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Agenda for Quarterly Meeting on MDUFA V (FY 2023-2027) Performance

May 19, 2026, 1:00 – 2:00 pm

Teams

Welcome –

FDA MDUFA Performance — Actions through March 31, 2026

- Report on performance goals for 2nd Quarter FY 2026

Guidance Development

Registration and Listing

Qualitative Update on Finances – 2nd Quarter FY 2026

- User fee receipts through the 2nd Quarter FY 2026

Annual Hiring Goals Update

ASCA Program Update

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 31 March 2026

Table of Contents

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

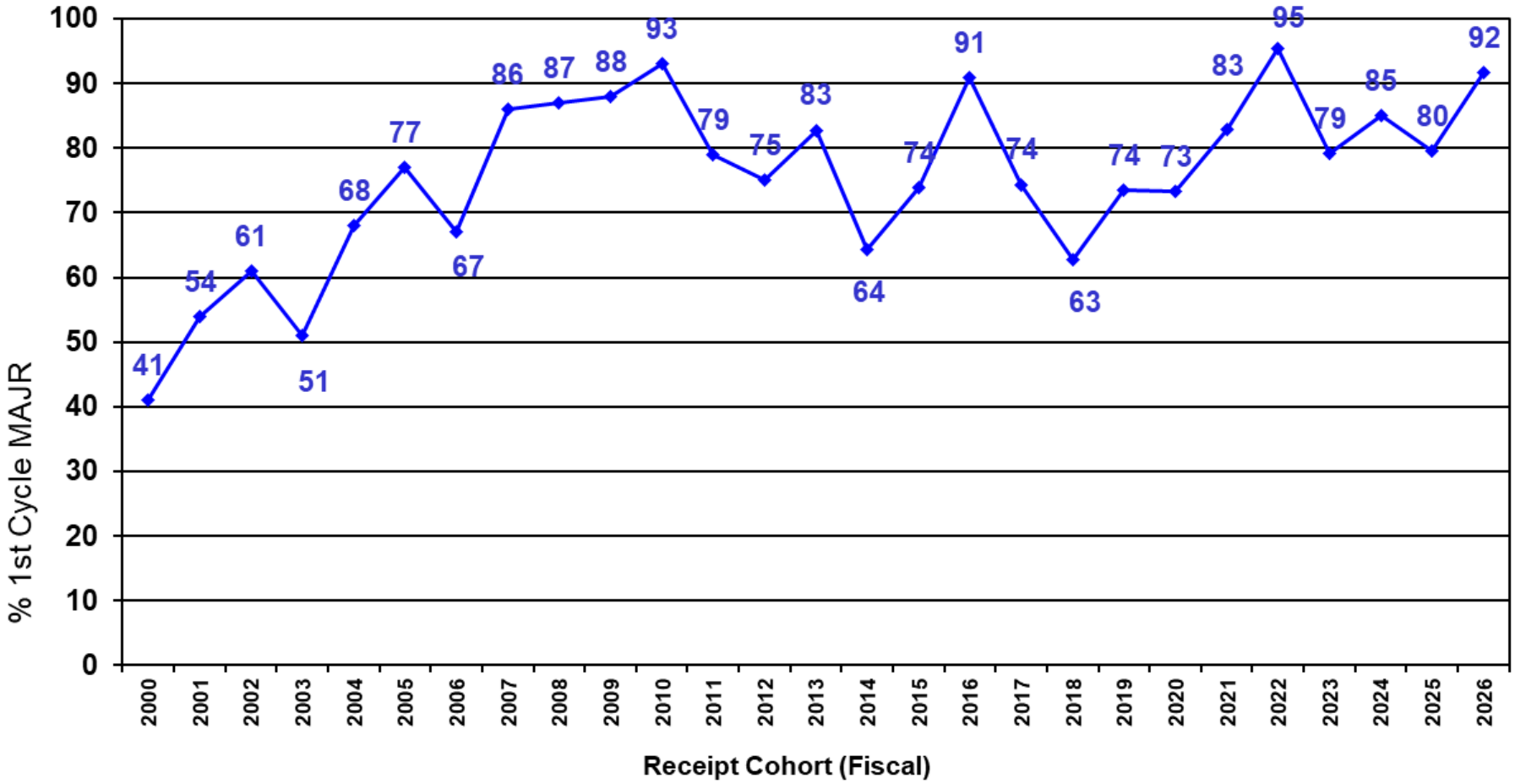
OHT8: Office of Radiological Health

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

PMAs

Q2FY2026

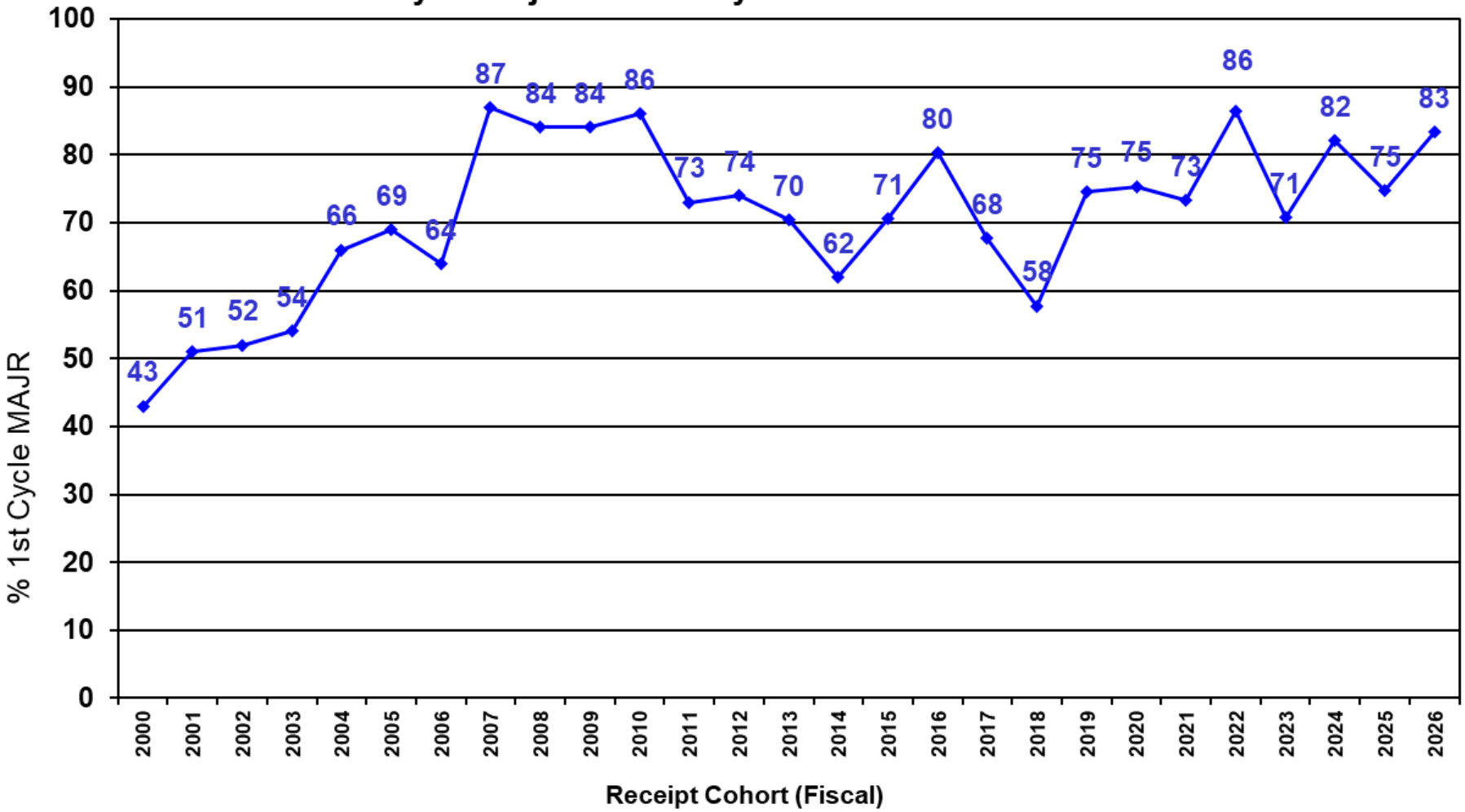
PMA Originals Filed as of 12/31/2025: 1st Cycle Major Deficiency Rate as of 03/31/2026



Data are based upon the number of submissions that received a major deficienecy 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 12/31/2025.
Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

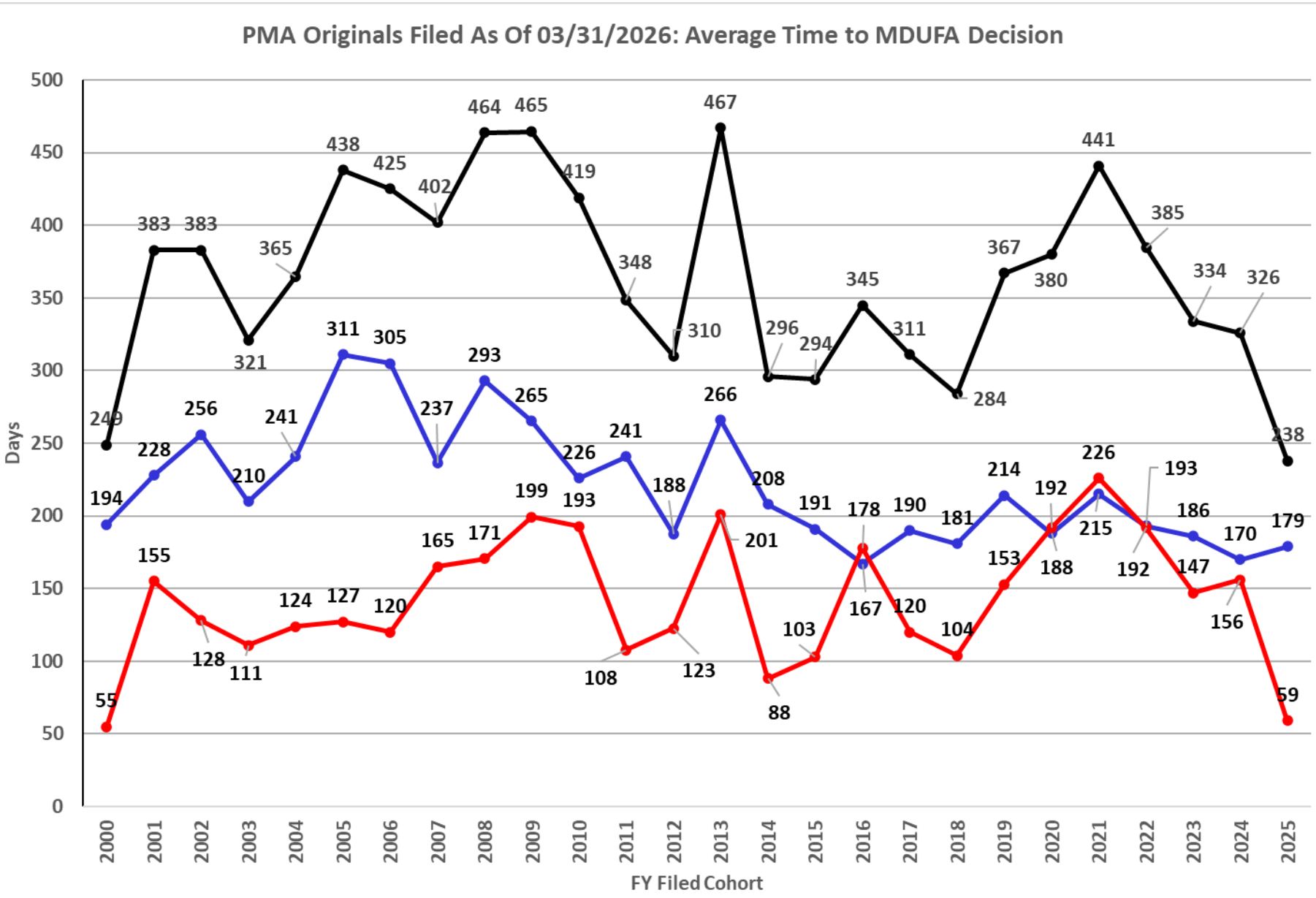
% 1st Cycle MAJR PMAO/PTS

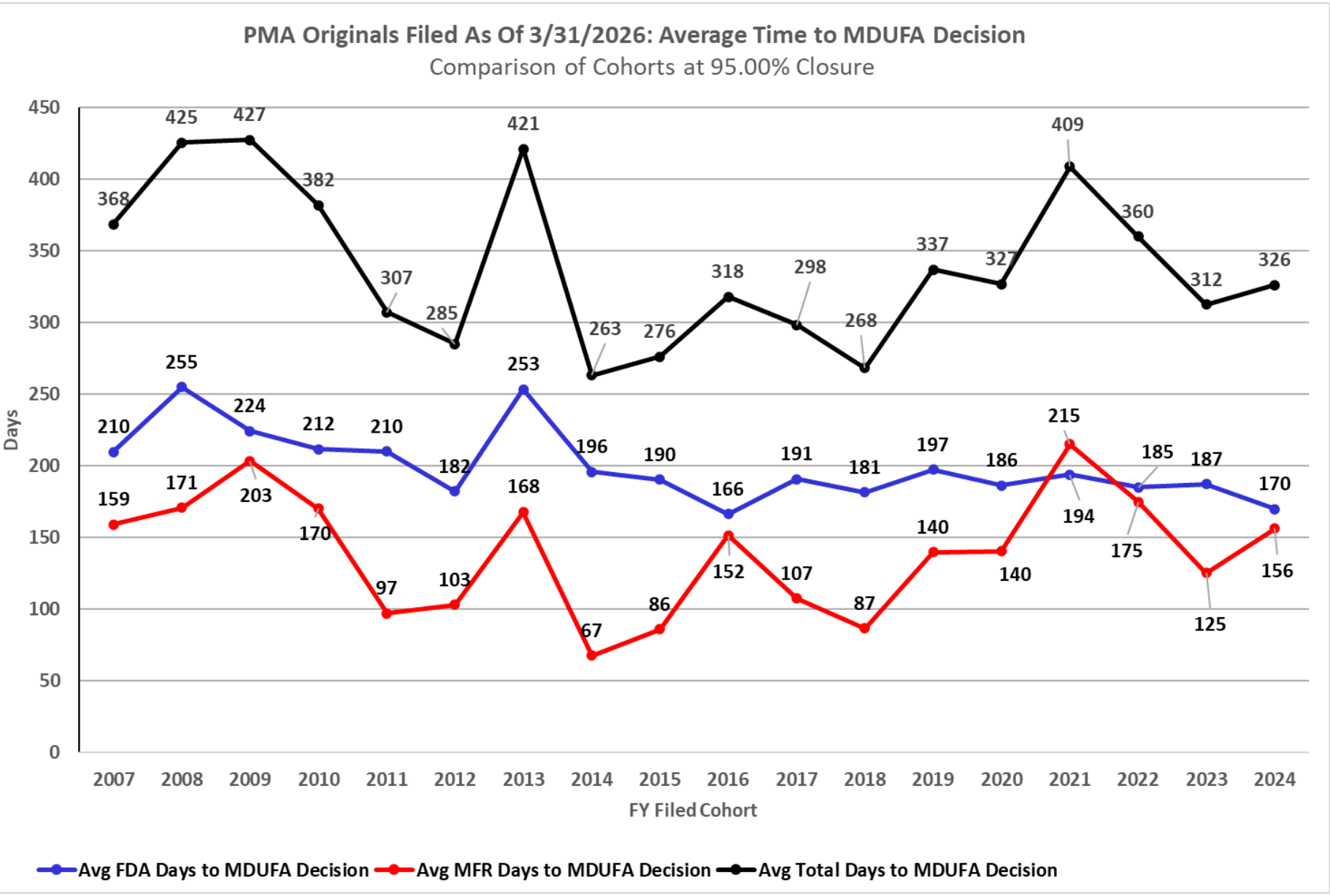
PMA Originals and Panel track Supplements Filed as of 12/31/2025: 1st Cycle Major Deficiency Rate as of 03/31/2026

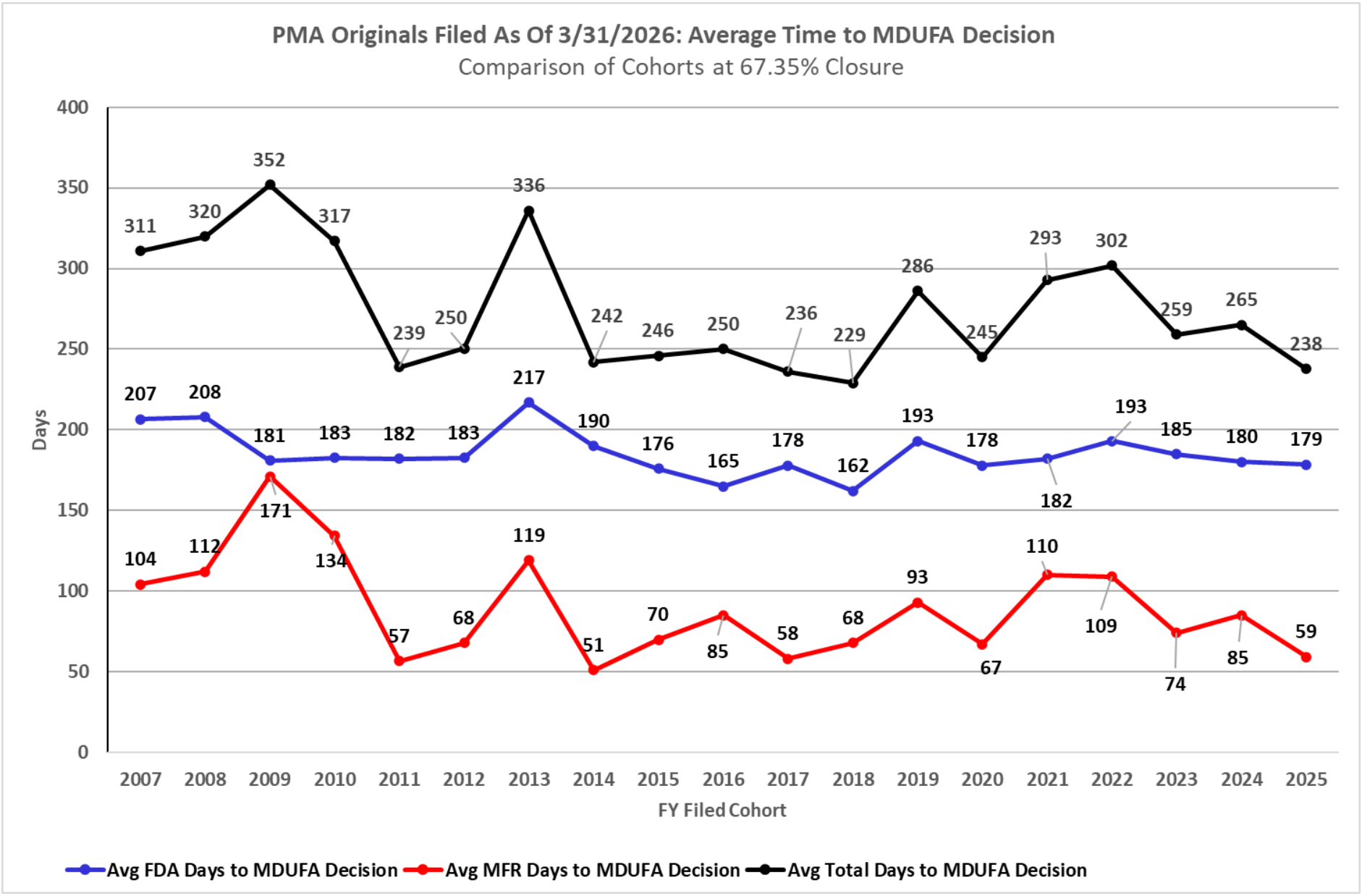


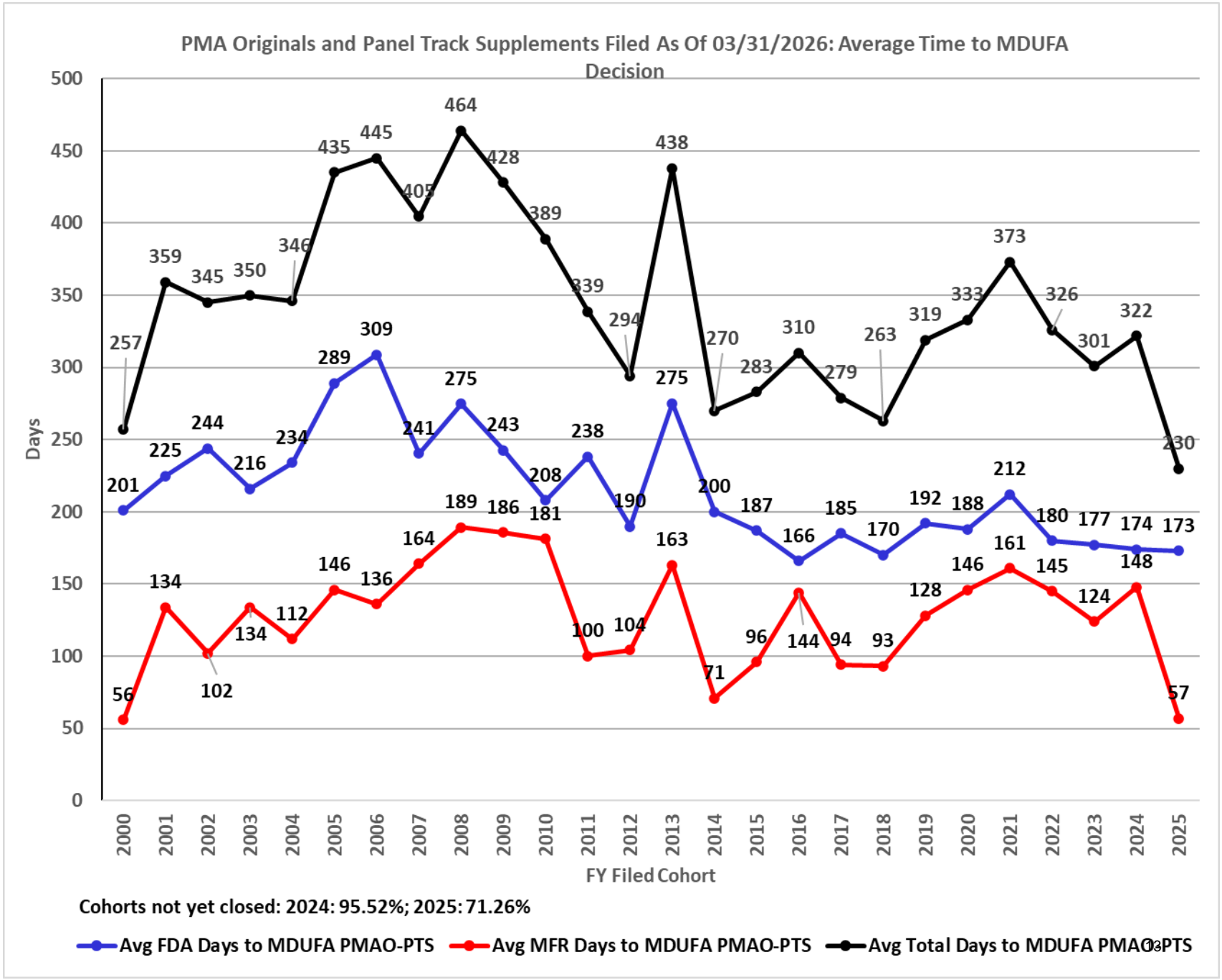
Data are based upon the number of submissions that received a major deficienecy letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submission rec'd, accepted & filed as of 12/31/25.
Note: For the current FY, a proceed Interactively decision is considered a completed 1st cycle.

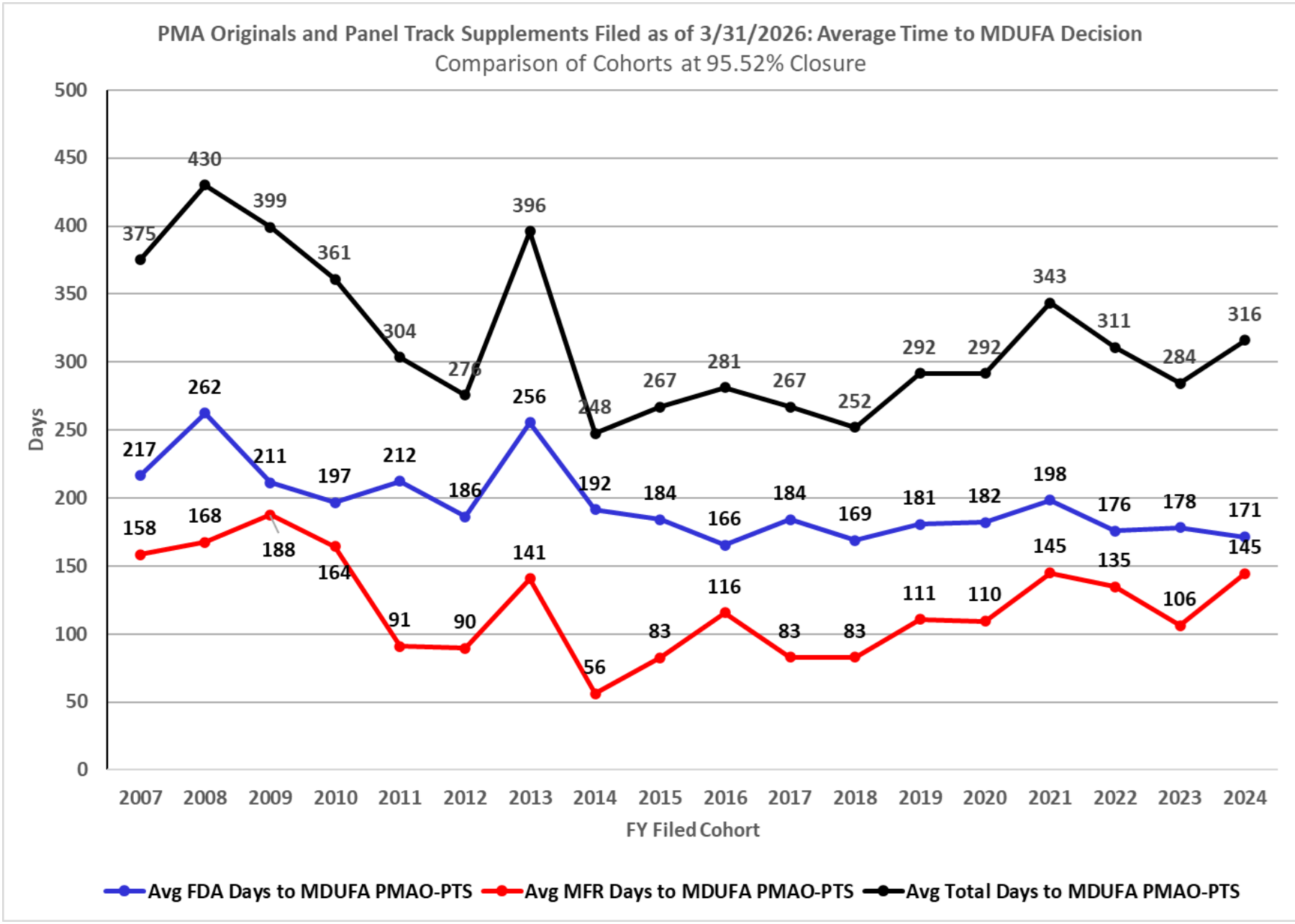
% 1st Cycle MAJR PMAO/PTS

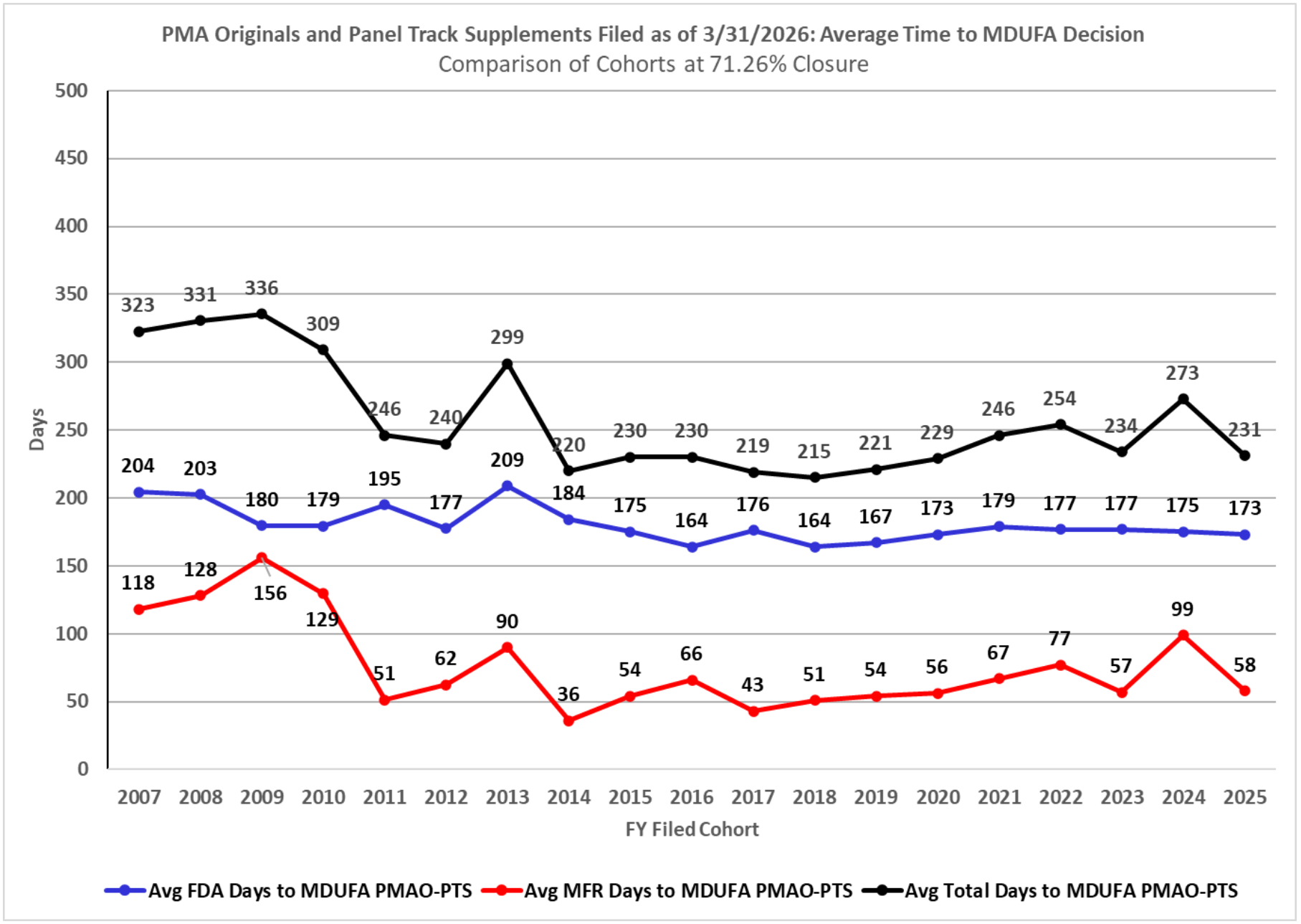

PMA Originals Filed As Of 03/31/2026: Average Time to MDUFA Decision
Days
FY Filed Cohort
Cohorts not yet closed: 2024: 95.00%; 2025: 67.35%
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals Filed As Of 3/31/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 95.00% Closure
Days
FY Filed Cohort
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024
0 50 100 150 200 250 300 350 400 450
368 425 427 382 307 285 421 263 276 318 298 268 337 327 409 360 312 326
210 255 224 212 210 182 253 196 190 166 191 181 197 186 215 185 187 170
159 171 203 170 97 103 168 67 86 152 107 87 140 140 194 175 125 156
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision

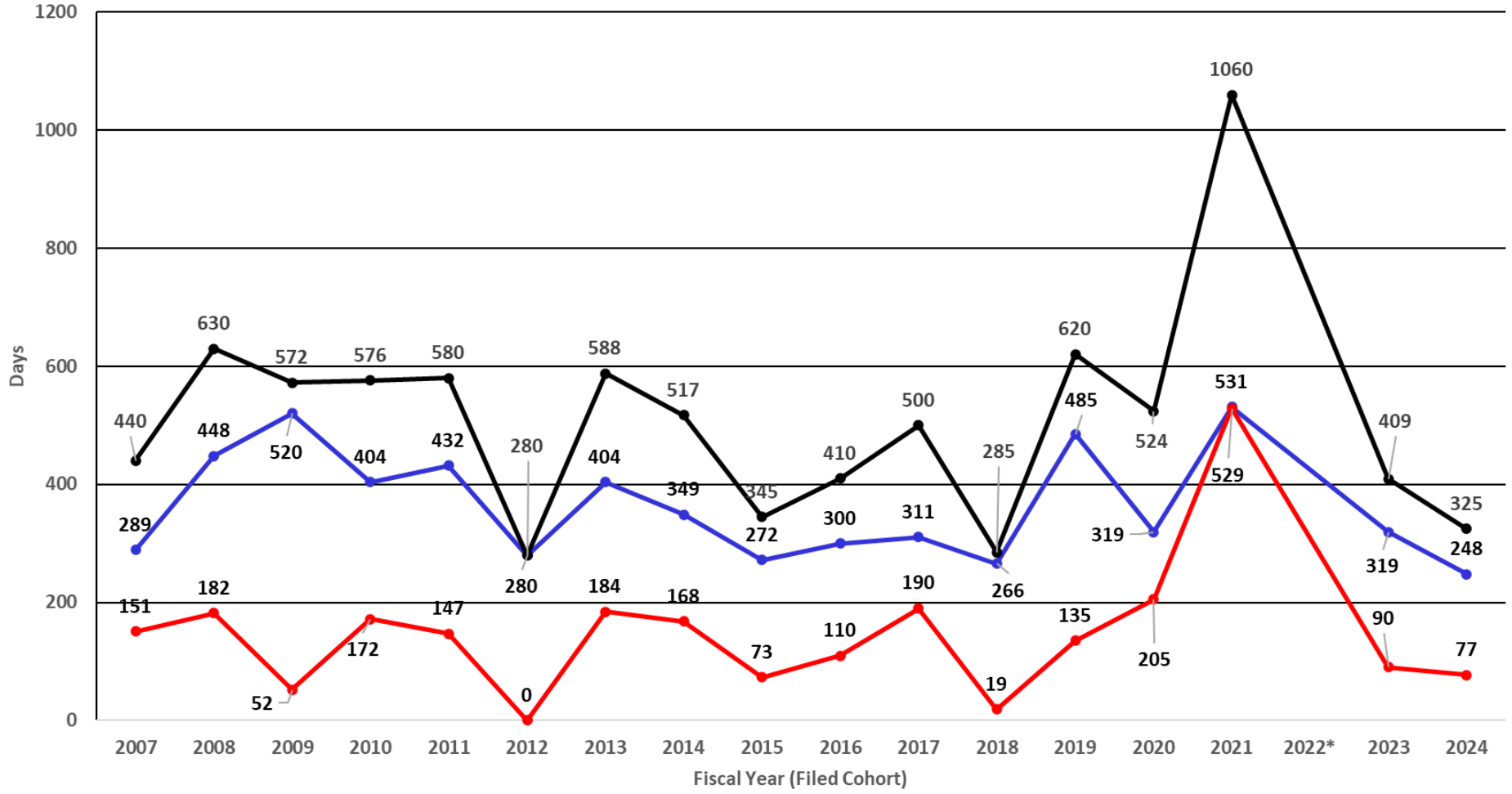

PMA Originals Filed As Of 3/31/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 67.35% Closure
Days
400
350
300
250
200
150
100
50
0
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
FY Filed Cohort
311 320 352 317 239 250 336 242 246 250 236 229 286 245 293 302 259 265 238
207 208 181 183 182 183 217 190 176 165 178 162 193 178 182 193 185 180 179
104 112 171 134 57 68 119 51 70 85 58 68 93 67 110 109 74 85 59
Avg FDA Days to MDUFA Decision
Avg MFR Days to MDUFA Decision
Avg Total Days to MDUFA Decision


PMA Originals and Panel Track Supplements Filed As Of 03/31/2026: Average Time to MDUFA Decision
Days
FY Filed Cohort
Cohorts not yet closed: 2024: 95.52%; 2025: 71.26%
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 3/31/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 95.52% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024
FY Filed Cohort
375 430 399 361 304 276 396 248 267 281 267 252 292 292 343 311 284 316
217 262 211 197 212 186 256 192 184 166 184 169 181 182 198 176 178 171
158 168 188 164 91 90 141 56 83 116 83 83 111 110 145 135 106 145
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 3/31/2026: Average Time to MDUFA Decision
Comparison of Cohorts at 71.26% Closure
Days
500
450
400
350
300
250
200
150
100
50
0
323 331 336 309 246 240 299 220 230 230 219 215 221 229 246 254 234 273 231
204 203 180 179 195 177 209 184 175 164 176 164 167 173 179 177 177 175 173
118 128 156 129 51 62 90 36 54 66 43 51 54 56 67 77 57 99 58
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025
FY Filed Cohort
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

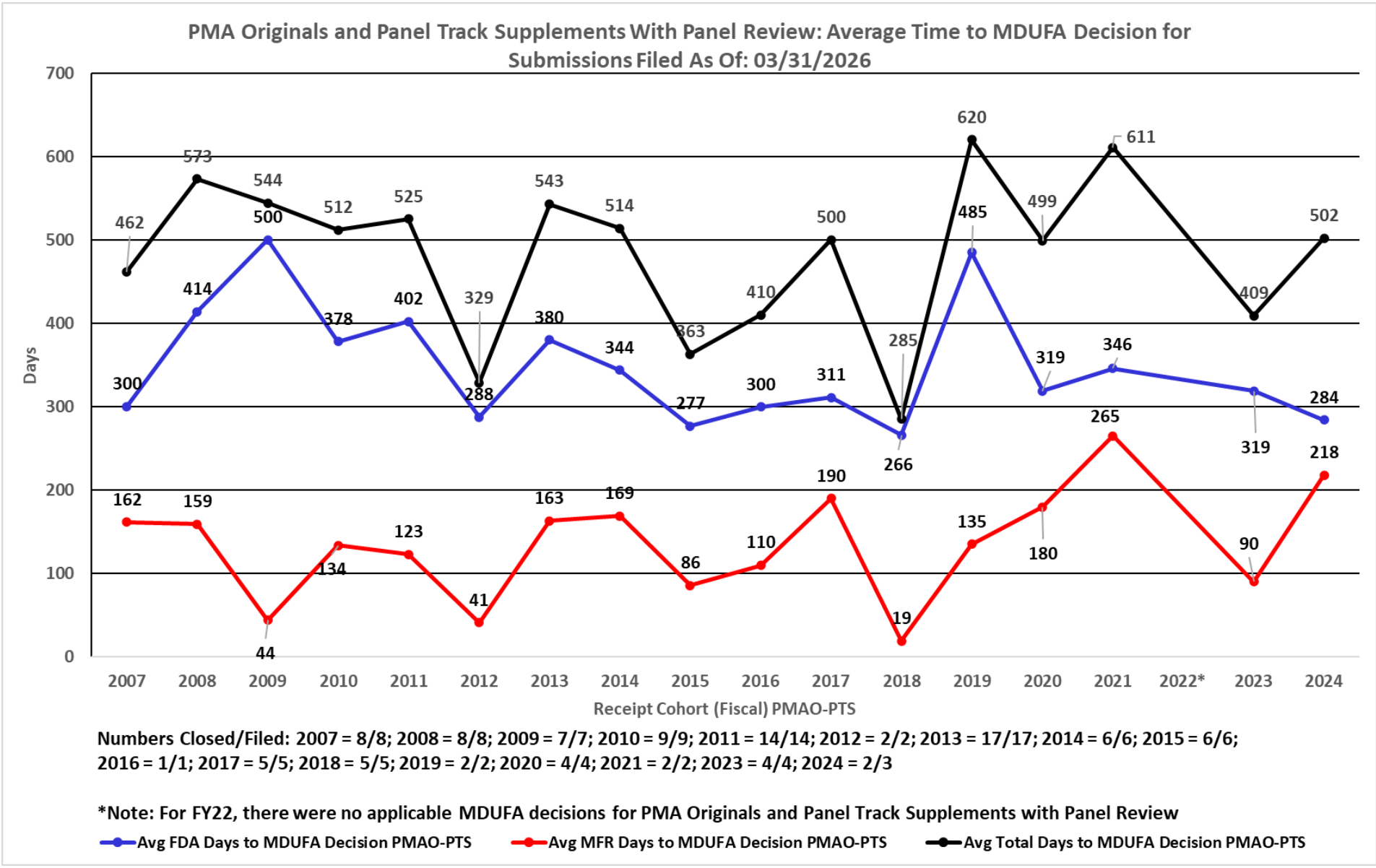
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 03/31/2026



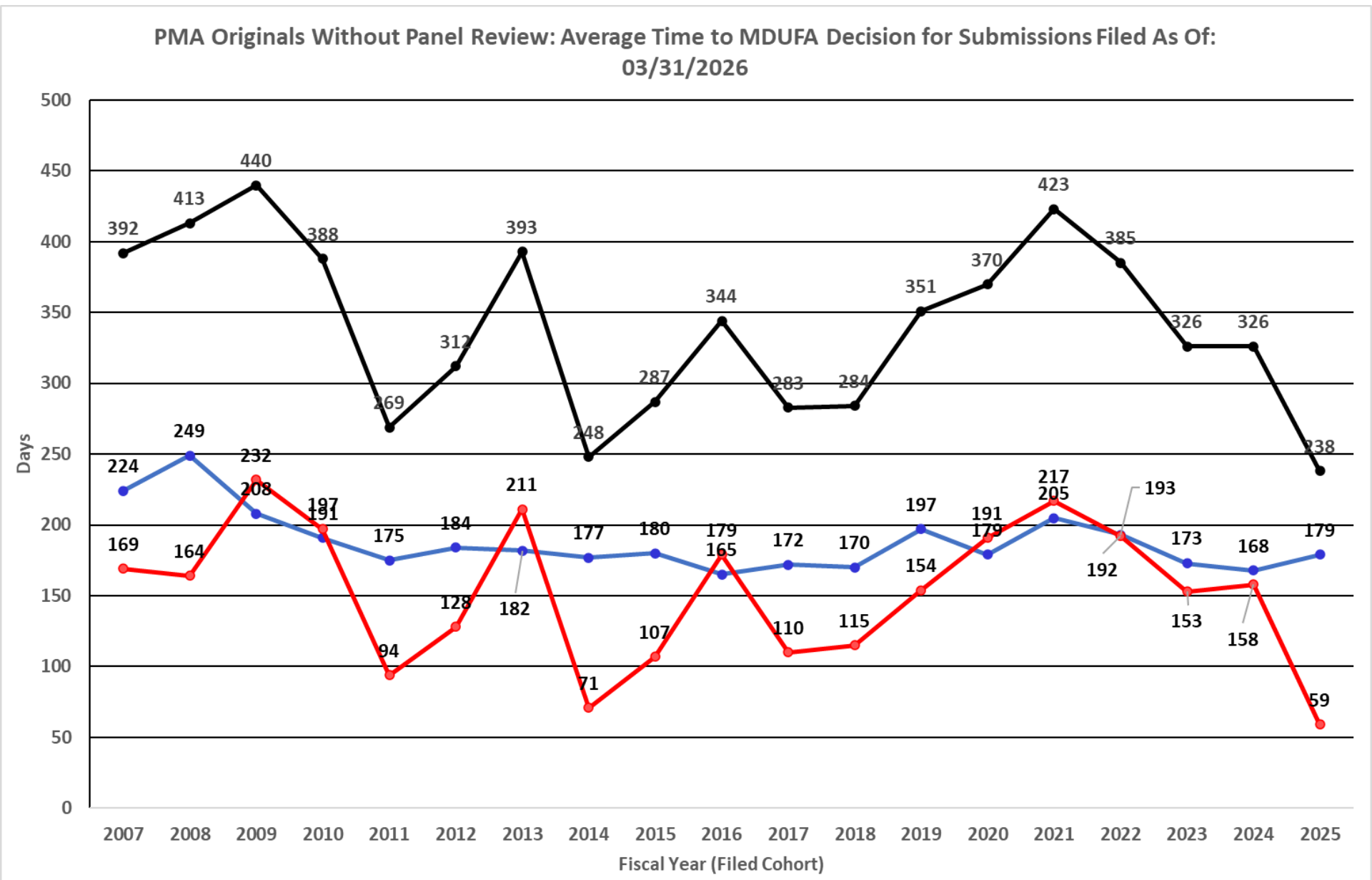
Numbers Closed/Filed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3; 2021 = 1/1; 2023 = 4/4; 2024 = 1/1

