.x****PMA 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.9 and Tables 1.9.x****PMA Originals and Panel Track Supplements (Without Panel Review) 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 <sup>st</sup> 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 <sup>th</sup> 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 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 6.4 and Tables 6.4.x 510(k) MDUFA 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA 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 <sup>th</sup> Percentile FDA Days to MDUFA Decision	The 90 <sup>th</sup> percentile of FDA days to MDUFA decision on 3 <sup>rd</sup> 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 <sup>st</sup> 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 <sup>th</sup> 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days to MDUFA 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 <sup>th</sup> Percentile FDA Days to Written Feedback	20 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
4	40 <sup>th</sup> Percentile FDA Days to Written Feedback	40 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
5	60 <sup>th</sup> Percentile FDA Days to Written Feedback	60 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
6	80 <sup>th</sup> Percentile FDA Days to Written Feedback	80 <sup>th</sup> percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100 <sup>th</sup> percentile) to Written Feedback for Pre-Subs with MDUFA 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 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 11.3 CLIA Waiver (without Panel Review) MDUFA 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

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

**Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn prior to 90 days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

**Table 12.2 Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications accepted in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 12.3    Dual 510(k) and CLIA Waiver (without panel review) MDUFA 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA 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 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

## Section 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 30 September 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		
Closed Before RTA Action	0	0	0		
Number with Accepted RTA Review	3	0	1		
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0		
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted for Filing Review	0	0	0		
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	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		
Number Accepted	3	0	1		
Completed RTF	3	0	1		
Number Not Filed	0	0	0		
Rate of Submissions Not Filed	0.00%	N/A	0.00%		

Table 1.3 CBER - PMA Original and Panel-Track Supplements Substantive Interaction Performance 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	3	0	1		
SI Goal Met	3	0	1		
SI Goal Not Met	0	0	0		
SI Pending Within Goal	0	0	0		
SI Pending Past Goal	0	0	0		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	100.00%	N/A	100.00%		

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		
Average Number of FDA Days to Substantive Interaction	88.33	0.00	90.00		
20th Percentile FDA Days to Substantive Interaction	87	0	90		
40th Percentile FDA Days to Substantive Interaction	88	0	90		
60th Percentile FDA Days to Substantive Interaction	88	0	90		
80th Percentile FDA Days to Substantive Interaction	89	0	90		
Maximum FDA Days to Substantive Interaction	90	0	90		

**Table 1.5 CBER - 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	0	1		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	3	0	0		
MDUFA V Decision Goal Met	3	0	0		
PMAs Pending MDUFA V Decision	0	0	1		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100.00%	N/A	N/A		

**Table 1.6 CBER - 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		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	0	0	0		
MDUFA V Decision Goal Met	0	0	0		
PMAs Pending MDUFA V Decision	0	0	0		
PMAs Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	0		
<b>Average FDA Days to MDUFA V Decision</b>	177.00	0.00	0.00		
20th Percentile FDA Days to MDUFA V Decision	175	0	0		
40th Percentile FDA Days to MDUFA V Decision	178	0	0		
60th Percentile FDA Days to MDUFA V Decision	179	0	0		
80th Percentile FDA Days to MDUFA V Decision	180	0	0		
Maximum FDA Days to MDUFA V Decision	180	0	0		
<b>Average Industry Days to MDUFA V Decision</b>	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	0	0		
80th Percentile Industry Days to MDUFA V Decision	0	0	0		
Maximum Industry Days to MDUFA V Decision	0	0	0		
<b>Average Total Days to MDUFA V Decision</b>	177.00	0.00	0.00		
20th Percentile Total Days to MDUFA V Decision	175	0	0		
40th Percentile Total Days to MDUFA V Decision	178	0	0		
60th Percentile Total Days to MDUFA V Decision	179	0	0		
80th Percentile Total Days to MDUFA V Decision	180	0	0		
Maximum Total Days to MDUFA V Decision	180	0	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		
<b>Average FDA Days to MDUFA V Decision</b>	0.00	0.00	0.00		
20th Percentile FDA Days to MDUFA V Decision	0	0	0		
40th Percentile FDA Days to MDUFA V Decision	0	0	0		
60th Percentile FDA Days to MDUFA V Decision	0	0	0		
80th Percentile FDA Days to MDUFA V Decision	0	0	0		
Maximum FDA Days to MDUFA V Decision	0	0	0		
<b>Average Industry Days to MDUFA V Decision</b>	0.00	0.00	0.00		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	0	0		
80th Percentile Industry Days to MDUFA V Decision	0.00	0.00	0		
Maximum Industry Days to MDUFA V Decision	0	0	0		
<b>Average Total Days to MDUFA V Decision</b>	0	0	0.00		
20th Percentile Total Days to MDUFA V Decision	0	0	0		
40th Percentile Total Days to MDUFA V Decision	0	0	0		
60th Percentile Total Days to MDUFA V Decision	0	0	0		
80th Percentile Total Days to MDUFA V Decision	0	0	0		
Maximum Total Days to MDUFA V Decision	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		
Number with MDUFA V Decision	3	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Not Approvable	0.00%	N/A	N/A		

**Table 1.10 CBER - PMA Original and Panel-Track Supplements (with Panel Review)**

**Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	0	0	0		
Number With MDUFA V Decision	0	0	0		
Number of Withdrawal	0	0	0		
Number of Not Approvable	0	0	0		
Number of Deleted	0	0	0		
Rate of Withdrawal	N/A	N/A	N/A		
Rate of Not Approvable	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 180 FDA Days				
Number of PMAs Filed	0	0	0		
Non-MDUFa V Decision	0	0	0		
MDUFa V Decision	0	0	0		
MDUFa V Decision Goal Met	0	0	0		
PMAs Pending MDUFa V Decision	0	0	0		
PMAs Pending MDUFa V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	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	FY 2024	FY 2025	FY 2026	FY 2027
	90% Within 320 FDA Days				
Number of PMAs Filed	0	0	0		
Non-MDUFa V Decision	0	0	0		
MDUFa V Decision	0	0	0		
MDUFa V Decision Goal Met	0	0	0		
PMAs Pending MDUFa V Decision	0	0	0		
PMAs Pending MDUFa V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	N/A	N/A	N/A		

\*Includes submission that went to panel

## Section 5 PMA Annual Metrics and Goals

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

PMA Submissions Received	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Premarket Report Submissions	0	0	0		
Original PMAs (Panel) – Priority	0	0	0		
Original PMAs (No Panel) – Priority	1	0	1		
Original PMAs (Panel) – Non-Priority	0	0	0		
Original PMAs (No Panel) – Non-Priority	0	0	0		
Panel-Tracked Supplements (Panel) – Priority	0	0	0		
Panel-Tracked Supplements (No Panel) – Priority	1	0	0		
Panel-Tracked Supplements (Panel) – Non-Priority	0	0	0		
Panel-Tracked Supplements (No Panel) – Non-Priority	1	0	0		
PMA Modules	0	0	0		
180-Day Supplements	4	5	8		
Real-Time Supplements	3	2	2		

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	3	0	1		
Number with a decision (MDUFA or Non-MDUFA)	3	0	0		
% of FY closed	100.00%	N/A	0.00%		

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

Performance Metric	FY 2023 3 year cohort 290 days	FY 2024 3 year cohort 290 days	FY 2025 3 year cohort 285 days	FY 2026 3 year cohort 285 days	FY 2027 3 year cohort 285 days
Number with a MDUFA decision	5	4	3		
Number with a MDUFA decision after trimming the upper and lower 5%	5	4	3		
Three-year Rolling Average Total Time to MDUFA decision	180.20	181.00	177.00		

## 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 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	4	5	8		
SI Goal Met	2	5	6		
SI Goal Not Met	2	0	0		
SI Pending Within Goal	0	0	1		
SI Pending Past Goal	0	0	1		
Closed Without SI	0	0	0		
Current SI Performance Percent Goal Met	50.00%	100.00%	85.71%		

Table 2.2 CBER - 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	4	5	8		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	4	5	4		
MDUFA V Decision Goal Met	3	5	4		
Supplements Pending MDUFA V Decision	0	0	4		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	75.00%	100.00%	100.00%		

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		
Number with MDUFA V Decision	4	5	4		
Number of Not Approvable	1	1	0		
Rate of Not Approvable	25.00%	20.00%	0.00%		

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		
Mean FDA Days for Submissions that Missed the Goal	206.00	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	121.00	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		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision	3	2	2		
MDUFA V Decision Goal Met	3	2	2		
Supplements Pending MDUFA V Decision	0	0	0		
Supplements Pending MDUFA V Decision Past Goal	0	0	0		
Current Performance Percent Goal Met	100%	100%	100%		

**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		
Number With MDUFA V Decision	3	2	2		
Number of Not Approvable	0	0	0		
Rate of Not Approvable	0%	0%	0%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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	56		
Closed Before First RTA or TS Action <sup>1</sup>	0	4	1		
Number Accepted or Passed TS on First Cycle <sup>2</sup>	30	25	40		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>3</sup>	0	0	1		
Number Without a RTA or TS Review and <= 15 Days Since Date Received <sup>1</sup>	0	0	5		
Number Not Accepted or Failed TS on First Cycle <sup>2</sup>	11	4	9		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle <sup>2</sup>	26.83%	13.79%	18.00%		

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.

Table 6.2 CBER - 510(k) Substantive Interaction 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	39	29	44		
Deleted or Withdrawn Prior to SI	0	0	0		
SI Within 60 FDA Days	37	29	35		
SI Over 60 FDA Days	2	0	1		
SI Pending Within 60 FDA Days	0	0	8		
SI Pending Over 60 FDA Days	0	0	0		
510(k)s NSE Without SI	0	1	0		
Current SI Performance Percent Within 60 FDA Days	94.87%	96.67%	97.22%		

**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	36		
Average Number of FDA Days to Substantive Interaction	55.53	56.79	51.75		
20th Percentile FDA Days to Substantive Interaction	51	56	37		
40th Percentile FDA Days to Substantive Interaction	56	57	58		
60th Percentile FDA Days to Substantive Interaction	59	58	59		
80th Percentile FDA Days to Substantive Interaction	60	60	60		
Maximum FDA Days to Substantive Interaction	90	60	62		

**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	44		
Non-MDUFA V Decision	3	3	1		
MDUFA V Decision (SE/NSE)	36	26	19		
MDUFA V Decision Within 90 FDA Days	36	26	19		
510(k)s Pending MDUFA V Decision	0	0	24		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		