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

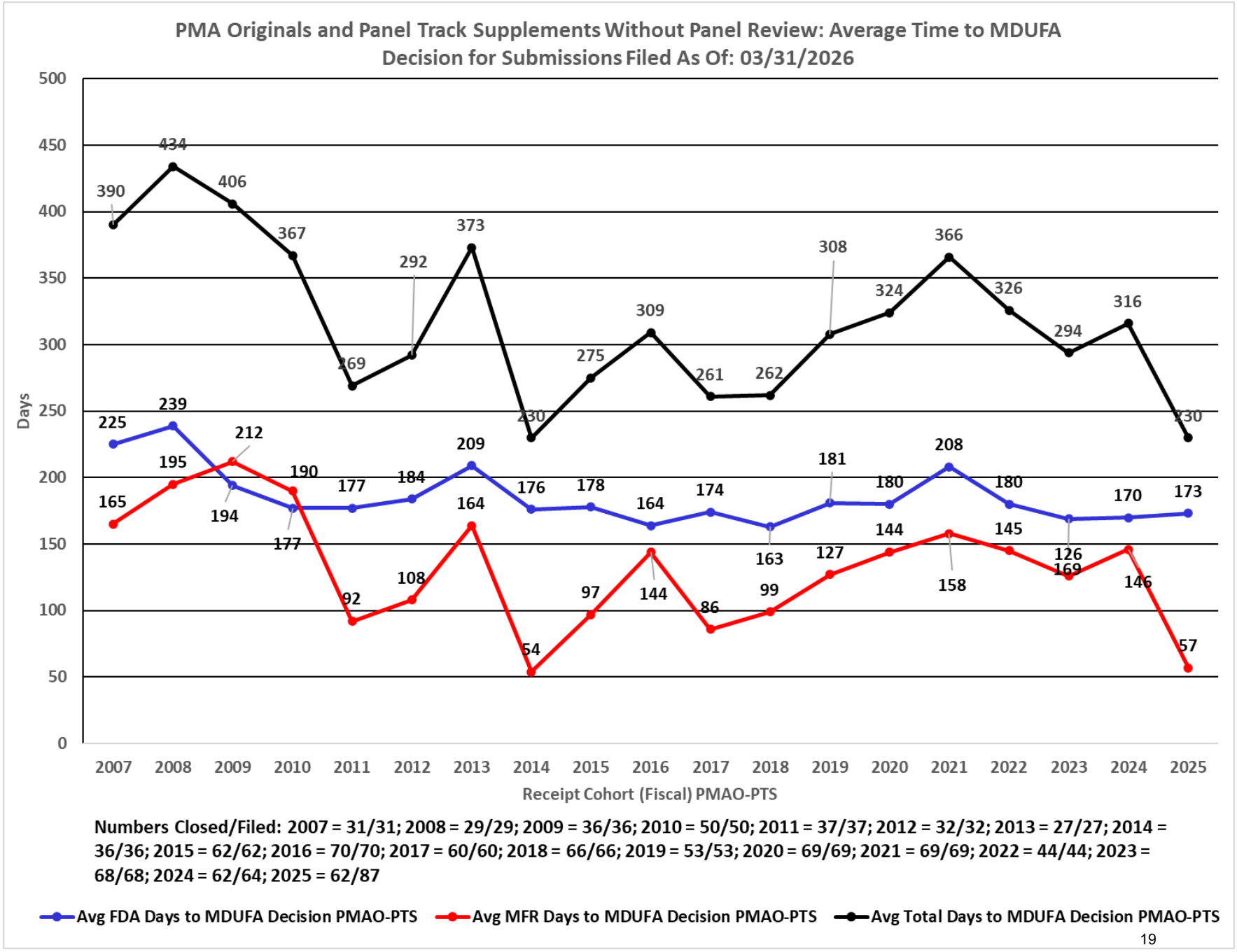
Avg FDA Days to MDUFA Decision PMAO **Avg MFR Days to MDUFA Decision PMAO** **Avg Total Days to MDUFA Decision PMAO**



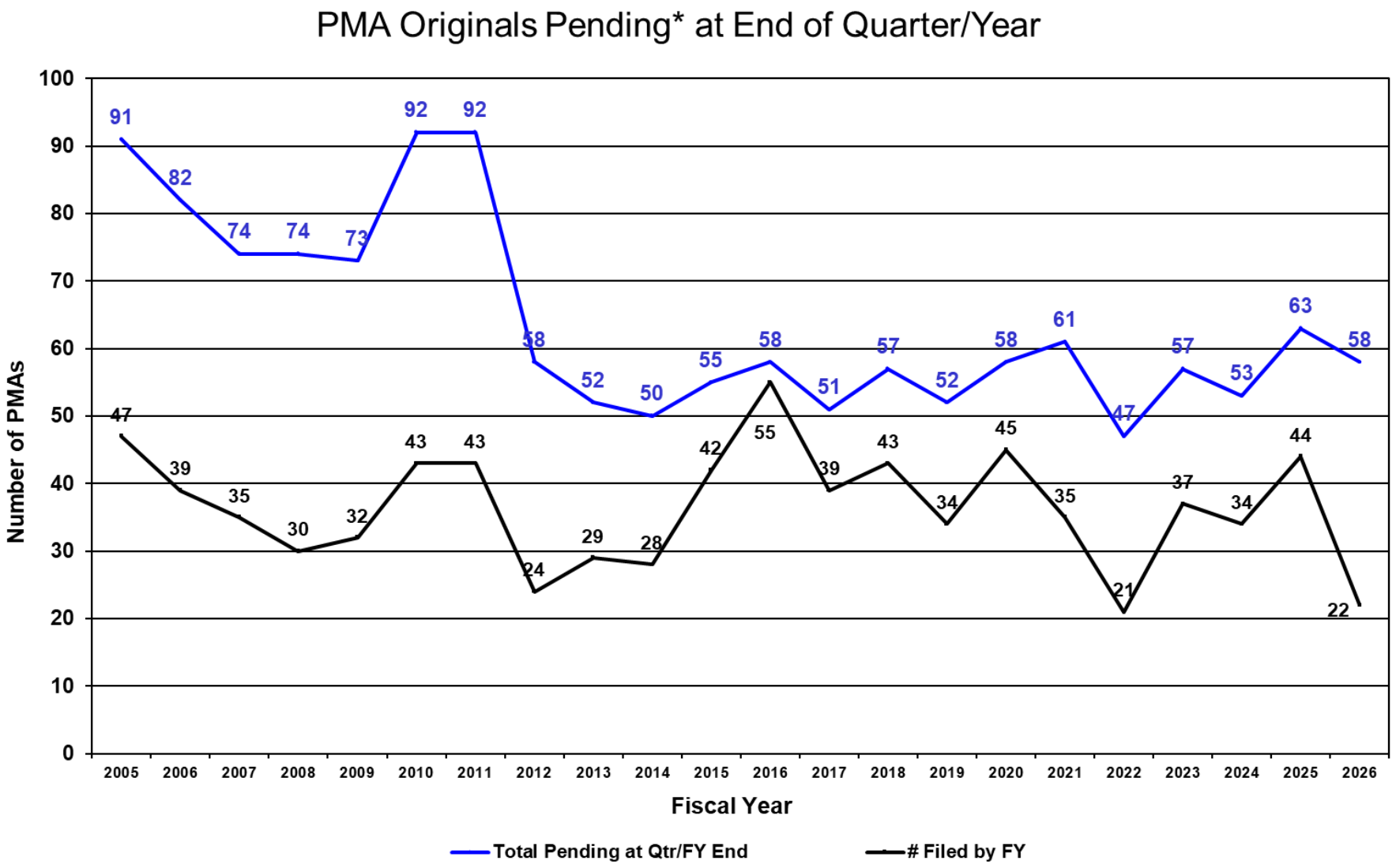
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.



Numbers Closed/Filed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/42; 2021 = 34/34; 2022 = 22/22; 2023 = 39/39; 2024 = 37/39; 2025 = 33/49

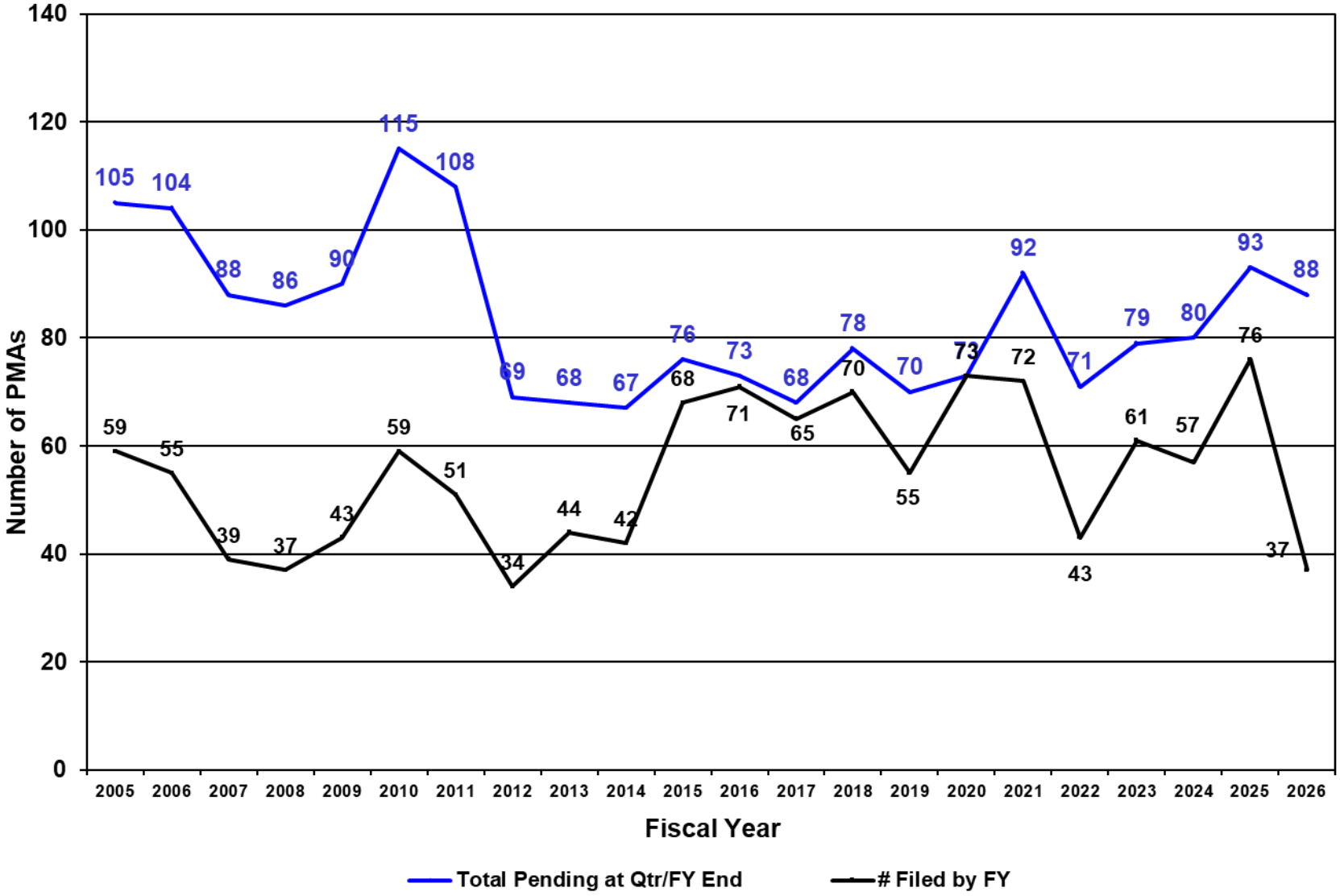


Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

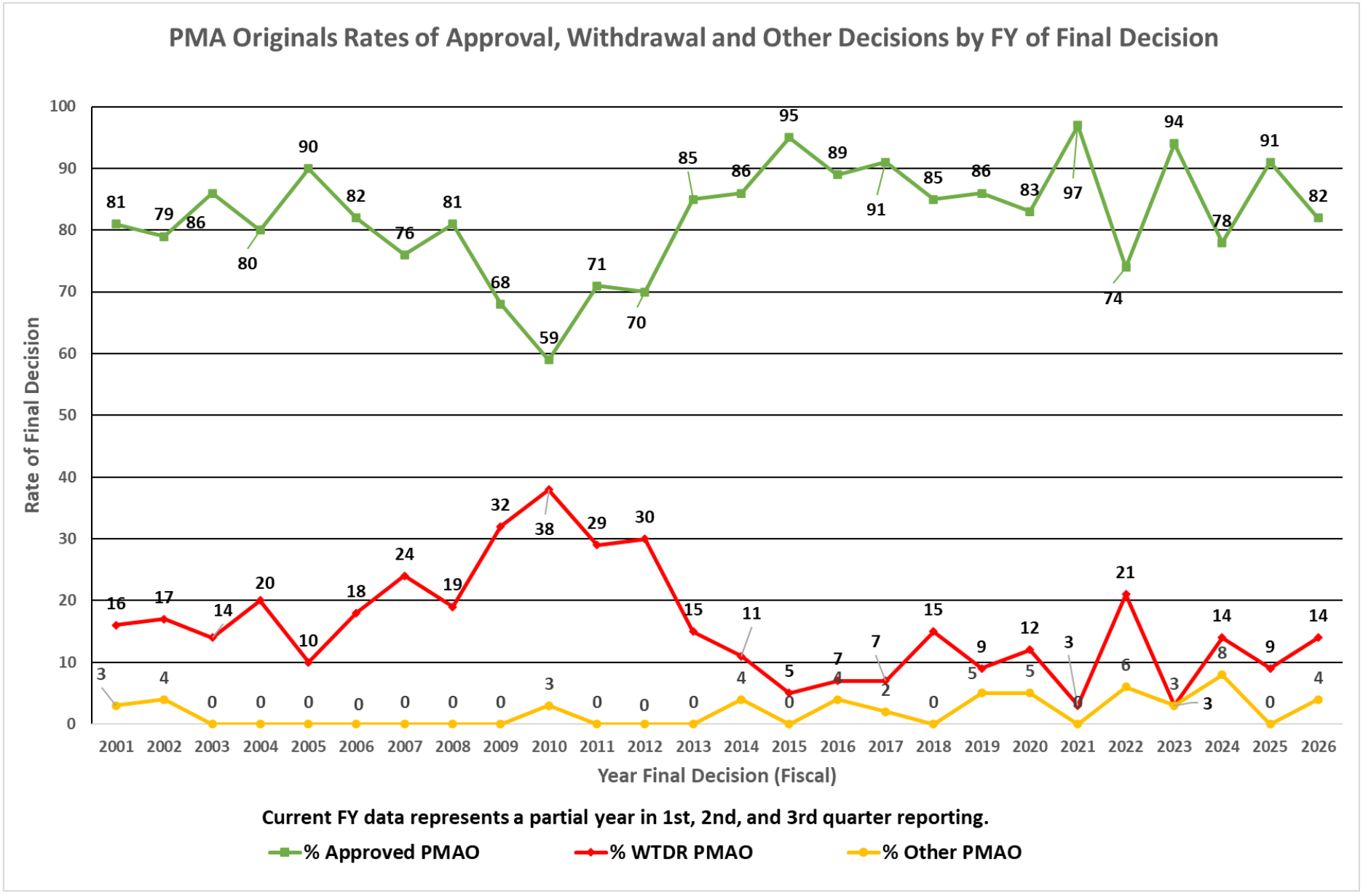


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

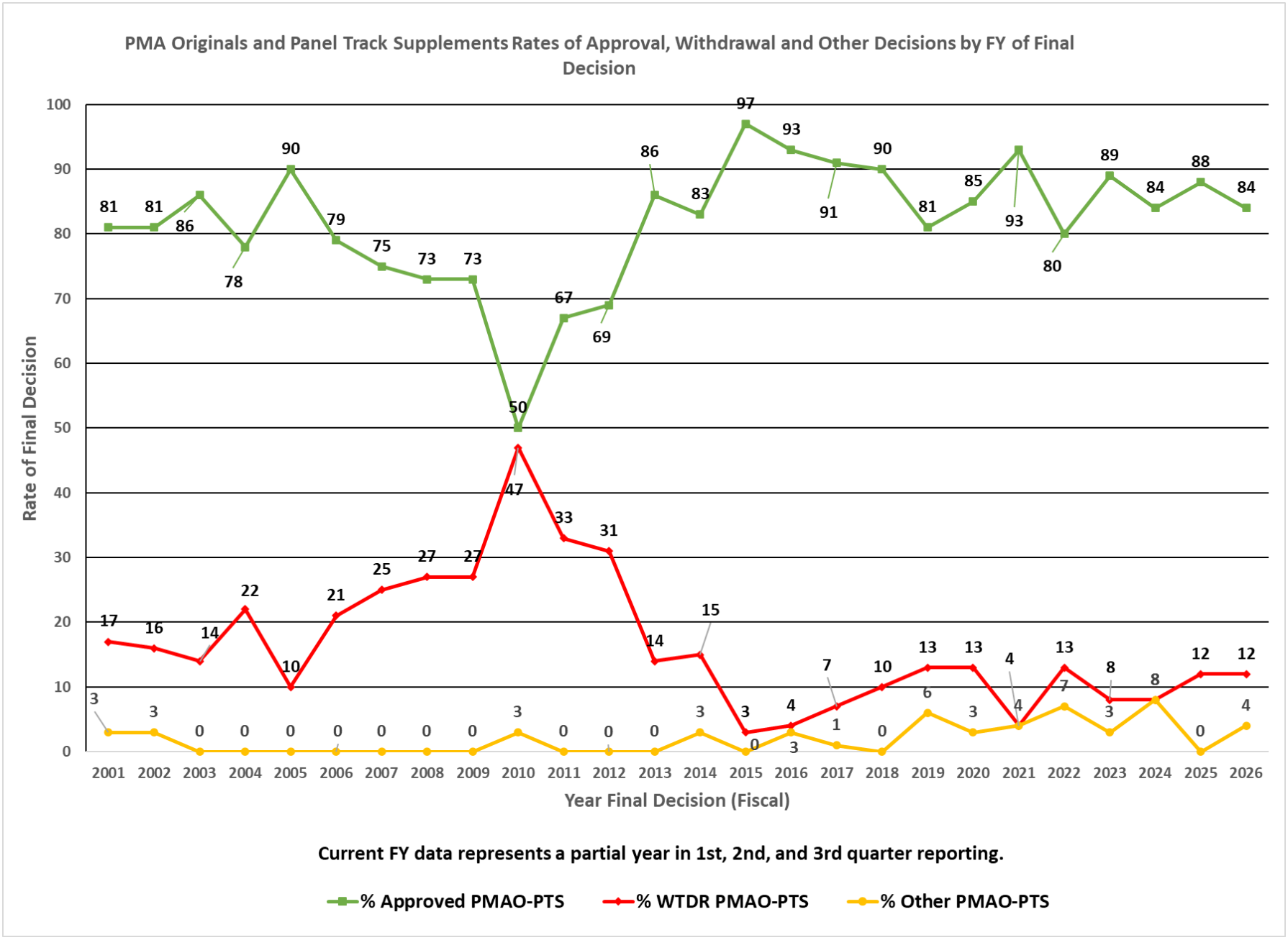
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



*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.

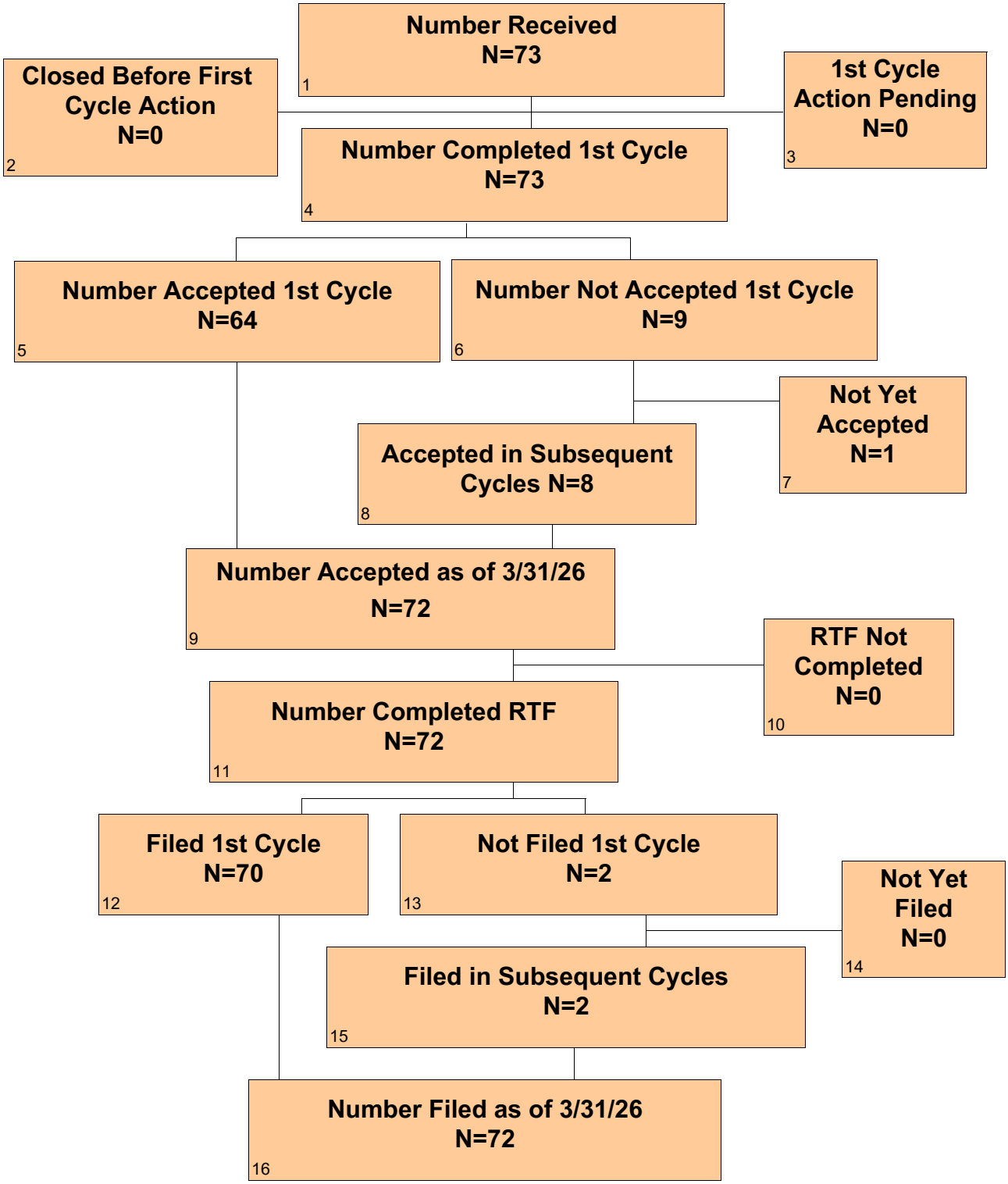


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

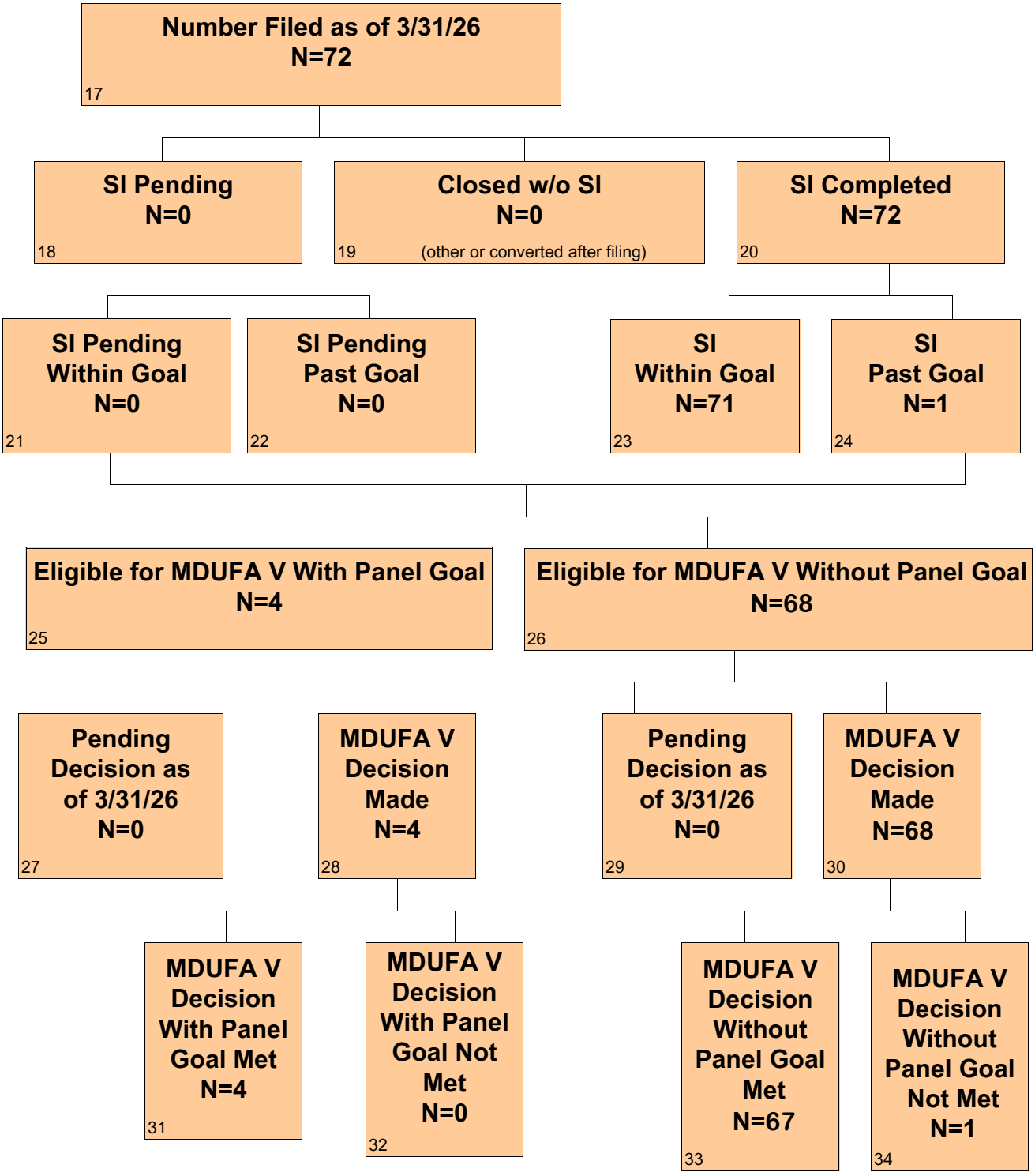


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

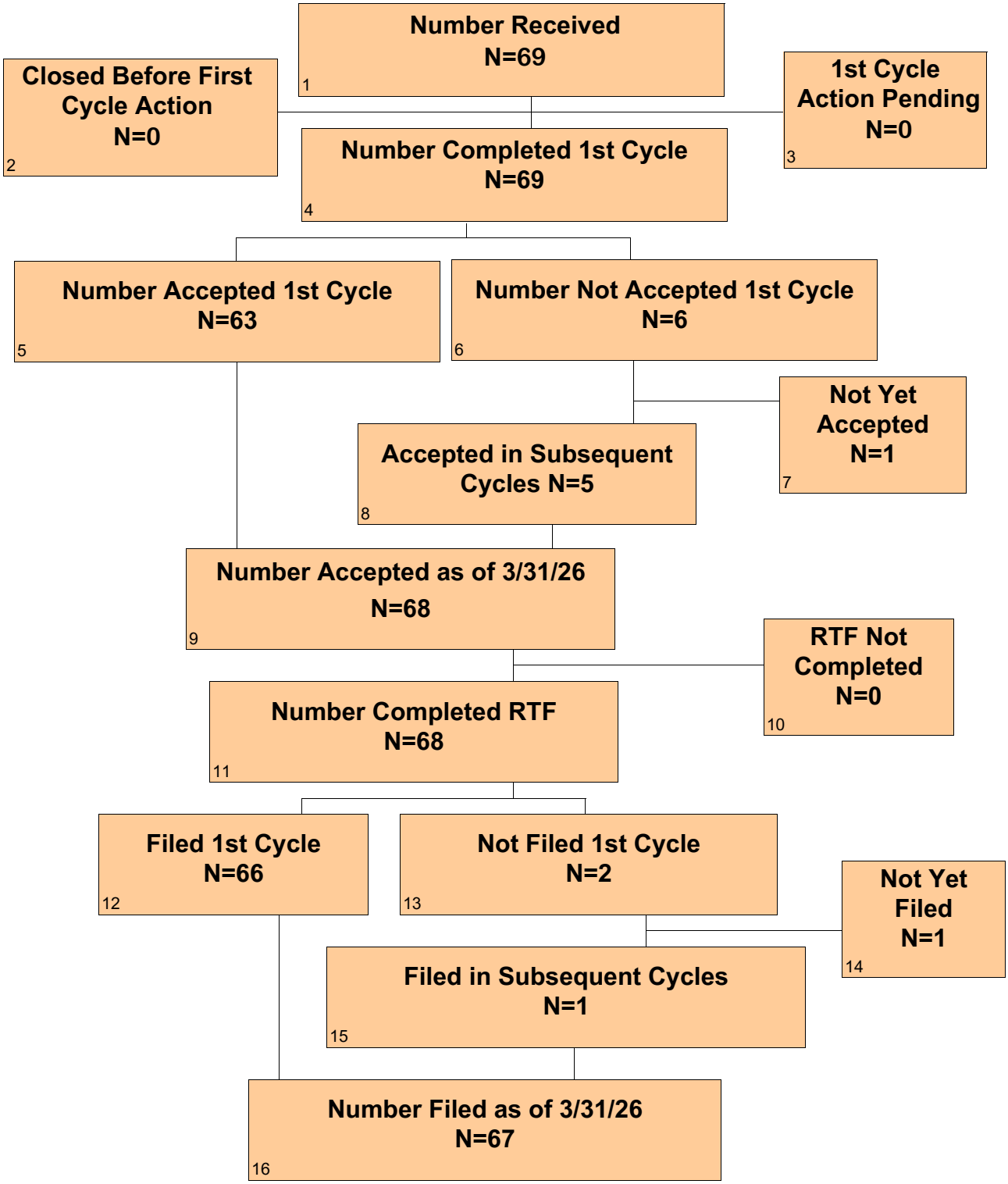
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 3/31/26



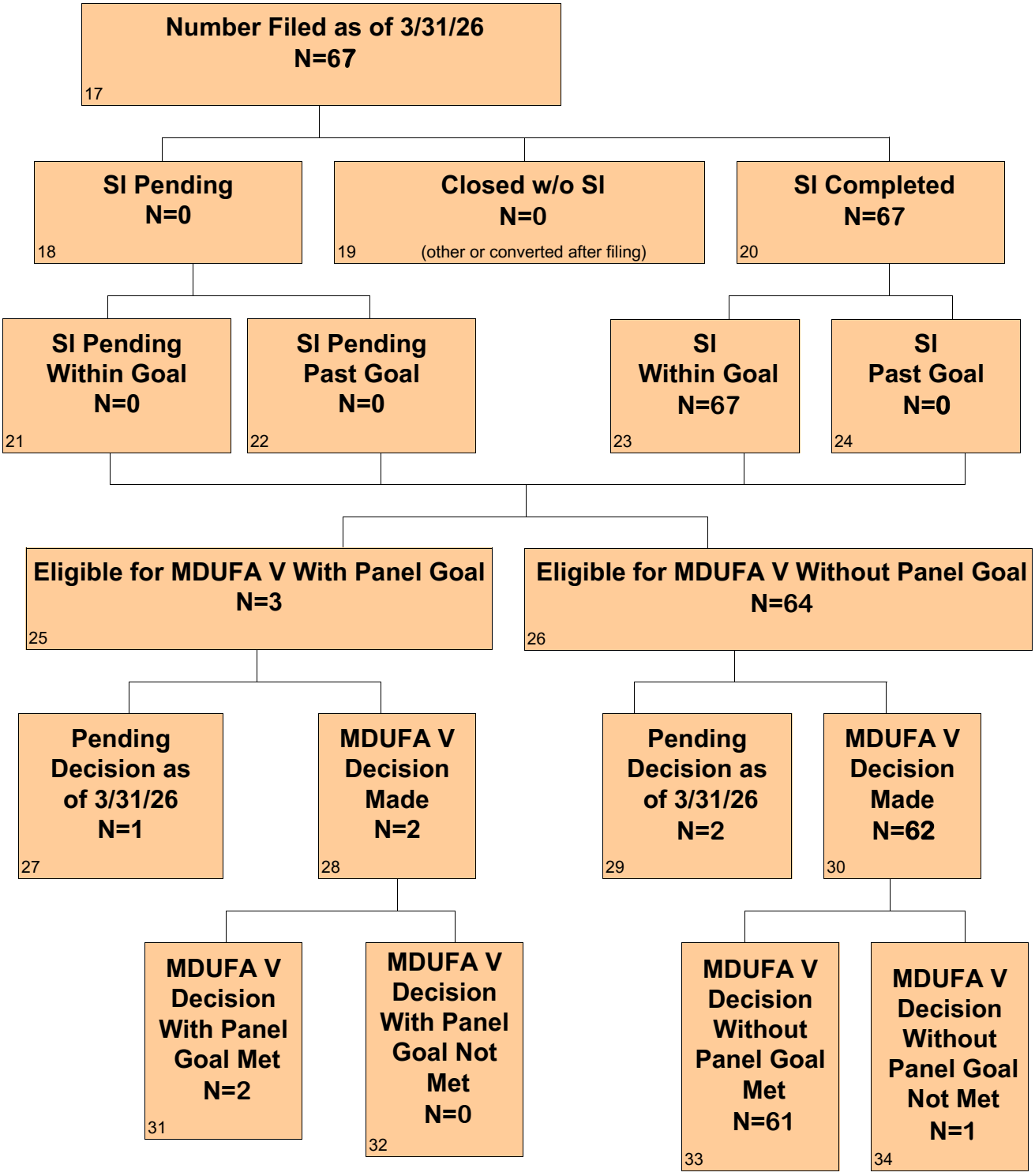
CDRH PMA Original and Panel Track Supplements - FY 2023 as of 3/31/26 Con't



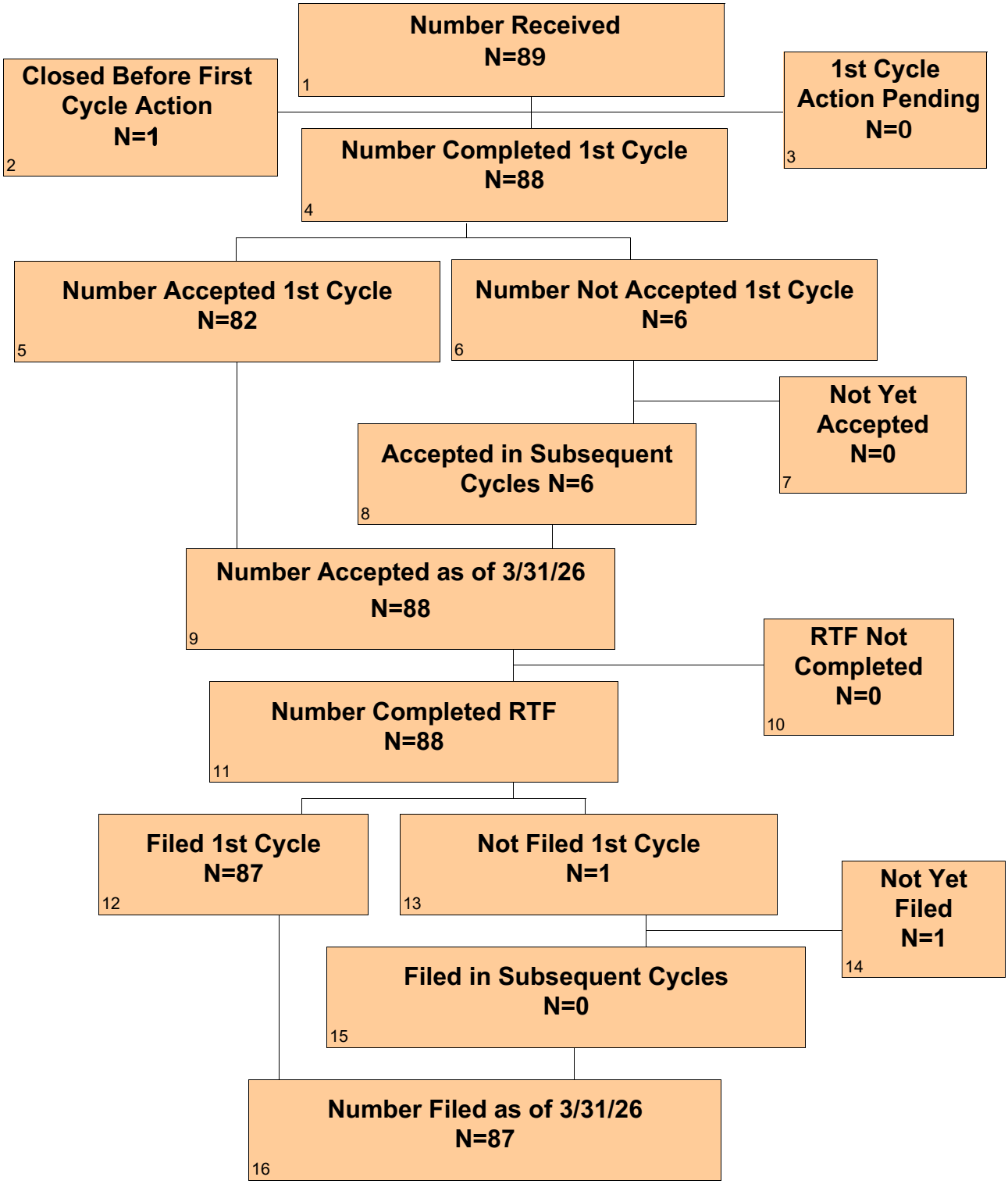
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 3/31/26



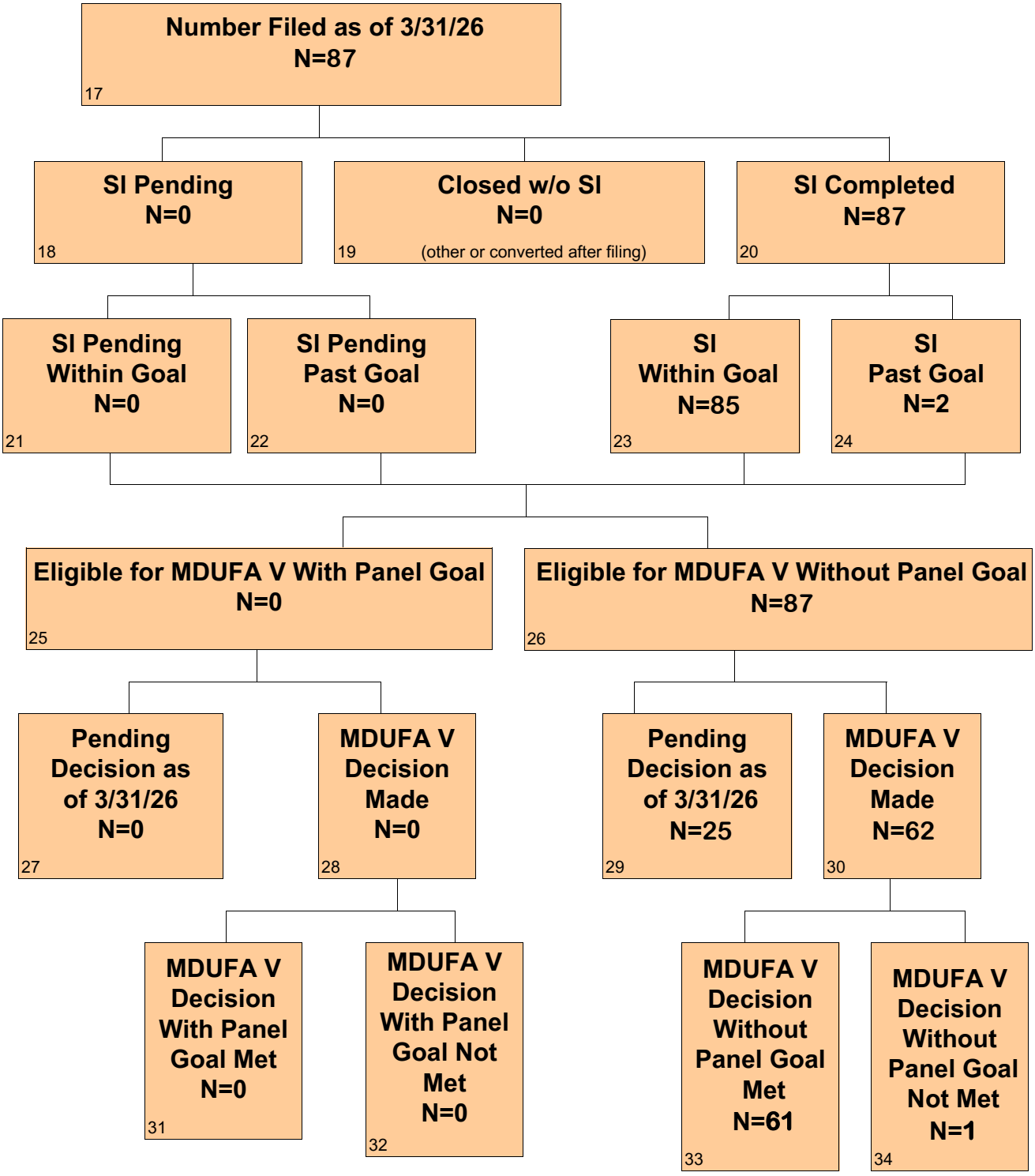
CDRH PMA Original and Panel Track Supplements - FY 2024 as of 3/31/26 Con't