**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	1.26		
Number With MDUFA V Decision	36	26	19		
<b>Average Number of FDA Days to MDUFA V Decision</b>	77.33	80.08	66.26		
20th Percentile FDA Days to MDUFA V Decision	69	73	28		
40th Percentile FDA Days to MDUFA V Decision	84	86	75		
60th Percentile FDA Days to MDUFA V Decision	89	87	87		
80th Percentile FDA Days to MDUFA V Decision	90	89	88		
Maximum FDA Days to MDUFA V Decision	90	90	89		
<b>Average Number of Industry Days to MDUFA V Decision</b>	48.92	82.12	16.89		
20th Percentile Industry Days to MDUFA V Decision	0	0	0		
40th Percentile Industry Days to MDUFA V Decision	0	0	0		
60th Percentile Industry Days to MDUFA V Decision	0	102	0		
80th Percentile Industry Days to MDUFA V Decision	115	180	25		
Maximum Industry Days to MDUFA V Decision	315	207	193		
<b>Average Number of Total Days to MDUFA V Decision</b>	126.25	162.19	83.16		
20th Percentile Total Days to MDUFA V Decision	81	79	28		
40th Percentile Total Days to MDUFA V Decision	88	90	79		
60th Percentile Total Days to MDUFA V Decision	90	188	88		
80th Percentile Total Days to MDUFA V Decision	90	266	113		
Maximum Total Days to MDUFA V Decision	375	288	267		

**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	44		
Number With MDUFA V Decision	36	26	19		
Number of SE Decision	35	20	15		
Number of NSE Decision	1	6	4		
Number of Withdrawal	2	1	1		
Number of Deleted	1	2	0		
Rate of SE Decision	97.22%	76.92%	78.95%		
Rate of NSE Decision	2.78%	23.08%	21.05%		
Rate of Withdrawal	5.13%	3.45%	2.27%		
Rate of Deleted	2.56%	6.90%	0.00%		

**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		
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	0	0	0		
MDUFA V Decision Within 90 FDA Days	0	0	0		
510(k)s Pending MDUFA V Decision	0	0	0		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	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	5		
Non-MDUFA V Decision	0	0	0		
MDUFA V Decision (SE/NSE)	7	4	4		
MDUFA V Decision Within 90 FDA Days	7	4	4		
510(k)s Pending MDUFA V Decision	0	0	1		
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0		
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%		

## Section 7 510(k) Annual General Metrics

**Table 7.1 CBER - 510(k) Annual General Metrics - 510(k)s Received by Type**

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted	39	29	44		
Number of Traditional Submissions	35	28	36		
Number of Special Submissions	4	1	8		
Number of Abbreviated Submissions	0	0	0		
Average Number of Days to Accept/Refuse to Accept	13.27	12.45	12.02		
Number of Third Party Submissions	0	0	0		

**Table 7.2 CBER - 510(k) Annual Shared Outcome Goal**

Performance Metrics	FY 2023 128 Days	FY 2024 124 Days	FY 2025 112 Days	FY 2026 112 Days	FY 2027 112 Days
Number Accepted	39.00	29.00	44.00		
Currently Under Review	0.00	0.00	24.00		
Number With Non-MDUFA V Decision	3.00	3.00	1.00		
Number With MDUFA V Decision	36.00	26.00	19.00		
Percent of Cohort Closed	100.00%	100.00%	44.19%		
Number With MDUFA V Decision After Trimming the Upper and Lower 2%	36	26	19		
Average Total Time to MDUFA V Decision	126.25	162.19	83.16		

**Table 7.3 CBER - 510(k) Third Party Performance**

Performance Metrics	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Third Party Submissions	0.00	0.00	0.00		
90th Percentile FDA Days to MDUFA V Decision	N/A	N/A	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		
Closed Before First RTA or TS Action	0	0	0		
Number Accepted or Passed TS on First Cycle	0	0	1		
Number Without a RTA or TS Review and > 15 Days Since Date Received <sup>1</sup>	0	0	0		
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0		
Number Not Accepted or Failed TS on First Cycle	1	0	0		
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%	N/A	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 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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	1	0	0		
MDUFA Decision Within 150 FDA Days	1	0	0		
De Novos Pending MDUFA Decision	0	0	1		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	100.00%	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		
Number With MDUFA Decision	1	0	0		
<b>Average FDA Days to MDUFA Decision</b>	75.00	0.00	0.00		
20th Percentile FDA Days to MDUFA Decision	75	0			
40th Percentile FDA Days to MDUFA Decision	75	0	0		
60th Percentile FDA Days to MDUFA Decision	75	0	0		
80th Percentile FDA Days to MDUFA Decision	75	0	0		
Maximum FDA Days to MDUFA Decision	75	0	0		
<b>Average Industry Days to MDUFA Decision</b>	177.00	0.00	0.00		
20th Percentile Industry Days to MDUFA Decision	177	0	0		
40th Percentile Industry Days to MDUFA Decision	177	0	0		
60th Percentile Industry Days to MDUFA Decision	177	0	0		
80th Percentile Industry Days to MDUFA Decision	177	0	0		
Maximum Industry Days to MDUFA Decision	177	0	0		
<b>Average Total Days to MDUFA Decision</b>	252.00	0.00	0.00		
20th Percentile Total Days to MDUFA Decision	252	0	0		
40th Percentile Total Days to MDUFA Decision	252	0	0		
60th Percentile Total Days to MDUFA Decision	252	0	0		
80th Percentile Total Days to MDUFA Decision	252	0	0		
Maximum Total Days to MDUFA Decision	252	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		
Number With MDUFA Decision	1	0	0		
Number With Granted Decision	0	0	0		
Number With Declined Decision	1	0	0		
Number of Withdrawal	0	0	0		
Number of Deleted	0	0	0		
Rate of Granted Decision	0.00%	N/A	N/A		
Rate of Declined Decision	100.00%	N/A	N/A		
Rate of Withdrawal	0.00%	N/A	N/A		
Rate of Deleted	0.00%	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		
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00		
Mean Industry Days for Submissions that Missed the Goal	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	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		
Non-MDUFA Decision	0	0	0		
MDUFA Decision	0	0	0		
MDUFA Decision Within 150 FDA Days	0	0	0		
De Novos Pending MDUFA Decision	0	0	0		
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0		
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A		

**Table 8.8 CBER - De Novo Annual General Metrics**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Accepted First RTA Cycle	0	0	1		
Average Number of Days to Accept / Refuse to Accept on First RTA Cycle	14.00	0.00	15.00		

## 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	73		
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1	4		
Number Closed Before First RTA Action	7	1	1		
Number Accepted First RTA Cycle <sup>1</sup>	59	60	70		
Number Without First Cycle RTA Review and > 15 Days Since Date Received <sup>2</sup>	2	0	2		
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0		
Number Not Accepted First RTA Cycle	0	1	0		
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	1.64%	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 <sup>1</sup>	FY 2024 90% / 80% Within MDUFA Goal <sup>2</sup>	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	72		
Number with Non-MDUFA Action <sup>3</sup>	3	0	0		
Number with MDUFA Action	58	61	63		
Written Feedback Provided Within Goal	55	61	63		
Number Pending MDUFA Action	0	0	9		
Pending MDUFA Action Past Goal	0	0	0		
Number in MDUFA Cohort (up to max 4300) <sup>4</sup>	58	61	72		
Current Performance Percent Within Goal	94.83%	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	63		
Average FDA Days to Written Feedback	59.38	60.79	60.75		
20th Percentile FDA Days to Written Feedback	55	54	55		
40th Percentile FDA Days to Written Feedback	60	61	61		
60th Percentile FDA Days to Written Feedback	64	65	65		
80th Percentile FDA Days to Written Feedback	69	69	68		
Maximum FDA Days to Written Feedback	72	70	70		

**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		
Average Days to Scheduling for Meetings Scheduled After Day 30	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 <sup>1</sup>	24	31	21		
Meeting Minutes Submitted Within 15 Days of Meeting	21	26	16		
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	2		
Meeting Minutes Past 15 Days of Meeting	3	5	3		
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0	0		
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	83.87%	84.21%		

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		
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.07	1.00		
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.06	0.00		

**BLA****CBER – Annual General Metric Report for BLAs****\*\*Annual Metrics and Goals will be reported in the Annual Report\*\***

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard BLAs Filed	6	0	10		
Number of Standard BLA First Actions less than or equal to 10 months	6	0	0		
Number of Standard BLA Frist Actions greater than 10 months	0	0	0		
Number of Standard BLAs Pending	0	0	10		
Number of Priority BLA Filed	0	0	0		
Number of Priority BLA First Actions less than or equal to 6 months	0	0	0		
Number of Priority BLA Frist Actions greater than 6 months	0	0	0		
Number of Priority BLAs Pending	0	0	0		

## BLA Efficacy Supplements

### CBER – Annual General Metric Report for BLA Efficacy Supplements

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard Efficacy Supplements Filed	1	0	0		
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	1	0	0		
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0	0		
Number of Standard Efficacy Supplements Pending	0	0	0		
Number of Priority Efficacy Supplements Filed	0	0	0		
Number of Priority Efficacy Supplements First Actions less than or equal to 6 months	0	0	0		
Number of Priority Efficacy Supplements First Actions greater than 6 months	0	0	0		
Number of Priority Efficacy Supplements Pending	0	0	0		

**BLA Prior Approval Manufacturing Supplements**  
**CBER – Annual General Metric Report for BLA PAS Supplements**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Standard PAS Supplements Filed	88	153	113		
Number of Standard PAS Supplements First Actions less than or equal to 4 months	88	153	108		
Number of Standard PAS Supplements First Actions greater than 4 months	0	0	0		
Number of Standard PAS Supplements Pending	0	0	5		

**BLA/BLA Resubmissions**  
**CBER – Annual General Metric Report for BLA/BLA Resubmissions**

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Class 1 Resubmissions Received	0	0	0		
Number of Class 1 Resubmission Actions less than or equal to 2 months	0	0	0		
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0		
Number of Class 1 Resbumssions Pending	0	0	0		
Number of Class 2 Resubmissions Received	0	2	0		
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	2	0		
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0		
Number of Class 2 Resubmissions Pending	0	0	0		

# Medical Devices

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## Guidance Documents

Pursuant to the MDUFA V Commitment Letter,<sup>1</sup> the table below includes all FDA guidance documents issued in FY 2025 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.<sup>2</sup> The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).<sup>3</sup> Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for FY 2025.

**Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2025**

#	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	Endosseous Dental Implants and Endosseous Dental Implant Abutments - Performance Criteria for Safety and Performance Based Pathway <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/endosseous-dental-implants-and-endosseous-dental-implant-abutments-performance-criteria-safety-and">www.fda.gov/regulatory-information/search-fda-guidance-documents/endosseous-dental-implants-and-endosseous-dental-implant-abutments-performance-criteria-safety-and</a>	10/15/2024	Yes	No	N/A	No
2	Q1	Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-long-term-clinical-neurodevelopmental-safety-studies-neonatal-product-development">www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-long-term-clinical-neurodevelopmental-safety-studies-neonatal-product-development</a>	10/18/2024	Yes	No	N/A	No
3	Q1	510(k) Third Party Review Program and Third Party Emergency Use Authorization (EUA) Review <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review">www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program-and-third-party-emergency-use-authorization-eua-review</a>	11/21/2024	No	Yes	Section 2502 of the Food and Drug Omnibus Reform Act (FDORA)	A-List
4	Q1	Orthopedic Non-Spinal Metallic Bone Screws and Washers - Performance Criteria for Safety and Performance Based Pathway <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance">www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-metallic-bone-screws-and-washers-performance-criteria-safety-and-performance</a>	11/22/2024	Yes	No	N/A	No

<sup>1</sup> [www.fda.gov/media/158308/download](http://www.fda.gov/media/158308/download).