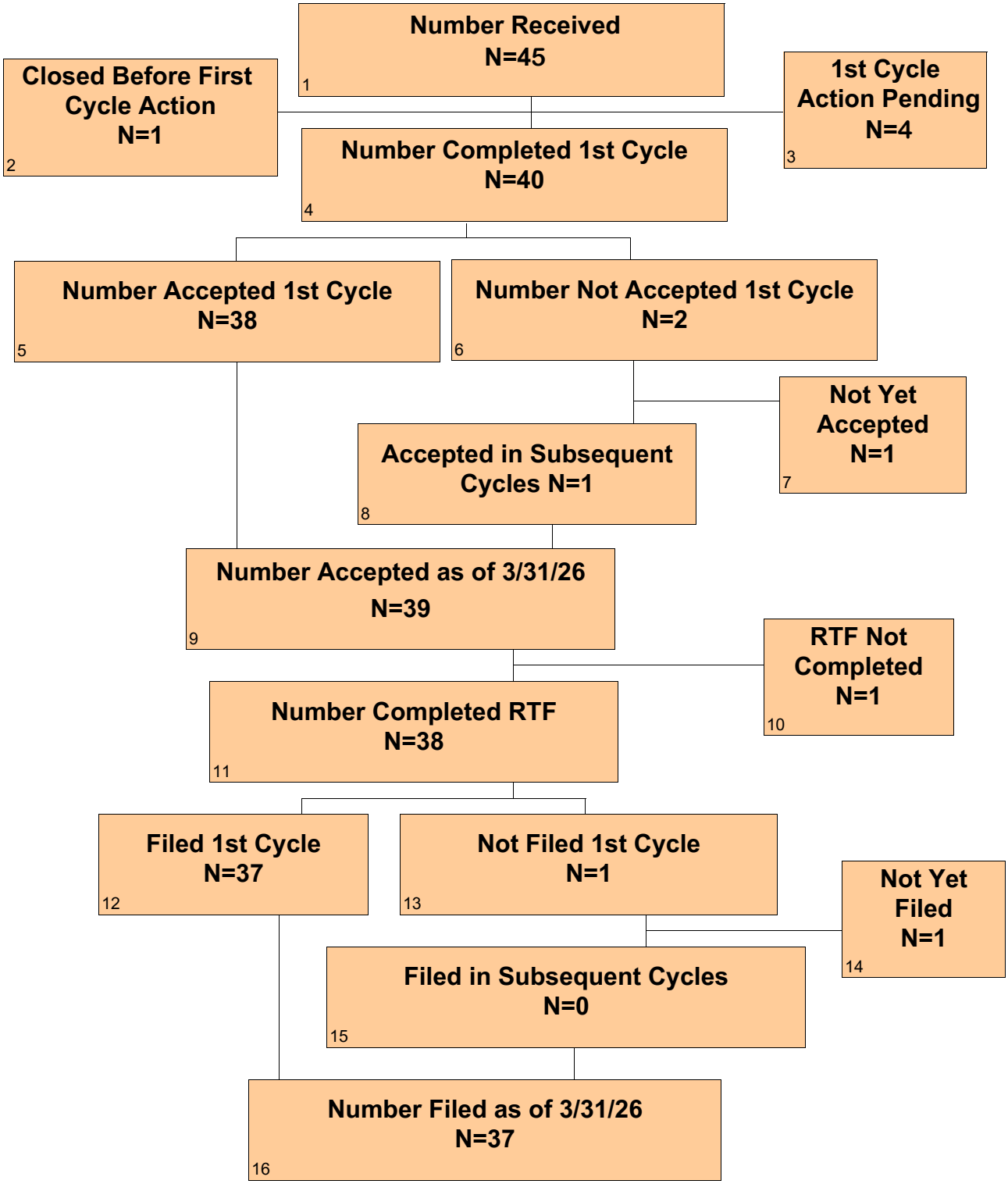
CDRH PMA Original and Panel Track Supplements - FY 2025 as of 3/31/26



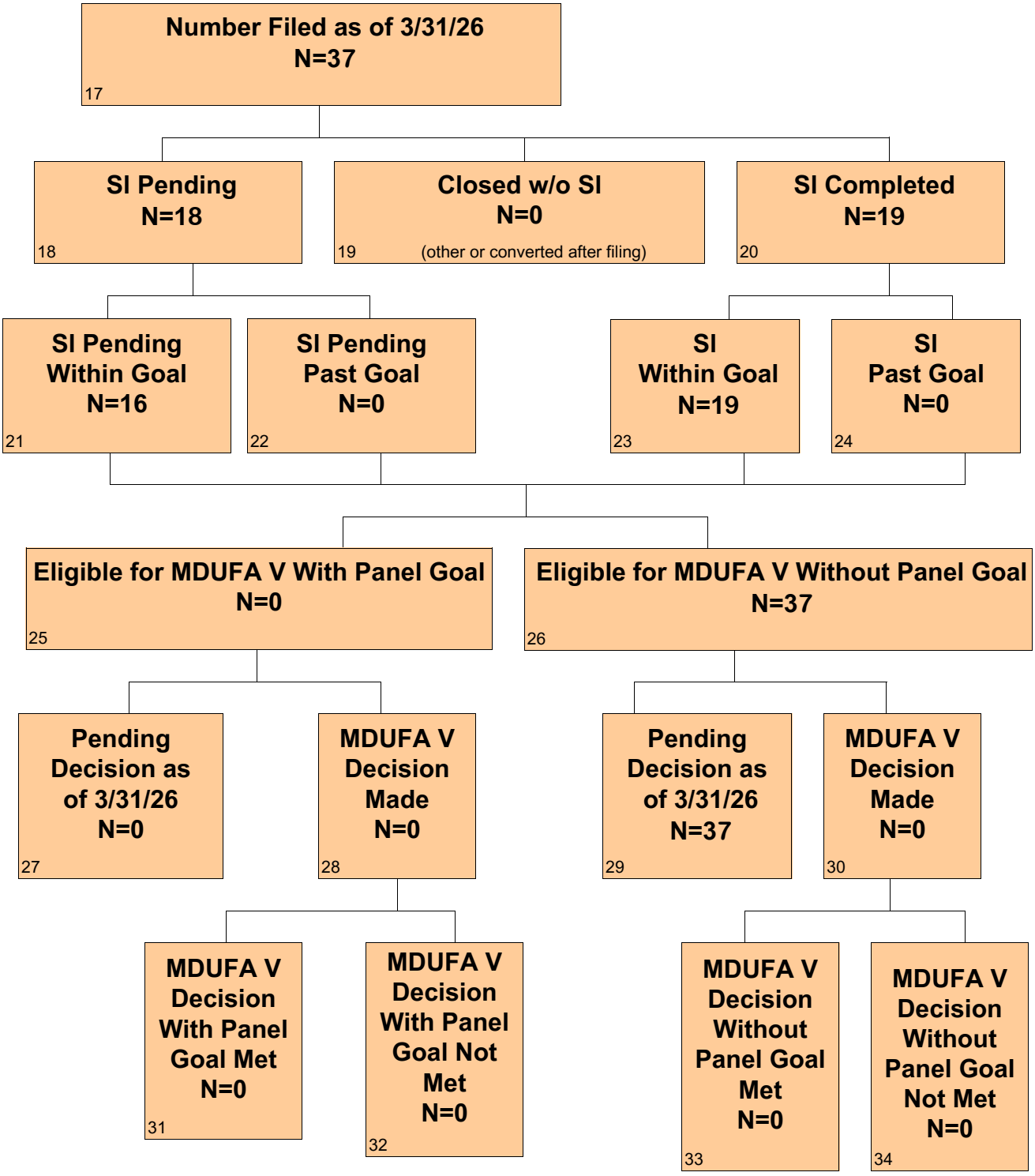
CDRH PMA Original and Panel Track Supplements - FY 2025 as of 3/31/26 Con't



CDRH PMA Original and Panel Track Supplements - FY 2026 as of 3/31/26



CDRH PMA Original and Panel Track Supplements - FY 2026 as of 3/31/26 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	45	
Number Closed Before First RTA Action	0	0	1	1	
Number Accepted First RTA Review	64	61	80	38	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	2	0	
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	4	
Number Not Accepted for Filing Review on First Cycle	9	6	6	2	
Rate of Submissions Not Accepted for Filing Review on First Cycle	12.33%	8.70%	6.82%	5.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	73	69	89	45	
Number Accepted	64	63	82	38	
Completed RTF	72	68	88	38	
Number Not Filed	2	2	1	1	
Rate of Submissions Not Filed	2.78%	2.94%	1.14%	2.63%	

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	87	37	
SI Goal Met	71	67	85	19	
SI Goal Not Met	1	0	2	0	
SI Pending Within Goal	0	0	0	18	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	98.61%	100.00%	97.70%	100.00%	

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	87	19	
Average Number of FDA Days to Substantive Interaction	87.42	89.13	87.45	89.05	
20th Percentile FDA Days to Substantive Interaction	86	88	86	88	
40th Percentile FDA Days to Substantive Interaction	88	89	88	89	
60th Percentile FDA Days to Substantive Interaction	90	90	89	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	91	153	151	90	

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	68	64	87	37	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	68	62	62	0	
MDUFA Decision Goal Met	67	61	61	0	
PMAs Pending MDUFA Decision	0	2	25	37	
PMAs Pending MDUFA Decision Past Goal	0	1	0	0	
Current Performance Percent Goal Met	98.53%	96.83%	98.39%	N/A	

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	68	62	62	0	
Average FDA Days to MDUFA Decision	168.60	170.23	173.08	N/A	
20th Percentile FDA Days to MDUFA Decision	171	175	176	0	
40th Percentile FDA Days to MDUFA Decision	178	178	178	0	
60th Percentile FDA Days to MDUFA Decision	180	180	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	271	228	311	0	
Average Industry Days to MDUFA Decision	125.78	145.76	57.27	N/A	
20th Percentile Industry Days to MDUFA Decision	0	12	0	0	
40th Percentile Industry Days to MDUFA Decision	40	58	17	0	
60th Percentile Industry Days to MDUFA Decision	100	145	66	0	
80th Percentile Industry Days to MDUFA Decision	284	325	101	0	
Maximum Industry Days to MDUFA Decision	629	368	241	0	
Average Total Days to MDUFA Decision	294.38	315.98	230.35	N/A	
20th Percentile Total Days to MDUFA Decision	179	196	178	0	
40th Percentile Total Days to MDUFA Decision	219	233	192	0	
60th Percentile Total Days to MDUFA Decision	284	324	243	0	
80th Percentile Total Days to MDUFA Decision	449	456	280	0	
Maximum Total Days to MDUFA Decision	809	537	419	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	4	2	0	0	
Average FDA Days to MDUFA Decision	319.00	284.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	318	262	0	0	
40th Percentile FDA Days to MDUFA Decision	318	277	0	0	
60th Percentile FDA Days to MDUFA Decision	320	291	0	0	
80th Percentile FDA Days to MDUFA Decision	320	306	0	0	
Maximum FDA Days to MDUFA Decision	320	320	0	0	
Average Industry Days to MDUFA Decision	90.00	217.50	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	51	133	0	0	
40th Percentile Industry Days to MDUFA Decision	61	189	0	0	
60th Percentile Industry Days to MDUFA Decision	72	246	0	0	
80th Percentile Industry Days to MDUFA Decision	120	302	0	0	
Maximum Industry Days to MDUFA Decision	186	358	0	0	
Average Total Days to MDUFA Decision	409.00	501.50	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	370	396	0	0	
40th Percentile Total Days to MDUFA Decision	381	466	0	0	
60th Percentile Total Days to MDUFA Decision	392	537	0	0	
80th Percentile Total Days to MDUFA Decision	439	607	0	0	
Maximum Total Days to MDUFA Decision	504	678	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	68	64	87	37	
Number with MDUFA Decision	68	62	62	0	
Number of Withdrawal	3	2	1	0	
Number of Not Approvable	13	8	4	0	
Number of Deleted	1	4	0	0	
Rate of Withdrawal	4.41%	3.23%	1.61%	N/A	
Rate of Not Approvable	19.12%	12.90%	6.45%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	4	3	0	0	
Number With MDUFA Decision	4	2	0	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	0	1	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	0.00%	N/A	N/A	
Rate of Not Approvable	0.00%	50.00%	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	2	1	0	
Mean FDA Days for Submissions that Missed the Goal	191.00	207.50	311.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	28.00	180.00	66.00	N/A	

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

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

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	5	6	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	5	4	0	
MDUFA Decision Goal Met	6	5	4	0	
PMAs Pending MDUFA Decision	0	0	2	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

***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	19	13	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	10	13	0	
MDUFA Decision Goal Met	15	10	13	0	
PMAs Pending MDUFA Decision	0	0	6	13	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

***Includes submission that went to panel**

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	7	7	3	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	3	6	6	1	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	6	1	1	2	
Rate of Submissions Not Accepted for Filing Review on First Cycle	66.67%	14.29%	14.29%	66.67%	

***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	3	
Number Accepted	3	6	6	1	
Completed RTF	8	7	7	2	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	12.50%	0.00%	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	2	
SI Goal Met	8	7	7	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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

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

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	8	7	7	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	8	7	6	0	
MDUFA Decision Goal Met	8	7	6	0	
PMAs Pending MDUFA Decision	0	0	1	2	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	8	7	6	0	
Average FDA Days to MDUFA Decision	138.00	180.00	179.17	N/A	
20th Percentile FDA Days to MDUFA Decision	90	180	179	0	
40th Percentile FDA Days to MDUFA Decision	157	180	180	0	
60th Percentile FDA Days to MDUFA Decision	179	180	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	217.75	145.43	79.83	N/A	
20th Percentile Industry Days to MDUFA Decision	65	65	26	0	
40th Percentile Industry Days to MDUFA Decision	247	102	48	0	
60th Percentile Industry Days to MDUFA Decision	295	148	107	0	
80th Percentile Industry Days to MDUFA Decision	337	236	136	0	
Maximum Industry Days to MDUFA Decision	362	311	147	0	
Average Total Days to MDUFA Decision	355.75	325.43	259.00	N/A	
20th Percentile Total Days to MDUFA Decision	245	245	206	0	
40th Percentile Total Days to MDUFA Decision	354	282	224	0	
60th Percentile Total Days to MDUFA Decision	456	328	287	0	
80th Percentile Total Days to MDUFA Decision	478	416	315	0	
Maximum Total Days to MDUFA Decision	536	491	327	0	

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	8	7	7	2	
Number with MDUFA Decision	8	7	6	0	
Number of Withdrawal	1	0	0	0	
Number of Not Approvable	0	1	1	0	
Number of Deleted	1	0	0	0	
Rate of Withdrawal	12.50%	0.00%	0.00%	N/A	
Rate of Not Approvable	0.00%	14.29%	16.67%	N/A	

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	20	20	28	13	
Number Closed Before First RTA Action	0	0	1	1	
Number Accepted First RTA Review	19	17	24	11	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	2	2	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	1	
Number Not Accepted for Filing Review on First Cycle	1	1	1	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	5.00%	5.00%	3.70%	0.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	20	20	28	13	
Number Accepted	19	19	26	11	
Completed RTF	20	20	27	11	
Number Not Filed	0	1	1	0	
Rate of Submissions Not Filed	0.00%	5.00%	3.70%	0.00%	

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

Substantive Interaction (SI) Goal	FY 2023 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	26	11	
SI Goal Met	20	20	25	6	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	5	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	96.15%	100.00%	

Table 1.4 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	20	20	26	6	
Average Number of FDA Days to Substantive Interaction	88.25	88.20	88.35	88.83	
20th Percentile FDA Days to Substantive Interaction	86	87	88	88	
40th Percentile FDA Days to Substantive Interaction	90	89	89	88	
60th Percentile FDA Days to Substantive Interaction	90	90	90	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	90	90	102	90	

Table 1.5 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	17	19	26	11	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	17	19	21	0	
MDUFA Decision Goal Met	17	18	20	0	
PMAs Pending MDUFA Decision	0	0	5	11	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	94.74%	95.24%	N/A	

Table 1.6 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

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

Table 1.7 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	17	19	21	0	
Average FDA Days to MDUFA Decision	177.65	174.37	183.05	N/A	
20th Percentile FDA Days to MDUFA Decision	172	177	177	0	
40th Percentile FDA Days to MDUFA Decision	177	178	179	0	
60th Percentile FDA Days to MDUFA Decision	180	180	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	271	228	311	0	
Average Industry Days to MDUFA Decision	64.29	70.00	32.29	N/A	
20th Percentile Industry Days to MDUFA Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA Decision	23	2	0	0	
60th Percentile Industry Days to MDUFA Decision	47	30	21	0	
80th Percentile Industry Days to MDUFA Decision	113	81	74	0	
Maximum Industry Days to MDUFA Decision	271	362	168	0	
Average Total Days to MDUFA Decision	241.94	244.37	215.33	N/A	
20th Percentile Total Days to MDUFA Decision	176	179	179	0	
40th Percentile Total Days to MDUFA Decision	201	191	180	0	
60th Percentile Total Days to MDUFA Decision	236	222	190	0	
80th Percentile Total Days to MDUFA Decision	305	259	260	0	
Maximum Total Days to MDUFA Decision	442	537	377	0	

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

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

Table 1.9 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	17	19	26	11	
Number with MDUFA Decision	17	19	21	0	
Number of Withdrawal	1	0	0	0	
Number of Not Approvable	3	0	3	0	
Number of Deleted	0	1	0	0	
Rate of Withdrawal	5.88%	0.00%	0.00%	N/A	
Rate of Not Approvable	17.65%	0.00%	14.29%	N/A	

Table 1.10 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

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

Table 1.11 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	1	1	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	228.00	311.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	0.00	66.00	N/A	

Table 1.12 OHT2 - Office of Cardiovascular Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	7	5	3	
Number Accepted	3	6	5	3	
Completed RTF	3	7	5	3	
Number Not Filed	0	1	0	1	
Rate of Submissions Not Filed	0.00%	14.29%	0.00%	33.33%	

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	2	
SI Goal Met	3	6	5	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	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	5	2	
Average Number of FDA Days to Substantive Interaction	88.33	96.67	87.80	90.00	
20th Percentile FDA Days to Substantive Interaction	87	88	87	90	
40th Percentile FDA Days to Substantive Interaction	88	88	88	90	
60th Percentile FDA Days to Substantive Interaction	88	90	88	90	
80th Percentile FDA Days to Substantive Interaction	89	90	88	90	
Maximum FDA Days to Substantive Interaction	90	153	90	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 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	3	6	5	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	5	3	0	
MDUFA Decision Goal Met	2	5	3	0	
PMAs Pending MDUFA Decision	0	1	2	2	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	66.67%	100.00%	100.00%	N/A	

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	3	5	3	0	
Average FDA Days to MDUFA Decision	180.67	177.20	178.67	N/A	
20th Percentile FDA Days to MDUFA Decision	175	176	178	0	
40th Percentile FDA Days to MDUFA Decision	178	179	179	0	
60th Percentile FDA Days to MDUFA Decision	181	179	180	0	
80th Percentile FDA Days to MDUFA Decision	186	180	180	0	
Maximum FDA Days to MDUFA Decision	191	180	180	0	
Average Industry Days to MDUFA Decision	18.67	230.20	74.67	N/A	
20th Percentile Industry Days to MDUFA Decision	11	169	64	0	
40th Percentile Industry Days to MDUFA Decision	22	206	69	0	
60th Percentile Industry Days to MDUFA Decision	28	252	76	0	
80th Percentile Industry Days to MDUFA Decision	28	314	85	0	
Maximum Industry Days to MDUFA Decision	28	354	94	0	
Average Total Days to MDUFA Decision	199.33	407.40	253.33	N/A	
20th Percentile Total Days to MDUFA Decision	187	340	241	0	
40th Percentile Total Days to MDUFA Decision	196	381	248	0	
60th Percentile Total Days to MDUFA Decision	204	431	256	0	
80th Percentile Total Days to MDUFA Decision	211	494	265	0	
Maximum Total Days to MDUFA Decision	219	532	274	0	

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

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

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

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

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	9	6	14	2	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	9	6	11	2	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	0	0	3	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	0.00%	21.43%	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 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	2	
Number Accepted	9	6	11	2	
Completed RTF	9	6	14	2	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	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	14	2	
SI Goal Met	9	6	13	1	
SI Goal Not Met	0	0	1	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	92.86%	100.00%	

Table 1.4 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	9	6	14	1	
Average Number of FDA Days to Substantive Interaction	88.78	89.33	92.64	87.00	
20th Percentile FDA Days to Substantive Interaction	88	89	87	87	
40th Percentile FDA Days to Substantive Interaction	90	89	89	87	
60th Percentile FDA Days to Substantive Interaction	90	90	90	87	
80th Percentile FDA Days to Substantive Interaction	90	90	90	87	
Maximum FDA Days to Substantive Interaction	90	90	151	87	

Table 1.5 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	9	4	14	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	9	4	6	0	
MDUFA Decision Goal Met	9	4	6	0	
PMAs Pending MDUFA Decision	0	0	8	2	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	9	4	6	0	
Average FDA Days to MDUFA Decision	179.11	156.25	179.17	N/A	
20th Percentile FDA Days to MDUFA Decision	178	141	178	0	
40th Percentile FDA Days to MDUFA Decision	179	177	180	0	
60th Percentile FDA Days to MDUFA Decision	180	179	180	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	123.56	281.50	76.17	N/A	
20th Percentile Industry Days to MDUFA Decision	0	233	19	0	
40th Percentile Industry Days to MDUFA Decision	42	351	55	0	
60th Percentile Industry Days to MDUFA Decision	60	353	98	0	
80th Percentile Industry Days to MDUFA Decision	145	358	110	0	
Maximum Industry Days to MDUFA Decision	629	365	175	0	
Average Total Days to MDUFA Decision	302.67	437.75	255.33	N/A	
20th Percentile Total Days to MDUFA Decision	180	367	196	0	
40th Percentile Total Days to MDUFA Decision	221	469	233	0	
60th Percentile Total Days to MDUFA Decision	238	515	278	0	
80th Percentile Total Days to MDUFA Decision	325	530	290	0	
Maximum Total Days to MDUFA Decision	809	530	355	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	1	0	0	
Average FDA Days to MDUFA Decision	N/A	320.00	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	320	0	0	
40th Percentile FDA Days to MDUFA Decision	0	320	0	0	
60th Percentile FDA Days to MDUFA Decision	0	320	0	0	
80th Percentile FDA Days to MDUFA Decision	0	320	0	0	
Maximum FDA Days to MDUFA Decision	0	320	0	0	
Average Industry Days to MDUFA Decision	N/A	358.00	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	358	0	0	
40th Percentile Industry Days to MDUFA Decision	0	358	0	0	
60th Percentile Industry Days to MDUFA Decision	0	358	0	0	
80th Percentile Industry Days to MDUFA Decision	0	358	0	0	
Maximum Industry Days to MDUFA Decision	0	358	0	0	
Average Total Days to MDUFA Decision	N/A	678.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	678	0	0	
40th Percentile Total Days to MDUFA Decision	0	678	0	0	
60th Percentile Total Days to MDUFA Decision	0	678	0	0	
80th Percentile Total Days to MDUFA Decision	0	678	0	0	
Maximum Total Days to MDUFA Decision	0	678	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	9	4	14	2	
Number with MDUFA Decision	9	4	6	0	
Number of Withdrawal	0	0	0	0	
Number of Not Approvable	2	1	0	0	
Number of Deleted	0	1	0	0	
Rate of Withdrawal	0.00%	0.00%	0.00%	N/A	
Rate of Not Approvable	22.22%	25.00%	0.00%	N/A	

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6	7	6	5	
Number Accepted	5	6	5	5	
Completed RTF	6	7	6	5	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	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	6	5	
SI Goal Met	5	7	6	3	
SI Goal Not Met	1	0	0	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	83.33%	100.00%	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	6	3	
Average Number of FDA Days to Substantive Interaction	88.50	86.43	89.00	88.67	
20th Percentile FDA Days to Substantive Interaction	88	86	88	88	
40th Percentile FDA Days to Substantive Interaction	90	89	89	88	
60th Percentile FDA Days to Substantive Interaction	90	90	89	88	
80th Percentile FDA Days to Substantive Interaction	90	90	90	89	
Maximum FDA Days to Substantive Interaction	91	90	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 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	7	6	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	7	5	0	
MDUFA Decision Goal Met	6	7	5	0	
PMAs Pending MDUFA Decision	0	0	1	5	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	6	7	5	0	
Average FDA Days to MDUFA Decision	175.33	165.14	179.60	N/A	
20th Percentile FDA Days to MDUFA Decision	179	176	179	0	
40th Percentile FDA Days to MDUFA Decision	180	177	180	0	
60th Percentile FDA Days to MDUFA Decision	180	178	180	0	
80th Percentile FDA Days to MDUFA Decision	180	179	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	55.17	133.57	140.00	N/A	
20th Percentile Industry Days to MDUFA Decision	0	43	98	0	
40th Percentile Industry Days to MDUFA Decision	37	84	121	0	
60th Percentile Industry Days to MDUFA Decision	71	114	136	0	
80th Percentile Industry Days to MDUFA Decision	101	223	157	0	
Maximum Industry Days to MDUFA Decision	122	355	239	0	
Average Total Days to MDUFA Decision	230.50	298.71	319.60	N/A	
20th Percentile Total Days to MDUFA Decision	180	221	278	0	
40th Percentile Total Days to MDUFA Decision	217	261	301	0	
60th Percentile Total Days to MDUFA Decision	251	292	315	0	
80th Percentile Total Days to MDUFA Decision	281	330	337	0	
Maximum Total Days to MDUFA Decision	301	534	419	0	

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	6	7	6	5	
Number with MDUFA Decision	6	7	5	0	
Number of Withdrawal	0	1	0	0	
Number of Not Approvable	1	2	0	0	
Number of Deleted	0	0	0	0	
Rate of Withdrawal	0.00%	14.29%	0.00%	N/A	
Rate of Not Approvable	16.67%	28.57%	0.00%	N/A	

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3	4	2	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	4	3	4	2	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	0	
Number Not Accepted for Filing Review on First Cycle	1	0	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	20.00%	0.00%	0.00%	0.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	5	3	4	2	
Number Accepted	4	3	4	2	
Completed RTF	5	3	4	2	
Number Not Filed	0	0	0	0	
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	

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

Substantive Interaction (SI) Goal	FY 2023 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	2	
SI Goal Met	5	3	4	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	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	4	1	
Average Number of FDA Days to Substantive Interaction	85.40	88.00	84.00	86	
20th Percentile FDA Days to Substantive Interaction	84	87	81	89	
40th Percentile FDA Days to Substantive Interaction	86	87	84	89	
60th Percentile FDA Days to Substantive Interaction	87	88	85	89	
80th Percentile FDA Days to Substantive Interaction	88	89	87	89	
Maximum FDA Days to Substantive Interaction	88	90	88	89	

Table 1.5 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

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

Table 1.6 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

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

Table 1.7 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	5	3	4	0	
Average FDA Days to MDUFA Decision	173.80	179.33	159.50	N/A	
20th Percentile FDA Days to MDUFA Decision	169	179	148	0	
40th Percentile FDA Days to MDUFA Decision	175	180	176	0	
60th Percentile FDA Days to MDUFA Decision	178	180	177	0	
80th Percentile FDA Days to MDUFA Decision	179	180	178	0	
Maximum FDA Days to MDUFA Decision	180	180	178	0	
Average Industry Days to MDUFA Decision	194.80	169.00	56.50	N/A	
20th Percentile Industry Days to MDUFA Decision	77	144	0	0	
40th Percentile Industry Days to MDUFA Decision	142	145	7	0	
60th Percentile Industry Days to MDUFA Decision	243	160	28	0	
80th Percentile Industry Days to MDUFA Decision	351	189	97	0	
Maximum Industry Days to MDUFA Decision	356	218	191	0	
Average Total Days to MDUFA Decision	368.60	348.33	216.00	N/A	
20th Percentile Total Days to MDUFA Decision	241	323	150	0	
40th Percentile Total Days to MDUFA Decision	309	324	184	0	
60th Percentile Total Days to MDUFA Decision	417	340	204	0	
80th Percentile Total Days to MDUFA Decision	530	369	274	0	
Maximum Total Days to MDUFA Decision	536	398	369	0	

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

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

Table 1.9 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

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

Table 1.10 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

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

Table 1.11 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

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

Table 1.12 OHT6 - Office of Orthopedic Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	25	17	
Number Closed Before First RTA Action	0	0	0	0	
Number Accepted First RTA Review	21	14	25	14	
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	3	
Number Not Accepted for Filing Review on First Cycle	0	2	0	0	
Rate of Submissions Not Accepted for Filing Review on First Cycle	0.00%	12.50%	0.00%	0.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	21	16	25	17	
Number Accepted	21	14	25	14	
Completed RTF	21	15	25	13	
Number Not Filed	1	0	0	0	
Rate of Submissions Not Filed	4.76%	0.00%	0.00%	0.00%	

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

Substantive Interaction (SI) Goal	FY 2023 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	25	13	
SI Goal Met	21	15	25	6	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	7	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	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	25	6	
Average Number of FDA Days to Substantive Interaction	88.14	88.60	83.36	89.50	
20th Percentile FDA Days to Substantive Interaction	87	88	83	89	
40th Percentile FDA Days to Substantive Interaction	87	89	87	90	
60th Percentile FDA Days to Substantive Interaction	89	89	89	90	
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	
Maximum FDA Days to Substantive Interaction	90	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 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	20	15	25	13	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	20	15	17	0	
MDUFA Decision Goal Met	20	15	17	0	
PMAs Pending MDUFA Decision	0	0	8	13	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 1.6 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

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

Table 1.7 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	20	15	17	0	
Average FDA Days to MDUFA Decision	163.30	161.40	156.76	N/A	
20th Percentile FDA Days to MDUFA Decision	136	150	139	0	
40th Percentile FDA Days to MDUFA Decision	178	177	176	0	
60th Percentile FDA Days to MDUFA Decision	179	180	178	0	
80th Percentile FDA Days to MDUFA Decision	180	180	180	0	
Maximum FDA Days to MDUFA Decision	180	180	180	0	
Average Industry Days to MDUFA Decision	162.25	152.33	46.29	N/A	
20th Percentile Industry Days to MDUFA Decision	0	23	0	0	
40th Percentile Industry Days to MDUFA Decision	68	59	0	0	
60th Percentile Industry Days to MDUFA Decision	236	138	47	0	
80th Percentile Industry Days to MDUFA Decision	322	352	90	0	
Maximum Industry Days to MDUFA Decision	354	368	241	0	
Average Total Days to MDUFA Decision	325.55	313.73	203.06	N/A	
20th Percentile Total Days to MDUFA Decision	179	202	176	0	
40th Percentile Total Days to MDUFA Decision	247	226	178	0	
60th Percentile Total Days to MDUFA Decision	364	318	217	0	
80th Percentile Total Days to MDUFA Decision	502	459	261	0	
Maximum Total Days to MDUFA Decision	534	532	290	0	

Table 1.8 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

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

Table 1.9 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	20	15	25	13	
Number with MDUFA Decision	20	15	17	0	
Number of Withdrawal	1	1	1	0	
Number of Not Approvable	3	1	0	0	
Number of Deleted	0	2	0	0	
Rate of Withdrawal	5.00%	6.67%	5.88%	N/A	
Rate of Not Approvable	15.00%	6.67%	0.00%	N/A	

Table 1.10 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

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

Table 1.11 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

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

Table 1.12 OHT7 - Office of In Vitro Diagnostics
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

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

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

Performance Metric	FY 2023 90% Within 180 FDA Days	FY 2024 90% Within 180 FDA Days	FY 2025 90% Within 180 FDA Days	FY 2026 90% Within 180 FDA Days	FY 2027 90% Within 180 FDA Days
Number of PMAs Filed	6	5	6	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	5	4	0	
MDUFA Decision Goal Met	6	5	4	0	
PMAs Pending MDUFA Decision	0	0	2	0	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

***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	19	13	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	10	13	0	
MDUFA Decision Goal Met	15	10	13	0	
PMAs Pending MDUFA Decision	0	0	6	13	
PMAs Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

***Includes submission that went to panel**

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

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

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

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

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

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

Substantive Interaction (SI) Goal	FY 2023 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	0	
SI Goal Met	0	3	0	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	N/A	100.00%	N/A	N/A	

Table 1.4 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

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

Table 1.5 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal

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

Table 1.6 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Decision Performance Goal

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

Table 1.7 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	0	2	0	0	
Average FDA Days to MDUFA Decision	N/A	177.50	N/A	N/A	
20th Percentile FDA Days to MDUFA Decision	0	176	0	0	
40th Percentile FDA Days to MDUFA Decision	0	177	0	0	
60th Percentile FDA Days to MDUFA Decision	0	178	0	0	
80th Percentile FDA Days to MDUFA Decision	0	179	0	0	
Maximum FDA Days to MDUFA Decision	0	180	0	0	
Average Industry Days to MDUFA Decision	N/A	342.50	N/A	N/A	
20th Percentile Industry Days to MDUFA Decision	0	334	0	0	
40th Percentile Industry Days to MDUFA Decision	0	340	0	0	
60th Percentile Industry Days to MDUFA Decision	0	345	0	0	
80th Percentile Industry Days to MDUFA Decision	0	351	0	0	
Maximum Industry Days to MDUFA Decision	0	357	0	0	
Average Total Days to MDUFA Decision	N/A	520.00	N/A	N/A	
20th Percentile Total Days to MDUFA Decision	0	513	0	0	
40th Percentile Total Days to MDUFA Decision	0	518	0	0	
60th Percentile Total Days to MDUFA Decision	0	522	0	0	
80th Percentile Total Days to MDUFA Decision	0	527	0	0	
Maximum Total Days to MDUFA Decision	0	532	0	0	

Table 1.8 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to MDUFA V Decision

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

Table 1.9 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

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

Table 1.10 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) MDUFA V Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

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

Table 1.11 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0	1	0	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	187.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	360.00	N/A	N/A	

Table 1.12 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal

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

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

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

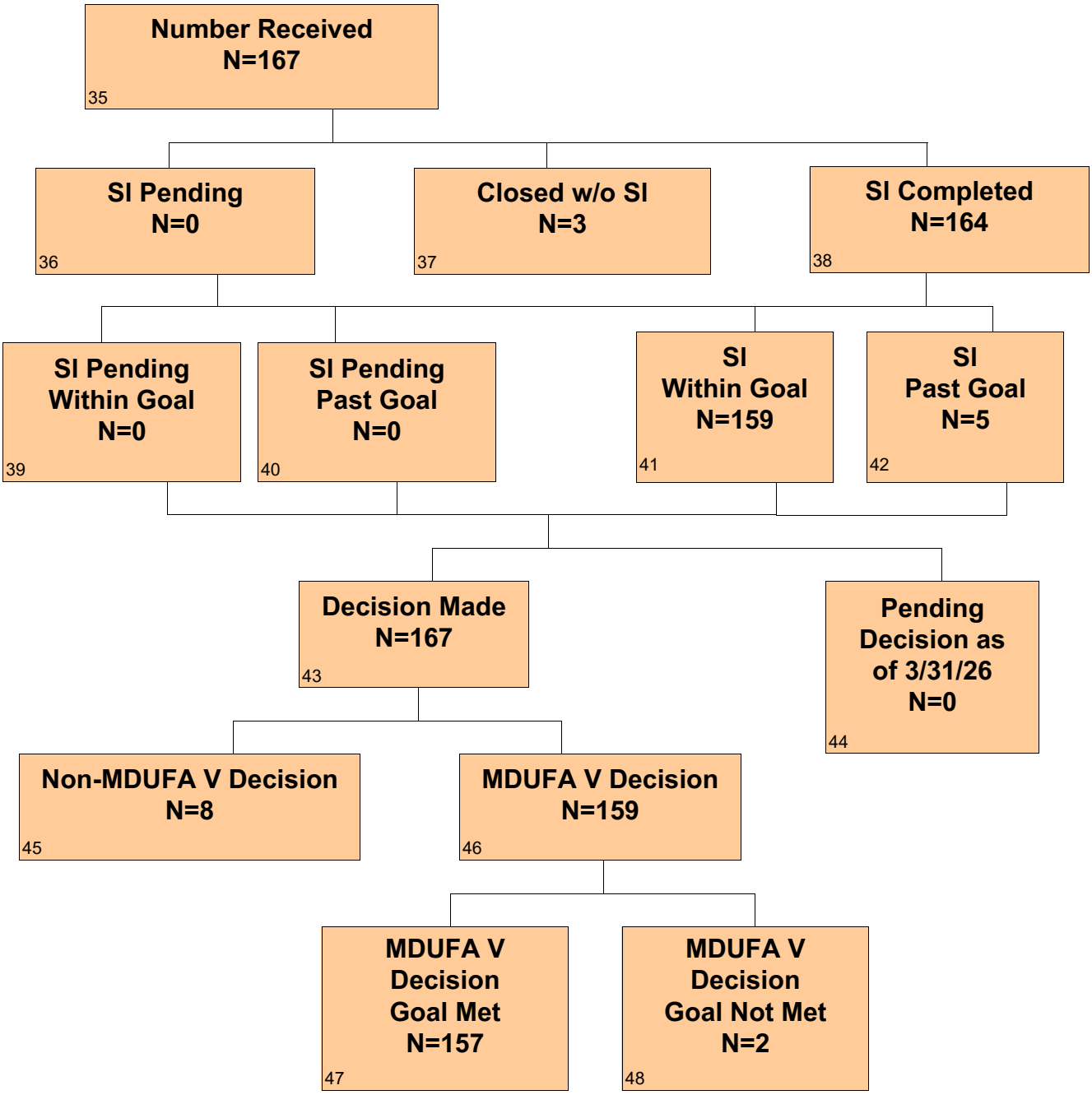
***Includes submission that went to panel**

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

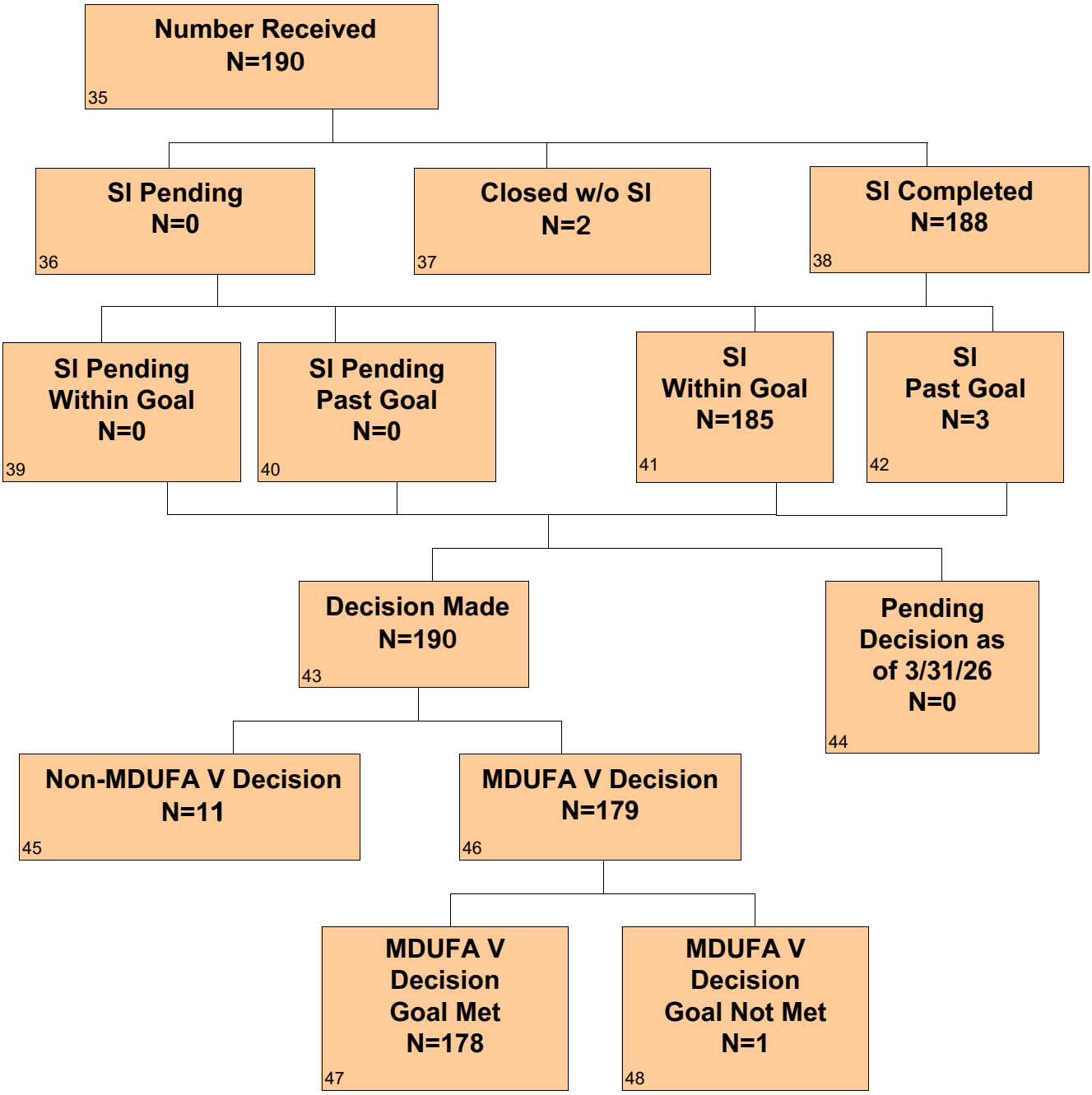
Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Goal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

***Includes submission that went to panel**

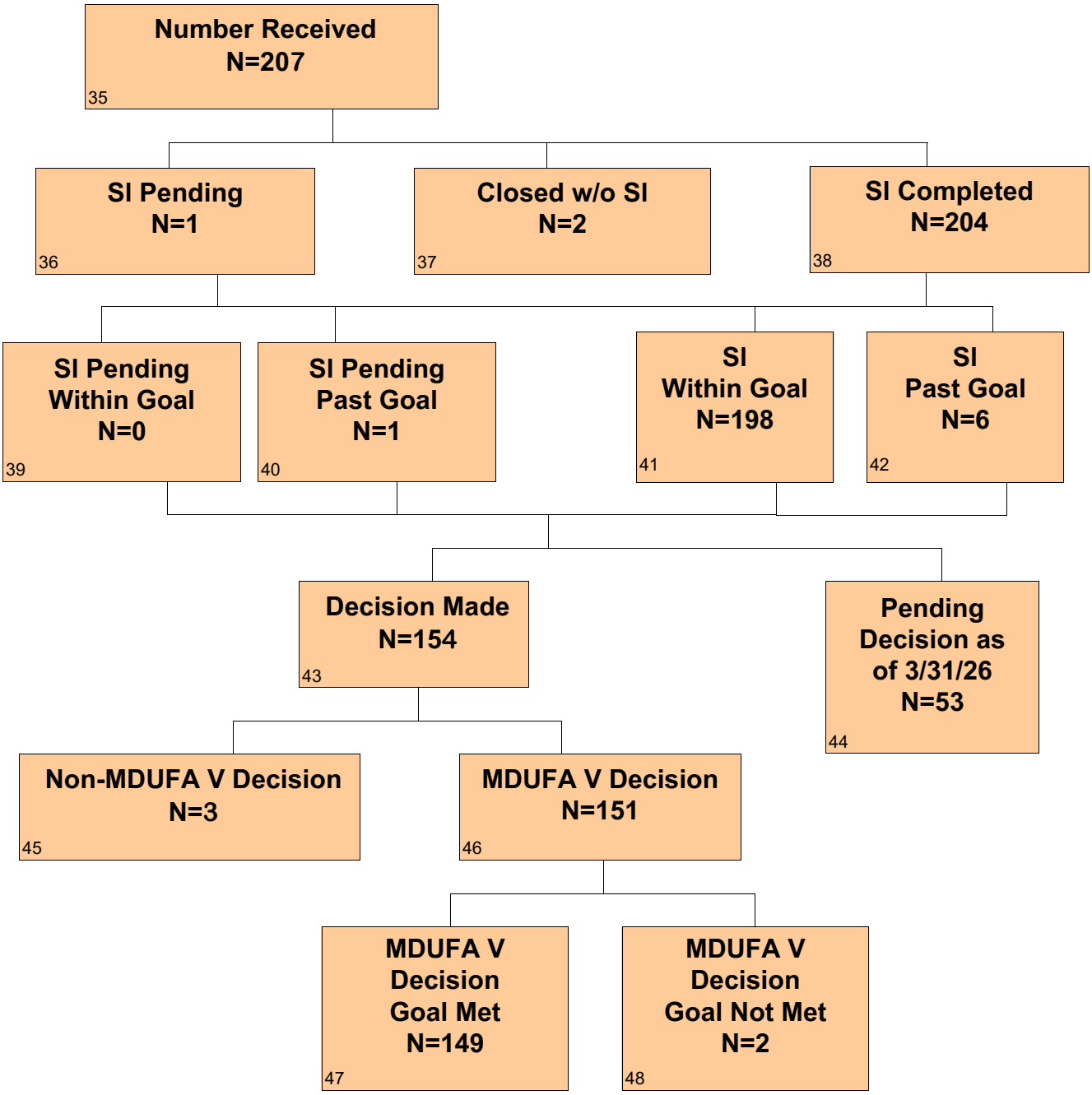
CDRH PMA 180 Day Supplements - FY 2023 as of 3/31/26