<sup>2</sup> 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.

<sup>3</sup> [CDRH Proposed Guidance Development | FDA](http://CDRH Proposed Guidance Development | FDA)

#	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
5	Q1	<sup>4</sup> Orthopedic Non-Spinal Bone Plates, Screws, and Washers - Premarket Notification (510(k)) Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions</a>	11/22/2024	Yes	No	N/A	No
6	Q1	<sup>5</sup> Transitional Enforcement Policy for Ethylene Oxide Sterilization Facility Changes for Class III Devices <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/transitional-enforcement-policy-ethylene-oxide-sterilization-facility-changes-class-iii-devices</a>	11/26/2024	Yes	No	N/A	No
7	Q1	Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence">www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence</a>	12/04/2024	Yes	No	N/A	A-List
8	Q1	<sup>4</sup> Global Unique Device Identification Database (GUDID) <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/global-unique-device-identification-database-guid">www.fda.gov/regulatory-information/search-fda-guidance-documents/global-unique-device-identification-database-guid</a>	12/17/2024	No	No	N/A	No
9	Q1	Protocol Deviations for Clinical Investigations of Drugs, Biological Products, and Devices <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/protocol-deviations-clinical-investigations-drugs-biological-products-and-devices">www.fda.gov/regulatory-information/search-fda-guidance-documents/protocol-deviations-clinical-investigations-drugs-biological-products-and-devices</a>	12/30/2024	Yes	No	N/A	No
10	Q2	Study of Sex Differences in the Clinical Evaluation of Medical Products <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products">www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products</a>	01/07/2025	Yes	No	N/A	No
11	Q2	Validation of Certain In Vitro Diagnostic Devices for Emerging Pathogens During a Section 564 Declared Emergency <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/validation-certain-in-vitro-diagnostic-devices-emerging-pathogens-during-section-564-declared-emergency">www.fda.gov/regulatory-information/search-fda-guidance-documents/validation-certain-in-vitro-diagnostic-devices-emerging-pathogens-during-section-564-declared-emergency</a>	01/07/2025	No	No	N/A	A-List

<sup>4</sup> This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)

<sup>5</sup> This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(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
12	Q2	Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses">www.fda.gov/regulatory-information/search-fda-guidance-documents/communications-firms-health-care-providers-regarding-scientific-information-unapproved-uses</a>	01/07/2025	No	No	N/A	No
13	Q2	Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological">www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological</a>	01/07/2025	Yes	No	N/A	No
14	Q2	Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing">www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing</a>	01/07/2025	Yes	No	N/A	A-List
15	Q2	Pulse Oximeters for Medical Purposes - Non-Clinical and Clinical Performance Testing, Labeling, and Premarket Submission Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and">www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-medical-purposes-non-clinical-and-clinical-performance-testing-labeling-and</a>	01/07/2025	Yes	No	N/A	A-List
16	Q2	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc">www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc</a>	01/07/2025	No	Yes	Section 2514 of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act	A-List
17	Q2	Developing Drugs for Optical Imaging <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-drugs-optical-imaging">www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-drugs-optical-imaging</a>	01/08/2025	Yes	No	N/A	No
18	Q2	<sup>4</sup> Premarket Approval Application and Humanitarian Device Exemption Modular Review <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-approval-application-and-humanitarian-device-exemption-modular-review">www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-approval-application-and-humanitarian-device-exemption-modular-review</a>	01/13/2025	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q2	<sup>4</sup> Institutional Review Board (IRB) Written Procedures <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-written-procedures">www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-board-irb-written-procedures</a>	02/05/2025	No	No	N/A	No
20	Q2	<sup>4</sup> Data Standards Catalog <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog">www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog</a>	03/24/2025	Yes	No	N/A	No
21	Q2	<sup>4</sup> Evaluation of Sex-Specific Data in Medical Device Clinical Studies - Guidance for Industry and Food and Drug Administration Staff <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug">www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-sex-specific-data-medical-device-clinical-studies-guidance-industry-and-food-and-drug</a>	03/31/2025	Yes	No	N/A	No
22	Q3	Electronic Submission Template for Medical Device Q-Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-q-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-q-submissions</a>	05/29/2025	Yes	Yes	745A(b) of the FD&C Act	No
23	Q3	Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program">www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program</a>	05/29/2025	Yes	Yes	MDUFA V Commitment Letter II.A.	A-List
24	Q3	Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/transfer-premarket-notification-510k-clearance-questions-and-answers">www.fda.gov/regulatory-information/search-fda-guidance-documents/transfer-premarket-notification-510k-clearance-questions-and-answers</a>	06/05/2025	Yes	No	N/A	No
25	Q3	Hernia Mesh – Package Labeling Recommendations <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/hernia-mesh-package-labeling-recommendations">www.fda.gov/regulatory-information/search-fda-guidance-documents/hernia-mesh-package-labeling-recommendations</a>	06/06/2025	Yes	No	N/A	No
26	Q3	Conducting Remote Regulatory Assessments Questions and Answers <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers">www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers</a>	06/26/2025	Yes	No	N/A	No

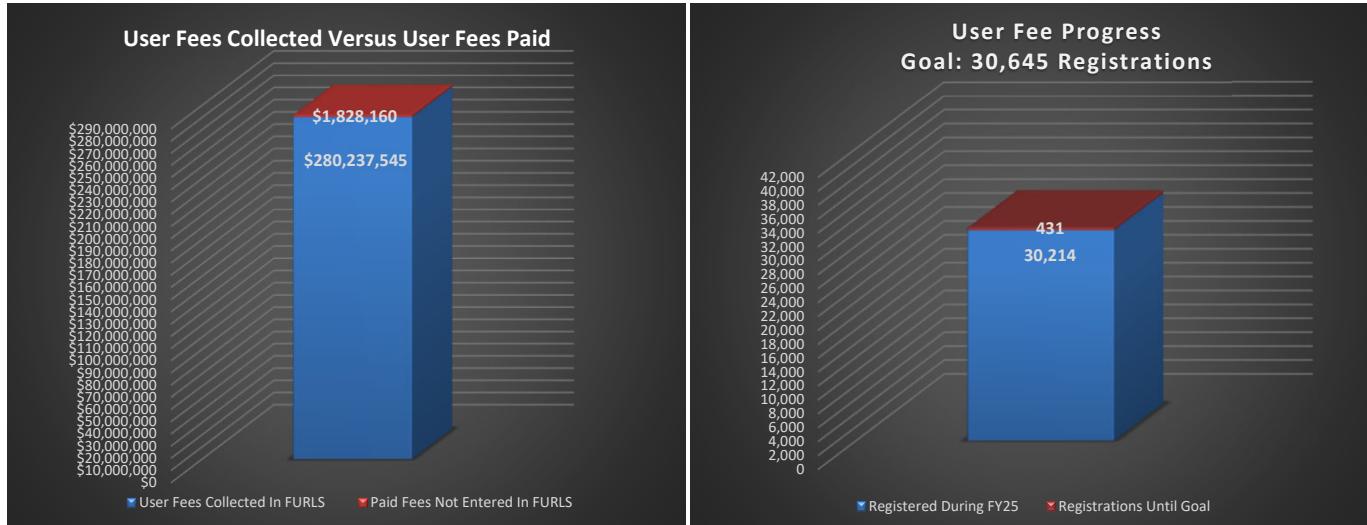
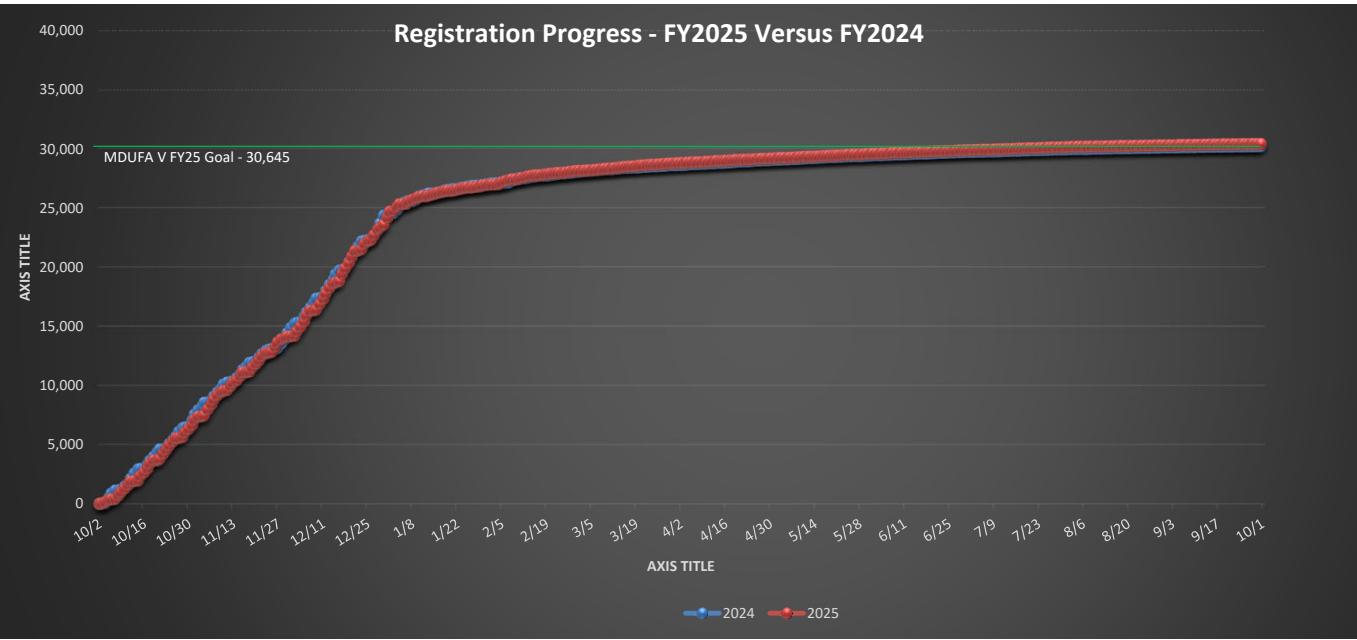
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
27	Q3	Unique Device Identifier Requirements for Combination Products <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identifier-requirements-combination-products">www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identifier-requirements-combination-products</a>	06/26/2025	No	No	N/A	No
28	Q3	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions</a>	06/27/2025	Yes	No	N/A	A-List
29	Q4	Medical Device User Fee Small Business Qualification and Determination <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination">www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-small-business-qualification-and-determination</a>	07/31/2025	Yes	No	N/A	A-List
30	Q4	<sup>4</sup> Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence">www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence</a>	08/18/2025	Yes	No	N/A	No
31	Q4	Animal Studies for Dental Bone Grafting Material Devices - Premarket Notification (510(k)) Submissions <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/animal-studies-dental-bone-grafting-material-devices-premarket-notification-510k-submissions">www.fda.gov/regulatory-information/search-fda-guidance-documents/animal-studies-dental-bone-grafting-material-devices-premarket-notification-510k-submissions</a>	08/22/2025	Yes	No	N/A	No
32	Q4	Consideration of Enforcement Policies for In Vitro Diagnostic Tests During a Section 564 Declared Emergency <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-in-vitro-diagnostic-tests-during-section-564-declared-emergency">www.fda.gov/regulatory-information/search-fda-guidance-documents/consideration-enforcement-policies-in-vitro-diagnostic-tests-during-section-564-declared-emergency</a>	09/23/2025	No	No	N/A	A-List
33	Q4	Computer Software Assurance for Production and Quality System Software <a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software-0">www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software-0</a>	09/24/2025	No	No	N/A	B-List

## Registrations and Listings

### MDUFA V Registrations - 4th Quarter Summary FY2025\*

Current Active Registrations by Type	FY25 Q4			FY24 Year End Active Totals			FY25 vs End FY24
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,499	12,045	18,544	6,677	12,332	19,009	97.55%
	1,267	2,101	3,368	1,243	1,893	3,136	107.40%
	77	181	258	76	169	245	105.31%
	1,579	551	2,130	1,668	557	2,225	95.73%
	23	4	27	34	3	37	72.97%
	113	0	113	127	0	127	88.98%
	1,057	189	1,246	1,116	221	1,337	93.19%
	15	8	23	14	9	23	100.00%
		1,064	1,064		1,132	1,132	93.99%
	3,063		3,063	3,357		3,357	91.24%
Initial Importer	0	0	0	6	11	17	0.00%
Unknown							
<b>Total:</b>	<b>13,693</b>	<b>16,143</b>	<b>29,836</b>	<b>14,318</b>	<b>16,327</b>	<b>30,645</b>	<b>97.36%</b>

\*Note: This data is current as of 9/26/2025



## Medical Device User Fee Collections

**Q4 FY 2025 Medical Device User Fee Collections**  
**as of September 30, 2025**  
**Excludes Unearned Revenue**

	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$281,609,358	-\$1,371,813	\$280,237,545		
Application Fees	\$134,234,218	-\$2,988,121	\$131,246,097		
<b>Total</b>	<b>\$415,843,577</b>	<b>-\$4,359,934</b>	<b>\$411,483,643</b>	<b>\$410,992,545</b>	<b>100%</b>

**Medical Device User Fee Collection History**  
**Excludes Unearned Revenue, Includes Refunds**

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007
	\$21,620,549	\$26,281,779	\$31,738,775	\$34,425,417	\$28,031,569
MD II	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
	\$47,794,823	\$56,962,602	\$63,699,312	\$69,720,145	\$65,324,184
MD III	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	\$101,306,430	\$122,346,416	\$136,098,825	\$147,165,318	\$137,782,995
MD IV	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	\$193,896,895	\$208,692,116	\$215,697,178	\$275,338,627	\$269,130,850
MD V	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	\$322,347,363	\$340,209,427	\$411,483,643		

## Number of Discretionary Fee Waivers or Reductions

### MDUFA V Commitment Letter - VII. Performance Reports

#### 2.12. Number of discretionary fee waivers or reductions granted by type of submission<sup>1/</sup>

CDRH and CBER Combined Data 4th Quarter FY 2025 by Submission type	# Waived	# Reduced
<b>Full Fee applications<sup>2/</sup></b>	8	1
PMA	8	1
PDP	0	0
PMR	0	0
BLA	0	0
BLA efficacy supplement	0	0
<b>Panel Track Supplements</b>	1	2
<b>De Novo Classification</b>	6	50
<b>180-Day Supplements</b>	3	31
<b>Real-Time Supplements</b>	3	42
<b>510(k)s</b>	50	2,232
<b>30-day Notices</b>	9	56
<b>513(g)s</b>	0	53
<b>PMA Annual Report</b>	0	0
<b>Total</b>	<b>80</b>	<b>2,467</b>

<sup>1/</sup> User fees may be waived for several reasons, including but not limited to: the submitter is a State or Federal Government entity who does not intend to distribute the device commercially; the proposed conditions of use for the device involved are solely for a pediatric population; and, the submitter is a small business submitting their first premarket approval application or premarket report. User fees are reduced for small businesses. 510(k)s reviewed through the Third Party Review program are not included because FDA does not collect user fees for 510(k)s reviewed through that program.

Counts are cumulative for the Fiscal Year.

<sup>2/</sup> As specified in the MDUFA V Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually. CBER counts are included in PMA's (0 reduced), Panel Track Supplements (0 reduced) DeNovo Classification (0 reduced), 180 Day Supplements (0 reduced), Real-Time Supplements (0 reduced), 510(k)s (13 reduced), 30-day Notices (2 reduced), and PMA Annual Reports (1 reduced).

# Return on MDUFA Investment

FDA U.S. FOOD & DRUG ADMINISTRATION

## FY25 Return on MDUFA Investment

**Marta Gozzi, Ph.D.**  
Policy Analyst, Office of Regulatory Programs  
OPEQ/CDRH/FDA

1

FDA

### Outline

- Background Information
  - Language in Commitment Letter
  - Definition of Return on MDUFA Investment (ROMI)
- Overall Summary for FY25
  - Review Performance
  - Other Accomplishments & Deliverables
- Main Takeaways

2

FDA

## BACKGROUND INFORMATION

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FDA

### ROI Reporting Language in MDUFA V Commitment Letter

*"The Agency will provide the following information on an annual basis: (...) The return on investment, which may include process improvements, improved performance, and other enhancements, under MDUFA V."* (MDUFA V Commitment Letter, Section VII, Item 4.15)

- During and after MDUFA V negotiations, we received clarification from Industry regarding their vision and expectations for this commitment.
- We reported on ROI for FY23 and FY24 and will now report on FY25.

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### Return on MDUFA Investment (ROMI)

- Traditionally, return on investment (ROI) is a financial performance measure used to evaluate the efficiency or profitability of an investment or to compare the efficiency of different investments. ROI measures the amount of return on a particular investment, relative to the investment's cost.
- In MDUFA, some types of returns cannot be easily monetized, so we adopted a broader framework that captures a wide range of returns, including qualitative and quantitative benefits that go beyond the typical financial measures used in business.

$$\text{ROMI} = \frac{\text{Value of Improvements}}{\text{MDUFA Fees Paid}}$$

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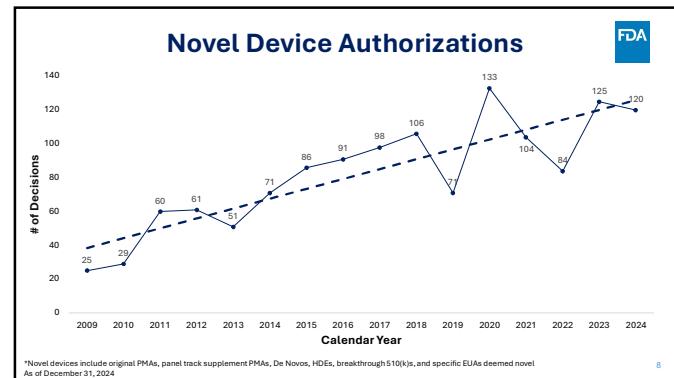
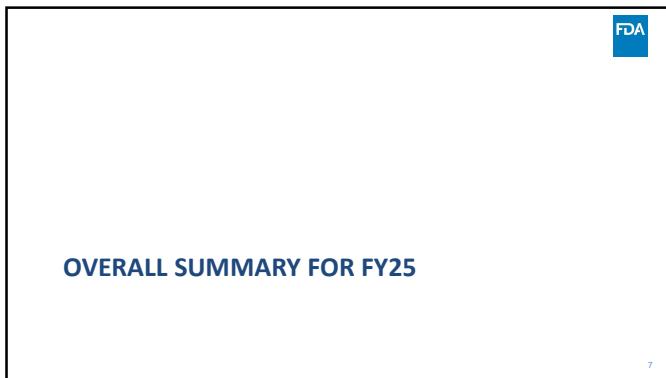
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### ROI in the Public Sector

Examples of Measures

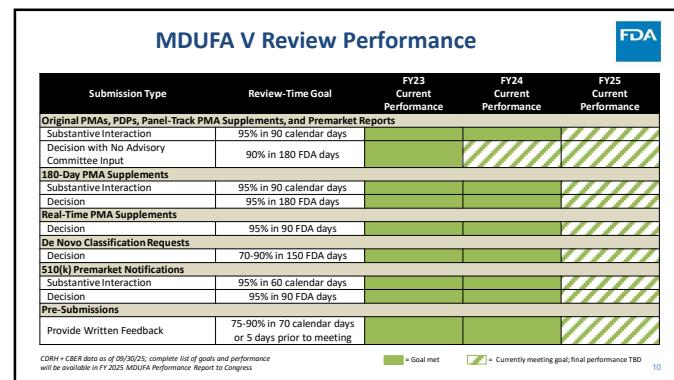
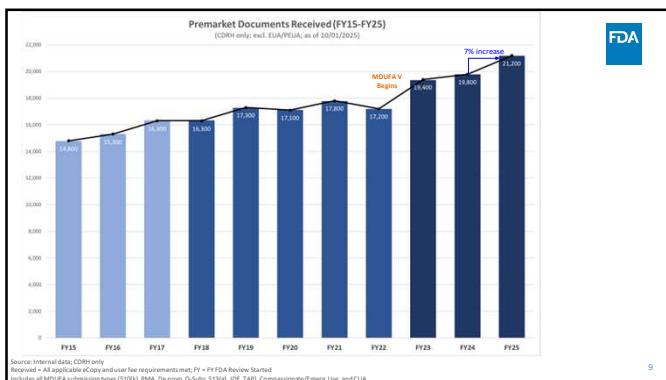
- Improved public health
- Decreased morbidity and mortality rates
- More timely access to high quality, safe and effective medical devices
- Reviews performance goals
- Other MDUFA commitments
- Activities such as reviewing, developing, improving
- \$\$\$
- FTEs