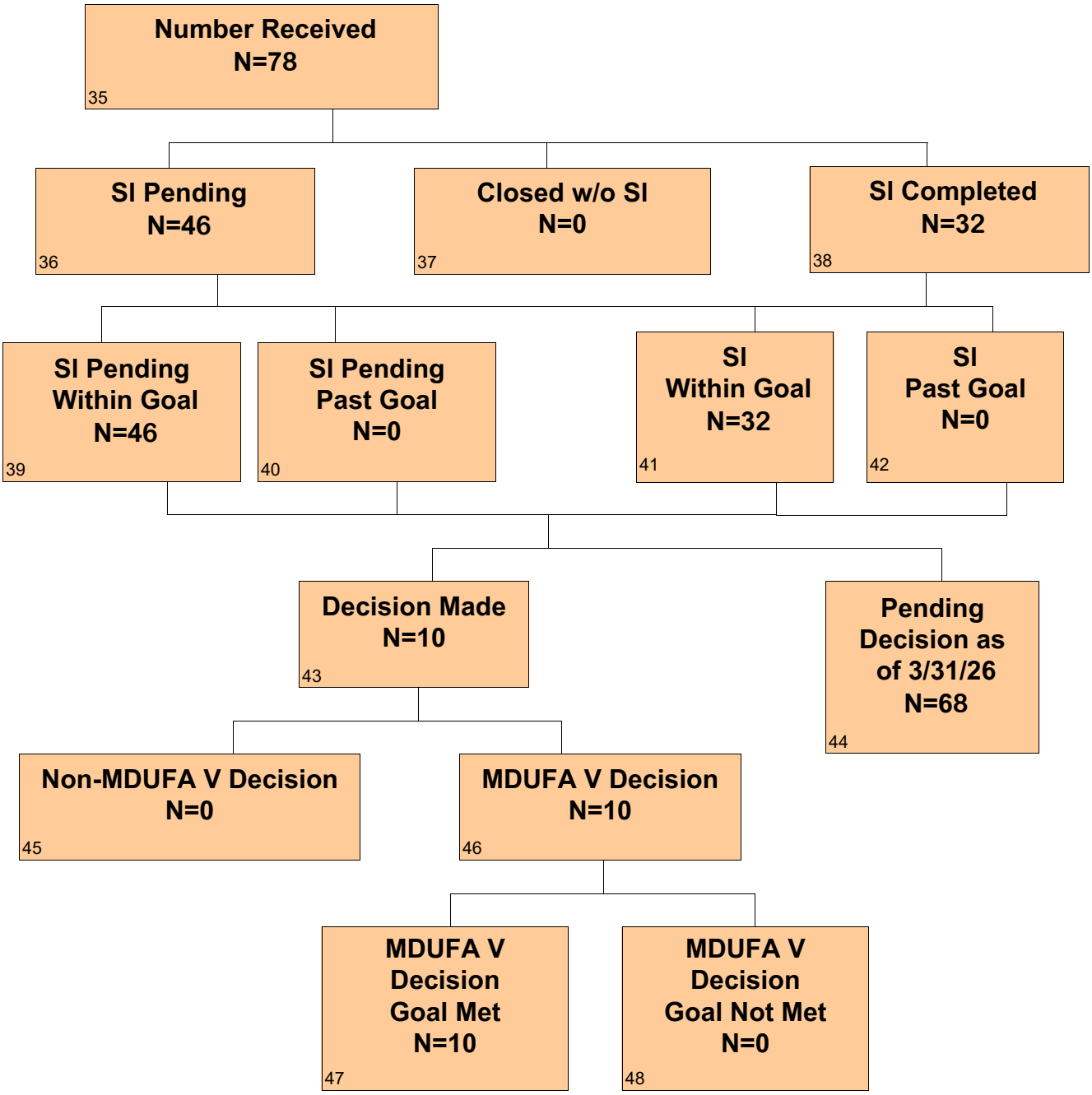
CDRH PMA 180 Day Supplements - FY 2024 as of 3/31/26



CDRH PMA 180 Day Supplements - FY 2025 as of 3/31/26



CDRH PMA 180 Day Supplements - FY 2026 as of 3/31/26



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	78	
SI Goal Met	159	185	198	32	
SI Goal Not Met	5	3	6	0	
SI Pending Within Goal	0	0	0	46	
SI Pending Past Goal	0	0	1	0	
Closed Without SI	3	2	2	0	
Current SI Performance Percent Goal Met	96.95%	98.40%	96.59%	100.00%	

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	78	
Non-MDUFA Decision	8	11	3	0	
MDUFA Decision	159	179	151	10	
MDUFA Decision Goal Met	157	178	149	10	
Supplements Pending MDUFA Decision	0	0	53	68	
Supplements Pending MDUFA Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	98.74%	99.44%	98.03%	100.00%	

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	78	
Number with MDUFA Decision	159	179	151	10	
Number of Not Approvable	7	15	9	0	
Rate of Not Approvable	4.40%	8.38%	5.96%	0.00%	

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

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

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	16	15	21	11	
SI Goal Met	16	15	2	2	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	9	9	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	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	11	
Non-MDUFA Decision	1	2	0	0	
MDUFA Decision	15	13	13	1	
MDUFA Decision Goal Met	15	13	13	1	
Supplements Pending MDUFA Decision	0	0	8	10	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	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	11	
Number with MDUFA Decision	15	13	13	1	
Number of Not Approvable	1	1	2	0	
Rate of Not Approvable	6.67%	7.69%	15.38%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	56	81	77	38	
SI Goal Met	55	80	71	19	
SI Goal Not Met	0	0	3	0	
SI Pending Within Goal	0	0	0	19	
SI Pending Past Goal	0	0	1	0	
Closed Without SI	1	1	2	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	94.67%	100.00%	

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	38	
Non-MDUFA Decision	3	6	2	0	
MDUFA Decision	53	75	60	7	
MDUFA Decision Goal Met	53	75	59	7	
Supplements Pending MDUFA Decision	0	0	15	31	
Supplements Pending MDUFA Decision Past Goal	0	0	1	0	
Current Performance Percent Goal Met	100.00%	100.00%	96.72%	100.00%	

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	38	
Number with MDUFA Decision	53	75	60	7	
Number of Not Approvable	1	12	1	0	
Rate of Not Approvable	1.89%	16.00%	1.67%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	187.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00	N/A	

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	21	17	19	7	
SI Goal Met	20	17	18	5	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	95.24%	100.00%	94.74%	100.00%	

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	7	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	21	17	16	1	
MDUFA Decision Goal Met	21	17	15	1	
Supplements Pending MDUFA Decision	0	0	3	6	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	93.75%	100.00%	

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	7	
Number with MDUFA Decision	21	17	16	1	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	182.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	0.00	N/A	

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	8	12	13	2	
SI Goal Met	8	12	13	0	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	2	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	8	12	13	2	
Non-MDUFA Decision	0	1	0	0	
MDUFA Decision	8	11	6	0	
MDUFA Decision Goal Met	8	11	6	0	
Supplements Pending MDUFA Decision	0	0	7	2	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 2.3 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	2	
Number with MDUFA Decision	8	11	6	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	23	20	31	5	
SI Goal Met	20	17	30	2	
SI Goal Not Met	3	3	1	0	
SI Pending Within Goal	0	0	0	3	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	86.96%	85.00%	96.77%	100.00%	

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	5	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	23	20	24	1	
MDUFA Decision Goal Met	21	19	24	1	
Supplements Pending MDUFA Decision	0	0	6	4	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	91.30%	95.00%	100.00%	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	5	
Number with MDUFA Decision	23	20	24	1	
Number of Not Approvable	3	1	4	0	
Rate of Not Approvable	13.04%	5.00%	16.67%	0.00%	

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	6	5	11	2	
SI Goal Met	6	5	11	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	1	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	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	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	6	5	6	0	
MDUFA Decision Goal Met	6	5	6	0	
Supplements Pending MDUFA Decision	0	0	5	2	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

Table 2.3 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	2	
Number with MDUFA Decision	6	5	6	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	

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

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 90 FDA Days	FY 2024 95% SI Within 90 FDA Days	FY 2025 95% SI Within 90 FDA Days	FY 2026 95% SI Within 90 FDA Days	FY 2027 95% SI Within 90 FDA Days
Eligible for SI	36	38	34	12	
SI Goal Met	33	37	33	2	
SI Goal Not Met	1	0	1	0	
SI Pending Within Goal	0	0	0	10	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	2	1	0	0	
Current SI Performance Percent Goal Met	97.06%	100.00%	97.06%	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	12	
Non-MDUFA Decision	4	2	0	0	
MDUFA Decision	32	36	25	0	
MDUFA Decision Goal Met	32	36	25	0	
Supplements Pending MDUFA Decision	0	0	9	12	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	36	38	34	12	
Number with MDUFA Decision	32	36	25	0	
Number of Not Approvable	2	1	2	0	
Rate of Not Approvable	6.25%	2.78%	8.00%	N/A	

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

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

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

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

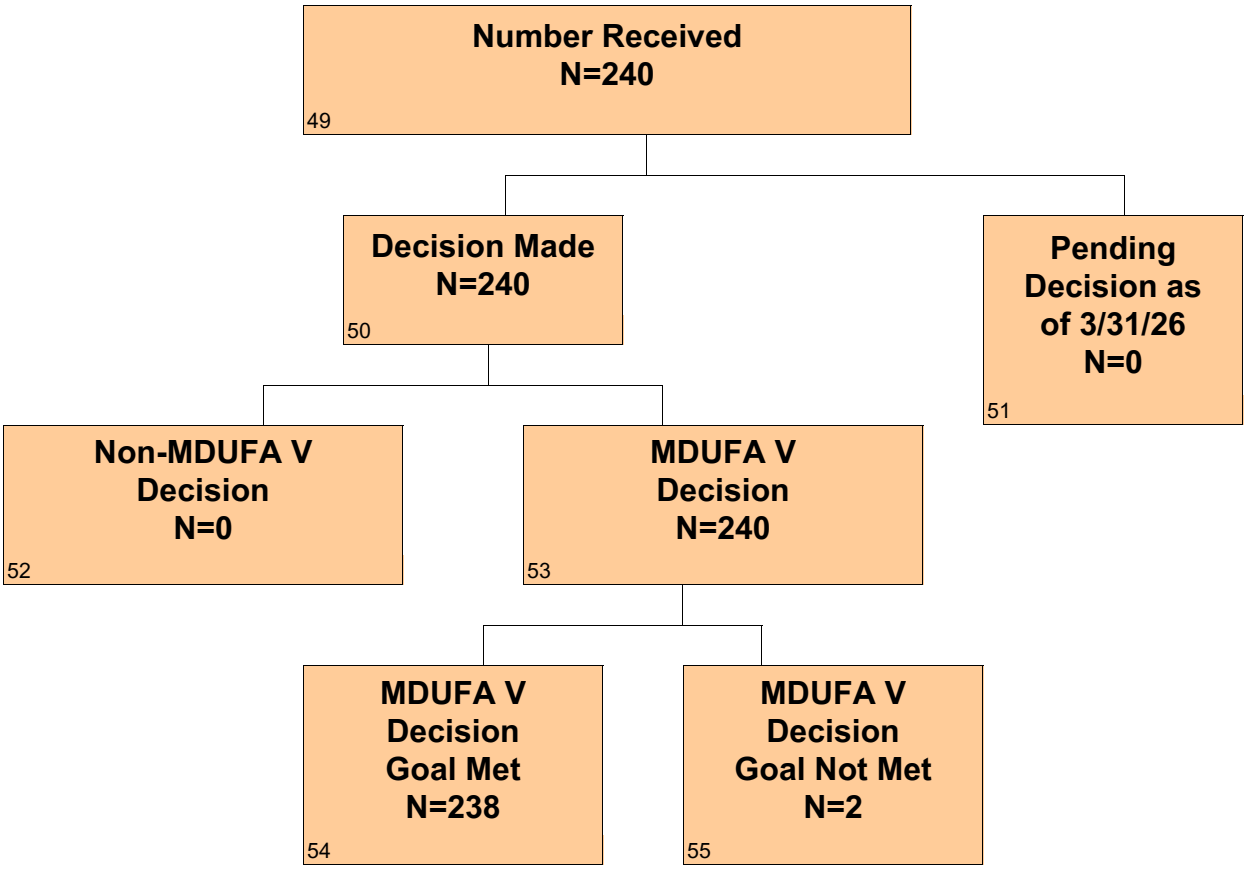
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

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

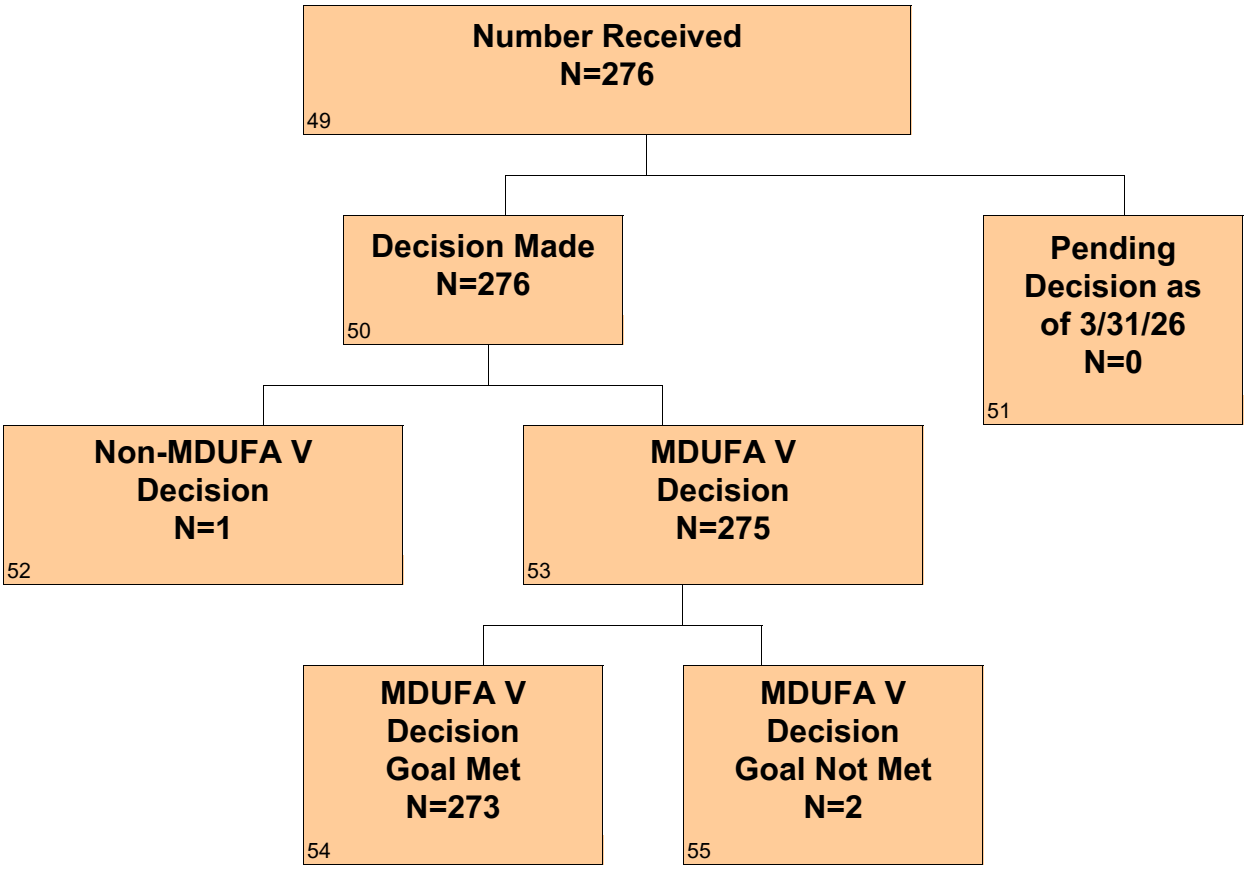
Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal

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

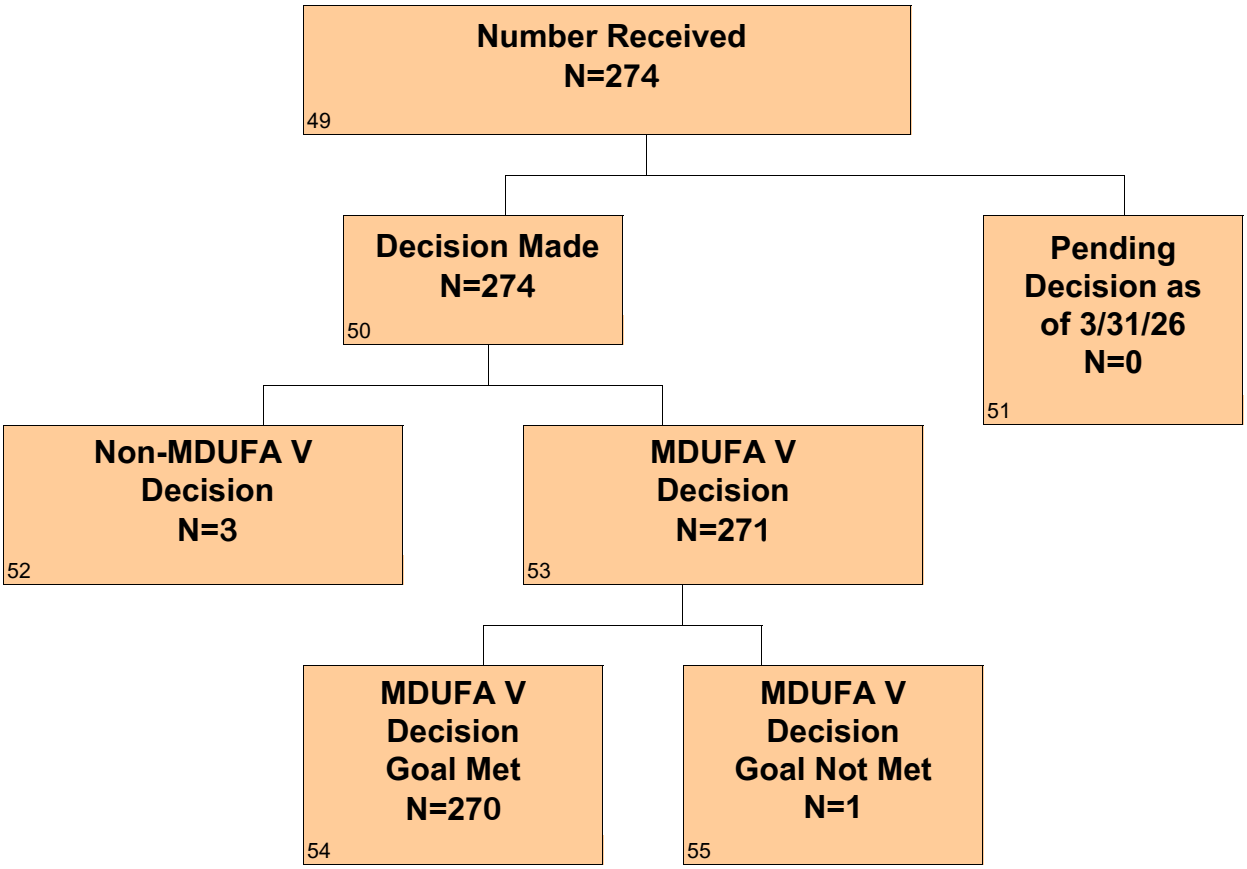
CDRH PMA Real Time Supplements - FY 2023 as of 3/31/26



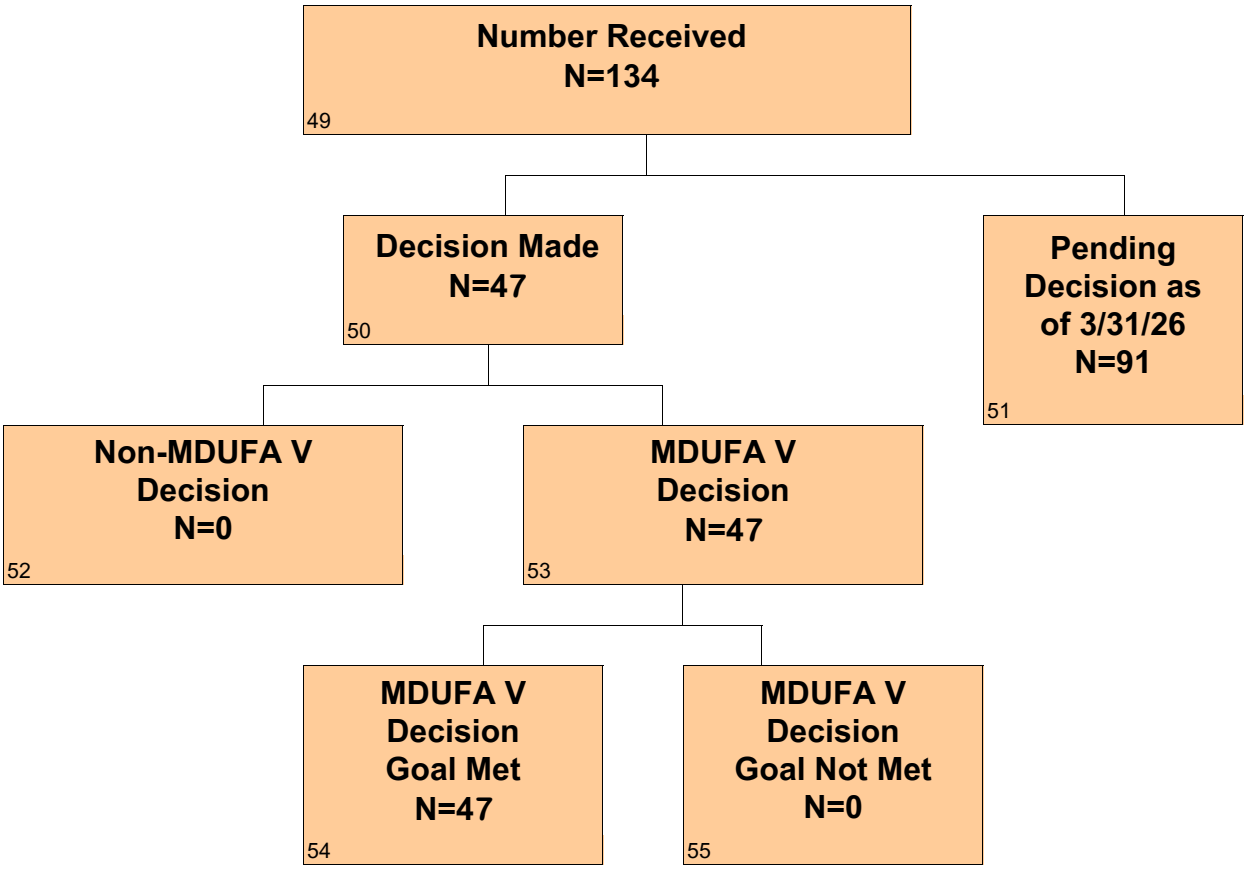
CDRH PMA Real Time Supplements - FY 2024 as of 3/31/26



CDRH PMA Real Time Supplements - FY 2025 as of 3/31/26



CDRH PMA Real Time Supplements - FY 2026 as of 3/31/26



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	134	
Non-MDUFA Decision	0	1	3	0	
MDUFA Decision	240	275	271	47	
MDUFA Decision Goal Met	238	273	270	47	
Supplements Pending MDUFA Decision	0	0	0	87	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	99.17%	99.27%	99.63%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	240	276	274	134	
Number With MDUFA Decision	240	275	271	47	
Number of Not Approvable	11	10	20	10	
Rate of Not Approvable	4.58%	3.64%	7.38%	21.28%	

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

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

Section 3 PMA Real-Time Supplements - Office Level Metric

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	24	19	27	9	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	24	19	26	4	
MDUFA Decision Goal Met	24	19	26	4	
Supplements Pending MDUFA Decision	0	0	0	5	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	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	9	
Number With MDUFA Decision	24	19	26	4	
Number of Not Approvable	3	2	1	1	
Rate of Not Approvable	12.50%	10.53%	3.85%	25.00%	

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	136	142	125	81	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	136	142	124	20	
MDUFA Decision Goal Met	136	142	123	20	
Supplements Pending MDUFA Decision	0	0	0	61	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	99.19%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	136	142	125	81	
Number With MDUFA Decision	136	142	124	20	
Number of Not Approvable	4	1	12	3	
Rate of Not Approvable	2.94%	0.70%	9.68%	15.00%	

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	19	23	17	9	
Non-MDUFA Decision	0	1	0	0	
MDUFA Decision	19	22	17	8	
MDUFA Decision Goal Met	18	21	17	8	
Supplements Pending MDUFA Decision	0	0	0	1	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	94.74%	95.45%	100.00%	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	9	
Number With MDUFA Decision	19	22	17	8	
Number of Not Approvable	2	4	2	2	
Rate of Not Approvable	10.53%	18.18%	11.76%	25.00%	

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	7	10	10	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	7	10	10	2	
MDUFA Decision Goal Met	7	10	10	2	
Supplements Pending MDUFA Decision	0	0	0	1	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

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

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

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	16	37	50	14	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	16	37	50	8	
MDUFA Decision Goal Met	15	36	50	8	
Supplements Pending MDUFA Decision	0	0	0	6	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	93.75%	97.30%	100.00%	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	14	
Number With MDUFA Decision	16	37	50	8	
Number of Not Approvable	0	1	2	1	
Rate of Not Approvable	0.00%	2.70%	4.00%	12.50%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	127.00	148.00	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	N/A	N/A	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	4	11	0	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	4	11	0	0	
MDUFA Decision Goal Met	4	11	0	0	
Supplements Pending MDUFA Decision	0	0	0	2	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	N/A	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	11	0	2	
Number With MDUFA Decision	4	11	0	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0.00%	0.00%	N/A	N/A	

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	32	33	45	16	
Non-MDUFA Decision	0	0	1	0	
MDUFA Decision	32	33	44	5	
MDUFA Decision Goal Met	32	33	44	5	
Supplements Pending MDUFA Decision	0	0	0	11	
Supplements Pending MDUFA Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	

Table 3.2 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	16	
Number With MDUFA Decision	32	33	44	5	
Number of Not Approvable	0	1	0	3	
Rate of Not Approvable	0.00%	3.03%	0.00%	60.00%	

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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

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

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

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

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

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

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

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between January 1, 2026 and March 31, 2026.

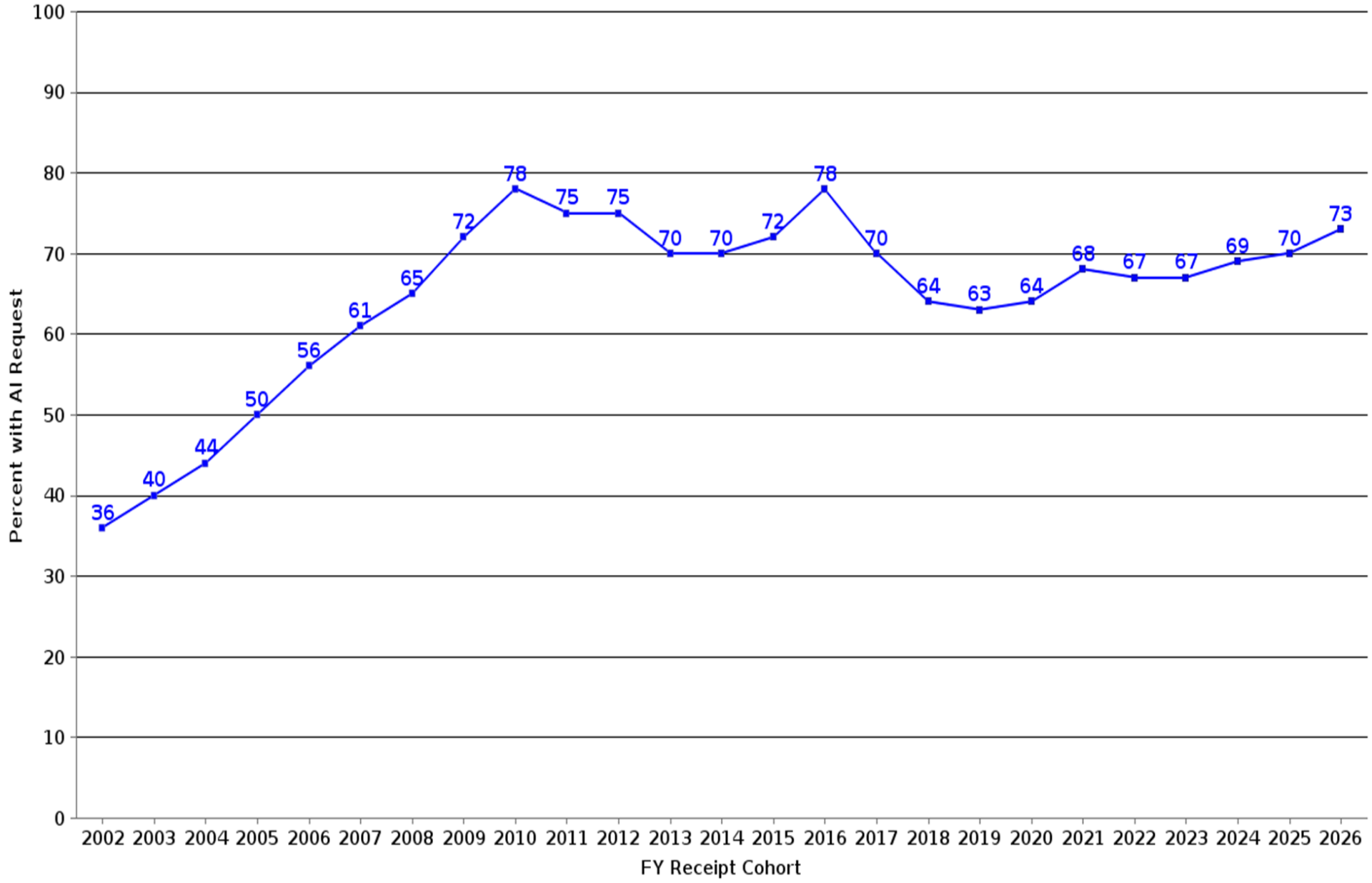
Section 5 PMA Annual Metrics and Goals

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

510(k)s

Q2FY2026

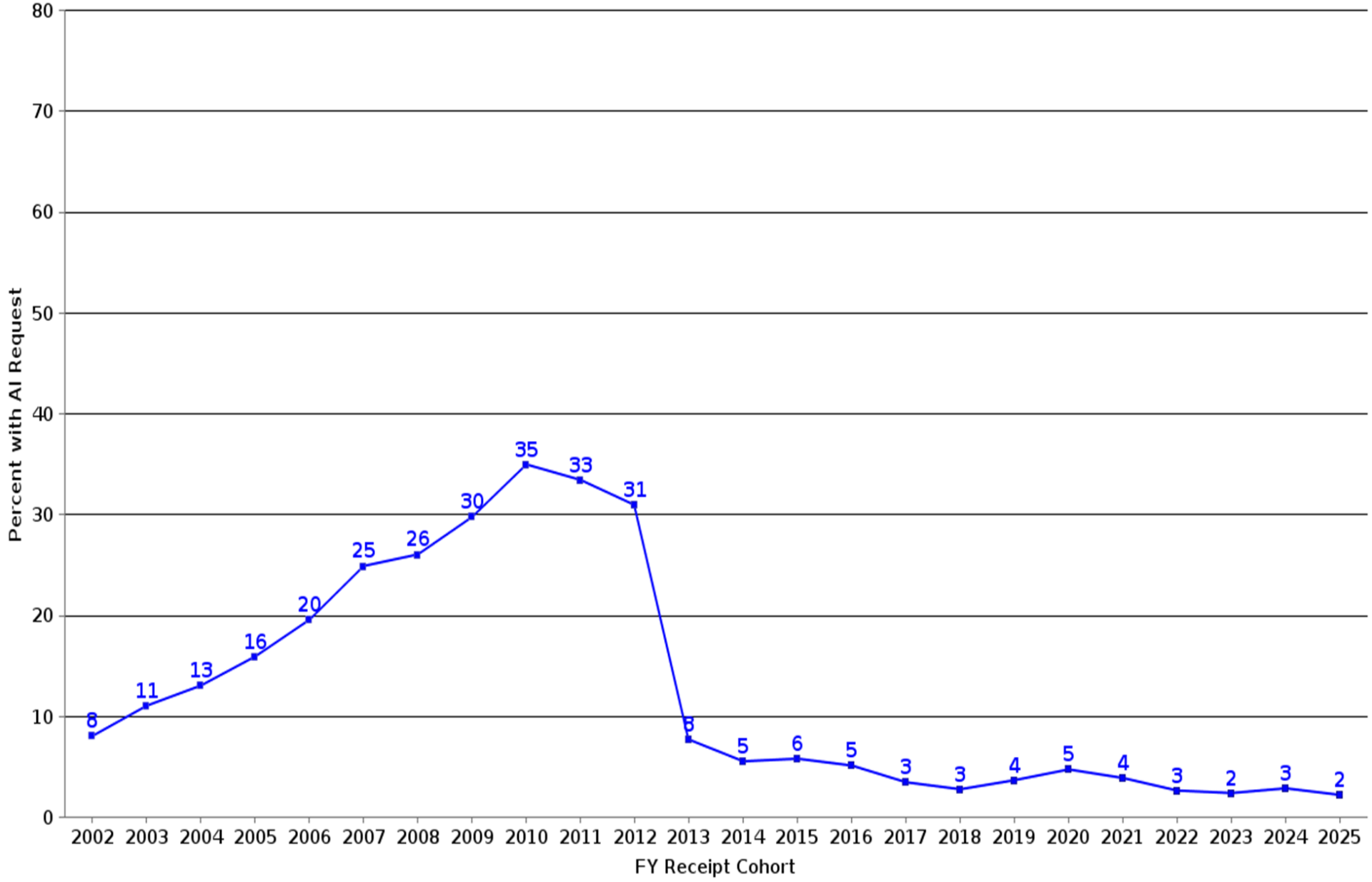
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 1/31/26

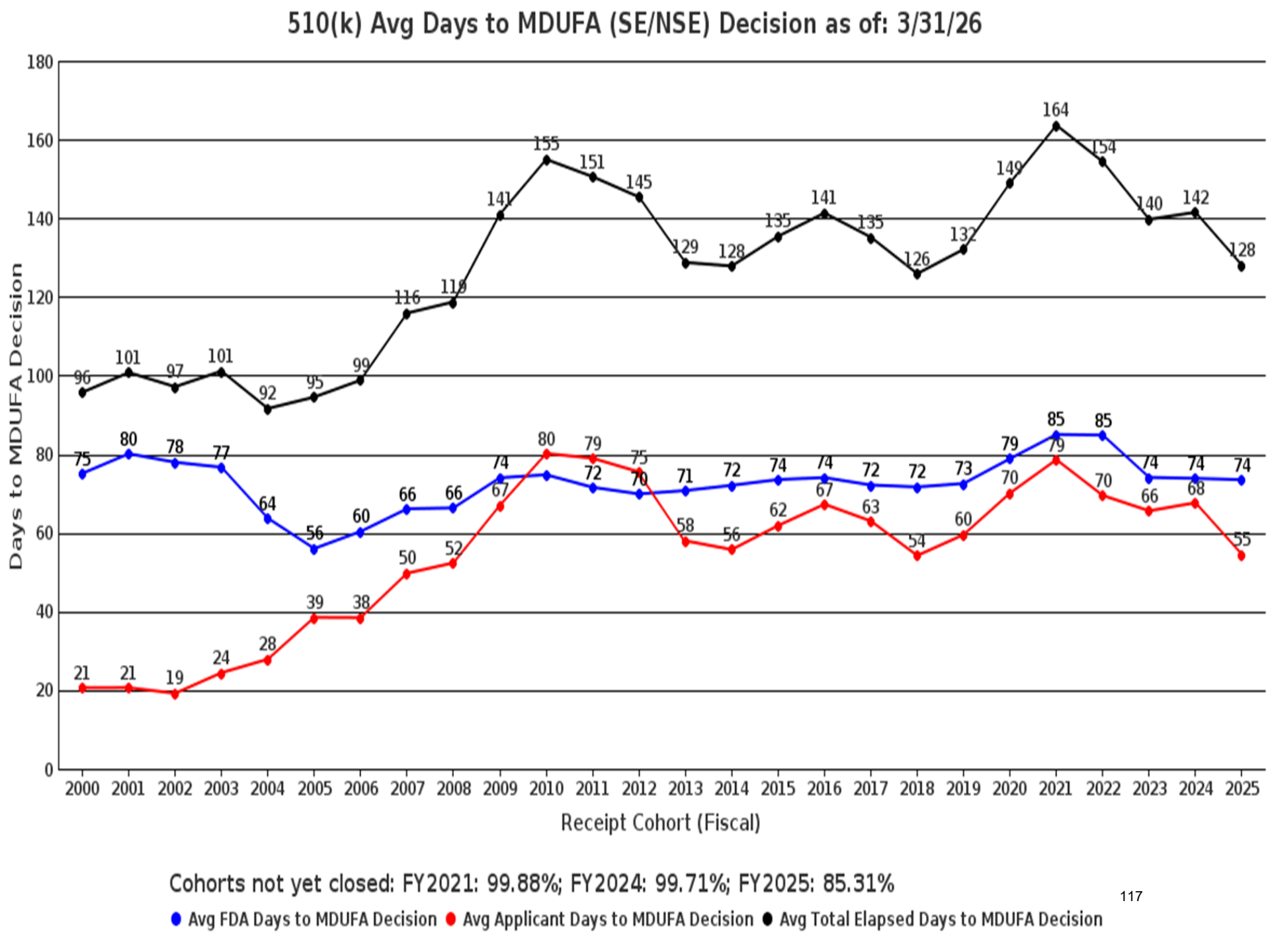
■ % with 1st Cycle AI Request

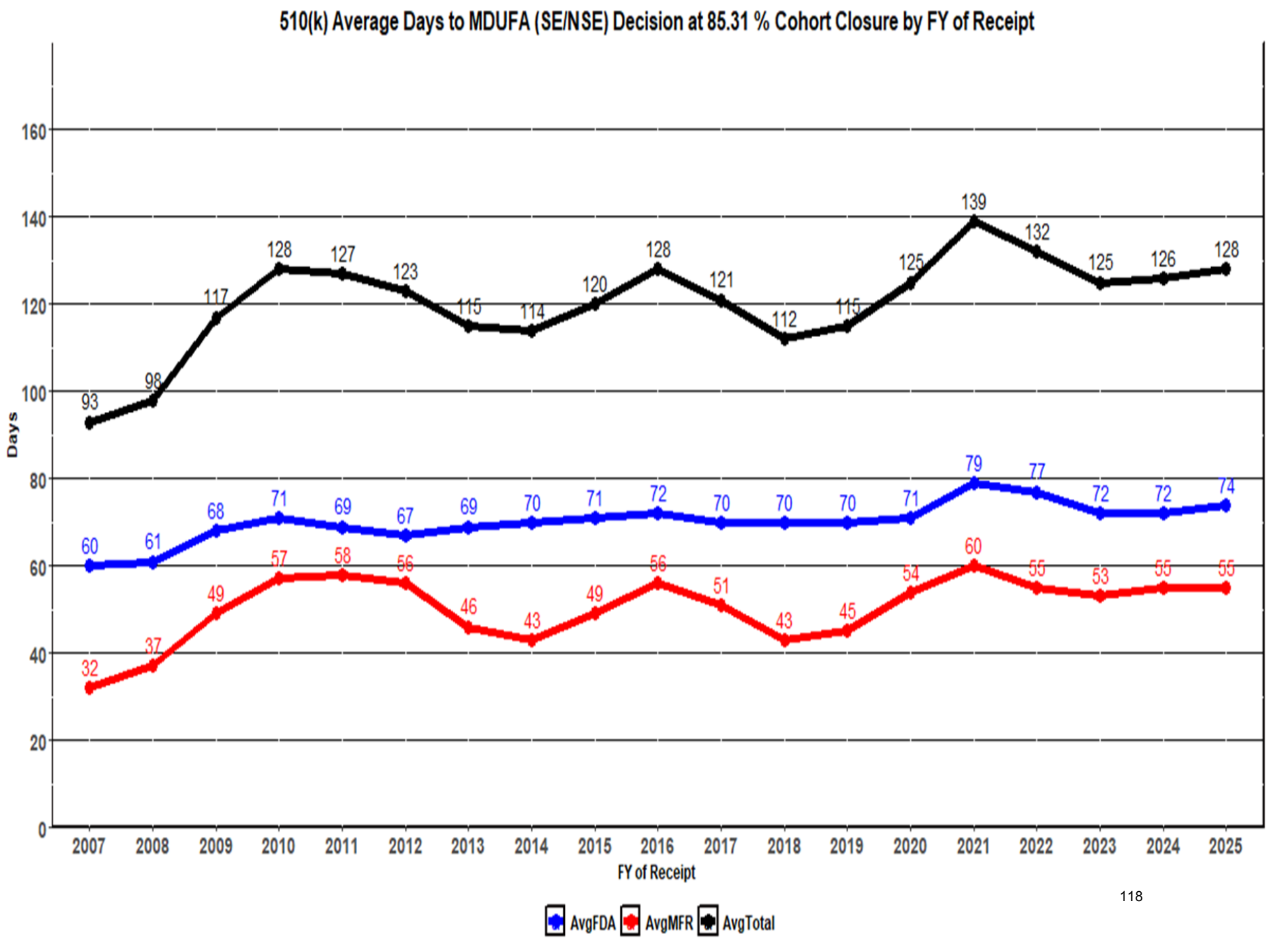
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 8/31/25

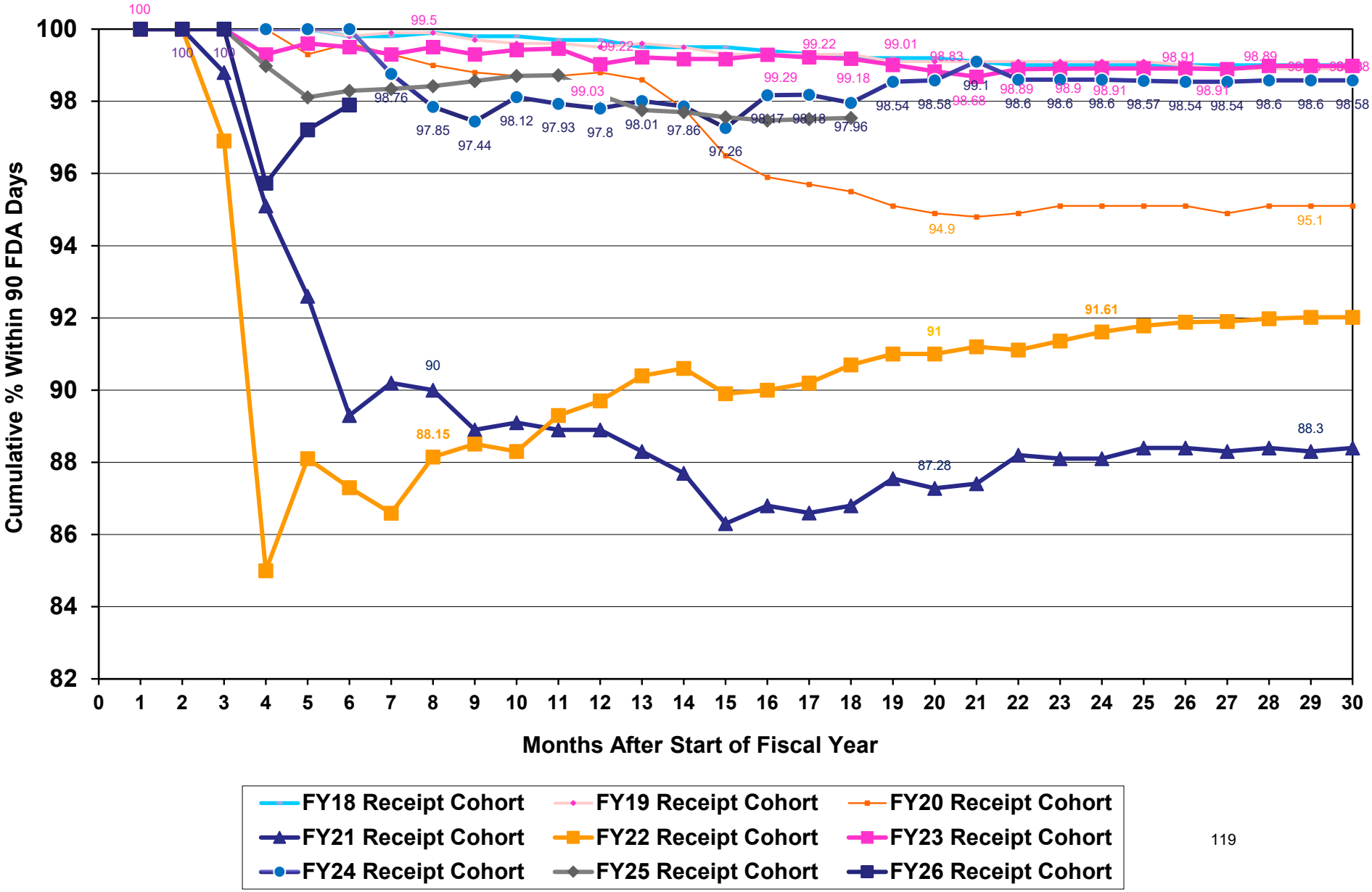
■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 3/31/26
Days to MDUFA Decision
Receipt Cohort (Fiscal)
Cohorts not yet closed: FY2021: 99.88%; FY2024: 99.71%; FY2025: 85.31%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision

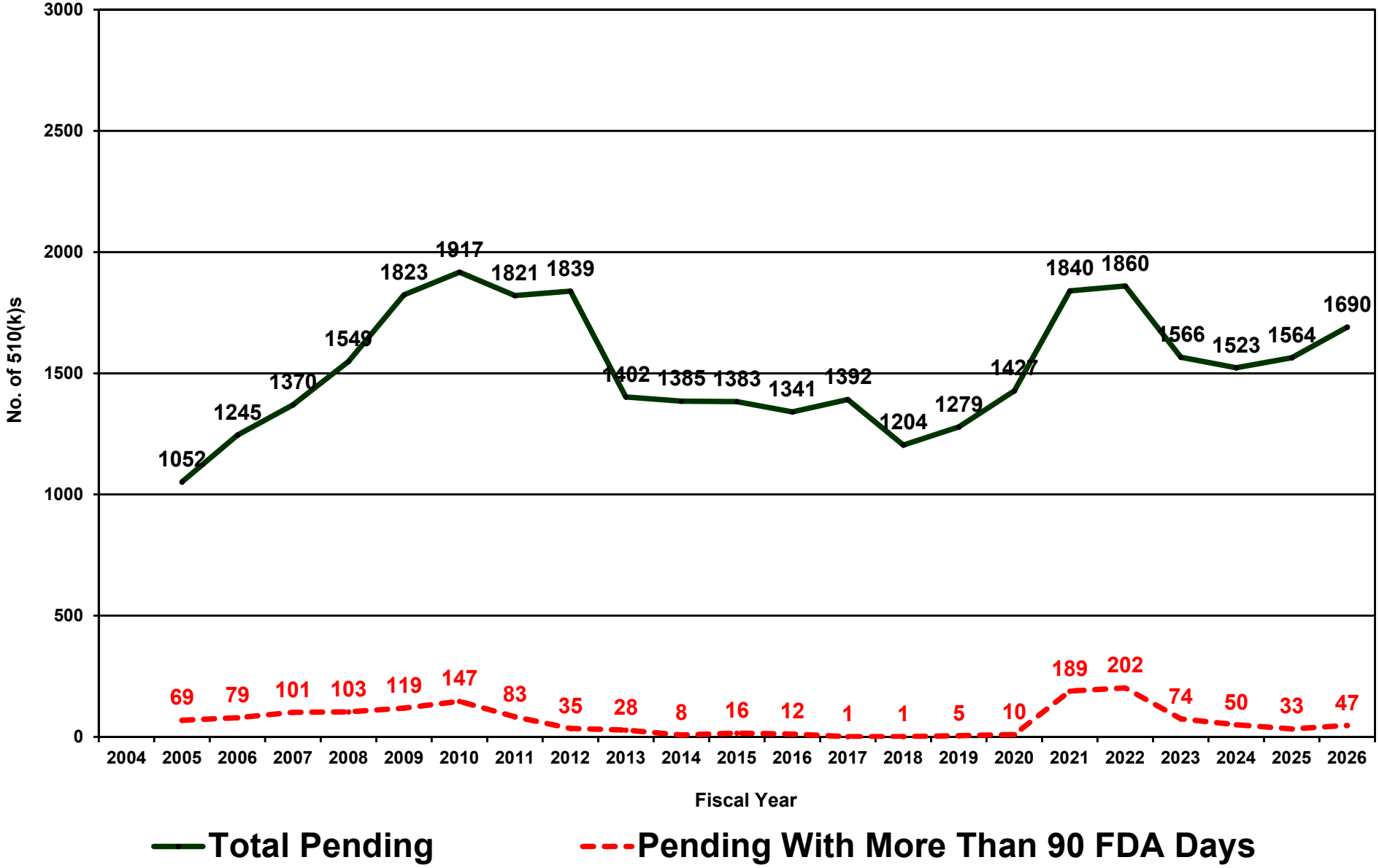

510(k) Average Days to MDUFA (SE/NSE) Decision at 85.31 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
2023
2024
2025
FY of Receipt
93
98
117
128
127
123
115
114
120
128
121
112
115
125
139
132
125
126
128
60
61
68
71
69
67
69
70
71
72
70
70
70
71
79
77
72
72
74
32
37
49
57
58
56
46
43
49
56
51
43
45
54
60
55
53
55
55
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

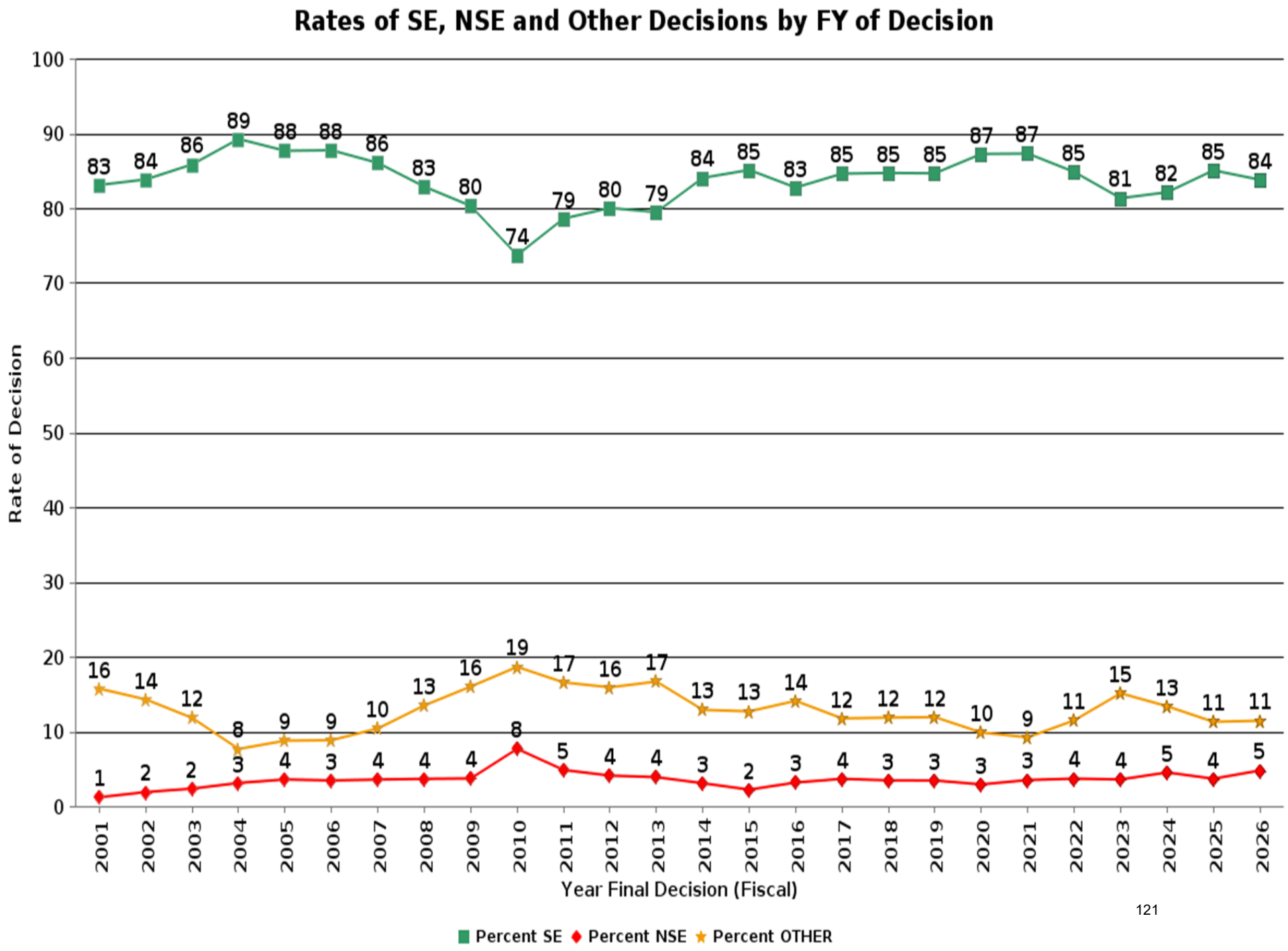
Comparison of FY18 – FY26 Receipt Cohorts



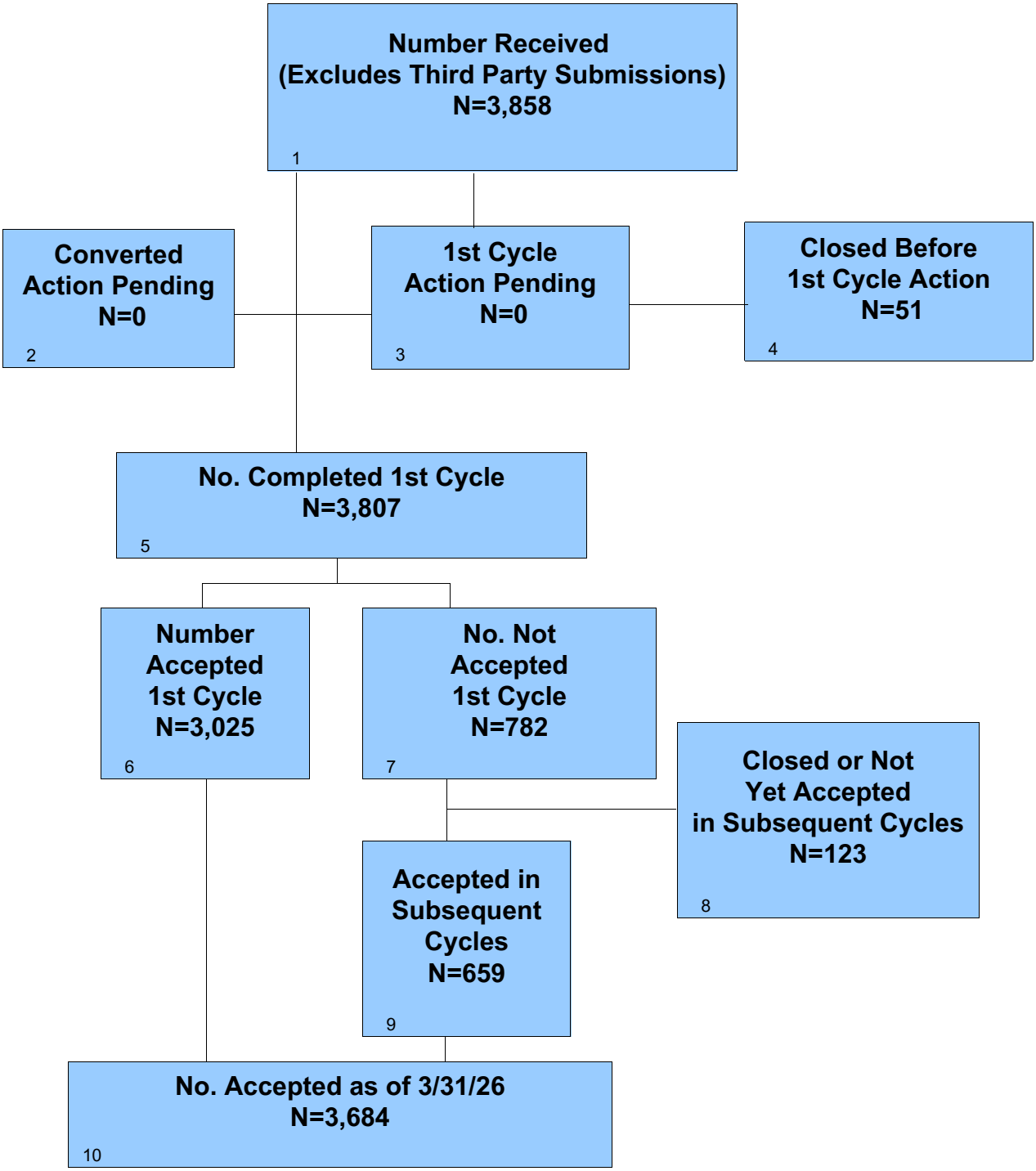
510(k)s Pending at End of Quarter/Year



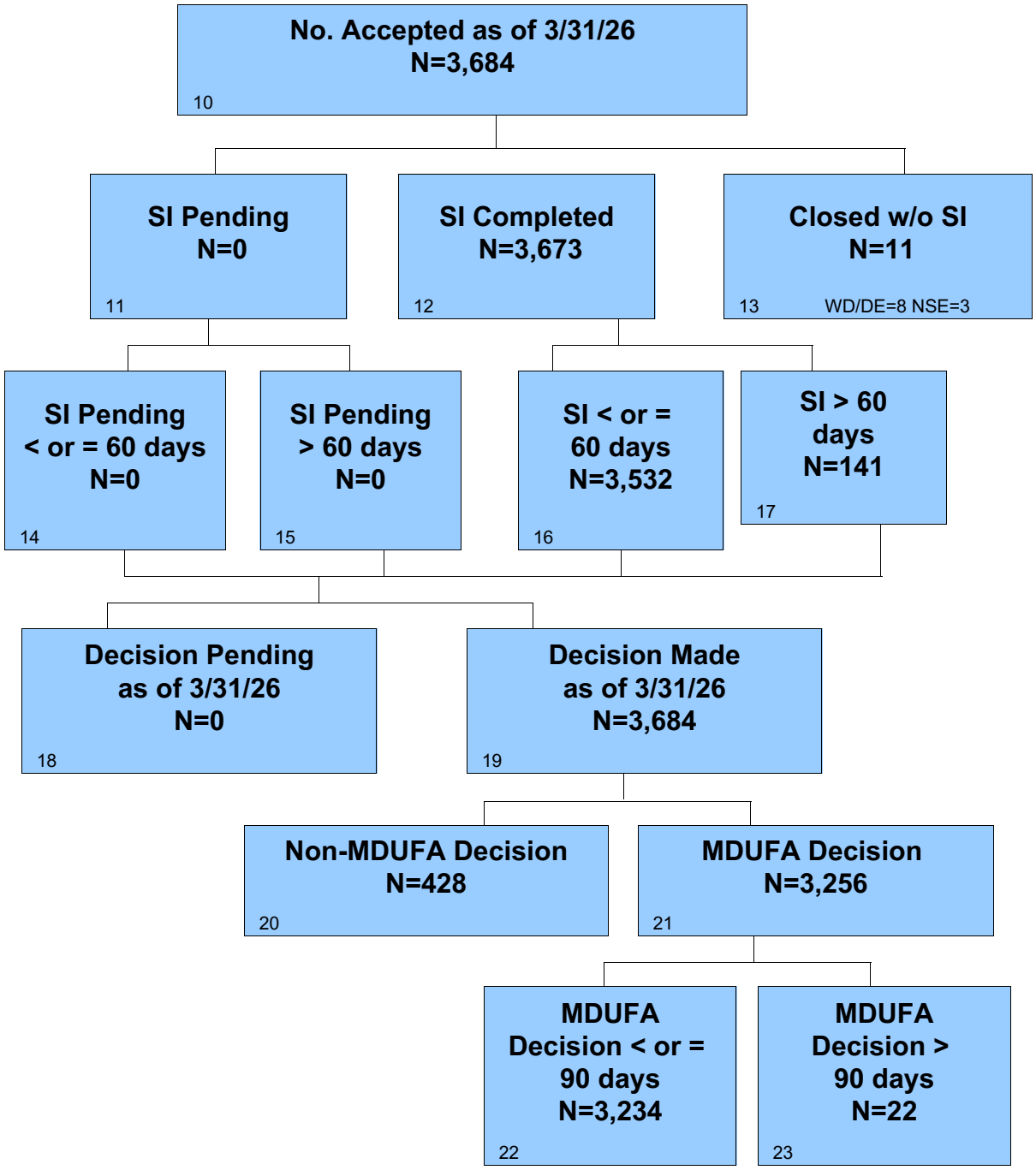
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


Rates of SE, NSE and Other Decisions by FY of Decision
Rate of Decision
100
90
80
70
60
50
40
30
20
10
0
83 84 86 89 88 88 86 83 80 74 79 80 79 84 85 83 85 85 85 87 87 85 81 82 85 84
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 15 13 11 11
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 4 4 5 4 5
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER

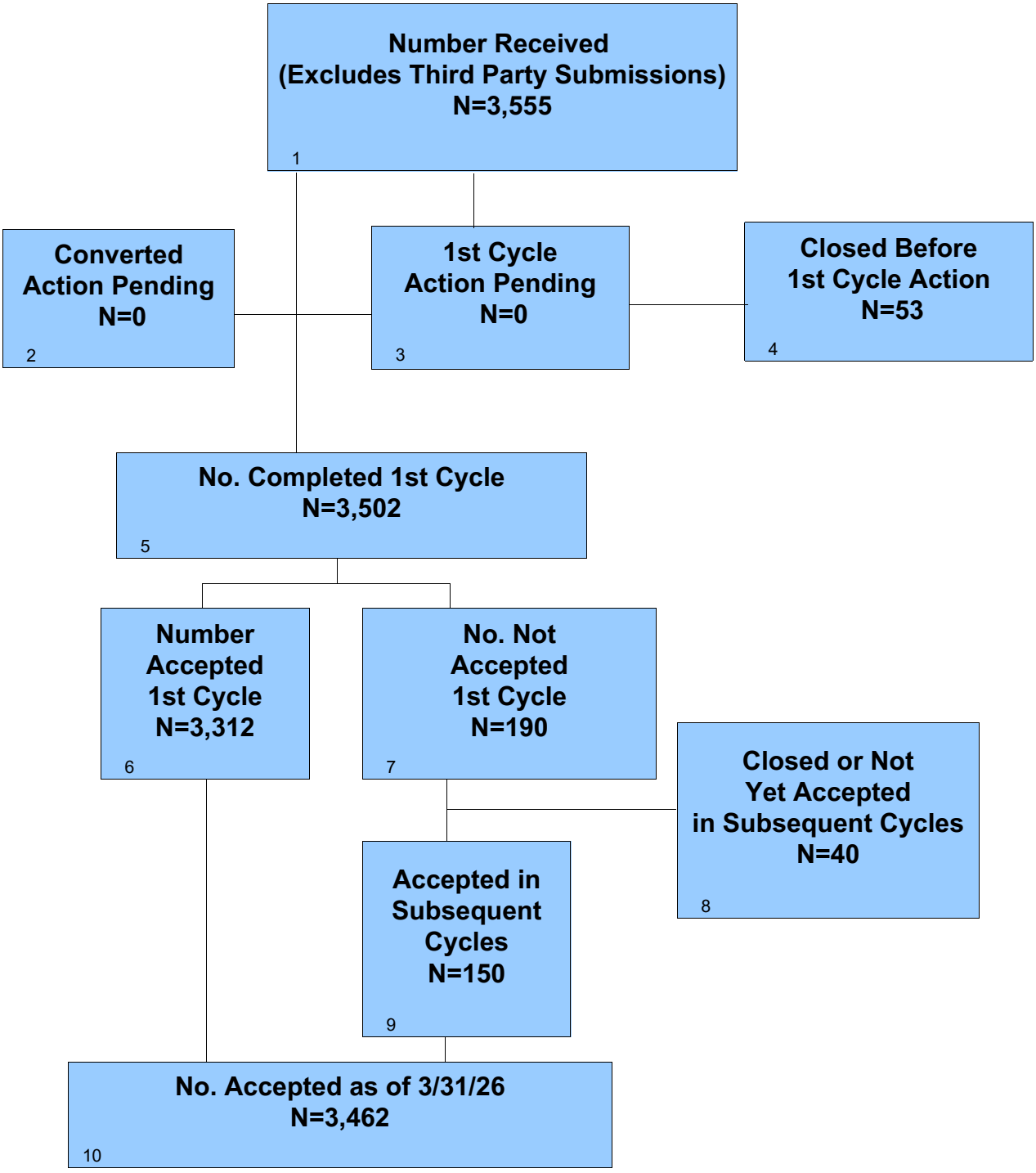
CDRH 510(k)s - FY 2023
as of 3/31/26



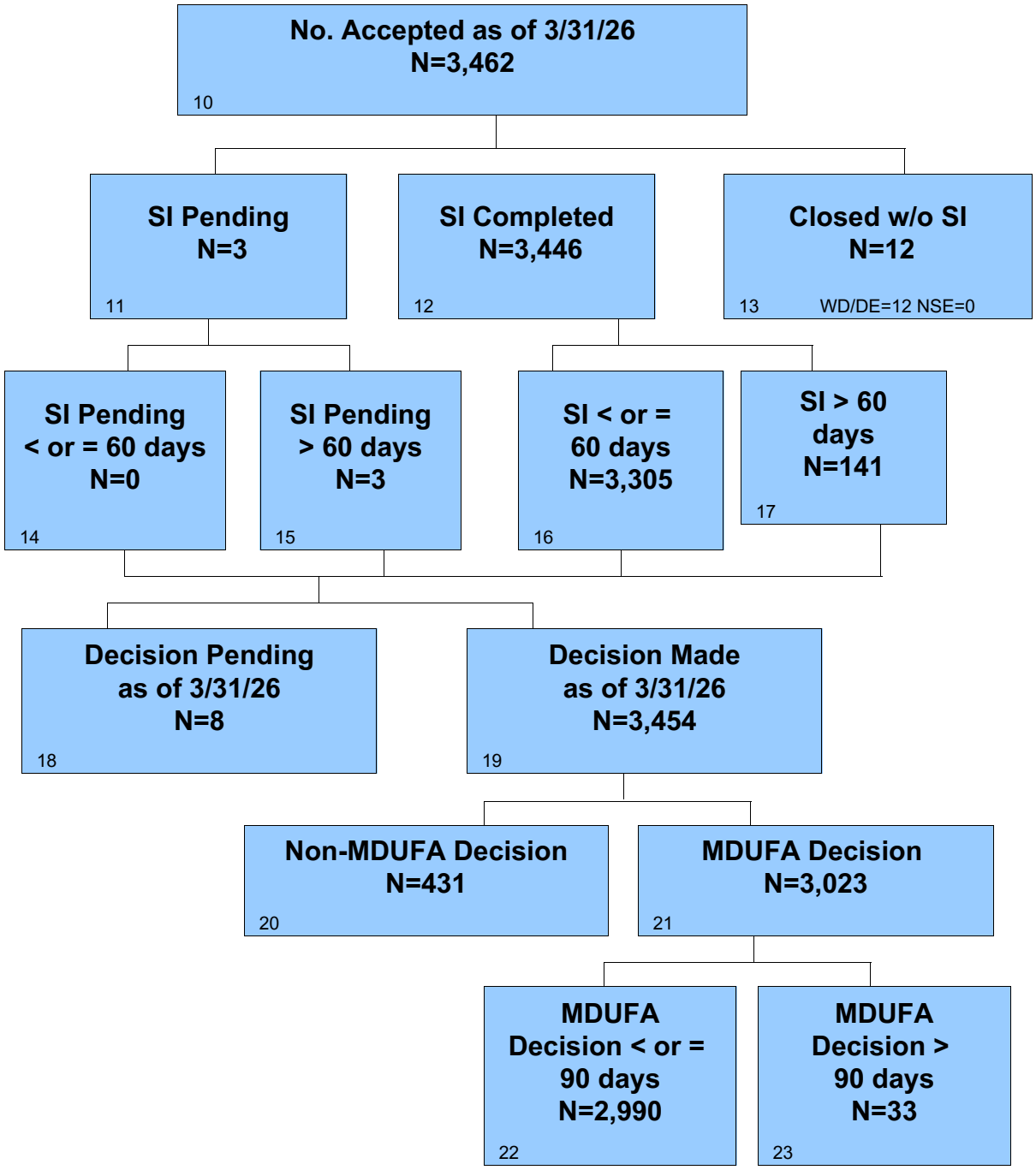
CDRH 510(k)s - FY 2023
as of 3/31/26 Continued



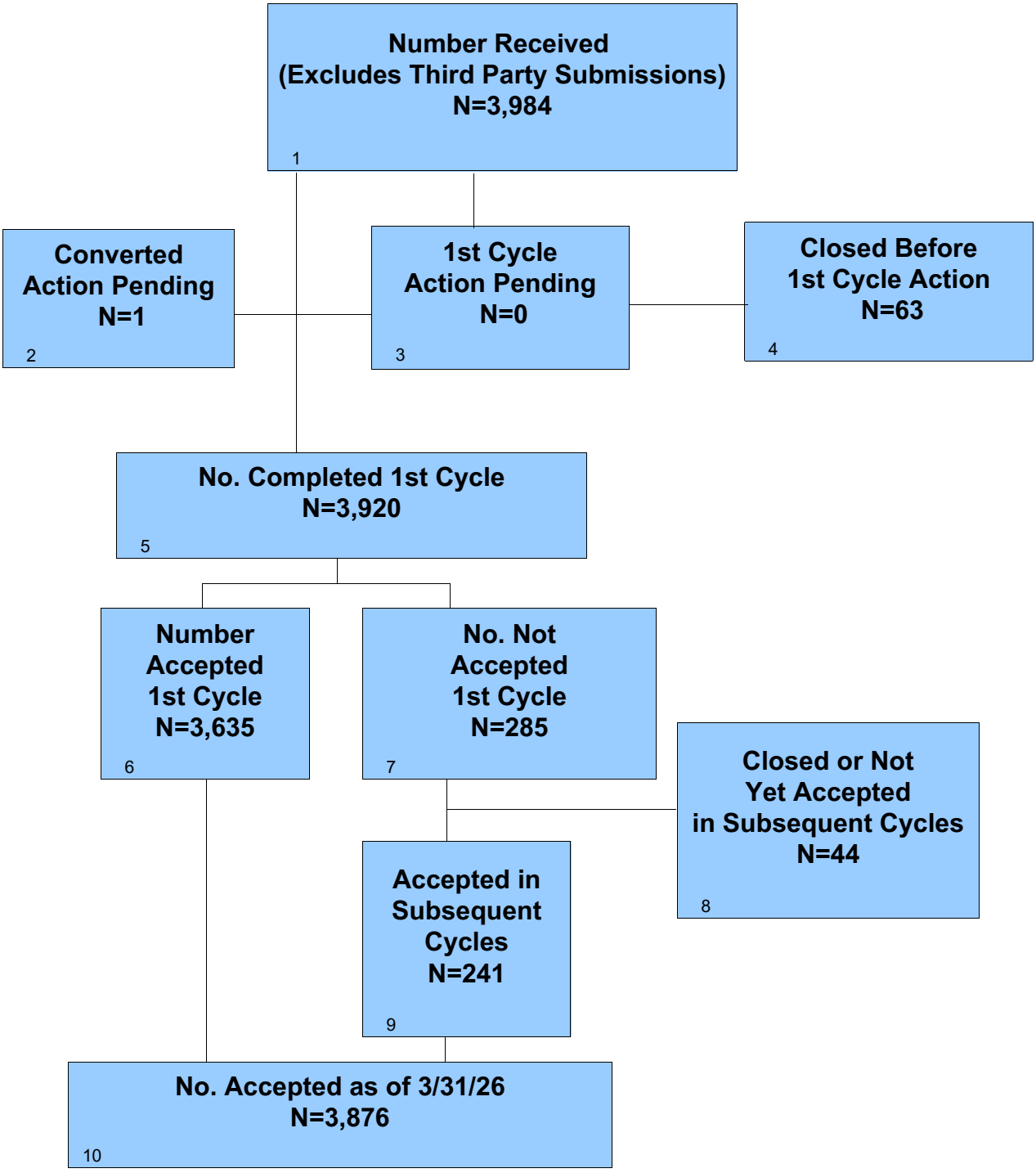
CDRH 510(k)s - FY 2024
as of 3/31/26



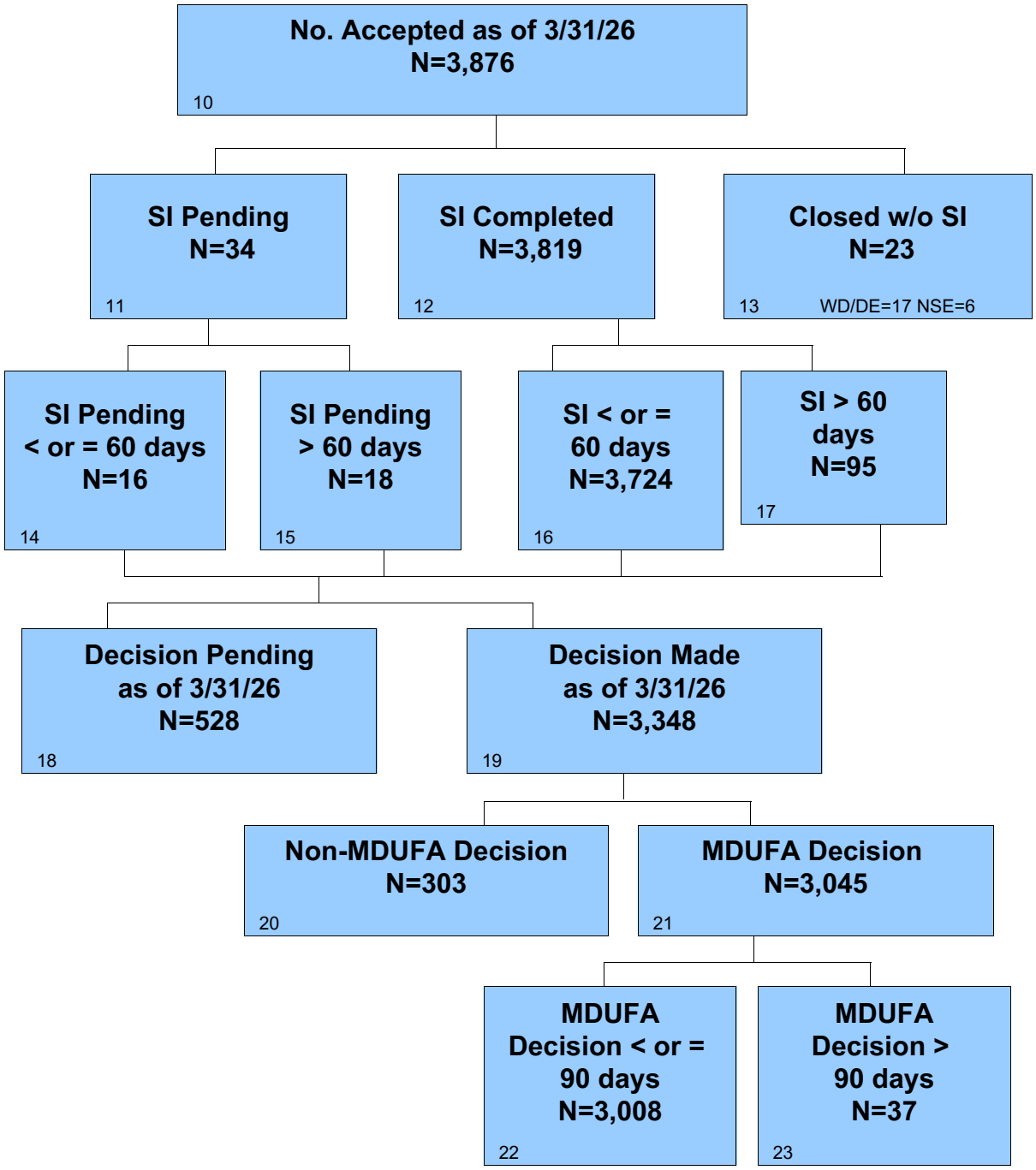
CDRH 510(k)s - FY 2024
as of 3/31/26 Continued



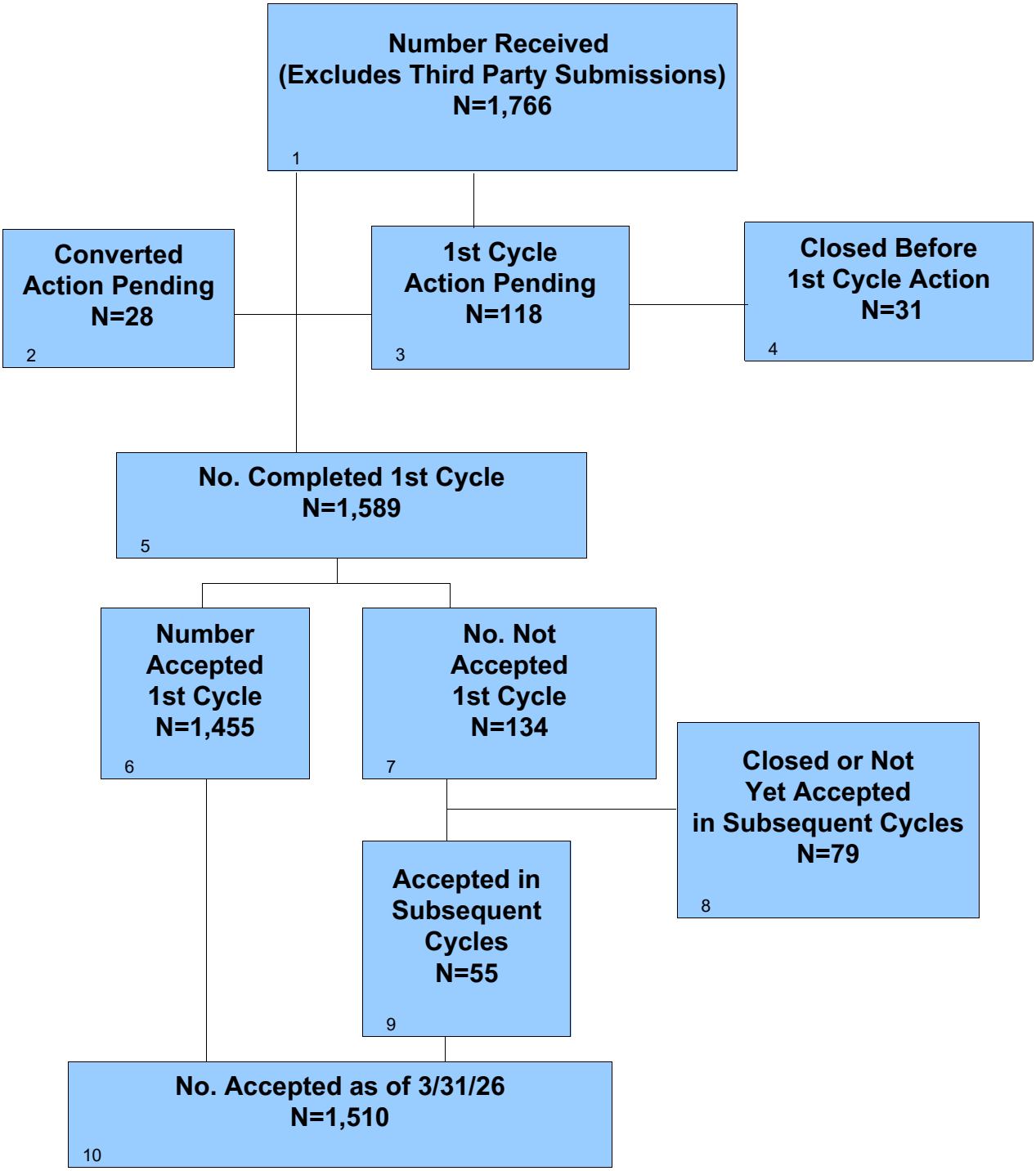
CDRH 510(k)s - FY 2025
as of 3/31/26



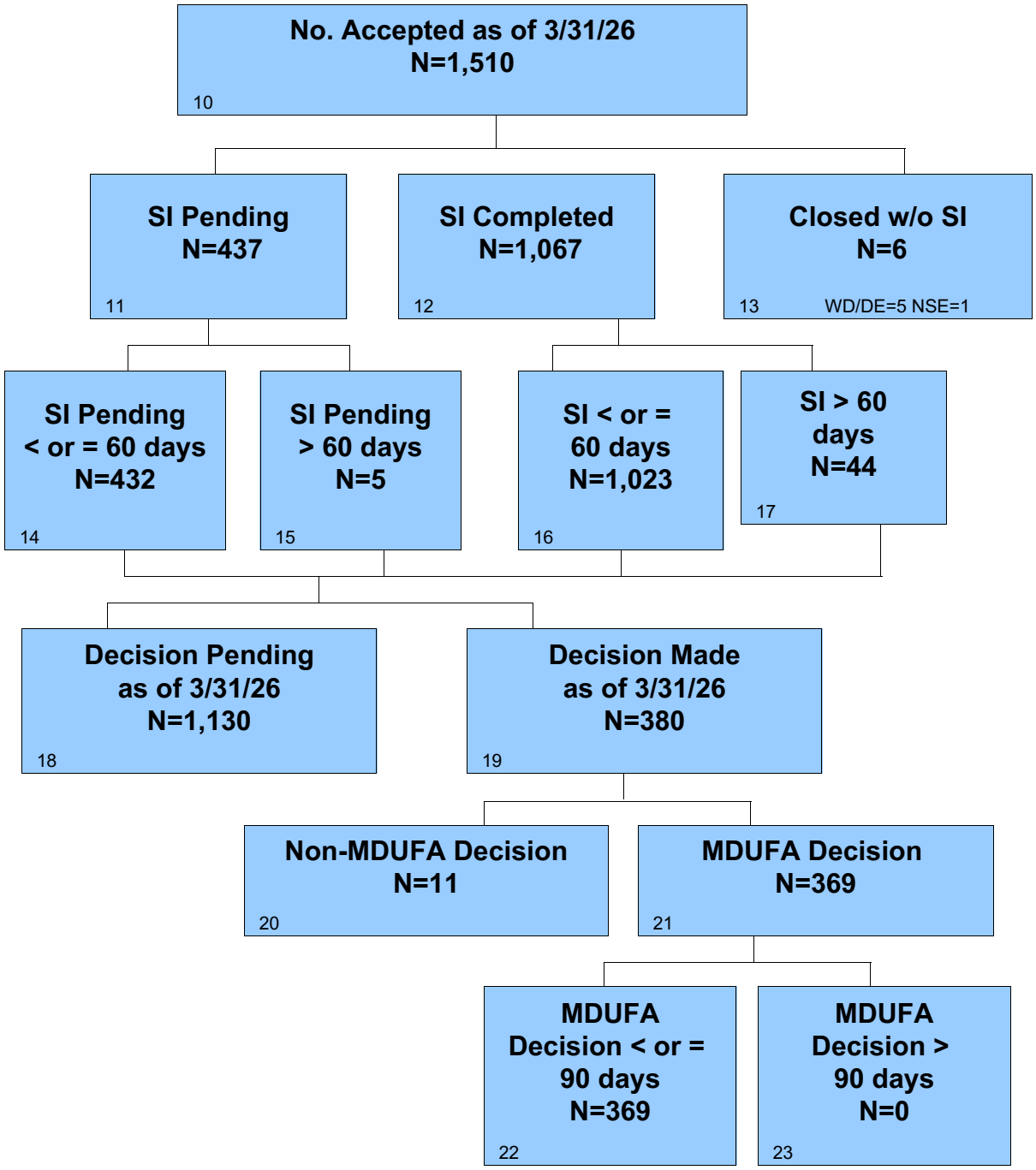
CDRH 510(k)s - FY 2025 as of 3/31/26 Continued



CDRH 510(k)s - FY 2026
as of 3/31/26



CDRH 510(k)s - FY 2026
as of 3/31/26 Continued



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

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3858	3555	3984	1766	
Closed Before First RTA or TS Action [1]	51	53	63	31	
Number Accepted or Passed TS on First Cycle [2]	3007	3284	3593	1433	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	18	28	42	22	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	1	146	
Number Not Accepted or Failed TS on First Cycle [2]	782	190	285	134	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.54%	5.43%	7.27%	8.43%	

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	3684	3462	3876	1510	
Deleted or Withdrawn Prior to SI	8	12	17	5	
SI Within 60 FDA Days	3532	3305	3724	1023	
SI Over 60 FDA Days	141	141	95	44	
SI Pending Within 60 FDA Days	0	0	16	432	
SI Pending Over 60 FDA Days	0	3	18	5	
510(k)s NSE Without SI	3	1	6	1	
Current SI Performance Percent Within 60 FDA Days	96.08%	95.80%	96.90%	95.34%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	3673	3446	3819	1067	
Average Number of FDA Days to Substantive Interaction	52.70	52.47	52.45	52.56	
20th Percentile FDA Days to Substantive Interaction	48	48	48	48	
40th Percentile FDA Days to Substantive Interaction	57	57	56	57	
60th Percentile FDA Days to Substantive Interaction	59	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	212	95	175	119	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	3684	3462	3876	1510	
Non-MDUFA V Decision	428	431	303	11	
MDUFA V Decision (SE/NSE)	3256	3023	3045	369	
MDUFA V Decision Within 90 FDA Days	3234	2990	3008	369	
510(k)s Pending MDUFA V Decision	0	8	528	1130	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	3	28	5	
Current Performance Percent Within 90 FDA Days	99.32%	98.81%	97.88%	98.66%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.67	1.69	1.65	1.28	
Number With MDUFA V Decision	3256	3023	3045	368	
Average Number of FDA Days to MDUFA V Decision	75.02	74.77	74.12	59.27	
20th Percentile FDA Days to MDUFA V Decision	57	57	56	29	
40th Percentile FDA Days to MDUFA V Decision	84	85	84	56	
60th Percentile FDA Days to MDUFA V Decision	88	88	88	74	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	88	
Maximum FDA Days to MDUFA V Decision	448	349	301	90	
Average Number of Industry Days to MDUFA V Decision	66.44	68.54	55.04	5.62	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	14	18	9	0	
60th Percentile Industry Days to MDUFA V Decision	70	73	52	0	
80th Percentile Industry Days to MDUFA V Decision	152	157	120	13	
Maximum Industry Days to MDUFA V Decision	417	392	362	50	
Average Number of Total Days to MDUFA V Decision	141.46	143.31	129.15	64.88	
20th Percentile Total Days to MDUFA V Decision	59	58	58	29	
40th Percentile Total Days to MDUFA V Decision	97	100	90	56	
60th Percentile Total Days to MDUFA V Decision	155	157	135	82	
80th Percentile Total Days to MDUFA V Decision	238	242	205	92	
Maximum Total Days to MDUFA V Decision	865	525	452	132	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	3684	3462	3876	1510	
Number With MDUFA V Decision	3256	3023	3045	369	
Number of SE Decision	3108	2883	2931	364	
Number of NSE Decision	148	140	114	5	
Number of Withdrawal	225	230	175	10	
Number of Deleted	194	194	122	0	
Rate of SE Decision	95.45%	95.37%	96.26%	98.64%	
Rate of NSE Decision	4.55%	4.63%	3.74%	1.36%	
Rate of Withdrawal	6.11%	6.64%	4.51%	0.66%	
Rate of Deleted	5.27%	5.60%	3.15%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	22	33	37	0	
Mean FDA Days for Submissions that Missed the Goal	150.86	115.94	120.22	N/A	
Mean Industry Days for Submissions that Missed the Goal	152.27	146.24	104.81	N/A	