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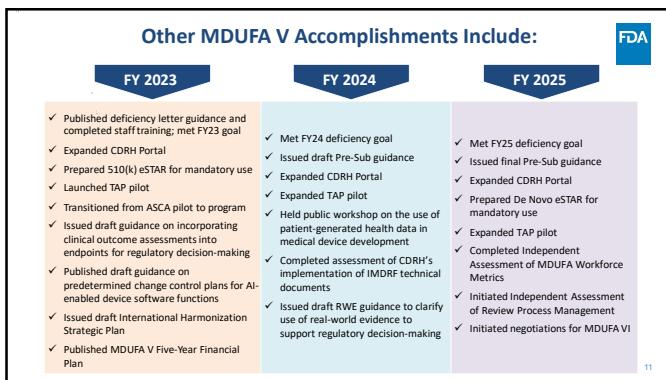
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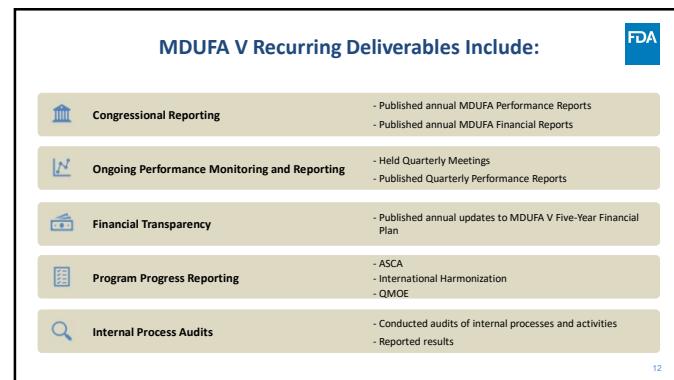


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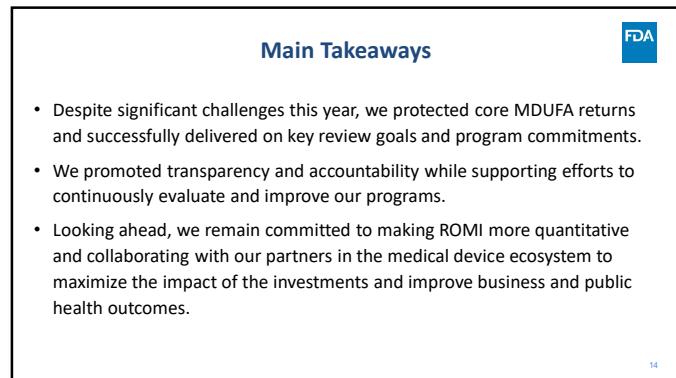




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## MAIN TAKEAWAYS

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## Main Takeaways

- Despite significant challenges this year, we protected core MDUFA returns and successfully delivered on key review goals and program commitments.
- We promoted transparency and accountability while supporting efforts to continuously evaluate and improve our programs.
- Looking ahead, we remain committed to making ROMI more quantitative and collaborating with our partners in the medical device ecosystem to maximize the impact of the investments and improve business and public health outcomes.

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# Quality Management Update - Annual Report

## Section I. Reporting Requirement

The CDRH Quality Management and Organizational Excellence (QMOE) Program FY 2025 Report meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement<sup>1</sup>:

*“VII. Performance Reports...4. In addition, the Agency will provide the following information on an annual basis... 4.12. Report on QMOE program... 4.13. Summary of QMOE audits, including annual audit of Deficiency Letters...”*

### I.A. Annual Report

This report fulfils FY 2025 reporting requirements.

## Section II. CDRH Quality Management Program

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement<sup>2</sup>:

*“IV.A... The CDRH Quality Management and Organizational Excellence (QMOE) Program is comprised of a team of certified quality management staff who report to the Center Director...”*

### II.A. Quality Management Unit Expertise

#### II.A.1. Quality Management Unit.

The CDRH QMOE Unit resides at the Office of the Center Director. Supporting quality management (QM) staff reside in CDRH Offices, including the Office of Product Evaluation and Quality (OPEQ).

#### II.A.2. ISO and Quality Credentials.

Collectively, CDRH QM staff hold one or more of the following quality-related credentials: ASQ Certified Quality Improvement Associate (CQIA), ASQ Certified Quality Auditor (CQA), ASQ Certified Quality Engineer (CQE), ASQ Certified Software Quality Engineer (CSQE), ASQ Certified Manager of Quality and Operational Excellence (CMQOE), ASQ Certified Lean Six Sigma Yellow Belt (CLSSYB), ASQ Certified Lean Six Sigma Green Belt (CLSSGB), Lean Six Sigma Master Black Belt (LSSMBB), ISO 13485:2013 Lead Auditor, ISO 9001:2015 Lead Auditor, Project Management Professional (PMP), PMI Agile Certified Practitioner (PMI-ACP)<sup>®</sup>, and Bronze Level Kirkpatrick Evaluation Certification.

<sup>1</sup> [MDUFA V Agreement](#) page 28

<sup>2</sup> [MDUFA V Agreement](#) page 12

## Section III. CDRH Quality Management System (QMS)

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 requirement<sup>3</sup>:

*“...The QMOE Program establishes and leads the CDRH Quality Management System (QMS) activities, facilitates process improvements, independently audits CDRH processes and activities, and assesses the effectiveness of actions taken to prevent potential (risk management) and resolve existing issues (nonconformity management)...”*

### III.A. ISO 9001:2015 Certification

ISO 9001:2015 certified since 2018, CDRH ISO 9001:2015 Certification includes the Office of the Center Director (OCD) and Office of Science and Engineering Laboratories (OSEL). The FY 2025 audit was conducted during October 28 through October 31, 2024. The CDRH QMS was found highly effective with no findings noted.

### III.B. Quality Management Training

To support the adoption of quality management across CDRH, the following training was provided in FY 2025:

- QMS Background and Evolution
- The Expanding Role of Risk Management
- Scatter Analysis
- Project Management and Lean Six Sigma

In FY 2025, the QMOE program continued the “CDRH Quality Lunch and Learn” series. CDRH Offices provide additional training to ensure staff have the skill and capability to deliver CDRH products and services.

### III.C. Document Control

All documents related to the CDRH QMS are controlled using the CDRH Document Control System (DCS).

#### III.C.1. Conforming Offices Documentation.

All documents related to the management and execution of the premarket review program processes are controlled using the CDRH DCS. The system houses 977 standard operating procedures, work instructions, forms templates, and governing body charters. As of 10/22/2025, 68 percent (664/977) of the CDRH controlled documentation pertains to OPEQ core processes. Of those, 44 percent (293/664) are associated with premarket review.

#### III.C.2. FY 2025 Improvements.

DCS continues to be CDRH’s repository for all controlled documents. In FY 2025, CDRH prepared to transition DCS infrastructure to the OpenText™ Documentum™ Content Management platform. This transition is currently planned to be completed in the next calendar year. CDRH also procured OpenText™ Documentum™ D2 to provide a modern, user-friendly interface for accessing documents

<sup>3</sup> [MDUFA V Agreement](#) page 12

needed to realize CDRH products and services.

### **III.D. Audit Activities**

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement<sup>4</sup>:

*“...At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan with the QMOE Program. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH’s nonconformity management process. FDA will continue to expand the scope of its annual audits as it implements and builds up its auditing capability, as resources permit. At a minimum, FDA audits in the following areas will be completed: Pre-Submissions and Third Party Review Program...”*

#### **III.D.1. Audit Schedule FY 2026.**

The FY 2026 data call for audit topics was submitted in Q3 FY 2025, and the audit schedule will be finalized in Q1 FY 2026.

<b>FY 2026 Audit Schedule (Tentative)*</b>	
ISO Required Audits of all QMS Functions	
MDUFA V Required Audit of Deficiency Letters	
Least Burdensome Flag	
No Submission Left Behind – MMD Process	
Real World Evidence	
Pre-submissions	
<i>*Additional programmatic audits as time permits</i>	

#### **III.D.2. Audit Schedule FY 2025.**

The following audits were conducted in FY 2025.

<b>Title</b>	<b>Purpose</b>	<b>Findings*</b>
<b>CDRH Processes/Programs</b>		
AF-2024-00092	FY 2025 Deficiency Letters Audit	CDRH committed to present results at the FY 2026 Q1 meeting. Audit is complete and CDRH is releasing FY 2025 results in this report. FY 2025 Performance goal met. No NCs were found.
AF-2025-00105	ASCA Program Audit	No NCs, 2 BPs, 4 OFIs.
AF-2025-00106	Deadline Provision Audit	Effectiveness check met. 1BP, no OFI.
AF-2025-00108	Record Placement Audit	Effectiveness check met.
AF-2025-00109	Biocompatibility Deficiency Letter Audit	No NCs, no BPs no OFI were found.
<b>CDRH QMS</b>		
AF-2025-00093	Office of the Center Director Audit	No NCs, no BPs and 2 OFIs were found.
AF-2025-00094	QMOE Tools and Services Audit	No NCs, BPs, or OFIs were found.
AF-2025-00095	Regulatory Science Tools Audit	No NCs, 5 BPs and 1 OFI were found.
AF-2025-00096	Design, Development, Verification and Validation Audit	No NCs, no BPs, and 1 OFI were found.
AF-2025-00097	Quality Management Review Audit	No NCs, BPs, or OFIs were found.
AF-2025-00098	Risk Management Audit	No NCs, BPs, or OFIs were found.

<sup>4</sup> [MDUFA V Agreement](#) page 12

Title	Purpose	Findings*
AF-2025-00099	Nonconformance Report Audit	No NCs, no BPs and 1 OFI were found.
AF-2025-00100	Voice of the Customer Audit	No NCs, no BPs, and 1 OFI were found.
AF-2025-00101	Document Control System Audit	No NCs, BPs, or OFIs were found.
AF-2025-00102	Audit Management System Audit	No NCs, BPs, or OFIs were found.
AF-2025-00103	QMOE Training Audit	No NCs, 1 BP, and 1 OFI were found.

\*NC = Nonconformity, BP = Best practice, OFI = Opportunity for improvement

### III.D.3. FY 2025 Audit Findings/ Next Steps.

- No nonconformities were found through audits. Best practices were highlighted to the auditee and communicated, where applicable, to the rest of the center.
- Audits are one source of nonconformities. Nonconformities identified outside audits are also recorded and addressed, as they are opportunities for improvement.
- The FY 2025 audit schedule included follow-up audits to assess actions taken to address nonconformities associated with the MDUFA IV required Special 510(k) Conversions, Interactive Review, Withdrawals audits<sup>5</sup>. A summary of FY 2025 audits follows:

#### AF-2024-00092: FY 2025 Deficiency Letters Audit

This audit meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 through 2027 requirement<sup>6</sup>:

*“...FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in deficiency letters as follows: 75% of deficiencies in FY 2023, 80% of deficiencies in FY 2024, 85% of deficiencies in FY 2025, 90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027 for Original PMA, Panel-Track Supplement, 510(k) and De Novo request submissions. Performance will be determined by means of annual audit conducted by QMOE. Sampling procedures will incorporate ISO 2859- 1:1999 (“Sampling Procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection”). FDA will review each fiscal year’s audit results with industry no later than the first quarterly meeting of the following fiscal year...”*

**Purpose:** This audit will measure the rate at which CDRH deficiencies meet the 4-Part Harmony (4PH) criteria in deficiencies within 510(k), De Novo, Original PMA, and Panel-Track Supplement deficiency letters issued in FY 2025. Specifically, this audit determines whether the deficiencies include a statement of “impact on decision” (Part 3A of 4PH) and whether a “specific reference” is included (Part 3B of 4PH).

**Sampling:** In FY 2025, FDA issued 2,859 letters that met the MDUFA V audit criteria. According to ISO 2859- 1:1999, auditors were to audit a sample size of 125 letters. The FY 2025 MDUFA V Audit sample consisted of 416 letters (~8 letters per week). In total 1,824 deficiencies were audited.

**Findings:** 90 percent (90%; 1,633 out of 1,824) of the deficiencies examined contained a statement of basis for the deficiency. The FY 2025 goal was 85 percent (85%). CDRH met and exceeded the agreed goal. No nonconformities were found.

**Supporting Process Improvement:** In addition, CDRH auditors examined 849 randomly selected letters in FY 2025 (additional 3,795 deficiencies). The additional 849 letters were audited to support OPEQ process improvement activities (see [III.E.3](#) for results) In addition to random sampling, QMOE also conducted targeted audits (33 Letters, 141 deficiencies audited) as requested by

<sup>5</sup> [November 16, 2022 MDUFA IV Performance Report](#) pages 360-361

<sup>6</sup> [MDUFA V Agreement](#) page 17

OPEQ to assess the effectiveness of improvements. Lastly, in addition to auditing issued letters and supporting OPEQ improvements efforts, QMOE audits stock deficiencies prior to their release for staff use.

#### **AF-2024-00105: Conformity Assessment Program (CAP) Audit (\*ASCA\*)**

**Purpose:** Assess whether the ASCA Program, operated out of the Conformity Assessment Program within the Division of Standards and Conformity Assessment, met its established policies, procedures, and MDUFA V commitments.

**Sampling:**

- All 510(k)s, De Novos, and PMAs submissions received between October 1, 2022, and March 31, 2025 with an ASCA Summary Test Report: random sample of 20 of 130 (20 of 126 510(k)s; none of the 3 De Novos or 1 PMAs were included in the random sample).
- ASCA Internal work items closed between October 1, 2022, and March 31, 2025: random sample of 42 of 245 total internal items; augmented with all eight work items in the total internal items associated with FDA audits and all two work items in the total internal items related to laboratories withdrawn from the ASCA Program by FDA. No items appeared in both the augmented and random samples.
- Three examples of Training Events held between October 1, 2022, and March 31, 2025.
- Three examples of Process Improvements that occurred between October 1, 2022, and March 31, 2025.
- Three examples of managing the review, addition, and removal of consensus standards from the scope of ASCA accredited testing labs.
- ASCA Audits of Accrediting Bodies and Testing Laboratories closed between October 1, 2022 and March 31, 2025.

**Findings:** No nonconformities were found related to ASCA Program training, process improvement, management of scope changes, audits of Accrediting Bodies and Testing Laboratories, and processing of internal work items.

- ASCA Program best practices included: (1) determining and scheduling Accrediting Body and Testing Laboratory audits based on evidence of past performance, program capacity, and risk assessment; (2) a multifaceted approach to communication to raise the profile of the ASCA Program, participating in professional society symposia, and holding joint outreach sessions with current ASCA participants to encourage industry involvement in the ASCA Program; and, regular training opportunities for testing laboratories including holding regular office hours and mandatory Testing Laboratory meetings to share best practices.

#### **AF-2024-00106: Deadline Provision Audit (Follow-up Audit)**

**Purpose:** Check the effectiveness of corrective actions taken to address NCR-2022-00134, found in Audits AF-2020-0010 (Withdrawal Audit), AF-2021-00027 (Interactive Review, IR audit), and AF-2021-00028 (Special 510k Audit) – Providing deadlines to sponsors.

**Sampling:** Based on all 510(k)s closed between July 1, 2025, and July 31, 2025 (MDUFA Decisions) with Interactive Review Files, a total of 729 submissions. Of that total, 173 submissions were included in the sample.

**Findings:** 88 % of all Interactive Review letters for 510(k) included deadlines to sponsors in compliance with documentation requirements. No nonconformities were found. A best practice was found, OPEQ has shown an extended commitment at communicating the deadline to manufacturers in interactive requests for information.

**AF-2024-00108: Record Placement Audit (Follow-up Audit)**

**Purpose:** Check the effectiveness of corrective actions taken to address NCR-2022-00133, found in Audits AF-2020-0010 (Withdrawal Audit), AF-2021-00027 (Interactive Review, IR audit), and AF-2021-00028 (Special 510k Audit) – Documentation not found.

**Sampling:** Based on all 510(k)s, PMAs and De Novos closed between July 1, 2025, and July 31, 2025 (MDUFA Decisions), a total of 364 submissions. Of that total, 98 submissions were included in the sample: all PMAs (13); all De Novos (1), and 84 of 350 510(k)s.

**Findings:** 100% of all submissions complied with the documentation requirements: Lead Reviewer (LR) memo - All found (100%); Deficiency Letters - All found (100%); Interactive Review Letters (IR) – All found (100%). No nonconformities were found.

**AF-2025-00109: Biocompatibility Deficiency Letter Audit**

**Purpose:** This is an industry requested audit. This audit will measure the rate at which CDRH deficiencies meet the 4-Part Harmony (4PH) criteria in biocompatibility related deficiencies within 510(k), De Novo, Original PMA, and Panel-Track Supplement deficiency letters issued in FY 2023, FY 2024 and FY 2025. Specifically, this audit determines whether biocompatibility related deficiencies include a statement of “impact on decision” (Part 3A of 4PH) and whether a “specific reference” is included (Part 3B of 4PH).

**Sampling:** All biocompatibility related deficiencies within 510(k)s, Original PMAs, De Novos, and Panel-Track supplements that were audited during FY 2023, FY 2024 and FY 2025 DL Audits. A total of 1,401 biocompatibility related deficiencies were included in the sample.

**Findings:** 84% (1,174 out of 1,401) of the biocompatibility related deficiencies included a complete statement of “impact on decision” (Part 3A of 4PH); and 82% (1,145 out of 1,401) of the biocompatibility related deficiencies included a specific reference (Part 3B of 4PH). No nonconformities were found.

**CDRH QMS Internal Audits (AF-2025-00093 through AF-2025-00103).**

**Purpose:** The audits below checked the quality management systems (QMS) for compliance with ISO 9001-2015 and established requirements.

- **AF-2025-00093.** Office of the Center Director components: International Harmonization, Strategic Communications, and Scientific and Regulatory programs.
- **AF-2025-00094.** The QMOE Tools and Services (TSR) process.
- **AF-2025-00095.** The CDRH Regulatory Science Tools
- **AF-2025-00096.** The CDRH Design, Development, Verification and Validation process
- **AF-2025-00097.** The CDRH Quality Management Review (QMR) process
- **AF-2025-00098.** The CDRH Risk Management process
- **AF-2025-00099.** The CDRH Nonconformance Record (NCR) and Corrective Action process
- **AF-2025-00100.** The CDRH Voice of the Customer (VoC) process
- **AF-2025-00101.** The CDRH Document Control System (DCS) process
- **AF-2025-00102.** The CDRH Audit Management System (AMS) process
- **AF-2025-00103.** The QMOE Training System process

**Findings:** All the QMS complied with ISO 9001-2015 and established requirements. No nonconformities (NCs), 6 Best Practices (BPs), and 7 Opportunities for Improvement (OFIs) were found.

### **III.E. Continuous Improvement.**

#### **III.E.1. Business Process Improvement (BPI; ongoing).**

BPI objectives include:

- Simplifying processes to improve process efficiency, repeatability, and effectiveness,
- Supporting process harmonization to increase standardization, and
- Improving clarity of process and supporting documents (e.g., Standard Operating Procedures, Work Instructions, etc.).

CDRH's simplicity initiatives continued through FY 2025. CDRH continues to work on improving its core businesses processes. In FY 2025, CDRH developed internal management dashboards to support monitoring of MDUFA V premarket review performance and activities.

#### **III.E.2. Audit Program Improvements**

CDRH continued to expand the Audit Program to support a planned expansion of the CDRH QMS scope and MDUFA V commitments, including the MDUFA V commitment to use audits to assess performance (deficiency letters). QMOE:

- Increased the number of auditors dedicated to premarket review processes and
- Streamlined internal audit processes.

As a result of these actions, QMOE increased the Audit Program's ability to execute audits and assessments and reduced time to deliver results.

#### **III.E.3. Deficiency Letter Assessments (expanded audit)**

As a process improvement project, QMOE auditors conducted additional deficiency letter reviews to support OPEQ's implementation of the FY 2025 MDUFA V deficiency letters performance commitment:

- Auditors examined 849 additional randomly selected (assessments) deficiency letters, observing that 3,351 out of 3,795 (88%) of the examined deficiencies had a complete "statement of basis for the deficiency."
- Overall, auditors examined 1,265 randomly selected (audit and assessments) letters in FY 2025, observing that 4,984 out of 5,619 (89%) of the examined deficiencies had a complete "statement of basis for the deficiency".
- Most OHTs and divisions performed above the FY 2025 MDUFA V goal.

#### **III.E.4. Innovative Technological Improvements: eSTAR Submission Tool**

In 2024, CDRH continued to advance innovative technologies and meet the MDUFA V commitment to develop electronic submission templates to improve the sponsor submission process through the electronic Submission Template and Resource (eSTAR) pilot. eSTAR was developed as a method to aid industry in preparing structured electronic submissions. With the publication of the guidance "Electronic Submission Template for Medical Device De Novo Requests" on August 23, 2024, De Novo submissions prepared as eSTARs are required as of October 1, 2025.

The use of eSTAR by Health Canada (HC) in an International Pilot began on January 10, 2023. As part of the pilot, FDA and HC conducted surveys, made changes based on the feedback, and have further

changes still in process. Additional improvements identified during the pilot were released in early 2025. So far, all submissions have been authorized in both jurisdictions. All participants had positive feedback regarding their experience. Both HC and FDA agree the eSTAR pilot was a success and are currently considering next steps which may include a more extensive pilot with at least one additional jurisdiction. In August 2025, Health Canada began a final pilot to test the latest changes implemented from the previous pilot feedback. eSTAR was updated to ensure consistency with the updated IMDRF TOC documents published on June 25, 2024.

In FY 2025:

- CDRH released 513(g) content in the Early Submission Requests eSTAR (PreSTAR) on March 29, 2024, which enables applicants to see the 513(g) workflow and provide what reviewers are expecting.
- PMA content was enabled in the nIVD and IVD eSTARs on December 6, 2023. Content for the 30-Day Notice PMA supplement type was released on September 30, 2025.
- CDRH previously conveyed that the Center would be developing eSTAR content for IDE Originals. In the process of development, it was decided to include all supplement types in the initial deployment as well. IDE content supporting IDE Originals and all supplements was added to the PreSTAR and released on September 30, 2025.
- Additional developments in 2025 included updates to cybersecurity content to reduce burden and CBER's announcement of acceptance of all eSTAR submission types.