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

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

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	236	274	121	
Non-MDUFA V Decision	51	45	36	1	
MDUFA V Decision (SE/NSE)	218	191	205	25	
MDUFA V Decision Within 90 FDA Days	218	191	205	25	
510(k)s Pending MDUFA V Decision	0	0	33	95	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	577	530	578	251	
Closed Before First RTA or TS Action [1]	8	8	7	2	
Number Accepted or Passed TS on First Cycle [2]	313	467	493	192	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	4	3	6	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	20	
Number Not Accepted or Failed TS on First Cycle [2]	253	51	75	31	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	44.46%	9.77%	13.13%	13.54%	

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	560	214	
Deleted or Withdrawn Prior to SI	2	2	4	1	
SI Within 60 FDA Days	425	427	534	125	
SI Over 60 FDA Days	105	84	18	11	
SI Pending Within 60 FDA Days	0	0	2	75	
SI Pending Over 60 FDA Days	0	0	1	2	
510(k)s NSE Without SI	1	0	1	0	
Current SI Performance Percent Within 60 FDA Days	80.04%	83.56%	96.39%	90.58%	

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	552	136	
Average Number of FDA Days to Substantive Interaction	56.90	55.87	54.14	55.71	
20th Percentile FDA Days to Substantive Interaction	55	53	50	55	
40th Percentile FDA Days to Substantive Interaction	58	57	56	58	
60th Percentile FDA Days to Substantive Interaction	60	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	212	80	79	96	

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	560	214	
Non-MDUFA V Decision	84	69	58	1	
MDUFA V Decision (SE/NSE)	449	444	405	28	
MDUFA V Decision Within 90 FDA Days	439	438	398	28	
510(k)s Pending MDUFA V Decision	0	0	97	185	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	1	2	
Current Performance Percent Within 90 FDA Days	97.77%	98.65%	98.03%	93.33%	

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	1.76	1.39	
Number With MDUFA V Decision	449	444	405	28	
Average Number of FDA Days to MDUFA V Decision	83.61	82.28	79.80	69.71	
20th Percentile FDA Days to MDUFA V Decision	82	83	77	52	
40th Percentile FDA Days to MDUFA V Decision	88	87	87	73	
60th Percentile FDA Days to MDUFA V Decision	89	89	89	86	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	89	
Maximum FDA Days to MDUFA V Decision	448	120	127	90	
Average Number of Industry Days to MDUFA V Decision	77.09	85.89	66.98	6.39	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	39	42	29	0	
60th Percentile Industry Days to MDUFA V Decision	88	106	73	0	
80th Percentile Industry Days to MDUFA V Decision	162	174	134	15	
Maximum Industry Days to MDUFA V Decision	417	392	322	41	
Average Number of Total Days to MDUFA V Decision	160.69	168.17	146.77	76.11	
20th Percentile Total Days to MDUFA V Decision	87	89	84	52	
40th Percentile Total Days to MDUFA V Decision	126	128	115	76	
60th Percentile Total Days to MDUFA V Decision	178	192	161	90	
80th Percentile Total Days to MDUFA V Decision	252	261	220	99	
Maximum Total Days to MDUFA V Decision	865	482	421	127	

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	560	214	
Number With MDUFA V Decision	449	444	405	28	
Number of SE Decision	413	413	382	28	
Number of NSE Decision	36	31	23	0	
Number of Withdrawal	41	31	29	1	
Number of Deleted	42	37	28	0	
Rate of SE Decision	91.98%	93.02%	94.32%	100.00%	
Rate of NSE Decision	8.02%	6.98%	5.68%	0.00%	
Rate of Withdrawal	7.69%	6.04%	5.18%	0.47%	
Rate of Deleted	7.88%	7.21%	5.00%	0.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	10	6	7	0	
Mean FDA Days for Submissions that Missed the Goal	178.70	102.67	104.86	N/A	
Mean Industry Days for Submissions that Missed the Goal	150.40	165.83	135.43	N/A	

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	379	378	416	204	
Closed Before First RTA or TS Action [1]	8	6	7	7	
Number Accepted or Passed TS on First Cycle [2]	332	354	365	164	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	6	5	3	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	7	
Number Not Accepted or Failed TS on First Cycle [2]	38	12	39	23	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	10.24%	3.23%	9.54%	12.11%	

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	404	180	
Deleted or Withdrawn Prior to SI	0	0	1	0	
SI Within 60 FDA Days	355	345	370	103	
SI Over 60 FDA Days	10	22	24	22	
SI Pending Within 60 FDA Days	0	0	2	53	
SI Pending Over 60 FDA Days	0	3	4	2	
510(k)s NSE Without SI	0	0	3	0	
Current SI Performance Percent Within 60 FDA Days	97.26%	93.24%	92.27%	81.10%	

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	394	125	
Average Number of FDA Days to Substantive Interaction	51.40	51.09	52.66	53.47	
20th Percentile FDA Days to Substantive Interaction	44	30	44	39	
40th Percentile FDA Days to Substantive Interaction	56	56	57	58	
60th Percentile FDA Days to Substantive Interaction	59	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	86	85	86	119	

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	404	180	
Non-MDUFA V Decision	34	46	25	1	
MDUFA V Decision (SE/NSE)	331	321	320	37	
MDUFA V Decision Within 90 FDA Days	327	310	302	37	
510(k)s Pending MDUFA V Decision	0	3	59	142	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	3	6	3	
Current Performance Percent Within 90 FDA Days	98.79%	95.68%	92.64%	92.50%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.77	1.75	1.16	
Number With MDUFA V Decision	331	321	320	37	
Average Number of FDA Days to MDUFA V Decision	73.39	73.88	76.26	46.73	
20th Percentile FDA Days to MDUFA V Decision	55	52	57	29	
40th Percentile FDA Days to MDUFA V Decision	84	83	85	30	
60th Percentile FDA Days to MDUFA V Decision	88	89	89	55	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	60	
Maximum FDA Days to MDUFA V Decision	95	349	301	90	
Average Number of Industry Days to MDUFA V Decision	71.75	79.21	66.35	3.46	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	27	35	28	0	
60th Percentile Industry Days to MDUFA V Decision	78	93	64	0	
80th Percentile Industry Days to MDUFA V Decision	155	171	136	0	
Maximum Industry Days to MDUFA V Decision	360	360	362	34	
Average Number of Total Days to MDUFA V Decision	145.14	153.09	142.62	50.19	
20th Percentile Total Days to MDUFA V Decision	57	56	59	29	
40th Percentile Total Days to MDUFA V Decision	107	113	113	30	
60th Percentile Total Days to MDUFA V Decision	162	177	150	56	
80th Percentile Total Days to MDUFA V Decision	238	260	227	65	
Maximum Total Days to MDUFA V Decision	448	525	452	111	

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	404	180	
Number With MDUFA V Decision	331	321	320	37	
Number of SE Decision	308	295	278	37	
Number of NSE Decision	23	26	42	0	
Number of Withdrawal	17	27	10	1	
Number of Deleted	17	17	15	0	
Rate of SE Decision	93.05%	91.90%	86.88%	100.00%	
Rate of NSE Decision	6.95%	8.10%	13.13%	0.00%	
Rate of Withdrawal	4.66%	7.30%	2.48%	0.56%	
Rate of Deleted	4.66%	4.59%	3.71%	0.00%	

Table 6.7 OHT2 - Office of Cardiovascular Devices
510(k) Performance Metric - Submission Missing Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	4	11	18	0	
Mean FDA Days for Submissions that Missed the Goal	92.75	142.73	121.72	N/A	
Mean Industry Days for Submissions that Missed the Goal	82.50	182.36	117.22	N/A	

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

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

Table 6.9 OHT2 - Office of Cardiovascular Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	477	445	549	216	
Closed Before First RTA or TS Action [1]	5	11	8	4	
Number Accepted or Passed TS on First Cycle [2]	389	417	506	177	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	1	4	2	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	1	19	
Number Not Accepted or Failed TS on First Cycle [2]	81	16	30	14	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	17.16%	3.69%	5.56%	7.25%	

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	459	431	536	183	
Deleted or Withdrawn Prior to SI	1	0	3	1	
SI Within 60 FDA Days	448	430	514	122	
SI Over 60 FDA Days	10	0	11	0	
SI Pending Within 60 FDA Days	0	0	5	60	
SI Pending Over 60 FDA Days	0	0	3	0	
510(k)s NSE Without SI	0	1	0	0	
Current SI Performance Percent Within 60 FDA Days	97.82%	99.77%	97.35%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	458	430	525	122	
Average Number of FDA Days to Substantive Interaction	54.93	52.87	53.28	53.70	
20th Percentile FDA Days to Substantive Interaction	55	49	49	54	
40th Percentile FDA Days to Substantive Interaction	58	57	57	58	
60th Percentile FDA Days to Substantive Interaction	59	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	77	60	175	60	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	459	431	536	183	
Non-MDUFA V Decision	54	69	45	2	
MDUFA V Decision (SE/NSE)	405	360	393	25	
MDUFA V Decision Within 90 FDA Days	404	358	389	25	
510(k)s Pending MDUFA V Decision	0	2	98	156	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	5	0	
Current Performance Percent Within 90 FDA Days	99.75%	99.44%	97.74%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.78	1.78	1.69	1.28	
Number With MDUFA V Decision	405	360	393	25	
Average Number of FDA Days to MDUFA V Decision	79.93	76.54	75.44	58.96	
20th Percentile FDA Days to MDUFA V Decision	79	58	57	28	
40th Percentile FDA Days to MDUFA V Decision	88	87	86	52	
60th Percentile FDA Days to MDUFA V Decision	89	89	89	78	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	88	
Maximum FDA Days to MDUFA V Decision	93	160	170	90	
Average Number of Industry Days to MDUFA V Decision	85.37	82.24	64.51	5.76	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	48	41	24	0	
60th Percentile Industry Days to MDUFA V Decision	106	105	64	0	
80th Percentile Industry Days to MDUFA V Decision	172	169	143	6	
Maximum Industry Days to MDUFA V Decision	354	349	282	50	
Average Number of Total Days to MDUFA V Decision	165.30	158.78	139.95	64.72	
20th Percentile Total Days to MDUFA V Decision	87	66	60	28	
40th Percentile Total Days to MDUFA V Decision	133	124	109	53	
60th Percentile Total Days to MDUFA V Decision	193	192	149	80	
80th Percentile Total Days to MDUFA V Decision	260	258	229	94	
Maximum Total Days to MDUFA V Decision	443	438	372	130	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	459	431	536	183	
Number With MDUFA V Decision	405	360	393	25	
Number of SE Decision	377	332	379	25	
Number of NSE Decision	28	28	14	0	
Number of Withdrawal	24	38	21	2	
Number of Deleted	29	29	21	0	
Rate of SE Decision	93.09%	92.22%	96.44%	100.00%	
Rate of NSE Decision	6.91%	7.78%	3.56%	0.00%	
Rate of Withdrawal	5.23%	8.82%	3.92%	1.09%	
Rate of Deleted	6.32%	6.73%	3.92%	0.00%	

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	709	614	640	271	
Closed Before First RTA or TS Action [1]	10	6	8	4	
Number Accepted or Passed TS on First Cycle [2]	558	561	566	211	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	12	22	8	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	24	
Number Not Accepted or Failed TS on First Cycle [2]	140	35	44	24	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	20.03%	5.76%	6.96%	9.88%	

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	619	227	
Deleted or Withdrawn Prior to SI	1	5	2	1	
SI Within 60 FDA Days	671	580	590	149	
SI Over 60 FDA Days	5	14	22	3	
SI Pending Within 60 FDA Days	0	0	3	73	
SI Pending Over 60 FDA Days	0	0	1	1	
510(k)s NSE Without SI	0	0	1	0	
Current SI Performance Percent Within 60 FDA Days	99.26%	97.64%	96.09%	97.39%	

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	612	152	
Average Number of FDA Days to Substantive Interaction	52.62	52.84	53.05	50.00	
20th Percentile FDA Days to Substantive Interaction	49	50	49	30	
40th Percentile FDA Days to Substantive Interaction	56	57	57	55	
60th Percentile FDA Days to Substantive Interaction	58	58	59	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	59	
Maximum FDA Days to Substantive Interaction	122	66	121	63	

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	619	227	
Non-MDUFA V Decision	89	83	47	3	
MDUFA V Decision (SE/NSE)	588	515	498	70	
MDUFA V Decision Within 90 FDA Days	586	510	494	70	
510(k)s Pending MDUFA V Decision	0	1	74	154	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	3	0	
Current Performance Percent Within 90 FDA Days	99.66%	99.03%	98.60%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.62	1.61	1.55	1.20	
Number With MDUFA V Decision	588	515	498	69	
Average Number of FDA Days to MDUFA V Decision	75.12	74.47	74.00	57.38	
20th Percentile FDA Days to MDUFA V Decision	58	57	57	27	
40th Percentile FDA Days to MDUFA V Decision	83	84	83	56	
60th Percentile FDA Days to MDUFA V Decision	87	88	87	65	
80th Percentile FDA Days to MDUFA V Decision	89	90	89	87	
Maximum FDA Days to MDUFA V Decision	101	95	234	90	
Average Number of Industry Days to MDUFA V Decision	56.52	52.84	44.95	3.58	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	47	40	32	0	
80th Percentile Industry Days to MDUFA V Decision	124	119	95	1	
Maximum Industry Days to MDUFA V Decision	359	360	241	44	
Average Number of Total Days to MDUFA V Decision	131.64	127.31	118.94	60.96	
20th Percentile Total Days to MDUFA V Decision	60	58	57	27	
40th Percentile Total Days to MDUFA V Decision	88	90	88	58	
60th Percentile Total Days to MDUFA V Decision	128	125	119	75	
80th Percentile Total Days to MDUFA V Decision	211	205	184	89	
Maximum Total Days to MDUFA V Decision	449	448	330	127	

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	619	227	
Number With MDUFA V Decision	588	515	498	70	
Number of SE Decision	571	508	488	69	
Number of NSE Decision	17	7	10	1	
Number of Withdrawal	52	40	30	2	
Number of Deleted	36	42	16	0	
Rate of SE Decision	97.11%	98.64%	97.99%	98.57%	
Rate of NSE Decision	2.89%	1.36%	2.01%	1.43%	
Rate of Withdrawal	7.68%	6.68%	4.85%	0.88%	
Rate of Deleted	5.32%	7.01%	2.58%	0.00%	

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	314	306	395	193	
Closed Before First RTA or TS Action [1]	3	3	10	3	
Number Accepted or Passed TS on First Cycle [2]	214	275	341	148	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1	1	7	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	24	
Number Not Accepted or Failed TS on First Cycle [2]	96	27	37	18	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	30.87%	8.91%	9.61%	10.84%	

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	381	154	
Deleted or Withdrawn Prior to SI	0	0	2	0	
SI Within 60 FDA Days	287	281	356	110	
SI Over 60 FDA Days	11	19	13	6	
SI Pending Within 60 FDA Days	0	0	1	38	
SI Pending Over 60 FDA Days	0	0	8	0	
510(k)s NSE Without SI	0	0	1	0	
Current SI Performance Percent Within 60 FDA Days	96.31%	93.67%	94.18%	94.83%	

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	369	116	
Average Number of FDA Days to Substantive Interaction	54.67	54.90	52.79	54.66	
20th Percentile FDA Days to Substantive Interaction	56	53	47	56	
40th Percentile FDA Days to Substantive Interaction	58	58	57	58	
60th Percentile FDA Days to Substantive Interaction	60	59	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	80	95	104	64	

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	381	154	
Non-MDUFA V Decision	34	32	26	0	
MDUFA V Decision (SE/NSE)	264	268	299	34	
MDUFA V Decision Within 90 FDA Days	259	259	296	34	
510(k)s Pending MDUFA V Decision	0	0	56	120	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	12	0	
Current Performance Percent Within 90 FDA Days	98.11%	96.64%	95.18%	100.00%	

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	1.79	1.72	1.59	
Number With MDUFA V Decision	264	268	299	34	
Average Number of FDA Days to MDUFA V Decision	79.01	78.52	75.29	73.03	
20th Percentile FDA Days to MDUFA V Decision	59	61	56	45	
40th Percentile FDA Days to MDUFA V Decision	87	87	86	86	
60th Percentile FDA Days to MDUFA V Decision	89	89	89	89	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	90	
Maximum FDA Days to MDUFA V Decision	382	126	100	90	
Average Number of Industry Days to MDUFA V Decision	77.26	77.13	55.49	9.79	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	35	37	18	0	
60th Percentile Industry Days to MDUFA V Decision	91	91	54	9	
80th Percentile Industry Days to MDUFA V Decision	168	157	107	23	
Maximum Industry Days to MDUFA V Decision	367	268	181	43	
Average Number of Total Days to MDUFA V Decision	156.27	155.65	130.78	82.74	
20th Percentile Total Days to MDUFA V Decision	62	83	61	45	
40th Percentile Total Days to MDUFA V Decision	118	124	102	89	
60th Percentile Total Days to MDUFA V Decision	177	181	137	97	
80th Percentile Total Days to MDUFA V Decision	255	240	196	107	
Maximum Total Days to MDUFA V Decision	732	356	281	132	

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	381	154	
Number With MDUFA V Decision	264	268	299	34	
Number of SE Decision	246	247	282	32	
Number of NSE Decision	18	21	17	2	
Number of Withdrawal	10	10	15	0	
Number of Deleted	21	21	11	0	
Rate of SE Decision	93.18%	92.16%	94.31%	94.12%	
Rate of NSE Decision	6.82%	7.84%	5.69%	5.88%	
Rate of Withdrawal	3.36%	3.33%	3.94%	0.00%	
Rate of Deleted	7.05%	7.00%	2.89%	0.00%	

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	619	563	614	252	
Closed Before First RTA or TS Action [1]	6	4	7	4	
Number Accepted or Passed TS on First Cycle [2]	517	535	576	208	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	3	0	1	3	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	26	
Number Not Accepted or Failed TS on First Cycle [2]	93	24	30	11	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	15.17%	4.29%	4.94%	4.95%	

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	605	216	
Deleted or Withdrawn Prior to SI	1	2	1	0	
SI Within 60 FDA Days	604	552	600	171	
SI Over 60 FDA Days	0	0	2	1	
SI Pending Within 60 FDA Days	0	0	1	44	
SI Pending Over 60 FDA Days	0	0	1	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	99.50%	99.42%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	604	552	602	172	
Average Number of FDA Days to Substantive Interaction	49.84	50.07	49.66	50.74	
20th Percentile FDA Days to Substantive Interaction	30	30	30	30	
40th Percentile FDA Days to Substantive Interaction	56	56	56	57	
60th Percentile FDA Days to Substantive Interaction	58	58	58	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	60	60	61	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	605	216	
Non-MDUFA V Decision	51	54	38	1	
MDUFA V Decision (SE/NSE)	554	498	507	89	
MDUFA V Decision Within 90 FDA Days	554	498	506	89	
510(k)s Pending MDUFA V Decision	0	2	60	126	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	1	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	99.61%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.48	1.47	1.46	1.18	
Number With MDUFA V Decision	554	498	507	89	
Average Number of FDA Days to MDUFA V Decision	65.77	65.63	64.47	57.04	
20th Percentile FDA Days to MDUFA V Decision	30	30	29	28	
40th Percentile FDA Days to MDUFA V Decision	59	60	59	54	
60th Percentile FDA Days to MDUFA V Decision	85	85	85	63	
80th Percentile FDA Days to MDUFA V Decision	89	89	89	87	
Maximum FDA Days to MDUFA V Decision	90	90	97	90	
Average Number of Industry Days to MDUFA V Decision	42.82	43.92	34.35	3.54	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
60th Percentile Industry Days to MDUFA V Decision	18	12	10	0	
80th Percentile Industry Days to MDUFA V Decision	92	107	74	0	
Maximum Industry Days to MDUFA V Decision	354	344	248	42	
Average Number of Total Days to MDUFA V Decision	108.59	109.56	98.82	60.57	
20th Percentile Total Days to MDUFA V Decision	30	30	29	28	
40th Percentile Total Days to MDUFA V Decision	60	60	59	55	
60th Percentile Total Days to MDUFA V Decision	98	98	91	67	
80th Percentile Total Days to MDUFA V Decision	179	188	159	90	
Maximum Total Days to MDUFA V Decision	443	434	336	125	

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	605	216	
Number With MDUFA V Decision	554	498	507	89	
Number of SE Decision	544	490	504	89	
Number of NSE Decision	10	8	3	0	
Number of Withdrawal	37	38	25	1	
Number of Deleted	12	16	12	0	
Rate of SE Decision	98.19%	98.39%	99.41%	100.00%	
Rate of NSE Decision	1.81%	1.61%	0.59%	0.00%	
Rate of Withdrawal	6.12%	6.86%	4.13%	0.46%	
Rate of Deleted	1.98%	2.89%	1.98%	0.00%	

Table 6.7 OHT6 - Office of Orthopedic Devices
510(k) Performance Metric - Submission Missing Performance Goal

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

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

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

Table 6.9 OHT6 - Office of Orthopedic Devices
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	295	258	285	138	
Closed Before First RTA or TS Action [1]	7	13	8	3	
Number Accepted or Passed TS on First Cycle [2]	243	228	264	121	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	5	4	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	10	
Number Not Accepted or Failed TS on First Cycle [2]	40	13	13	4	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	13.89%	5.31%	4.69%	3.20%	

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

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

Substantive Interaction (SI) Goal	FY 2023 95% SI Within 60 FDA Days	FY 2024 95% SI Within 60 FDA Days	FY 2025 95% SI Within 60 FDA Days	FY 2026 95% SI Within 60 FDA Days	FY 2027 95% SI Within 60 FDA Days
Eligible For SI	271	240	275	121	
Deleted or Withdrawn Prior to SI	3	0	3	1	
SI Within 60 FDA Days	266	239	270	82	
SI Over 60 FDA Days	0	1	2	0	
SI Pending Within 60 FDA Days	0	0	0	38	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	2	0	0	0	
Current SI Performance Percent Within 60 FDA Days	99.25%	99.58%	99.26%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	266	240	272	82	
Average Number of FDA Days to Substantive Interaction	52.54	51.18	51.74	51.93	
20th Percentile FDA Days to Substantive Interaction	47	43	45	48	
40th Percentile FDA Days to Substantive Interaction	56	55	56	55	
60th Percentile FDA Days to Substantive Interaction	58	58	58	58	
80th Percentile FDA Days to Substantive Interaction	60	60	60	59	
Maximum FDA Days to Substantive Interaction	60	81	67	60	

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	271	240	275	121	
Non-MDUFA V Decision	51	45	37	1	
MDUFA V Decision (SE/NSE)	220	195	205	25	
MDUFA V Decision Within 90 FDA Days	220	195	205	25	
510(k)s Pending MDUFA V Decision	0	0	33	95	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.59	1.64	1.46	1.08	
Number With MDUFA V Decision	220	195	205	25	
Average Number of FDA Days to MDUFA V Decision	76.25	74.90	73.73	62.88	
20th Percentile FDA Days to MDUFA V Decision	59	54	51	32	
40th Percentile FDA Days to MDUFA V Decision	87	87	86	56	
60th Percentile FDA Days to MDUFA V Decision	89	89	88	83	
80th Percentile FDA Days to MDUFA V Decision	90	90	90	88	
Maximum FDA Days to MDUFA V Decision	90	90	90	90	
Average Number of Industry Days to MDUFA V Decision	80.81	81.69	54.94	1.64	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	8	0	0	
60th Percentile Industry Days to MDUFA V Decision	119	110	30	0	
80th Percentile Industry Days to MDUFA V Decision	177	174	149	0	
Maximum Industry Days to MDUFA V Decision	361	361	222	21	
Average Number of Total Days to MDUFA V Decision	157.05	156.58	128.66	64.52	
20th Percentile Total Days to MDUFA V Decision	60	60	51	32	
40th Percentile Total Days to MDUFA V Decision	90	90	88	56	
60th Percentile Total Days to MDUFA V Decision	205	200	119	83	
80th Percentile Total Days to MDUFA V Decision	265	260	236	90	
Maximum Total Days to MDUFA V Decision	451	451	312	110	

Table 6.6 OHT7 - Office of In Vitro Diagnostics
510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k) Accepted	271	240	275	121	
Number With MDUFA V Decision	220	195	205	25	
Number of SE Decision	211	187	202	25	
Number of NSE Decision	9	8	3	0	
Number of Withdrawal	28	22	28	1	
Number of Deleted	23	23	9	0	
Rate of SE Decision	95.91%	95.90%	98.54%	100.00%	
Rate of NSE Decision	4.09%	4.10%	1.46%	0.00%	
Rate of Withdrawal	10.33%	9.17%	10.18%	0.83%	
Rate of Deleted	8.49%	9.58%	3.27%	0.00%	

Table 6.7 OHT7 - Office of In Vitro Diagnostics
510(k) Performance Metric - Submission Missing Performance Goal

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

Table 6.8 OHT7 - Office of In Vitro Diagnostics
LDT 510(k) MDUFA V Decision Metric

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

Table 6.9 OHT7 - Office of In Vitro Diagnostics
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	269	236	274	121	
Non-MDUFA V Decision	51	45	36	1	
MDUFA V Decision (SE/NSE)	218	191	205	25	
MDUFA V Decision Within 90 FDA Days	218	191	205	25	
510(k)s Pending MDUFA V Decision	0	0	33	95	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	488	461	507	241	
Closed Before First RTA or TS Action [1]	4	2	8	4	
Number Accepted or Passed TS on First Cycle [2]	441	447	482	212	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	16	
Number Not Accepted or Failed TS on First Cycle [2]	41	12	17	9	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	8.47%	2.61%	3.41%	4.07%	

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	496	215	
Deleted or Withdrawn Prior to SI	0	3	1	1	
SI Within 60 FDA Days	476	451	490	161	
SI Over 60 FDA Days	0	1	3	1	
SI Pending Within 60 FDA Days	0	0	2	51	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	1	
Current SI Performance Percent Within 60 FDA Days	100.00%	99.78%	99.39%	98.77%	

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	493	162	
Average Number of FDA Days to Substantive Interaction	49.51	50.89	52.27	51.51	
20th Percentile FDA Days to Substantive Interaction	35	46	49	45	
40th Percentile FDA Days to Substantive Interaction	53	55	56	56	
60th Percentile FDA Days to Substantive Interaction	57	58	58	58	
80th Percentile FDA Days to Substantive Interaction	59	59	60	60	
Maximum FDA Days to Substantive Interaction	60	61	67	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	496	215	
Non-MDUFA V Decision	31	33	27	2	
MDUFA V Decision (SE/NSE)	445	422	418	61	
MDUFA V Decision Within 90 FDA Days	445	422	418	61	
510(k)s Pending MDUFA V Decision	0	0	51	152	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.72	1.76	1.80	1.46	
Number With MDUFA V Decision	445	422	418	61	
Average Number of FDA Days to MDUFA V Decision	71.52	74.77	76.91	58.43	
20th Percentile FDA Days to MDUFA V Decision	52	57	68	28	
40th Percentile FDA Days to MDUFA V Decision	79	84	84	56	
60th Percentile FDA Days to MDUFA V Decision	86	88	88	71	
80th Percentile FDA Days to MDUFA V Decision	89	89	89	87	
Maximum FDA Days to MDUFA V Decision	90	90	90	90	
Average Number of Industry Days to MDUFA V Decision	63.50	67.15	62.73	11.18	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	24	31	31	0	
60th Percentile Industry Days to MDUFA V Decision	62	71	65	10	
80th Percentile Industry Days to MDUFA V Decision	138	144	121	28	
Maximum Industry Days to MDUFA V Decision	182	215	185	48	
Average Number of Total Days to MDUFA V Decision	135.03	141.93	139.65	69.61	
20th Percentile Total Days to MDUFA V Decision	56	66	83	29	
40th Percentile Total Days to MDUFA V Decision	107	114	116	57	
60th Percentile Total Days to MDUFA V Decision	146	156	149	88	
80th Percentile Total Days to MDUFA V Decision	222	219	205	107	
Maximum Total Days to MDUFA V Decision	272	304	275	126	

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	496	215	
Number With MDUFA V Decision	445	422	418	61	
Number of SE Decision	438	411	416	59	
Number of NSE Decision	7	11	2	2	
Number of Withdrawal	16	24	17	2	
Number of Deleted	14	9	10	0	
Rate of SE Decision	98.43%	97.39%	99.52%	96.72%	
Rate of NSE Decision	1.57%	2.61%	0.48%	3.28%	
Rate of Withdrawal	3.36%	5.27%	3.43%	0.93%	
Rate of Deleted	2.94%	1.98%	2.02%	0.00%	

Table 6.7 OHT8 - Office of Radiological Health
510(k) Performance Metric - Submission Missing Performance Goal

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

Table 6.8 OHT8 - Office of Radiological Health
LDT 510(k) MDUFA V Decision Metric

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

Table 6.9 OHT8 - Office of Radiological Health
Conventional VD (Non-LDT) 510(k) MDUFA V Decision Metric

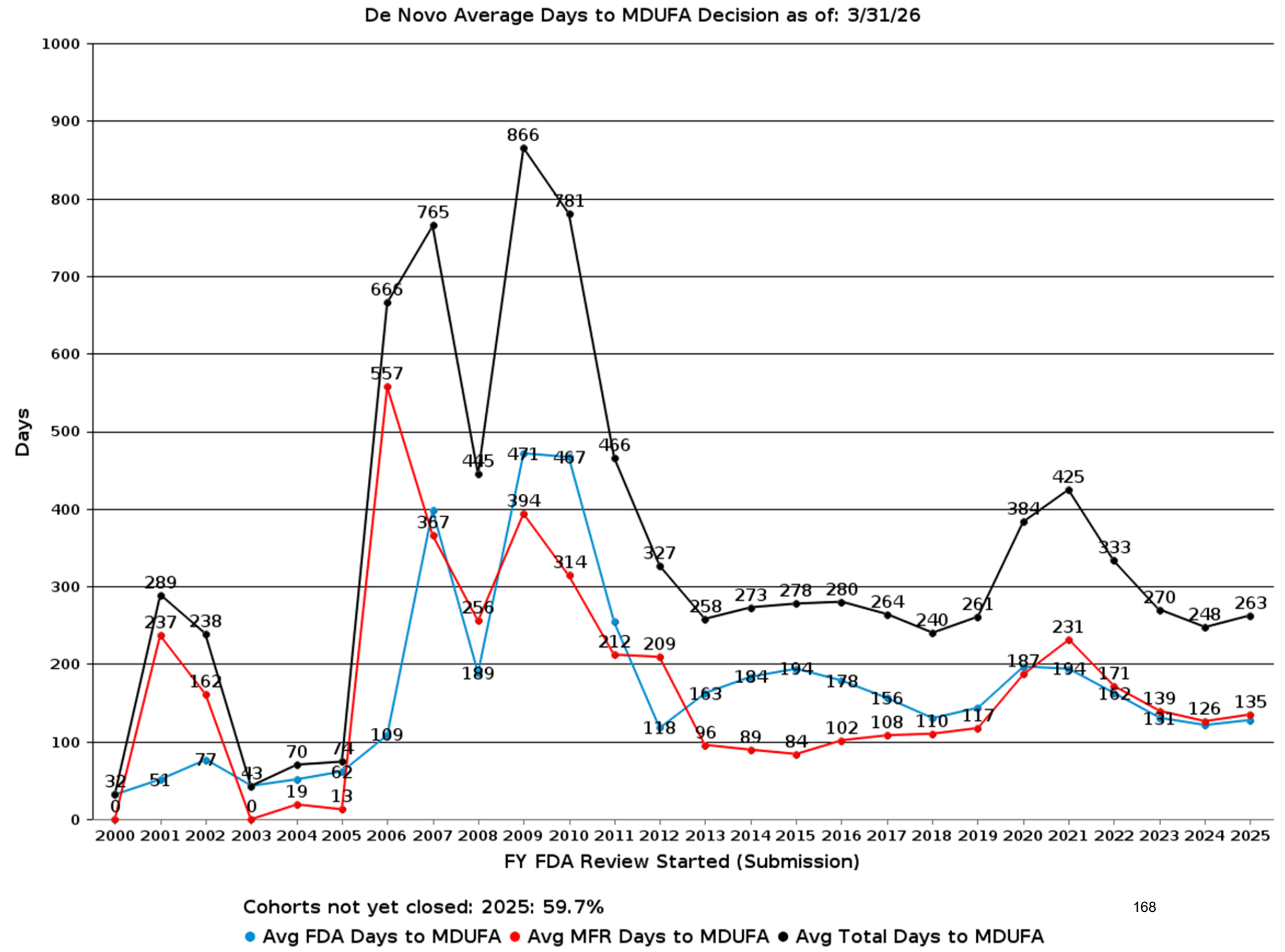
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA V Decision	N/A	N/A	N/A	N/A	
MDUFA V Decision (SE/NSE)	N/A	N/A	N/A	N/A	
MDUFA V Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V Decision	N/A	N/A	N/A	N/A	
510(k)s Pending MDUFA V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

Section 7 510(k) Annual General Metrics

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

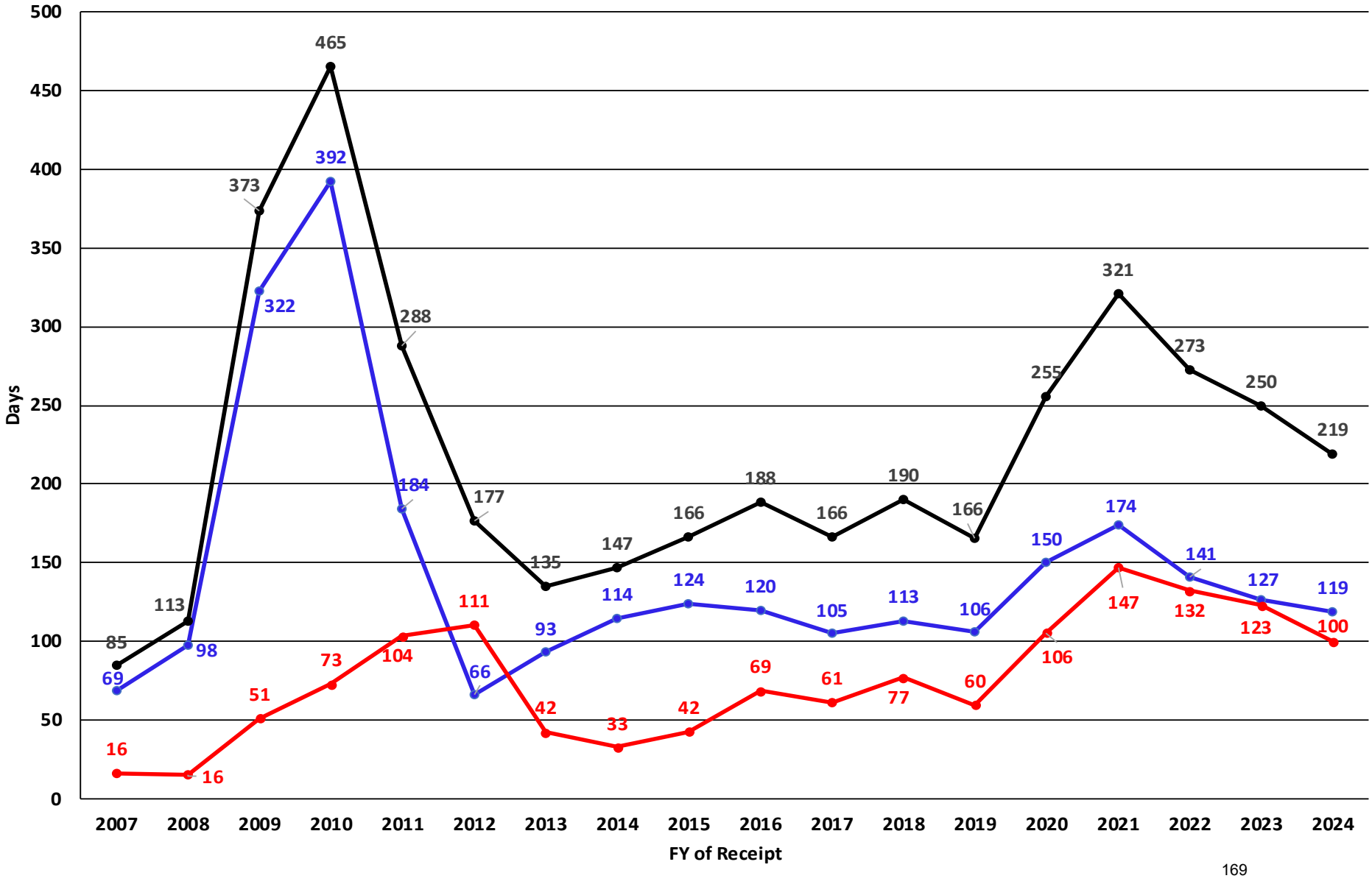
De Novos

Q2FY2026

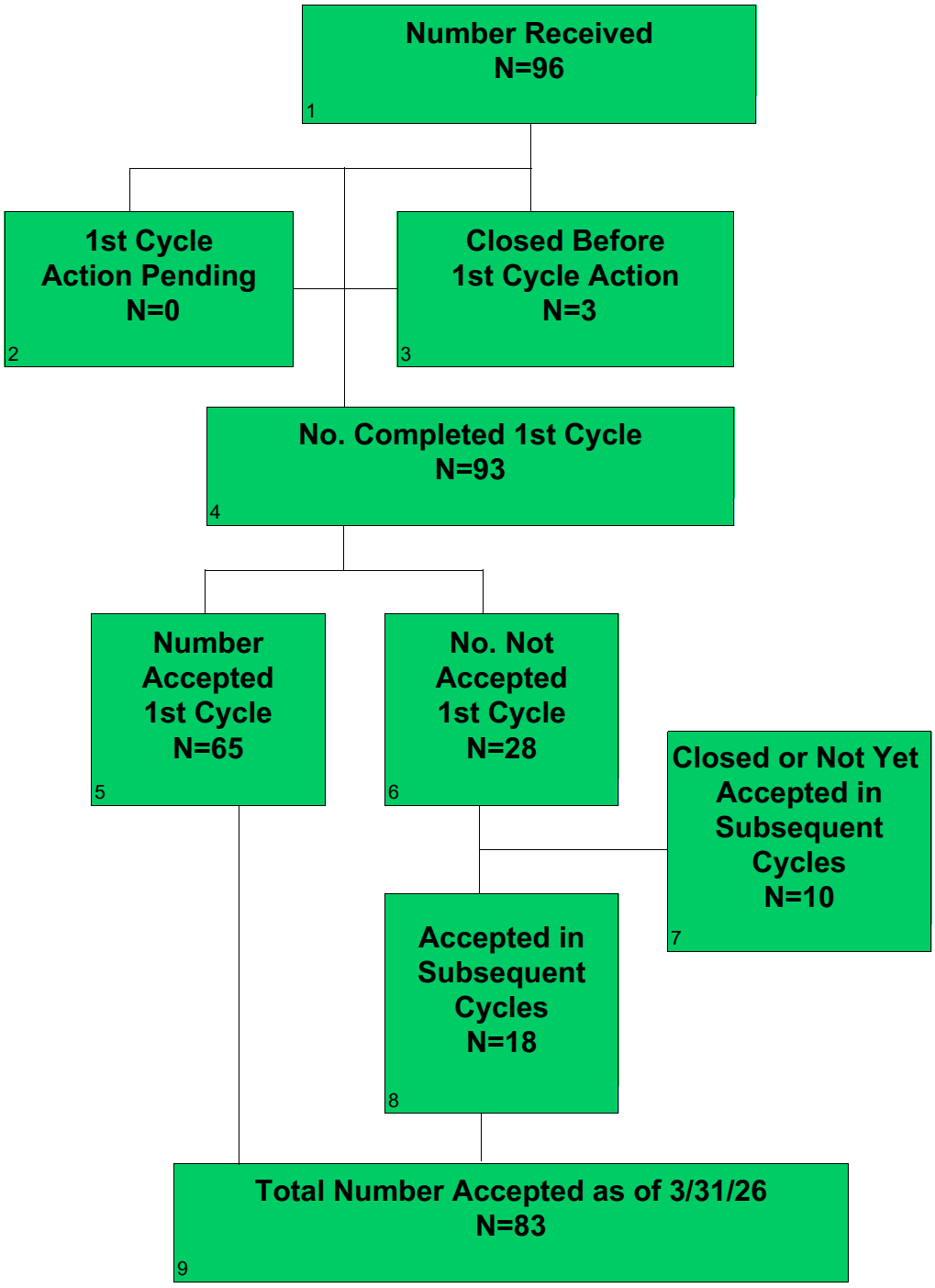

De Novo Average Days to MDUFA Decision as of: 3/31/26
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2025: 59.7%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

Average Time to MDUFA Decision: De Novos

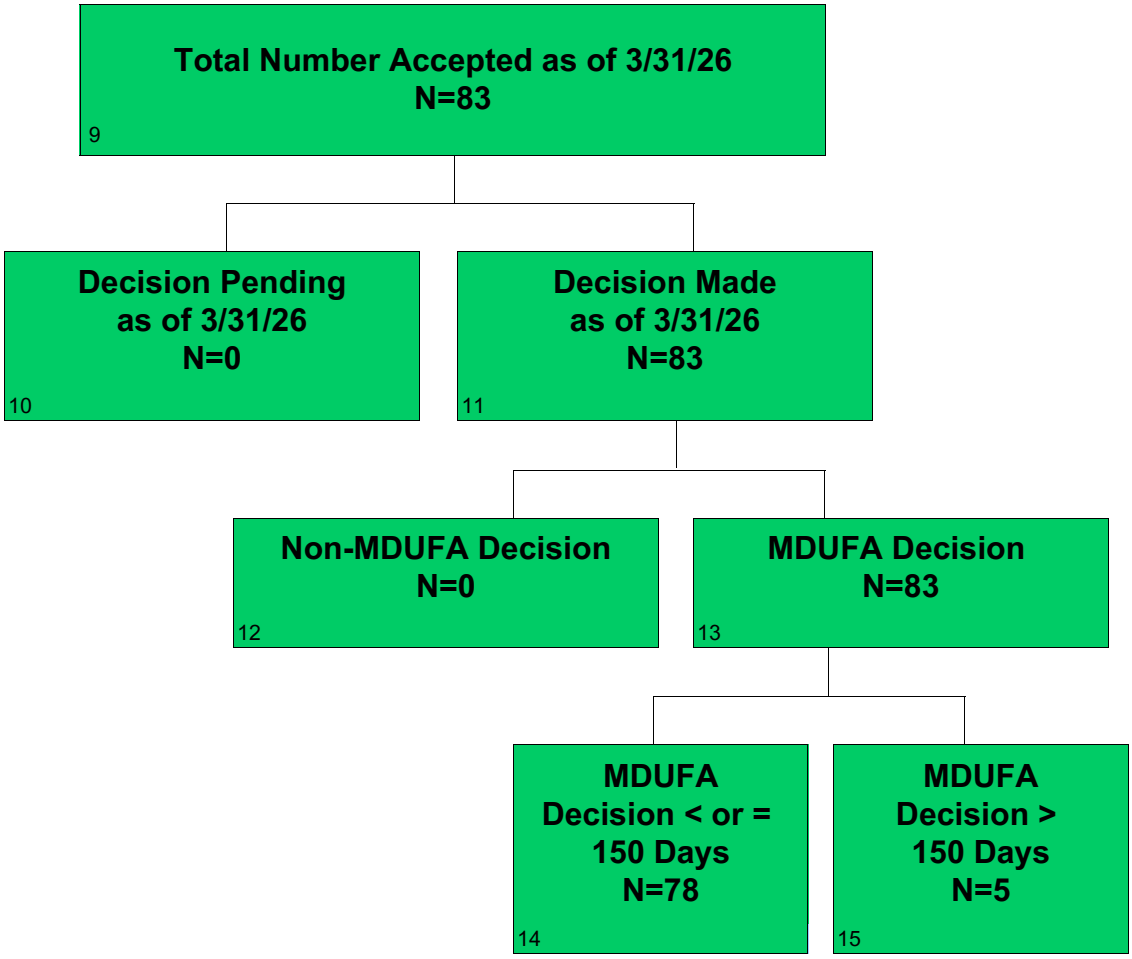
(59.7% closure comparison)



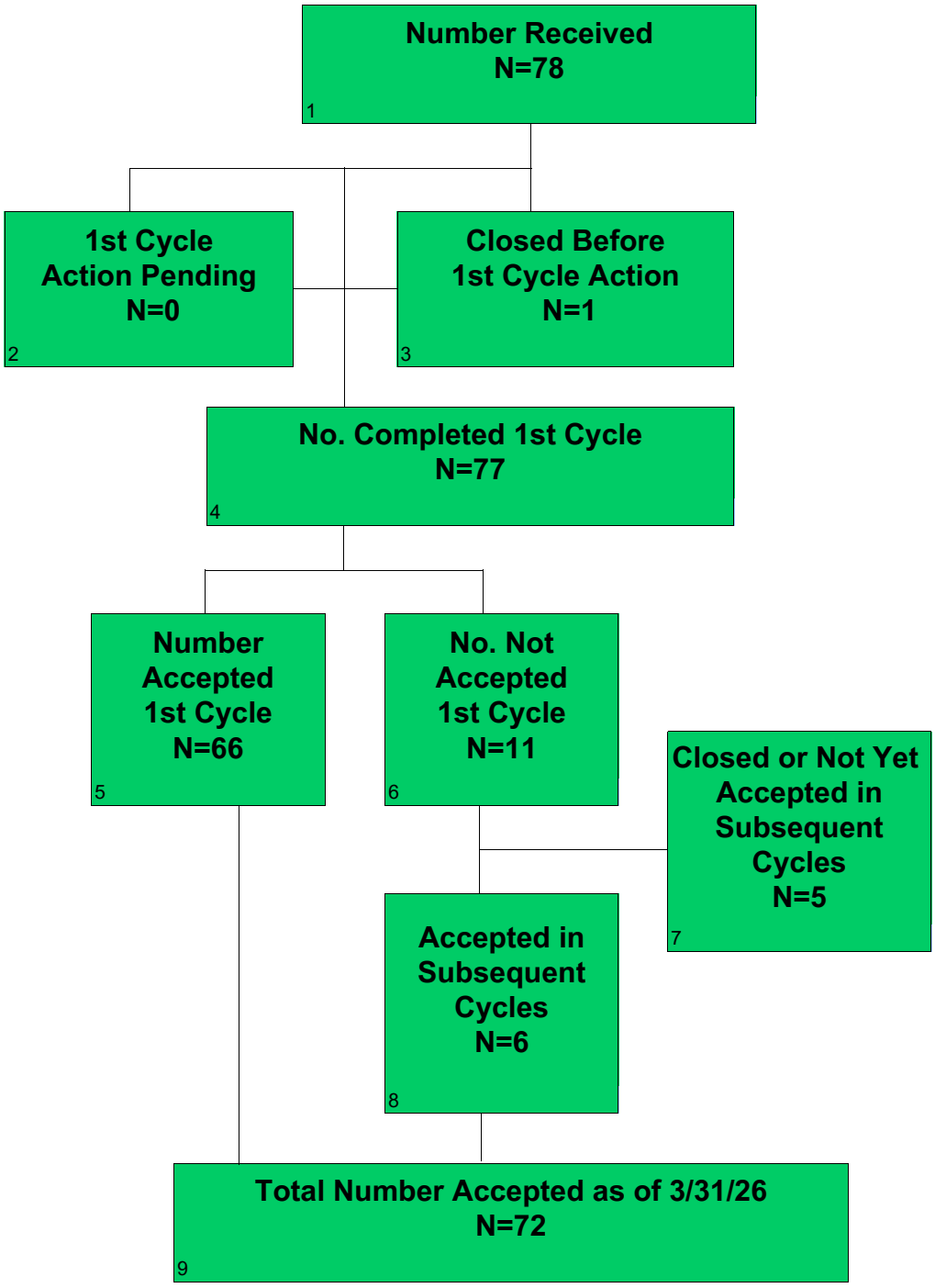
CDRH De Novo - FY 2023
as of 3/31/26



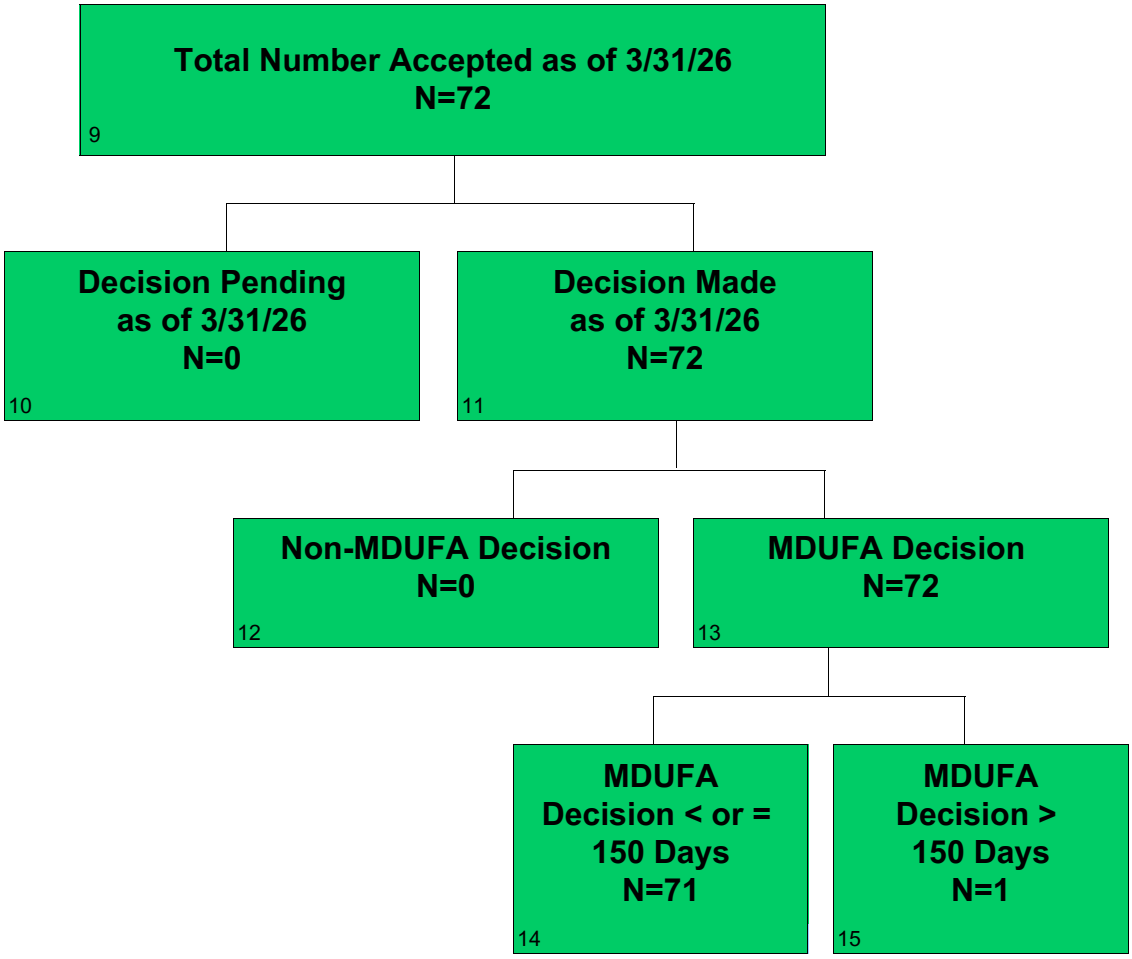
CDRH De Novo - FY 2023
as of 3/31/26 Continued



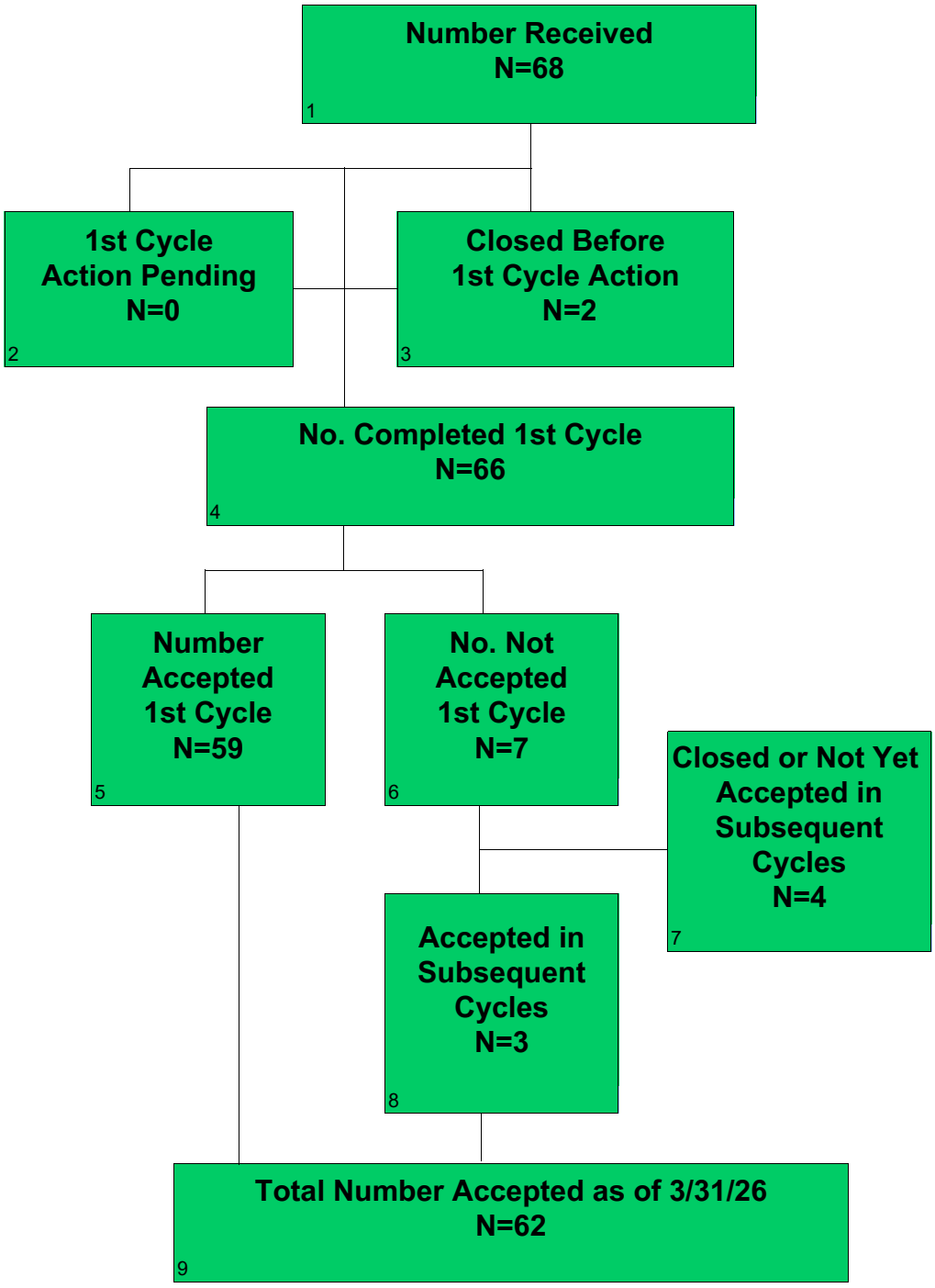
CDRH De Novo - FY 2024
as of 3/31/26



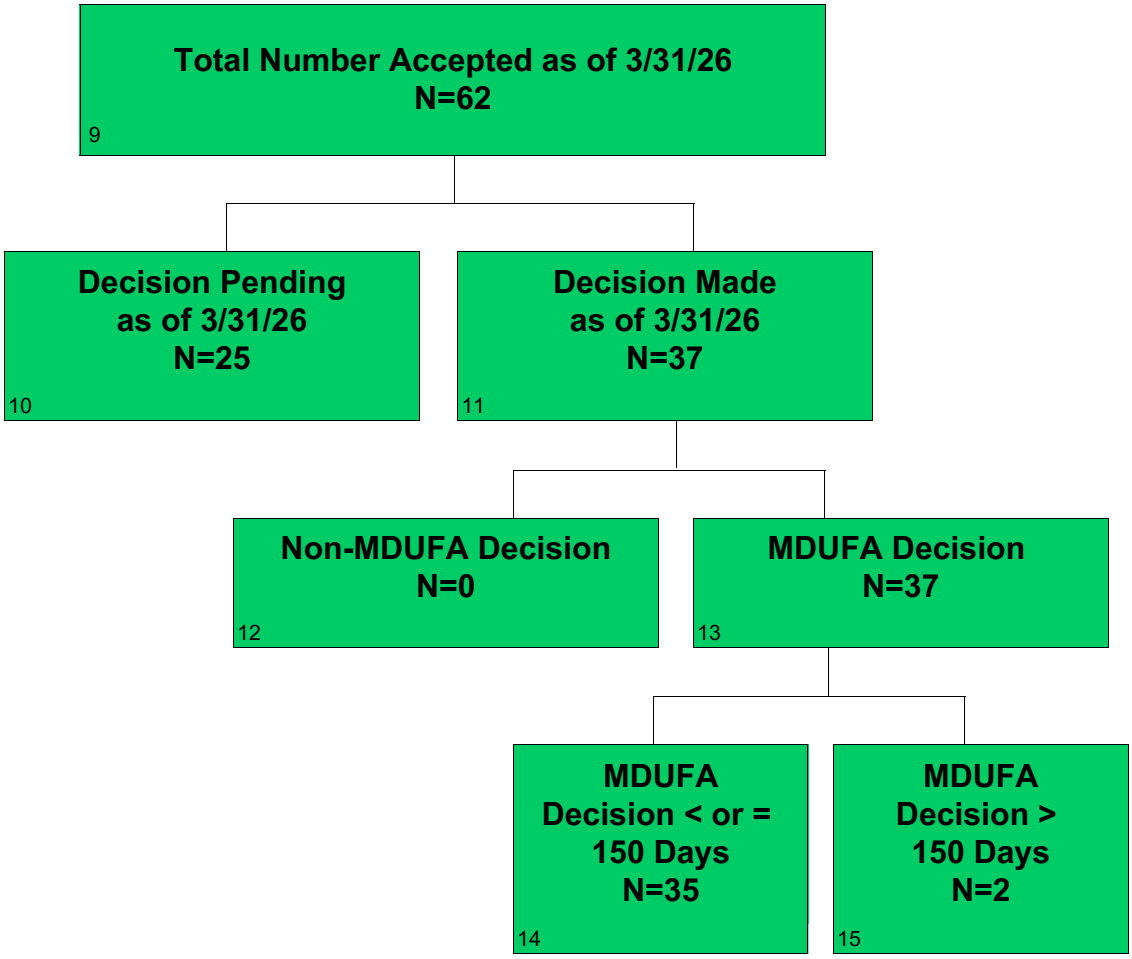
CDRH De Novo - FY 2024
as of 3/31/26 Continued



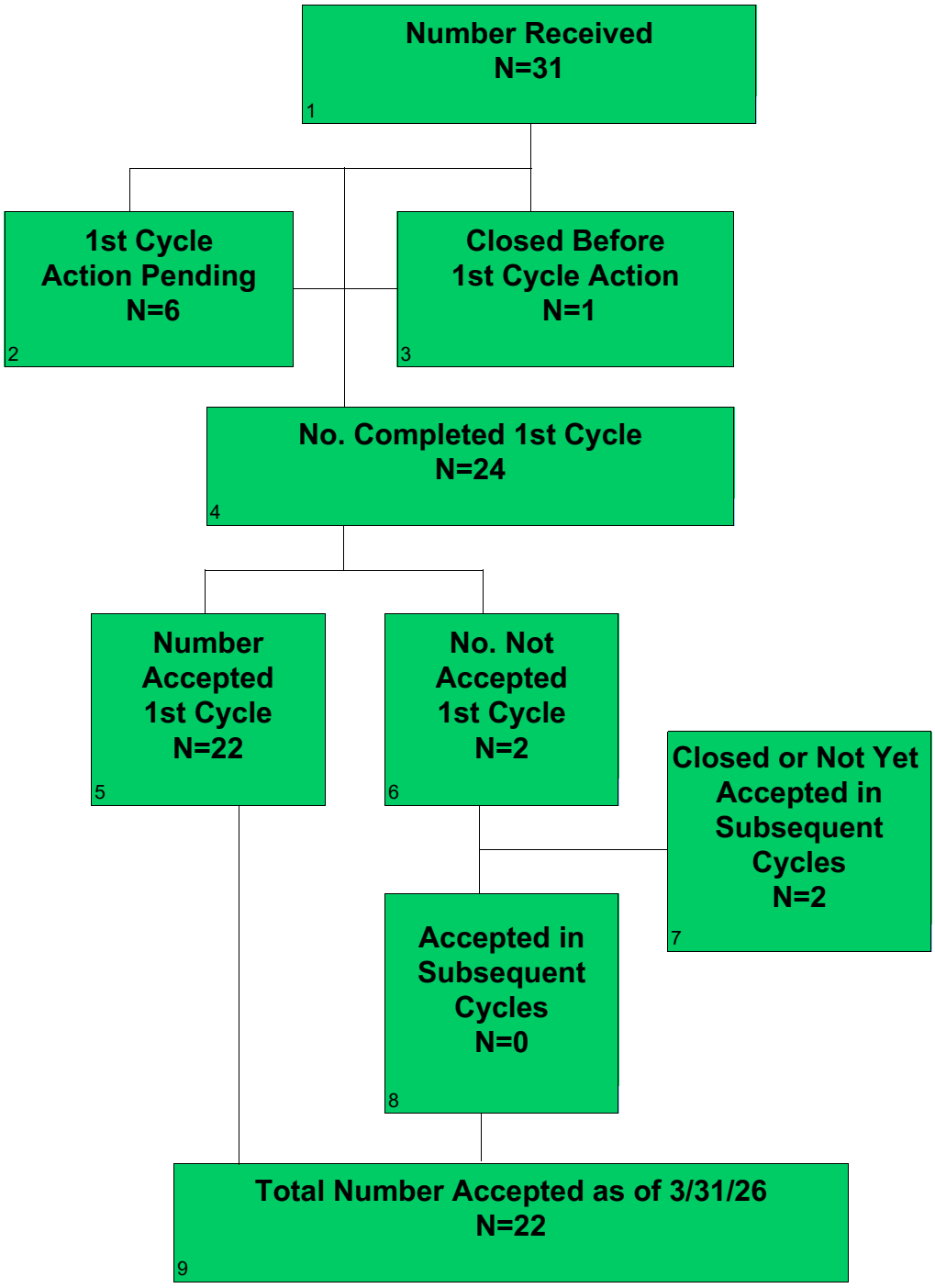
CDRH De Novo - FY 2025
as of 3/31/26



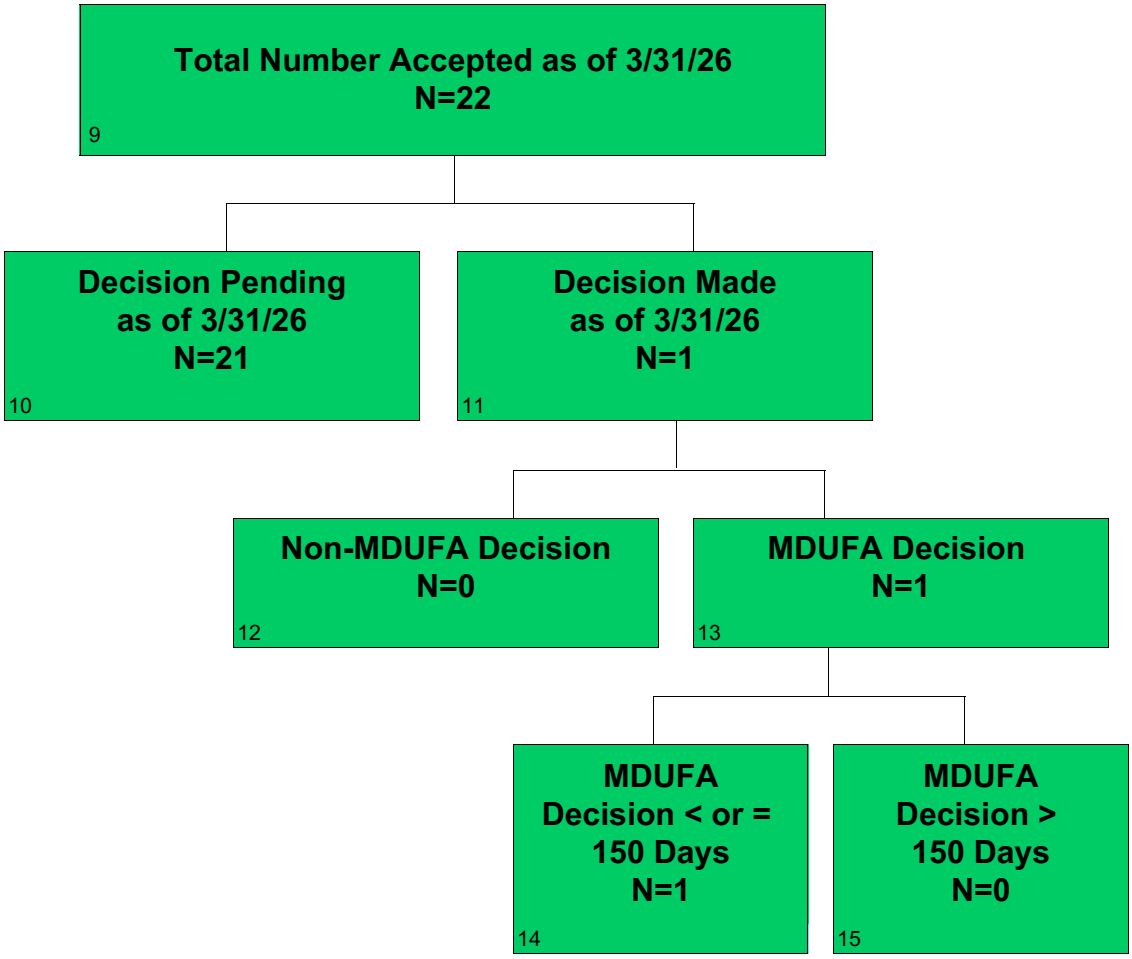
CDRH De Novo - FY 2025
as of 3/31/26 Continued



CDRH De Novo - FY 2026
as of 3/31/26



CDRH De Novo - FY 2026
as of 3/31/26 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	31	
Closed Before First RTA or TS Action	3	1	2	1	
Number Accepted or Passed TS on First Cycle	65	66	59	22	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	6	
Number Not Accepted or Failed TS on First Cycle	28	11	7	2	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	30.11%	14.29%	10.61%	8.33%	

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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	83	72	62	22	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	83	72	37	1	
MDUFA Decision Within 150 FDA Days	78	71	35	1	
De Novos Pending MDUFA Decision	0	0	25	21	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	2	0	
Current Performance Percent Within 150 FDA Days	93.98%	98.61%	89.74%	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	1.60	1.62	1.00	
Number With MDUFA Decision	83	72	37	1	
Average FDA Days to MDUFA Decision	130.60	121.26	127.81	75.00	
20th Percentile FDA Days to MDUFA Decision	75	75	76	75	
40th Percentile FDA Days to MDUFA Decision	148	134	147	75	
60th Percentile FDA Days to MDUFA Decision	150	149	149	75	
80th Percentile FDA Days to MDUFA Decision	150	150	150	75	
Maximum FDA Days to MDUFA Decision	251	151	165	75	
Average Industry Days to MDUFA Decision	139.47	126.25	134.97	N/A	
20th Percentile Industry Days to MDUFA Decision	72	34	79	0	
40th Percentile Industry Days to MDUFA Decision	152	143	153	0	
60th Percentile Industry Days to MDUFA Decision	178	177	177	0	
80th Percentile Industry Days to MDUFA Decision	181	181	181	0	
Maximum Industry Days to MDUFA Decision	350	185	189	0	
Average Total Days to MDUFA Decision	270.07	247.51	262.78	75.00	
20th Percentile Total Days to MDUFA Decision	214	178	228	75	
40th Percentile Total Days to MDUFA Decision	256	255	254	75	
60th Percentile Total Days to MDUFA Decision	303	284	284	75	
80th Percentile Total Days to MDUFA Decision	329	327	323	75	
Maximum Total Days to MDUFA Decision	437	330	340	75	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	83	72	62	22	
Number With MDUFA Decision	83	72	37	1	
Number With Granted Decision	37	29	21	0	
Number With Declined Decision	18	18	4	1	
Number of Withdrawal	17	13	4	0	
Number of Deleted	11	12	8	0	
Rate of Granted Decision	44.58%	40.28%	56.76%	0.00%	
Rate of Declined Decision	21.69%	25.00%	10.81%	100.00%	
Rate of Withdrawal	20.48%	18.06%	10.81%	0.00%	
Rate of Deleted	13.25%	16.67%	21.62%	0.00%	

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	2	0	
Mean FDA Days for Submissions that Missed the Goal	194.80	151.00	162.00	N/A	
Mean Industry Days for Submissions that Missed the Goal	111.20	150.00	177.00	N/A	

Table 8.6 CDRH - LDT De Novo MDUFA V Decision Metrics

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	11	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	19	18	6	0	
MDUFA Decision Within 150 FDA Days	19	18	6	0	
De Novos Pending MDUFA Decision	0	0	5	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

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	2	
Closed Before First RTA or TS Action	0	0	1	0	
Number Accepted or Passed TS on First Cycle	6	10	5	1	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted or Failed TS on First Cycle	6	3	4	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	50.00%	23.08%	44.44%	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 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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	11	12	7	1	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	11	12	5	0	
MDUFA Decision Within 150 FDA Days	8	11	4	0	
De Novos Pending MDUFA Decision	0	0	2	1	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	72.73%	91.67%	80.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.58	1.60	N/A	
Number With MDUFA Decision	11	12	5	0	
Average FDA Days to MDUFA Decision	130.82	118.42	139.20	N/A	
20th Percentile FDA Days to MDUFA Decision	73	73	137	0	
40th Percentile FDA Days to MDUFA Decision	75	109	150	0	
60th Percentile FDA Days to MDUFA Decision	150	148	150	0	
80th Percentile FDA Days to MDUFA Decision	178	150	152	0	
Maximum FDA Days to MDUFA Decision	251	151	159	0	
Average Industry Days to MDUFA Decision	137.45	131.75	143.40	N/A	
20th Percentile Industry Days to MDUFA Decision	81	125	142	0	
40th Percentile Industry Days to MDUFA Decision	152	137	178	0	
60th Percentile Industry Days to MDUFA Decision	178	166	179	0	
80th Percentile Industry Days to MDUFA Decision	182	181	180	0	
Maximum Industry Days to MDUFA Decision	189	181	181	0	
Average Total Days to MDUFA Decision	268.27	250.17	282.60	N/A	
20th Percentile Total Days to MDUFA Decision	231	222	244	0	
40th Percentile Total Days to MDUFA Decision	255	261	303	0	
60th Percentile Total Days to MDUFA Decision	262	284	328	0	
80th Percentile Total Days to MDUFA Decision	328	321	332	0	
Maximum Total Days to MDUFA Decision	343	328	338	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	12	7	1	
Number With MDUFA Decision	11	12	5	0	
Number With Granted Decision	5	3	4	0	
Number With Declined Decision	1	4	0	0	
Number of Withdrawal	1	3	0	0	
Number of Deleted	4	2	1	0	
Rate of Granted Decision	45.45%	25.00%	80.00%	N/A	
Rate of Declined Decision	9.09%	33.33%	0.00%	N/A	
Rate of Withdrawal	9.09%	25.00%	0.00%	N/A	
Rate of Deleted	36.36%	16.67%	20.00%	N/A	

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	12	4	4	3	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	10	4	4	2	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	1	
Number Not Accepted or Failed TS on First Cycle	2	0	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	16.67%	0.00%	0.00%	0.00%	

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	10	4	4	2	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	10	4	1	0	
MDUFA Decision Within 150 FDA Days	10	4	1	0	
De Novos Pending MDUFA Decision	0	0	3	2	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

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

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

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

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

Table 8.5 OHT2 - Office of Cardiovascular Devices
De Novo Performance Metrics-Submissions Missing Performance Goal

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

Table 8.6 OHT2 - Office of Cardiovascular Devices
LDT De Novo MDUFA V Metrics

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

Table 8.7 OHT2 - Office of Cardiovascular Devices
Conventional IVD (non-LDT) De Novo MDUFA V Decision Metrics

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	11	8	12	3	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	9	7	11	3	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	2	1	1	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	18.18%	12.50%	8.33%	0.00%	

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	11	8	12	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	11	8	5	0	
MDUFA Decision Within 150 FDA Days	11	8	5	0	
De Novos Pending MDUFA Decision	0	0	7	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.55	1.88	1.80	N/A	
Number With MDUFA Decision	11	8	5	0	
Average FDA Days to MDUFA Decision	128.45	131.50	127.80	N/A	
20th Percentile FDA Days to MDUFA Decision	74	114	108	0	
40th Percentile FDA Days to MDUFA Decision	148	143	136	0	
60th Percentile FDA Days to MDUFA Decision	150	148	149	0	
80th Percentile FDA Days to MDUFA Decision	150	149	149	0	
Maximum FDA Days to MDUFA Decision	150	150	150	0	
Average Industry Days to MDUFA Decision	122.73	160.50	156.60	N/A	
20th Percentile Industry Days to MDUFA Decision	83	156	137	0	
40th Percentile Industry Days to MDUFA Decision	124	179	148	0	
60th Percentile Industry Days to MDUFA Decision	163	180	164	0	
80th Percentile Industry Days to MDUFA Decision	180	182	181	0	
Maximum Industry Days to MDUFA Decision	214	183	184	0	
Average Total Days to MDUFA Decision	251.18	292.00	284.40	N/A	
20th Percentile Total Days to MDUFA Decision	231	264	270	0	
40th Percentile Total Days to MDUFA Decision	247	288	284	0	
60th Percentile Total Days to MDUFA Decision	274	324	294	0	
80th Percentile Total Days to MDUFA Decision	293	327	301	0	
Maximum Total Days to MDUFA Decision	330	329	303	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	11	8	12	3	
Number With MDUFA Decision	11	8	5	0	
Number With Granted Decision	7	2	2	0	
Number With Declined Decision	1	2	1	0	
Number of Withdrawal	1	3	1	0	
Number of Deleted	2	1	1	0	
Rate of Granted Decision	63.64%	25.00%	40.00%	N/A	
Rate of Declined Decision	9.09%	25.00%	20.00%	N/A	
Rate of Withdrawal	9.09%	37.50%	20.00%	N/A	
Rate of Deleted	18.18%	12.50%	20.00%	N/A	

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

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	15	12	5	5	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	15	12	3	1	
MDUFA Decision Within 150 FDA Days	13	12	2	1	
De Novos Pending MDUFA Decision	0	0	2	4	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	1	0	
Current Performance Percent Within 150 FDA Days	86.67%	100.00%	50.00%	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	1.67	1.00	
Number With MDUFA Decision	15	12	3	1	
Average FDA Days to MDUFA Decision	126.87	119.92	129.33	75.00	
20th Percentile FDA Days to MDUFA Decision	75	74	104	75	
40th Percentile FDA Days to MDUFA Decision	143	117	134	75	
60th Percentile FDA Days to MDUFA Decision	148	150	152	75	
80th Percentile FDA Days to MDUFA Decision	150	150	159	75	
Maximum FDA Days to MDUFA Decision	203	150	165	75	
Average Industry Days to MDUFA Decision	134.87	129.00	180.67	N/A	
20th Percentile Industry Days to MDUFA Decision	80	29	176	0	
40th Percentile Industry Days to MDUFA Decision	156	165	177	0	
60th Percentile Industry Days to MDUFA Decision	180	174	180	0	
80th Percentile Industry Days to MDUFA Decision	181	179	185	0	
Maximum Industry Days to MDUFA Decision	198	185	189	0	
Average Total Days to MDUFA Decision	261.73	248.92	310.00	75.00	
20th Percentile Total Days to MDUFA Decision	228	164	289	75	
40th Percentile Total Days to MDUFA Decision	254	247	314	75	
60th Percentile Total Days to MDUFA Decision	302	319	330	75	
80th Percentile Total Days to MDUFA Decision	329	326	335	75	
Maximum Total Days to MDUFA Decision	346	330	340	75	

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	5	
Number With MDUFA Decision	15	12	3	1	
Number With Granted Decision	7	7	2	0	
Number With Declined Decision	2	2	0	1	
Number of Withdrawal	5	2	0	0	
Number of Deleted	1	1	1	0	
Rate of Granted Decision	46.67%	58.33%	66.67%	0.00%	
Rate of Declined Decision	13.33%	16.67%	0.00%	100.00%	
Rate of Withdrawal	33.33%	16.67%	0.00%	0.00%	
Rate of Deleted	6.67%	8.33%	33.33%	0.00%	

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	1	0	
Mean FDA Days for Submissions That Missed the Goal	177.00	N/A	165.00	N/A	
Mean Industry Days for Submissions That Missed the Goal	94.50	N/A	175.00	N/A	

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	10	12	15	6	
Closed Before First RTA or TS Action	1	0	0	0	
Number Accepted or Passed TS on First Cycle	5	11	15	4	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	2	
Number Not Accepted or Failed TS on First Cycle	4	1	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	44.44%	8.33%	0.00%	0.00%	

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	9	12	15	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	9	12	11	0	
MDUFA Decision Within 150 FDA Days	9	12	11	0	
De Novos Pending MDUFA Decision	0	0	4	4	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	1	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	91.67%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.11	1.67	1.64	N/A	
Number With MDUFA Decision	9	12	11	0	
Average FDA Days to MDUFA Decision	141.44	118.92	136.09	N/A	
20th Percentile FDA Days to MDUFA Decision	149	76	147	0	
40th Percentile FDA Days to MDUFA Decision	150	109	149	0	
60th Percentile FDA Days to MDUFA Decision	150	148	150	0	
80th Percentile FDA Days to MDUFA Decision	150	150	150	0	
Maximum FDA Days to MDUFA Decision	150	150	150	0	
Average Industry Days to MDUFA Decision	145.56	110.58	90.00	N/A	
20th Percentile Industry Days to MDUFA Decision	112	6	31	0	
40th Percentile Industry Days to MDUFA Decision	154	111	58	0	
60th Percentile Industry Days to MDUFA Decision	172	176	79	0	
80th Percentile Industry Days to MDUFA Decision	182	179	172	0	
Maximum Industry Days to MDUFA Decision	231	183	185	0	
Average Total Days to MDUFA Decision	287.00	229.50	226.09	N/A	
20th Percentile Total Days to MDUFA Decision	237	105	181	0	
40th Percentile Total Days to MDUFA Decision	300	255	208	0	
60th Percentile Total Days to MDUFA Decision	313	263	229	0	
80th Percentile Total Days to MDUFA Decision	326	326	260	0	
Maximum Total Days to MDUFA Decision	381	328	319	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	9	12	15	4	
Number With MDUFA Decision	9	12	11	0	
Number With Granted Decision	3	3	7	0	
Number With Declined Decision	5	6	2	0	
Number of Withdrawal	0	1	0	0	
Number of Deleted	1	2	2	0	
Rate of Granted Decision	33.33%	25.00%	63.64%	N/A	
Rate of Declined Decision	55.56%	50.00%	18.18%	N/A	
Rate of Withdrawal	0.00%	8.33%	0.00%	N/A	
Rate of Deleted	11.11%	16.67%	18.18%	N/A	

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

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	3	2	5	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	3	2	3	0	
MDUFA Decision Within 150 FDA Days	3	2	3	0	
De Novos Pending MDUFA Decision	0	0	2	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

Table 8.3 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	1.33	N/A	
Number With MDUFA Decision	3	2	3	0	
Average FDA Days to MDUFA Decision	149.00	111.50	89.67	N/A	
20th Percentile FDA Days to MDUFA Decision	148	88	63	0	
40th Percentile FDA Days to MDUFA Decision	149	104	68	0	
60th Percentile FDA Days to MDUFA Decision	149	119	85	0	
80th Percentile FDA Days to MDUFA Decision	150	135	113	0	
Maximum FDA Days to MDUFA Decision	150	150	141	0	
Average Industry Days to MDUFA Decision	119.33	180.00	179.67	N/A	
20th Percentile Industry Days to MDUFA Decision	71	179	176	0	
40th Percentile Industry Days to MDUFA Decision	142	180	179	0	
60th Percentile Industry Days to MDUFA Decision	178	180	182	0	
80th Percentile Industry Days to MDUFA Decision	179	181	183	0	
Maximum Industry Days to MDUFA Decision	180	181	185	0	
Average Total Days to MDUFA Decision	268.33	291.50	269.33	N/A	
20th Percentile Total Days to MDUFA Decision	220	269	240	0	
40th Percentile Total Days to MDUFA Decision	292	284	243	0	
60th Percentile Total Days to MDUFA Decision	328	299	260	0	
80th Percentile Total Days to MDUFA Decision	329	314	293	0	
Maximum Total Days to MDUFA Decision	329	329	326	0	

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	23	20	13	8	
Closed Before First RTA or TS Action	1	1	1	1	
Number Accepted or Passed TS on First Cycle	17	17	11	4	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	2	
Number Not Accepted or Failed TS on First Cycle	5	2	1	1	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	22.73%	10.53%	8.33%	20.00%	

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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	20	18	11	4	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	20	18	6	0	
MDUFA Decision Within 150 FDA Days	20	18	6	0	
De Novos Pending MDUFA Decision	0	0	5	4	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	19	18	11	3	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	19	18	6	0	
MDUFA Decision Within 150 FDA Days	19	18	6	0	
De Novos Pending MDUFA Decision	0	0	5	3	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	3	1	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	4	4	3	0	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	0	1	0	1	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%	20.00%	0.00%	100.00%	

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 80% Within 150 FDA Days	FY 2027 90% Within 150 FDA Days
De Novos Accepted	4	4	3	0	
Non-MDUFA Decision	0	0	0	0	
MDUFA Decision	4	4	3	0	
MDUFA Decision Within 150 FDA Days	4	4	3	0	
De Novos Pending MDUFA Decision	0	0	0	0	
De Novos Pending MDUFA Decision Over 150 FDA Days	0	0	0	0	
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.25	1.50	1.67	N/A	
Number With MDUFA Decision	4	4	3	0	
Average FDA Days to MDUFA Decision	108.75	117.75	123.33	N/A	
20th Percentile FDA Days to MDUFA Decision	70	95	102	0	
40th Percentile FDA Days to MDUFA Decision	89	115	133	0	
60th Percentile FDA Days to MDUFA Decision	133	133	149	0	
80th Percentile FDA Days to MDUFA Decision	149	143	150	0	
Maximum FDA Days to MDUFA Decision	150	149	150	0	
Average Industry Days to MDUFA Decision	130.50	118.50	177.33	N/A	
20th Percentile Industry Days to MDUFA Decision	83	70	175	0	
40th Percentile Industry Days to MDUFA Decision	132	129	176	0	
60th Percentile Industry Days to MDUFA Decision	169	164	177	0	
80th Percentile Industry Days to MDUFA Decision	186	178	179	0	
Maximum Industry Days to MDUFA Decision	193	181	181	0	
Average Total Days to MDUFA Decision	239.25	236.25	300.67	N/A	
20th Percentile Total Days to MDUFA Decision	190	197	278	0	
40th Percentile Total Days to MDUFA Decision	258	257	309	0	
60th Percentile Total Days to MDUFA Decision	265	264	325	0	
80th Percentile Total Days to MDUFA Decision	297	286	328	0	
Maximum Total Days to MDUFA Decision	343	315	331	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	4	4	3	0	
Number With MDUFA Decision	4	4	3	0	
Number With Granted Decision	2	1	2	0	
Number With Declined Decision	0	1	0	0	
Number of Withdrawal	1	1	1	0	
Number of Deleted	1	1	0	0	
Rate of Granted Decision	50.00%	25.00%	66.67%	N/A	
Rate of Declined Decision	0.00%	25.00%	0.00%	N/A	
Rate of Withdrawal	25.00%	25.00%	33.33%	N/A	
Rate of Deleted	25.00%	25.00%	0.00%	N/A	

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

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

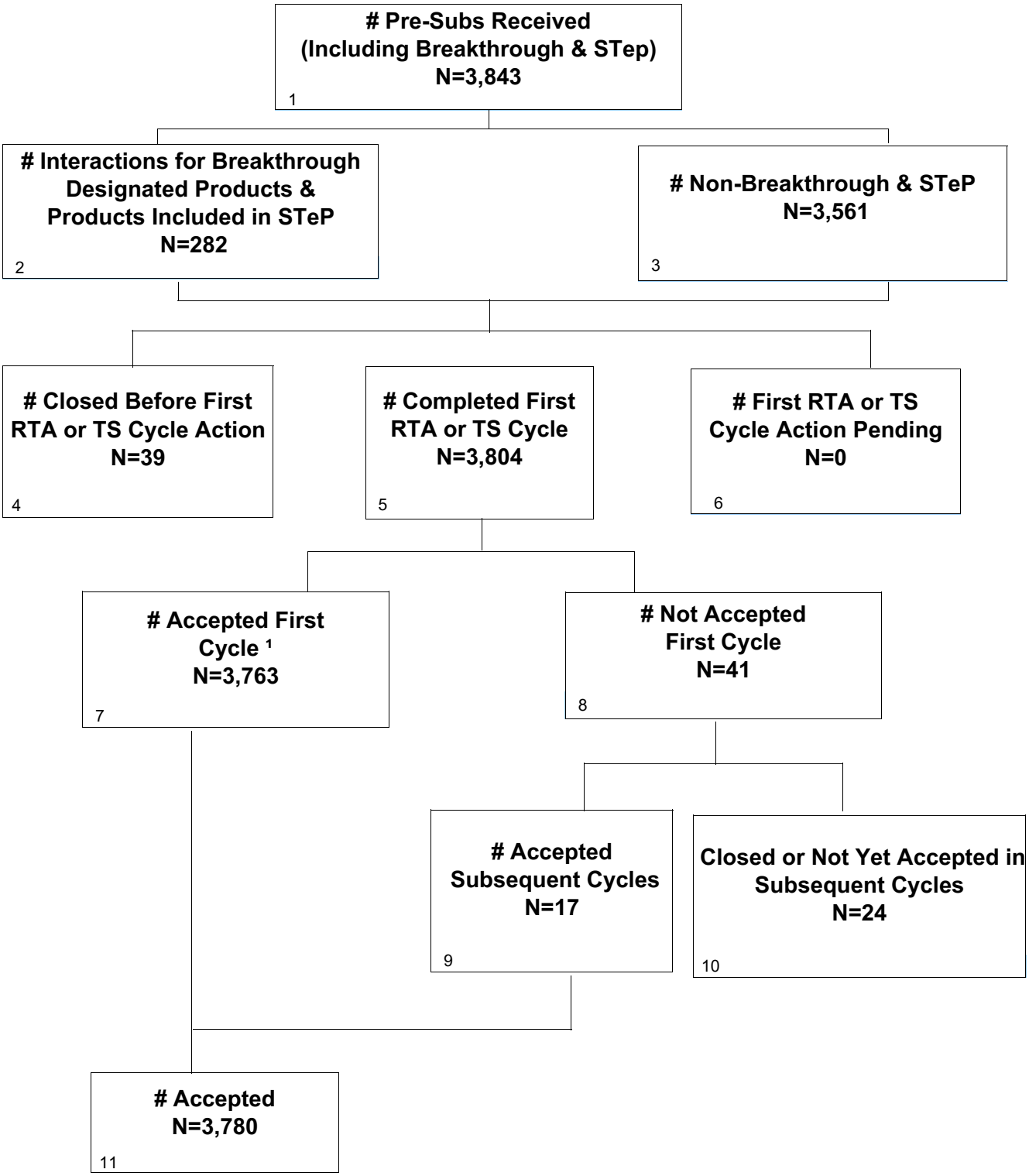
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

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

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

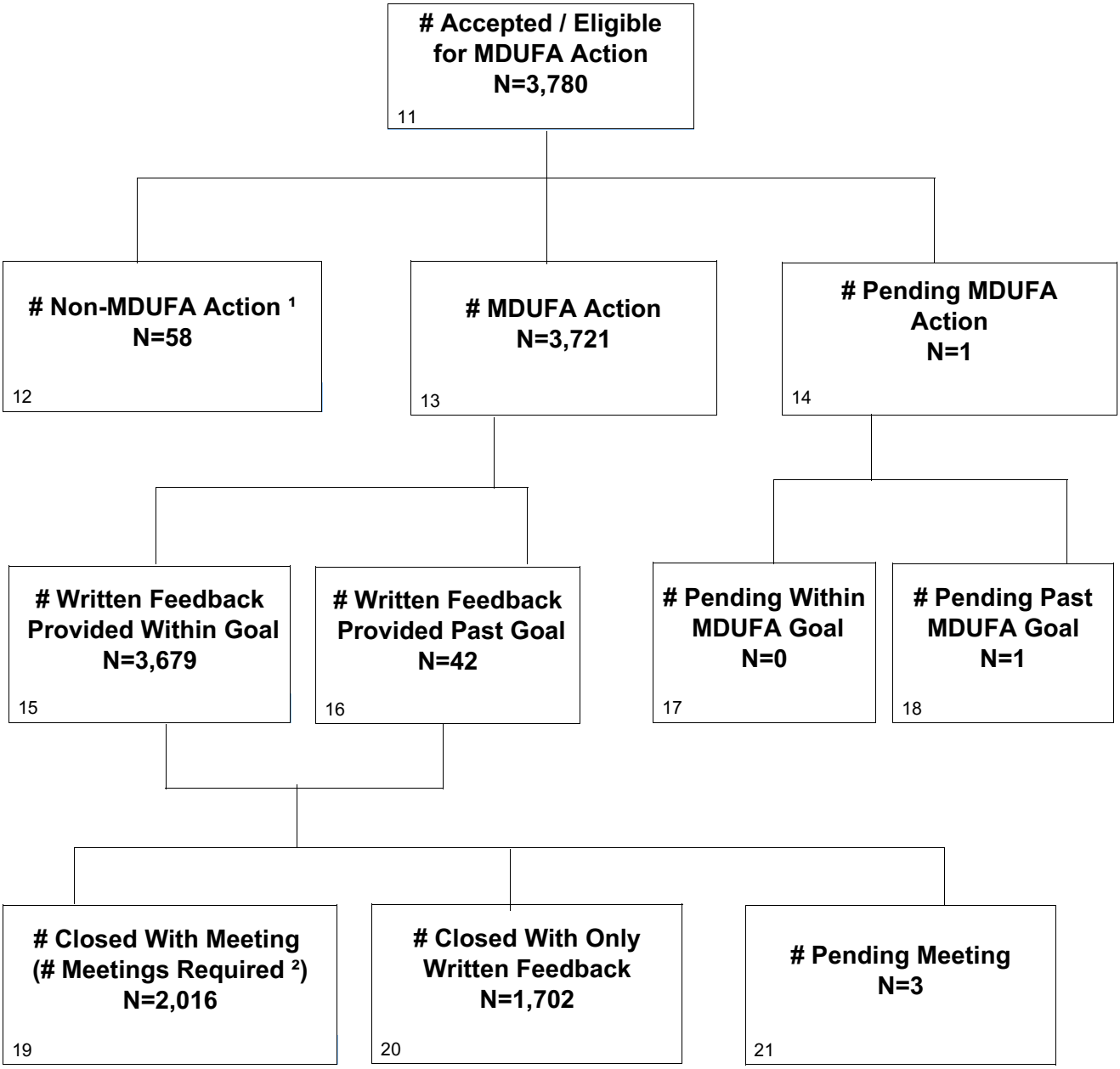
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A	N/A	N/A	N/A	
Non-MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision	N/A	N/A	N/A	N/A	
MDUFA Decision Within 150 FDA Days	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision	N/A	N/A	N/A	N/A	
De Novos Pending MDUFA Decision Over 150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

CDRH Pre-Sub - FY 2023
as of 3/31/26



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.