Planned for 2026 are the international harmonization eSTAR updates, completion of all Q-Sub types in eSTAR, and addition of an additional PMA supplement type in eSTAR.

## Section IV. Independent Assessment of Review Process

This section meets the following MDUFA Performance Goals and Procedures, Fiscal Years 2023 Through 2027 requirement<sup>7</sup>:

*“...FDA and the industry will participate in a targeted assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry at the start of the assessment and prior to issuance of the final report. The assessment shall be conducted under contract to FDA by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment scope described below within the budget provided under this user fee agreement.*

*The contractor will:*

1. Evaluate FDA’s premarket review program to identify efficiencies that were realized as a result of the process improvements and investments under MDUFA IV and V;
2. Assess the alignment of resource needs with the training and expertise of hires;
3. Identify and share best practices across OHTs in OPEQ;
4. Assess the effectiveness of program areas targeted for improvement under this agreement, including the following:
  - a. Implementation and impact of changes to the guidance “Developing and Responding to the Deficiencies in Accordance with the Least Burdensome Provisions,
  - b. Implementation and impact of changes to the guidance “Requests for Feedback and Meetings for Medical Device Submissions: The QSubmission Program,”
  - c. Third Party Review program (continued reduction of routine re-review by FDA of Third Party reviews)
  - d. Digital Health program,
  - e. Patient Engagement program,
  - f. Real World Evidence program;
  - g. International Harmonization
5. Assess other key areas identified by FDA and industry as resources permit

*FDA will award the contract no later than March 31, 2025. However, the contractor would not begin the audit of Pre-Submissions before October 1, 2025. The contractor will publish comprehensive findings and recommendations within 1 year, after reviews with FDA and industry and opportunities to provide feedback for the contractor’s consideration prior to finalizing the final report. For all recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable.*

*FDA will incorporate findings and recommendations, as appropriate, into its management of the process for the review of device applications. FDA will analyze the recommendations for improvement opportunities identified in the assessment and, as appropriate, develop and implement a corrective action plan, and assure its effectiveness.”*

### IV.A. Status Report.

The contract for the MDUFA V was awarded on December 11, 2024. The Assessor started the assessment soon after dividing the assessment into three major phases:

- Phase 1: Patient Science and Engagement (PSE), Real World Evidence (RWE), Training

<sup>7</sup> [MDUFA V Agreement](#) page 27

- Phase 2: Premarket Review Efficiencies (PME), Deficiencies, Third Party review
- Phase 3: Q-Submissions, International Harmonization, Digital health

Phase 1 was completed in FY 2025 and preliminary results presented to FDA and Industry. As of the beginning of FY2026, Phase 2 is underway.

# QMOE Annual Report

**FY 2025 QMOE Annual Report**

**Nancy Braier**  
Office of the Center Director  
CDRH Quality Management and Organizational Excellence Program (QMOE)

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**Agenda**

- Reporting Requirements
- Report on the QMOE program
- Audit Schedules
- Summary of QMOE audits
- Annual Audit of Deficiency Letters
  - Lessons Learned and Next Steps

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**Reporting Requirements**

**VII. Performance Report**

4. In addition, the Agency will provide the following information on an annual basis...

4.12. **Report on QMOE program,**  
4.13. **Summary of QMOE audits, including annual audit of Deficiency Letters..."**

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**Report on the QMOE Program**

- **Certification:** CDRH ISO 9001:2015 Certification includes the Office of the Center Director (OCD) and Office of Science and Engineering Laboratories (OSEL). The FY 2025 audit was conducted during October 28 through October 31, 2024. The CDRH QMS was found highly effective with no findings noted.
- **Quality Training:** In FY 2025, the QMOE program continued the "CDRH Quality Lunch and Learn" series.
- **Document Control:** As of 10/22/2025, **68 percent (664/977) of the CDRH controlled documentation pertains to OPEQ core processes.** Of those, 44 percent (293/664) are associated with premarket review.
- **Process Improvements:** OpenText™ Documentum™ D2, eStar, Deficiency Letter Assessments

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**Report on the QMOE Program**  
Value of the CDRH QMS



How QMOE Programs address **Cost of Quality**

- QMS reduces the total cost of quality
- QMS shifts quality cost from failure to prevention

**Controlled Documents (CDRH Docs)**

- Managed Nonconformances
- Active Audit Program
- Risk Management

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**Report on the QMOE Program**  
CDRH without CDRH Docs shifts costs from failure to prevention, saves  $\approx 18$  FTE/yr

<b>CDRH without CDRH Docs: Costs of Internal/External Failure</b>	<b>CDRH with CDRH Docs: Reduces costs of Internal/External Failure</b>
<ul style="list-style-type: none"><li>- Staff take longer to find/verify correct versions of SOPs/WIs</li><li>- Staff takes time to rework because they used an incorrect/out-of-date/wrong SOPs and WIs</li><li>- Staff rework contributes to loss of customer satisfaction</li><li>- Increased Staff frustration due to difficulty finding current SOPs/WIs</li></ul>	<ul style="list-style-type: none"><li>- Staff finds documents faster</li><li>- Staff has less rework because they are using the correct SOPs/WIs</li><li>- Increases in work quality improves customer satisfaction</li><li>- Reduced staff frustration because they can find current SOPs/WIs faster</li></ul>

**Assumptions**

**Cost of prevention: FTE to maintain CDRH Docs = 2 CDRH FTEs/year**

<b>Cost of Internal/External Failure</b>
<ul style="list-style-type: none"><li>- CDRH staff members referencing SOPs/WIs</li><li>- save about 6 mins to find doc</li><li>- refer to about 1 document per day</li><li>- In a year cost savings is about <math>\approx 20</math> FTEs/year</li></ul>

**Quantitative savings in failure costs using standard document library (FTEs without CDRH Docs - FTEs to maintain CDRH Docs)**

$= 20 \text{ FTEs/yr} - 2 \text{ FTEs/yr} = 18 \text{ FTEs/yr savings or } \approx \$3 \text{ million/year}$

**Qualitative savings in failure costs using standard document library**

Reduced staff frustration; internal failure; rework; external failure; customer frustration; need to revise decisions

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**2026 Audit Schedule**

• Requested topics from CDRH & Industry summer 2025.  
 • Schedule finalized Q1 FY 2026.

**FY 2026 Audit Schedule**

- ISO Required Audits of all QMS Functions
- MDUFA V Required Audit of Deficiency Letters
- Least Burdensome Flag
- No Submission Left Behind – MMD Process
- Real World Evidence
- Pre-submissions

\*Additional programmatic audits as time permits

 CDRH QMDE | QMS

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**2025 Audit Schedule**

• Requested topics from CDRH & industry summer 2024.  
 • Schedule finalized Q1 FY 2025.

Title	Findings*
*NC = Nonconformity, BP = Best practice, OFI = Opportunity for improvement	
<b>Programmatic</b>	
FY 2025 Deficiency Letters Audit	FY 2025 Performance goal met.
ASCA Program Audit	No NCs, 2 BPs, 4 OFIs.
Deadline Provision Audit	Effectiveness check met; 1BP, no OFI.
Record Placement Audit	Effectiveness check met.
Biocompatibility Deficiency Letter Audit	No NCs, no BPs no OFI were found.
<b>CDRH QMS</b>	
Office of the Center Director Audit	No NCs, no BPs and 2 OFIs were found.
QMOE Tools and Services Audit	No NCs, no BPs, or OFIs were found.
Regulatory Science Tools Audit	No NCs, 5 BPs and 1 OFI were found.
Design, Development, Verification and Validation Audit	No NCs, no BPs, and 1 OFI were found.
Quality Management Review Audit	No NCs, no BPs, or OFIs were found.
Human Factors Audit	No NCs, no BPs, or OFIs were found.
Nonconformance Report Audit	No NCs; no BPs and 1 OFI were found.
Voice of the Customer Audit	No NCs, no BPs, and 1 OFI were found.
Document Control System Audit	No NCs, no BPs, or OFIs were found.
Audit Management System Audit	No NCs, no BPs, or OFIs were found.
QMOE Training Audit	No NCs, 1 BP, and 1 OFI were found.

 CDRH QMDE | QMS

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**Summary of Audits**  
OPEQ Placement of Records Nonconformity

Sample (98 of 364)	Stratified 510(k)s by Office (84 of 350)	PMAs (13 of 13)	De Novos (1 of 1)
<b>Lead Review Memo Evaluation</b> (Checked for existence of Lead Review Memo)	100% ✓ (84/84) compliance	100% ✓ (13/13) compliance	100% ✓ (1/1) compliance
<b>Deficiency Letter Evaluation</b> (Checked if AINN/MAJR letter was needed and present)	100% ✓ (84/84) AINN compliance	100% ✓ (13/13) MAJR compliance	100% ✓ (1/1) AINN compliance
<b>IR Evaluation</b> (Checked for existence/location of IR letters)	100% ✓ (84/84 in compliance; two were provided during follow-up and added to DocMan and one confirmed not required)	Out of Scope	100% ✓ (1/1) compliance

Effectiveness Check Passed – NC will be closed

 CDRH QMDE | QMS

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**Summary of Audits**  
Interactive Review Deadlines Nonconformity

Objective	MDUFA IV Results	MDUFA V Results
<b>Objective 1:</b> Review submissions for compliance with "What to Sign Upload and Send" SOP (Doc. <a href="#">MDA022</a> ) documentation requirements for 510k submissions.	50 %	88% ✓
of the interactive review files analyzed included a deadline (NCR-2022-0134)	of the interactive review files analyzed included a deadline	of the interactive review files analyzed included a deadline

Effectiveness Check Passed – NC will be closed

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**Summary of Audits**  
ASCA Program

Objective	Audit Results
<b>Objective 1:</b> Assess FDA's ASCA processes for the qualification (i.e., grant ASCA Accreditation or ASCA Recognition) of program participants	✓ Meets requirements (42 of 245 files reviewed, all met requirements)
<b>Objective 2:</b> Assess the effectiveness of FDA's ASCA training program	✓ Meets audit objective (3 of 3 records reviewed, all support audit objective)
<b>Objective 3:</b> Assess impact of program objectives on program goals and MDUFA V requirements	✓ See Final Checklist (20 of 130 submissions reviewed)
<b>Objective 4:</b> Assess how effective the program is at implementing program improvement efforts	✓ Meets audit objective (2 of 2 records reviewed, all support audit objective)
<b>Objective 5:</b> Assess how effective the program is at updating and communicating changes in scope to stakeholders	✓ Meets audit objective (3 of 3 records reviewed, all support audit objective)
<b>Objective 6:</b> Assess the effectiveness of ASCA's audit program	✓ Meets audit objective (8 of 8 records reviewed, all support audit objective)

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**Biocompatibility Audit**

- MDUFA V performance for **biocompatibility** related deficiencies has significantly improved since FY 2023.

**Primary Objective (4 PH Part 3A)**  
Determine the number of deficiencies with a complete "statement of basis for the deficiency" (i.e., include a statement of "impact on decision" (Part 3A))

FY	Percentage of biocompatibility related deficiencies including a statement of "impact on decision" *	MDUFA V Performance Goal
2023	65%	75%
2024	86%	80%
2025	92%	85%

\* Performance reported for Biocompatibility Related Deficiencies only

 CDRH QMDE | QMS

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**Annual Audit of Deficiency Letters**





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**MDUFA V Commitment | Audit Performance as a Goal**



FDA will provide a statement of the basis for the deficiency, consistent with the updated guidance, in deficiency letters as follows: 75% of deficiencies in FY 2023, 80% of deficiencies in FY 2024, 85% of deficiencies in FY 2025, 90% of deficiencies in FY 2026, and 95% of deficiencies in FY 2027. For Original PMA, Panel-Track Supplement 510(k) and De Novo devices, FDA will use a performance-based determination means of annual audits conducted by QM&E. Sampling procedures will incorporate ISO 2859-1 (VIM) and will be based on a lot size of 100. Sampling will be based on a lot size indexed by acceptance quality limit (AQL) for lot-by-lot inspection. FDA will review each final year's audit results with industry no later than the first quarterly meeting of the following fiscal year.

[MDUFA V Commitment Letter, Section V.B  
https://www.fda.gov/media/158386/download](https://www.fda.gov/media/158386/download)

**MDUFA V Deficiency Letters Commitments**

FY	Performance Goal (Percent of deficiencies with statement of basis for the deficiency)
FY23	75%
FY24	80%
FY25	85%
FY26	90%
FY27	95%

For....

- Original PMA
- Panel-Track Supplement
- 510(k)
- De Novo



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**Deficiency MDUFA V Commitment | Audit Team Training**



**OPEQ SMEs taught auditors how to identify "statement of basis for the deficiency" in deficiency letters, consistent with the updated deficiency guidance, internal procedures, and training provided to review staff.**

- Initial MDUFA V training was held November 2022
- Supplemental sessions were held in FY23 (to address statutory cybersecurity updates) and FY24 (to address clarified criteria)
- Auditors applied the trainings when auditing deficiencies
- Audit incorporating clarified criteria began March 2024
- Auditors and OPEQ leads maintained frequent communications. A channel was established to discuss challenging decisions.
- In FY 25, expanded Auditor pool and trained new auditors

**QM&E reporting practices, focused on promoting improvements. Audit results and raw data (market letters) were made available on a near real-time basis**

- Results and audited letters shared with OPEQ weekly
- A summary dashboard was made available to OPEQ

Deficiency guidance = "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" guidance, published Oct 2022 (<https://www.fda.gov/media/71735/download>)

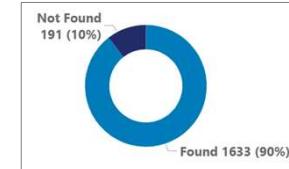


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**Annual Audit of Deficiency Letters  
MDUFA V Audit Sample Results**



**FY25** | 1824 Deficiencies Audited | 416 Letters



Not Found  
191 (10%)

Found 1633 (90%)

**Primary Audit Objective**  
Determine the number of deficiencies with a complete "statement of basis for the deficiency" (i.e., include a statement of "impact on decision" (OI))

- Audit Team examined 416 Deficiency Letters, observing 1,633 out of 1,824 (90%) compliant deficiencies.
- The MDUFA V audit random sample met the FY 25 goal (85%).
- These results will be reported during the MDUFA V FY2025 Q4 meeting.

90%  
of the examined deficiencies had a complete "statement of basis for the deficiency"  
**FY25 MDUFA V Performance Goal (85%) Met**



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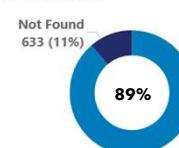
**Deficiency MDUFA V Commitment | Expanded Sample**



**Audit + Additional Sample Activities**

FY25	Deficiencies Audited	Letters
5619	1265	

**3A Citations**



Not Found  
633 (11%)

Found 4986 (89%)

- Overall, the Audit Team examined 1,265 randomly selected deficiency letters, observing 4,986 out of 5,619 (89%) of the examined deficiencies had a complete "statement of basis for the deficiency".
- This sample performed above the FY 2025 MDUFA V goal
- Most OHTs performed above the FY 2025 MDUFA V goal
- Most divisions performed above the FY 2025 MDUFA V goal



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**Lessons Learned & Next Steps**

**Sara Doll Aguel – OPEQ/ORP**  
Senior Advisor for Premarket Programs





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**Our deficiency policy has both a broad purpose and is subject to specific MDUFA goals**

In our deficiencies, we aim for... 

**Good communication that is...**

- **Clear and direct**
- **Least Burdensome**

**MDUFA V Deficiency Goals include...**

FDA will provide a statement of basis in [xx]% of deficiencies

FY	Goal
FY23	75%
FY24	80%
FY25	85%
FY26	90%
FY27	95%

(In certain premarket submissions)





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**We have created multiple resources and tools to help staff meet the MDUFA goal**



**FY23-FY24**

- **Clarified policy**  
(thru updated [Guidance](#) and internal procedures)
- **Training (for new and existing staff)**  
(thru multiple modalities, at multiple levels)
- **Improved internal resources**  
(including good examples in key areas)
- **Deficiency liaison network**  
(1 per OHT division, x23)
- **Performance dashboard**  
(for managers and review staff)

**FY25**

- **Continued improvement of internal resources**
- **Staff survey of high-priority needs**
- **Continued updates to review staff's performance dashboard**



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**Examples of shared best practices (FY25)**

**Sharing across OHTs**

- Cross-office teams met regularly to discuss and share best practices for **cross-cutting** deficiencies and best way to ensure adequate "statement of basis" in key topic areas, including:
  - Biocompatibility
  - MR Safety

**Sharing within OHTs**

- Office liaisons and division managers continued to regularly review results from deficiency performance audit, identifying both good and "need to improve" deficiencies in **device-specific** topic areas.
- Examples were shared within OHTs, informally at recurring team meetings or formally as part of targeted training sessions led and delivered by OHT staff.

\* Per the MDUFA Commitment (Section IV.A.) to identify and share "high-performing premarket review best practices utilized in one [OHT]...with other OHTs to improve efficiencies and effectiveness"



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**Deficiency MDUFA V Commitment | FY25 Lessons Learned**



- **Strong and stable MDUFA deficiency goal performance in FY25 is directly attributable to the strong foundation we built in earlier years.**
  - Key pillars include robust data (provided quickly and directly to staff), clarified policy, targeted resource improvements, and collaborative staff engagement
  - Maintaining and building on this foundation was (and will continue to be) resource intensive
- **Achieving (and sustaining) our future 90-95% goals will be a challenge**
  - Much of the progress so far has been by tackling the biggest issues first
  - The smaller number of challenges that remain are varied and unique
  - Continued vigilance will be necessary to meet more stringent goals, in FY26 and beyond
- **The best deficiencies are ones that meet the MDUFA goal and clearly communicate our concerns. Staff and industry feedback is critical to getting that right.**



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**Deficiency Letters MDUFA V Commitment | Next Steps for FY26**

**QMOE**

- Continue auditing and reporting weekly
- Continue to provide access to marked letter to OPEQ
- Get industry feedback on high-priority needs (send to CDRH\_Quality@fda.hhs.gov)

**OPEQ**

- Continued robust and timely feedback to staff about performance
- Continue to get staff feedback on next high-priority needs
- Continue to develop and improve tools and resources



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**Deficiency Letters**  
**FY24 Performance Results**  
**Questions?**





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# Internal Training Annual Report

## Internal Training Annual Report

In FY 2025, FDA began an efficiency effort that included transition to Shared Services Organization that will include training services. Tracking of FY 2025 services was impacted by the transition.

### V.A. Introduction

CDRH is committed to providing high-quality developmental opportunities that ensure Center staff are successful in their roles regulating medical devices and radiation emitting products. To help further the Center's mission, CDRH facilitates a culture of continuous learning and growth with an approach to developing employees' knowledge and skills incorporating instructor-led, experiential, and self-paced learning, mentoring, self-study initiatives, and specialty programs.

### V.B. Formal Training

Formal training is structured instruction to ensure review staff have the requisite knowledge and skills to perform their jobs. It is designed to accomplish specific objectives through a set curriculum that includes videos, self-paced modules, instructor-led courses, activities, and assessments. Table 1 summarizes CDRH's formal training in FY25.

Category	Program	# of Events	# of Completions
Regulatory and Law (LAW)	ELP	2	62
	MDUFA V	2	87
	Other LAW	198	1963
<b>LAW Subtotal:</b>		<b>202</b>	<b>2112</b>
Leadership Development (LED)	Leadership for Managers	13	212
	Leadership for Non-Managers	4	26
	Other LED	7	76
<b>LED Subtotal:</b>		<b>24</b>	<b>314</b>
Professional Development (PD)	New Employee Information Sessions	3	88
	Other PD	69	4373
<b>PD Subtotal:</b>		<b>72</b>	<b>4461</b>
Science (SCI)	All SCI	93	1919
<b>SCI Subtotal:</b>		<b>93</b>	<b>1,919</b>
<b>FY 2025 Training Total</b>		<b>391</b>	<b>8806</b>

### V.C. Reviewer Certification Program (RCP)

The RCP curriculum provides new review staff with the knowledge and skills they need to do their jobs. The program includes about 22 online modules, 14 instructor-led courses, practical activities, hands-on exercises, and assessments.

Cohort	Participants	#Events	Training Hours
RCP Fall 1 2024	16	405	601
RCP Fall 2 2024	15	477	624
RCP Spring 1 2025	6	200	218
<b>FY 2025 Total</b>	<b>37</b>	<b>1082</b>	<b>1443</b>

#### **V.D. Experiential Learning Program (ELP)**

ELP provides CDRH review staff with immersive training experiences designed to close the gap between emerging and innovative technology and the review of the resulting medical devices. Program participants learn about medical device development, testing, and manufacturing from the medical device industry, clinical community, and academic stakeholders. By participating in the program, regulatory personnel have the opportunity to gain insights into advancements in industry through exposure to manufacturing facilities, surgical centers, clinical trials, and other sites. In FY 2025, CDRH conducted 2 site visits for 62 attendees. Participants received a total of 434 hours of training.

#### **V.E. CDRH Informal Training**

Informal training is offered by Offices, Divisions, Branches, and Teams to provide specific audiences with specialized knowledge and skills related to their roles, processes, and challenges. It is composed of on-the-job training, all-hands meetings, informational webinars, communities of practice, small group sessions, and instructor-led and self-paced training. Informal training is an integral part of meeting the mission-critical training needs of CDRH staff.

Examples of informal training topics include:

- Monitored practical activities following formal training
- Device-specific processes and procedures
- Best practices for specific product areas
- Overview of policy changes and updates
- Introduction to new technology and recent advancements
- In FY 2025 CDRH 363 participants engaged in 14 documented informal events, for a total of 936 hours.