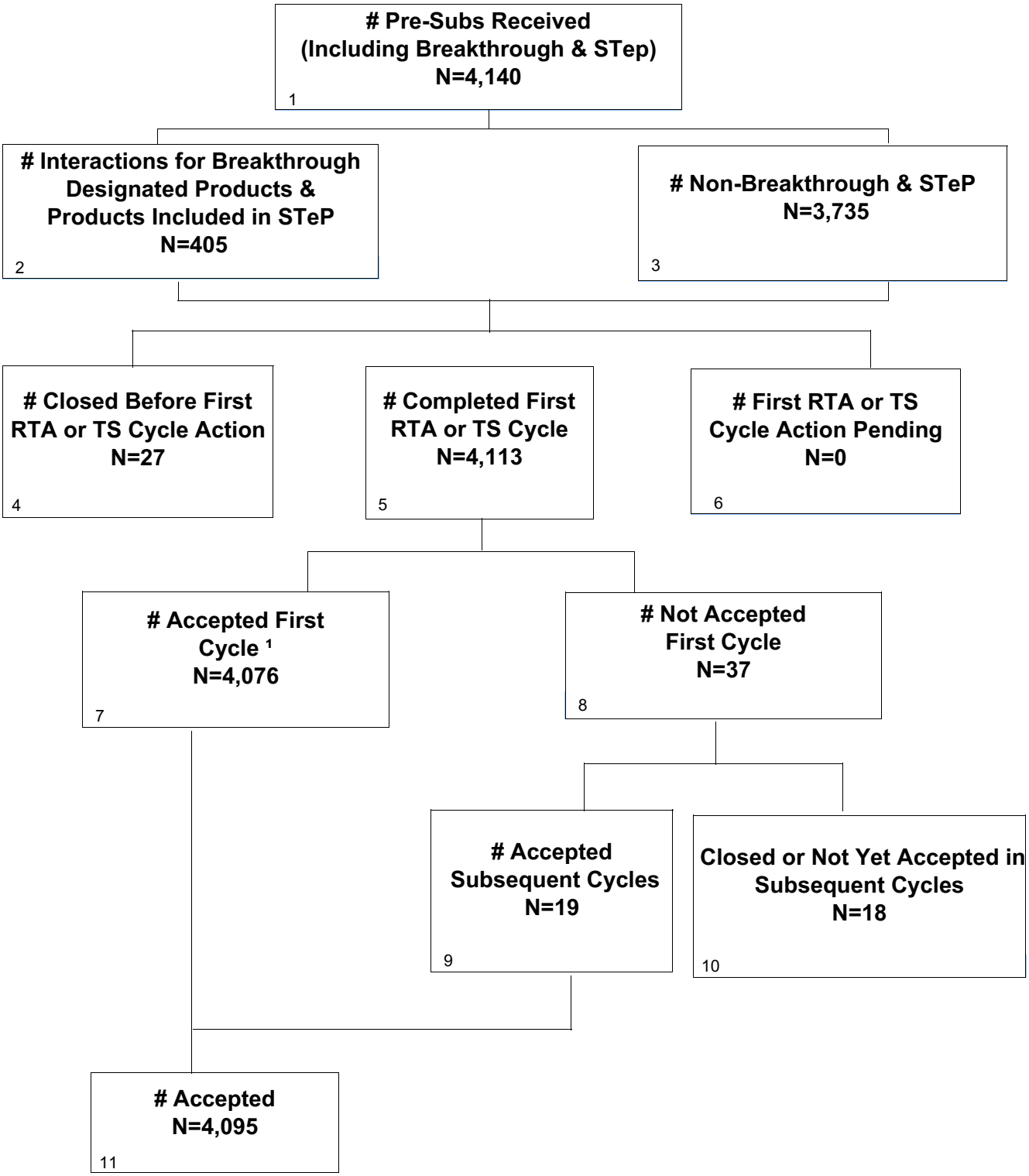
CDRH Pre-Sub - FY 2023
as of 3/31/26 Continued



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.

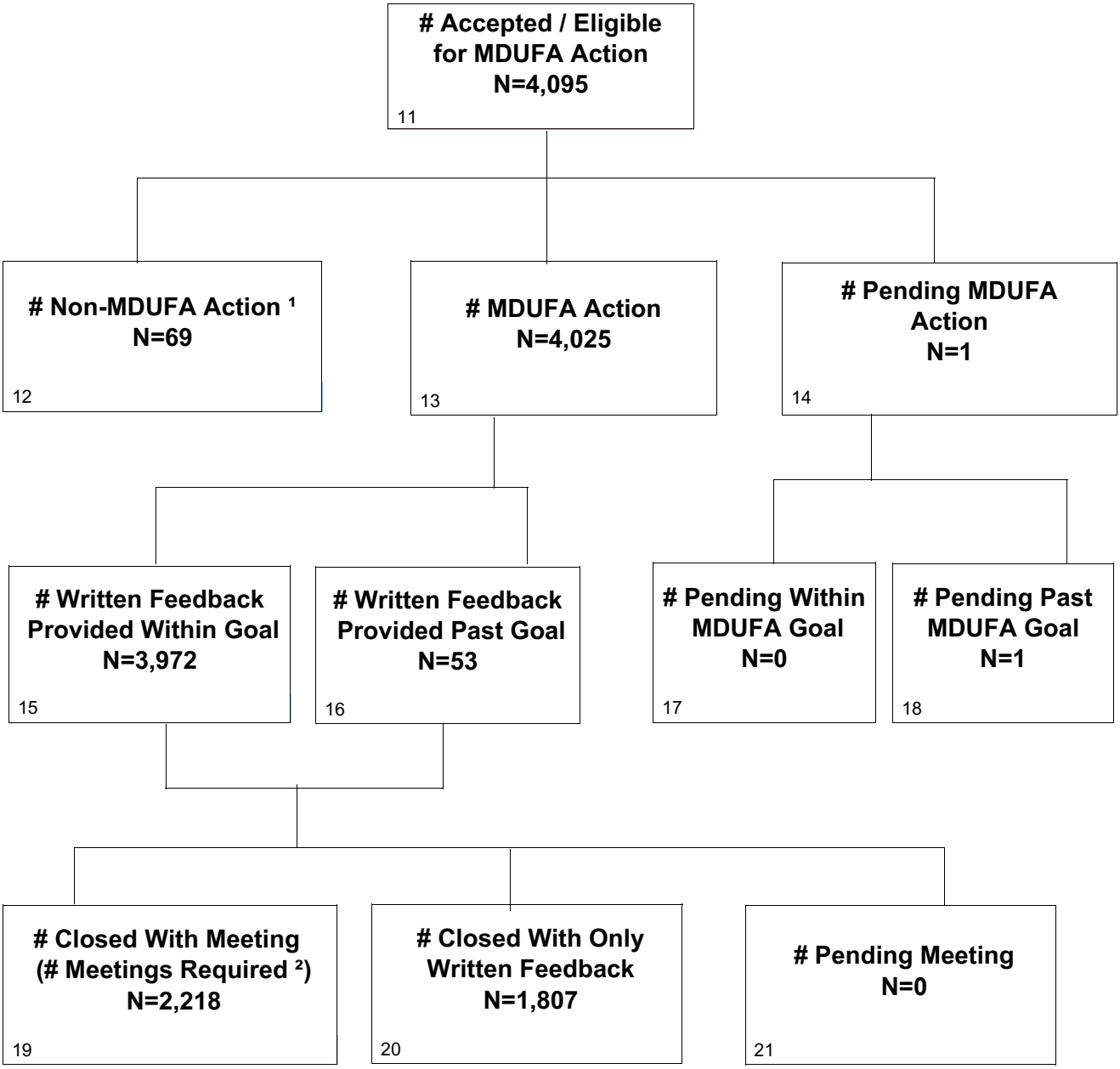
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2024
as of 3/31/26



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.

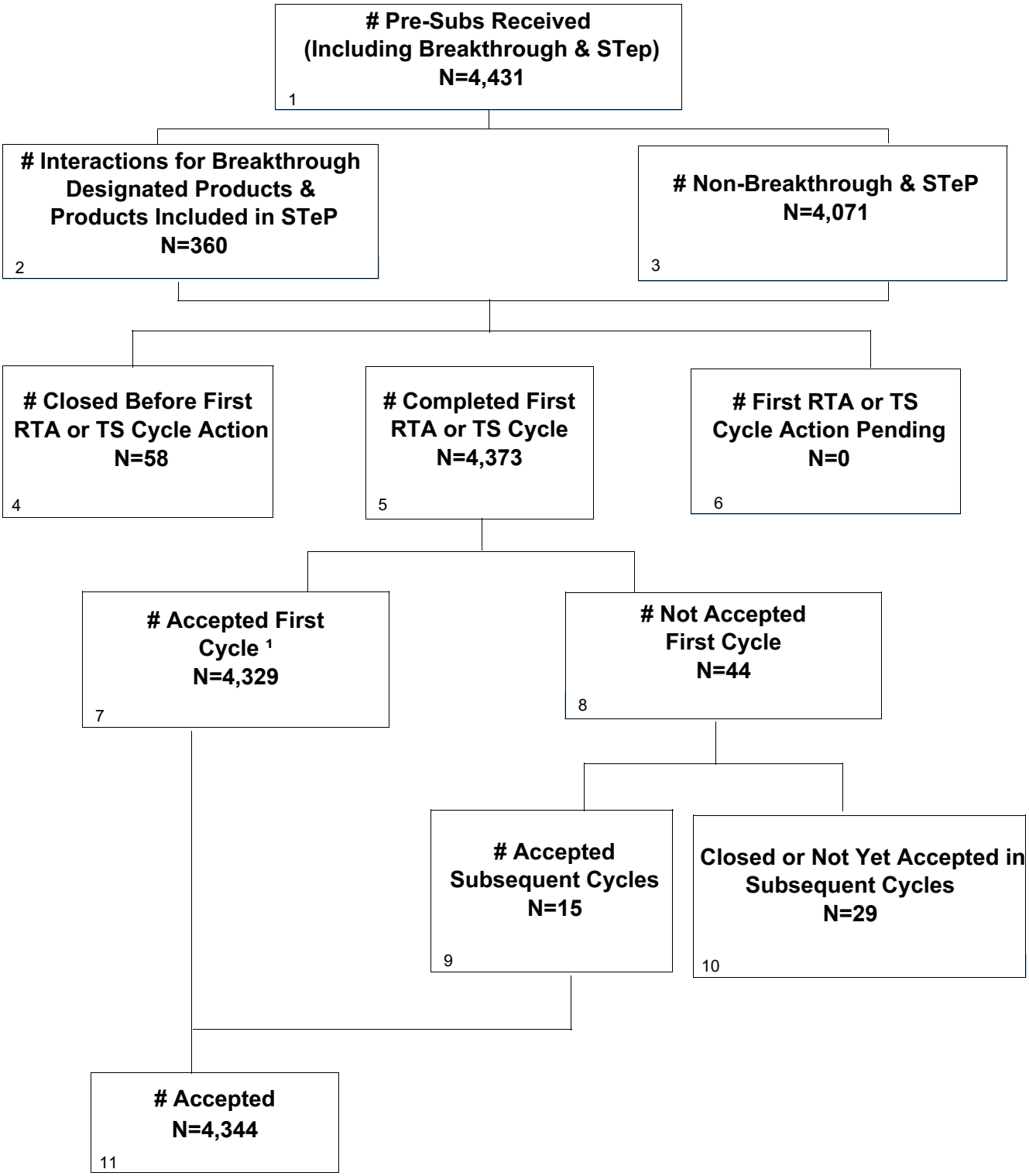
CDRH Pre-Sub - FY 2024 as of 3/31/26 Continued



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.

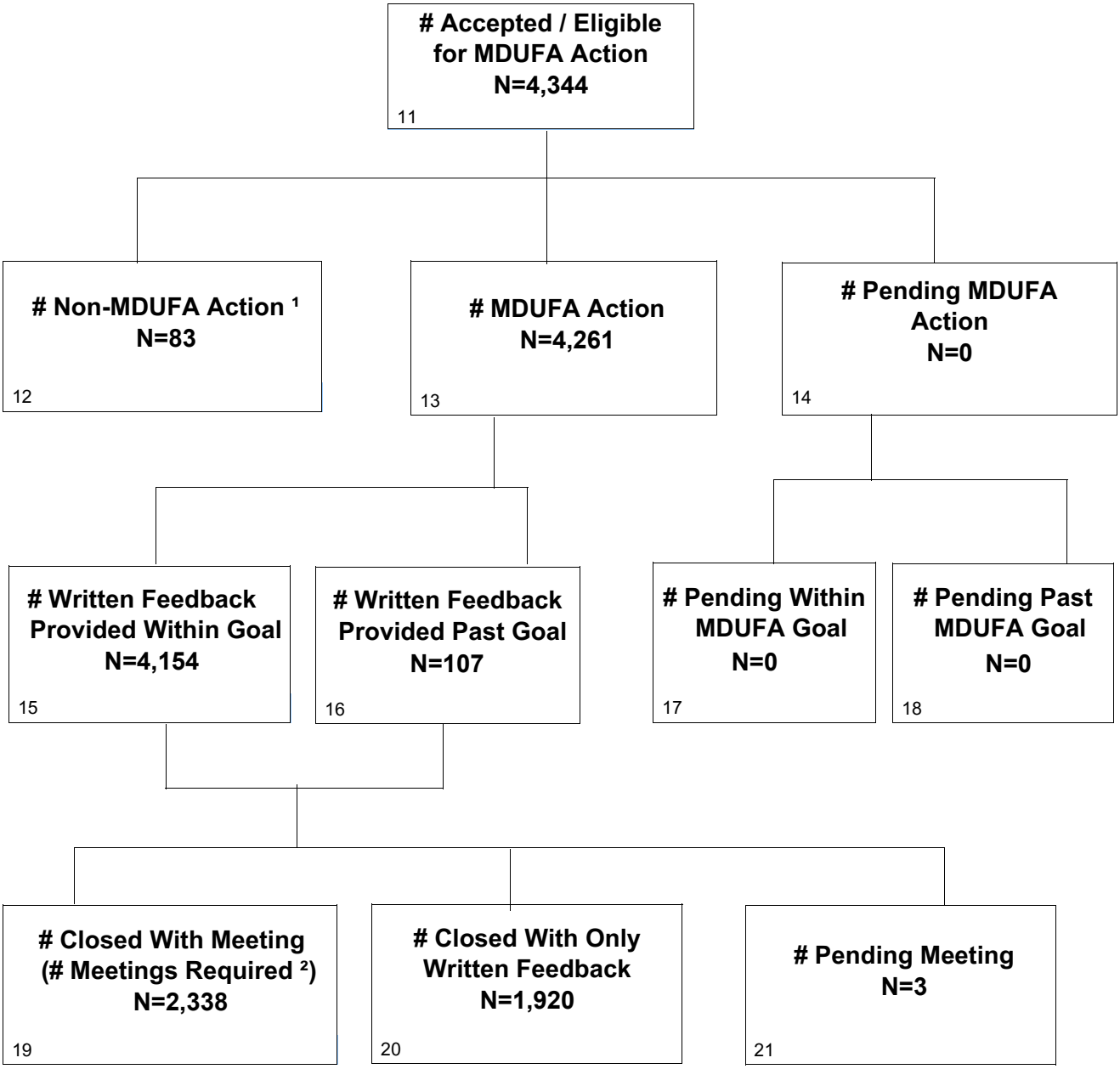
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2025
as of 3/31/26



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.

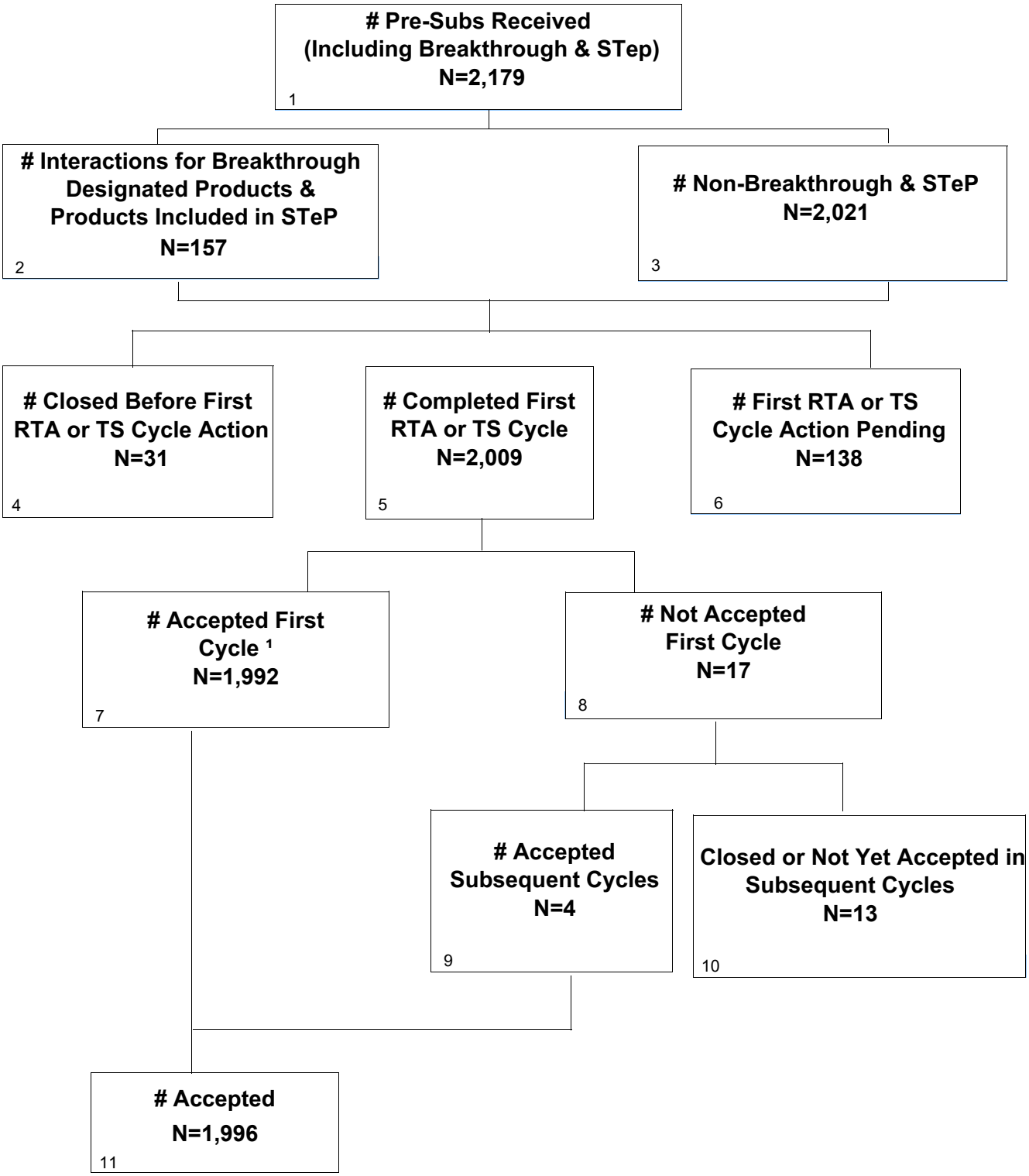
CDRH Pre-Sub - FY 2025 as of 3/31/26 Continued



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

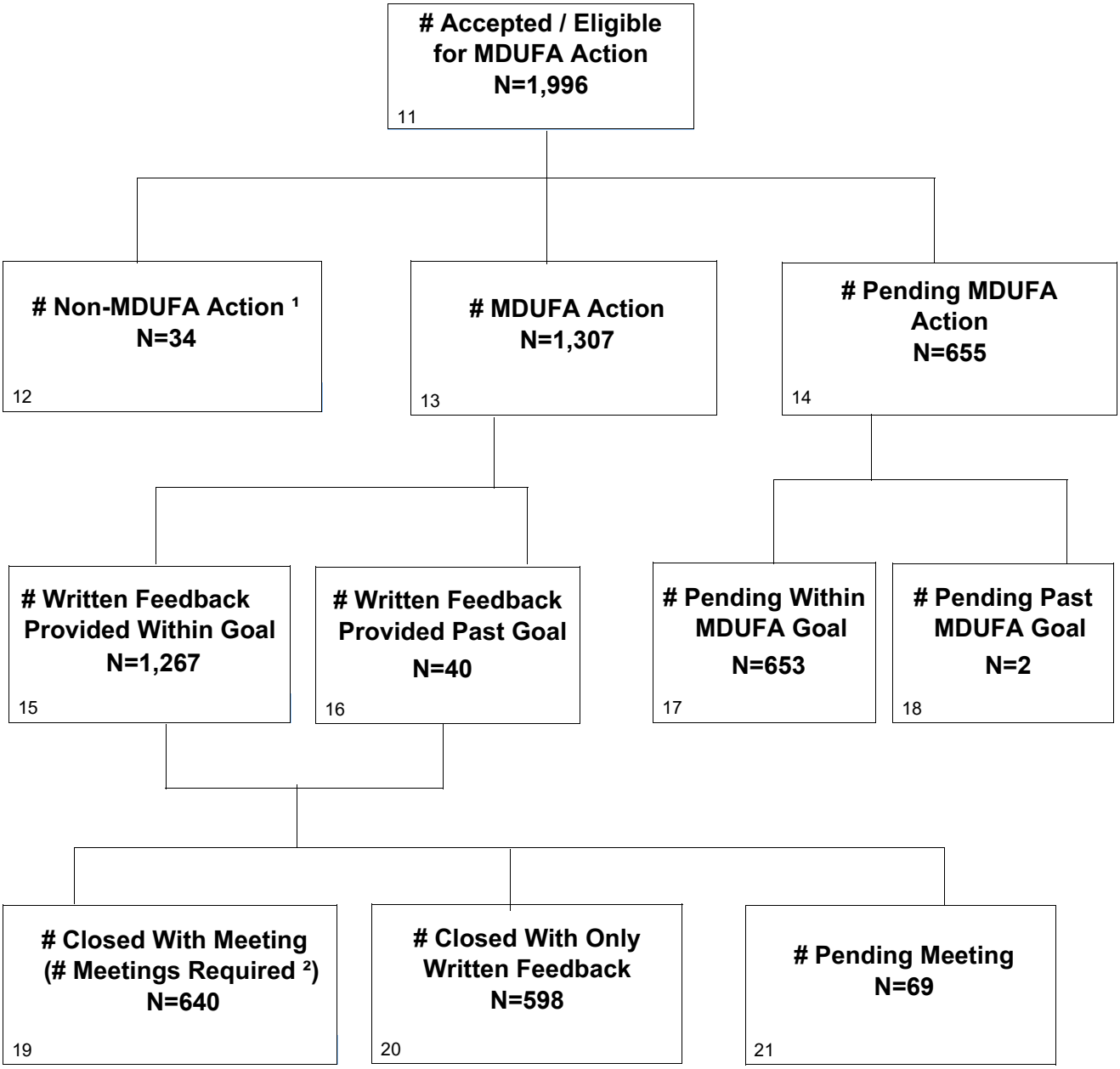
2. Number of meetings requested and then held after written feedback is provided.

CDRH Pre-Sub - FY 2026
as of 3/31/26



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

CDRH Pre-Sub - FY 2026 as of 3/31/26 Continued



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

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3,843	4,140	4,431	2,178	
Interactions for Breakthrough Designated Products & Products Included in STeP	282	405	360	157	
Number Closed Before First RTA Action	39	27	58	31	
Number Accepted First RTA Cycle [1]	3,642	3,979	4,175	1,928	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	121	97	154	65	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	138	
Number Not Accepted First RTA Cycle	41	37	44	17	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.08%	0.90%	1.01%	0.85%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 CDRH - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	3,780	4,095	4,344	1,996	
Number with Non-MDUFA Action [3]	58	69	83	34	
Number with MDUFA Action	3,721	4,025	4,261	1,307	
Written Feedback Provided Within Goal	3,679	3,972	4,154	1,267	
Number Pending MDUFA Action	1	1	0	655	
Pending MDUFA Action Past Goal	1	1	0	2	
Number in MDUFA Cohort (up to max 4300)[4]	3,722	4,026	4,261	1,962	
Current Performance Percent Within Goal	98.84%	98.66%	97.49%	96.79%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

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

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 CDRH – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	3,721	4,025	4,261	1,307	
Average FDA Days to Written Feedback	62.20	62.25	61.89	61.21	
20th Percentile FDA Days to Written Feedback	56	56	56	52	
40th Percentile FDA Days to Written Feedback	64	64	64	64	
60th Percentile FDA Days to Written Feedback	68	67	67	68	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	141	245	307	104	

Table 9.4 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	136	130	153	92	
Average Days to Scheduling for Meetings Scheduled After Day 30	41.52	40.57	40.50	39.52	

Table 9.5 CDRH - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	2,015	2,218	2,338	640	
Meeting Minutes Submitted Within 15 Days of Meeting	1,531	1,787	1,888	470	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	53	
Meeting Minutes Past 15 Days of Meeting	434	369	380	86	
Meeting Minutes Not Submitted and >15 Days Since Meeting	50	62	70	32	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.98%	80.57%	80.75%	79.93%	

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	524	243	
Interactions for Breakthrough Designated Products & Products Included in STeP	20	27	23	13	
Number Closed Before First RTA Action	4	6	10	5	
Number Accepted First RTA Cycle [1]	411	461	492	216	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	20	20	10	9	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	10	
Number Not Accepted First RTA Cycle	9	5	12	3	
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.05%	1.03%	2.33%	1.32%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT1 -Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	435	485	508	225	
Number with Non-MDUFA Action [3]	12	12	15	8	
Number with MDUFA Action	423	473	493	133	
Written Feedback Provided Within Goal	410	460	474	126	
Number Pending MDUFA Action	0	0	0	84	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	423	473	493	217	
Current Performance Percent Within Goal	96.93%	97.25%	96.15%	94.74%	

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	493	133	
Average FDA Days to Written Feedback	65.34	65.26	65.23	64.11	
20th Percentile FDA Days to Written Feedback	62	62	62	59	
40th Percentile FDA Days to Written Feedback	66	66	66	67	
60th Percentile FDA Days to Written Feedback	69	69	69	69	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	141	101	107	98	

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	21	7	
Average Days to Scheduling for Meetings Scheduled After Day 30	48.47	42.70	41.57	50.00	

Table 9.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	249	275	284	68	
Meeting Minutes Submitted Within 15 Days of Meeting	179	226	228	46	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	6	
Meeting Minutes Past 15 Days of Meeting	59	40	42	9	
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	9	14	7	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.89%	82.18%	80.28%	74.19%	

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	745	799	370	
Interactions for Breakthrough Designated Products & Products Included in STeP	73	84	78	23	
Number Closed Before First RTA Action	6	2	3	6	
Number Accepted First RTA Cycle [1]	701	726	759	332	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	13	14	36	5	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	24	
Number Not Accepted First RTA Cycle	4	3	1	3	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.56%	0.40%	0.13%	0.88%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	717	741	795	338	
Number with Non-MDUFA Action [3]	4	4	4	1	
Number with MDUFA Action	712	736	791	218	
Written Feedback Provided Within Goal	697	715	751	195	
Number Pending MDUFA Action	1	1	0	119	
Pending MDUFA Action Past Goal	1	1	0	1	
Number in MDUFA Cohort (up to max 4300)[4]	713	737	791	337	
Current Performance Percent Within Goal	97.76%	97.01%	94.94%	89.04%	

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	736	791	218	
Average FDA Days to Written Feedback	59.32	59.61	61.59	64.13	
20th Percentile FDA Days to Written Feedback	50	51	55	57	
40th Percentile FDA Days to Written Feedback	60	61	63	65	
60th Percentile FDA Days to Written Feedback	66	65	67	69	
80th Percentile FDA Days to Written Feedback	69	69	70	70	
Maximum FDA Days to Written Feedback	103	113	119	104	

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	39	31	
Average Days to Scheduling for Meetings Scheduled After Day 30	38.09	36.90	39.38	39.32	

Table 9.5 OHT2 - Office of Cardiovascular Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	406	423	429	112	
Meeting Minutes Submitted Within 15 Days of Meeting	308	317	314	87	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	7	
Meeting Minutes Past 15 Days of Meeting	91	90	99	15	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	16	16	4	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.86%	74.94%	73.19%	82.08%	

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

Table 9.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	461	510	560	309	
Interactions for Breakthrough Designated Products & Products Included in STeP	42	63	54	23	
Number Closed Before First RTA Action	5	4	10	5	
Number Accepted First RTA Cycle [1]	438	484	522	279	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12	11	14	3	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	17	
Number Not Accepted First RTA Cycle	6	11	14	5	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.32%	2.17%	2.55%	1.74%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	453	499	540	283	
Number with Non-MDUFA Action [3]	10	11	8	7	
Number with MDUFA Action	443	488	532	189	
Written Feedback Provided Within Goal	439	485	526	188	
Number Pending MDUFA Action	0	0	0	87	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	443	488	532	276	
Current Performance Percent Within Goal	99.10%	99.39%	98.87%	99.47%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

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

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	443	488	532	189	
Average FDA Days to Written Feedback	62.13	61.74	61.43	62.99	
20th Percentile FDA Days to Written Feedback	56	56	56	57	
40th Percentile FDA Days to Written Feedback	64	63	63	65	
60th Percentile FDA Days to Written Feedback	67	67	67	69	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	78	78	79	104	

Table 9.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	12	12	15	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	42.67	43.50	39.93	39.00	

Table 9.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	254	268	294	92	
Meeting Minutes Submitted Within 15 Days of Meeting	200	222	244	70	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	5	
Meeting Minutes Past 15 Days of Meeting	48	39	41	12	
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	7	9	5	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.74%	82.84%	82.99%	80.46%	

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	377	462	531	273	
Interactions for Breakthrough Designated Products & Products Included in STeP	21	35	32	13	
Number Closed Before First RTA Action	4	5	13	9	
Number Accepted First RTA Cycle [1]	357	435	483	229	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9	14	32	14	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	21	
Number Not Accepted First RTA Cycle	7	8	3	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.88%	1.75%	0.58%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	369	454	517	243	
Number with Non-MDUFA Action [3]	11	18	18	8	
Number with MDUFA Action	358	436	499	163	
Written Feedback Provided Within Goal	358	434	481	160	
Number Pending MDUFA Action	0	0	0	72	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	358	436	499	235	
Current Performance Percent Within Goal	100.00%	99.54%	96.39%	98.16%	

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	358	436	499	163	
Average FDA Days to Written Feedback	60.47	61.99	60.46	61.00	
20th Percentile FDA Days to Written Feedback	54	56	54	52	
40th Percentile FDA Days to Written Feedback	62	63	63	64	
60th Percentile FDA Days to Written Feedback	65	67	67	68	
80th Percentile FDA Days to Written Feedback	69	70	70	70	
Maximum FDA Days to Written Feedback	70	70	141	72	

Table 9.4 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	14	15	15	20	
Average Days to Scheduling for Meetings Scheduled After Day 30	37.71	40.00	41.73	35.00	

Table 9.5 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	204	233	281	85	
Meeting Minutes Submitted Within 15 Days of Meeting	157	183	223	57	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	8	
Meeting Minutes Past 15 Days of Meeting	39	46	47	15	
Meeting Minutes Not Submitted and >15 Days Since Meeting	8	4	11	5	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	76.96%	78.54%	79.36%	74.03%	

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

Table 9.1 OHT5 - Office of Neurological and Physical Medicine Devices
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	397	429	469	281	
Interactions for Breakthrough Designated Products & Products Included in STeP	42	42	37	29	
Number Closed Before First RTA Action	5	3	2	2	
Number Accepted First RTA Cycle [1]	371	407	433	239	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	17	10	24	18	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	18	
Number Not Accepted First RTA Cycle	4	9	10	4	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.02%	2.11%	2.14%	1.53%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	390	422	459	258	
Number with Non-MDUFA Action [3]	5	5	11	4	
Number with MDUFA Action	385	417	448	150	
Written Feedback Provided Within Goal	383	409	428	147	
Number Pending MDUFA Action	0	0	0	104	
Pending MDUFA Action Past Goal	0	0	0	1	
Number in MDUFA Cohort (up to max 4300)[4]	385	417	448	254	
Current Performance Percent Within Goal	99.48%	98.08%	95.54%	97.35%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

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

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	385	417	448	150	
Average FDA Days to Written Feedback	66.14	67.22	67.05	63.51	
20th Percentile FDA Days to Written Feedback	64	65	63	61	
40th Percentile FDA Days to Written Feedback	68	69	69	66	
60th Percentile FDA Days to Written Feedback	70	70	70	70	
80th Percentile FDA Days to Written Feedback	70	70	70	70	
Maximum FDA Days to Written Feedback	108	245	307	82	

Table 9.4 CDRH- OHT5 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	26	39	36	26	
Average Days to Scheduling for Meetings Scheduled After Day 30	39.04	39.26	39.00	41.08	

Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	250	261	276	72	
Meeting Minutes Submitted Within 15 Days of Meeting	178	208	214	49	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	11	
Meeting Minutes Past 15 Days of Meeting	65	45	53	9	
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	8	9	3	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.20%	79.69%	77.54%	80.33%	

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	290	294	299	134	
Interactions for Breakthrough Designated Products & Products Included in STeP	52	79	57	23	
Number Closed Before First RTA Action	5	1	2	0	
Number Accepted First RTA Cycle [1]	271	286	288	120	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	10	7	7	2	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	12	
Number Not Accepted First RTA Cycle	4	0	2	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.40%	0.00%	0.67%	0.81%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	283	293	296	122	
Number with Non-MDUFA Action [3]	6	8	11	2	
Number with MDUFA Action	277	285	285	81	
Written Feedback Provided Within Goal	273	280	285	80	
Number Pending MDUFA Action	0	0	0	39	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	277	285	285	120	
Current Performance Percent Within Goal	98.56%	98.25%	100.00%	98.77%	

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	277	285	285	81	
Average FDA Days to Written Feedback	58.48	56.93	58.58	55.80	
20th Percentile FDA Days to Written Feedback	45	43	45	43	
40th Percentile FDA Days to Written Feedback	58	57	60	55	
60th Percentile FDA Days to Written Feedback	65	64	65	64	
80th Percentile FDA Days to Written Feedback	69	68	69	68	
Maximum FDA Days to Written Feedback	97	92	70	70	

Table 9.4 CDRH- OHT6 - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	4	2	5	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	48.75	54.50	39.40	31.00	

Table 9.5 OHT6 - Office of Orthopedic Devices
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	125	129	139	33	
Meeting Minutes Submitted Within 15 Days of Meeting	92	103	117	22	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	5	
Meeting Minutes Past 15 Days of Meeting	29	17	20	4	
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	9	2	2	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.60%	79.84%	84.17%	78.57%	

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	881	922	909	408	
Interactions for Breakthrough Designated Products & Products Included in STeP	28	60	67	28	
Number Closed Before First RTA Action	9	5	15	4	
Number Accepted First RTA Cycle [1]	834	901	866	365	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	35	15	28	11	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	28	
Number Not Accepted First RTA Cycle	3	1	0	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.34%	0.11%	0.00%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	869	916	894	376	
Number with Non-MDUFA Action [3]	7	11	9	4	
Number with MDUFA Action	862	905	885	272	
Written Feedback Provided Within Goal	858	904	883	271	
Number Pending MDUFA Action	0	0	0	100	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	862	905	885	372	
Current Performance Percent Within Goal	99.54%	99.89%	99.77%	99.63%	

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	862	905	885	272	
Average FDA Days to Written Feedback	63.70	63.10	60.23	56.41	
20th Percentile FDA Days to Written Feedback	60	59	54	44	
40th Percentile FDA Days to Written Feedback	66	65	63	58	
60th Percentile FDA Days to Written Feedback	69	68	66	66	
80th Percentile FDA Days to Written Feedback	70	70	69	69	
Maximum FDA Days to Written Feedback	75	71	89	70	

Table 9.4 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	12	14	20	5	
Average Days to Scheduling for Meetings Scheduled After Day 30	38.83	41.00	42.05	38.40	

Table 9.5 OHT7 - Office of In Vitro Diagnostics
MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	321	415	421	115	
Meeting Minutes Submitted Within 15 Days of Meeting	258	355	360	92	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	8	
Meeting Minutes Past 15 Days of Meeting	59	54	53	11	
Meeting Minutes Not Submitted and >15 Days Since Meeting	4	6	8	4	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	80.37%	85.54%	85.51%	85.98%	

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	160	
Interactions for Breakthrough Designated Products & Products Included in STeP	4	15	12	5	
Number Closed Before First RTA Action	1	1	3	0	
Number Accepted First RTA Cycle [1]	259	279	332	148	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5	6	3	3	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	8	
Number Not Accepted First RTA Cycle	4	0	2	1	
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.49%	0.00%	0.59%	0.66%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	264	285	335	151	
Number with Non-MDUFA Action [3]	3	0	7	0	
Number with MDUFA Action	261	285	328	101	
Written Feedback Provided Within Goal	261	285	326	100	
Number Pending MDUFA Action	0	0	0	50	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	261	285	328	151	
Current Performance Percent Within Goal	100.00%	100.00%	99.39%	99.01%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

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

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	261	285	328	101	
Average FDA Days to Written Feedback	60.57	60.68	60.75	61.97	
20th Percentile FDA Days to Written Feedback	55	55	55	55	
40th Percentile FDA Days to Written Feedback	60	62	62	64	
60th Percentile FDA Days to Written Feedback	64	65	65	67	
80th Percentile FDA Days to Written Feedback	67	69	69	70	
Maximum FDA Days to Written Feedback	70	70	85	71	

Table 9.4 OHT8 - Office of Radiological Health
MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

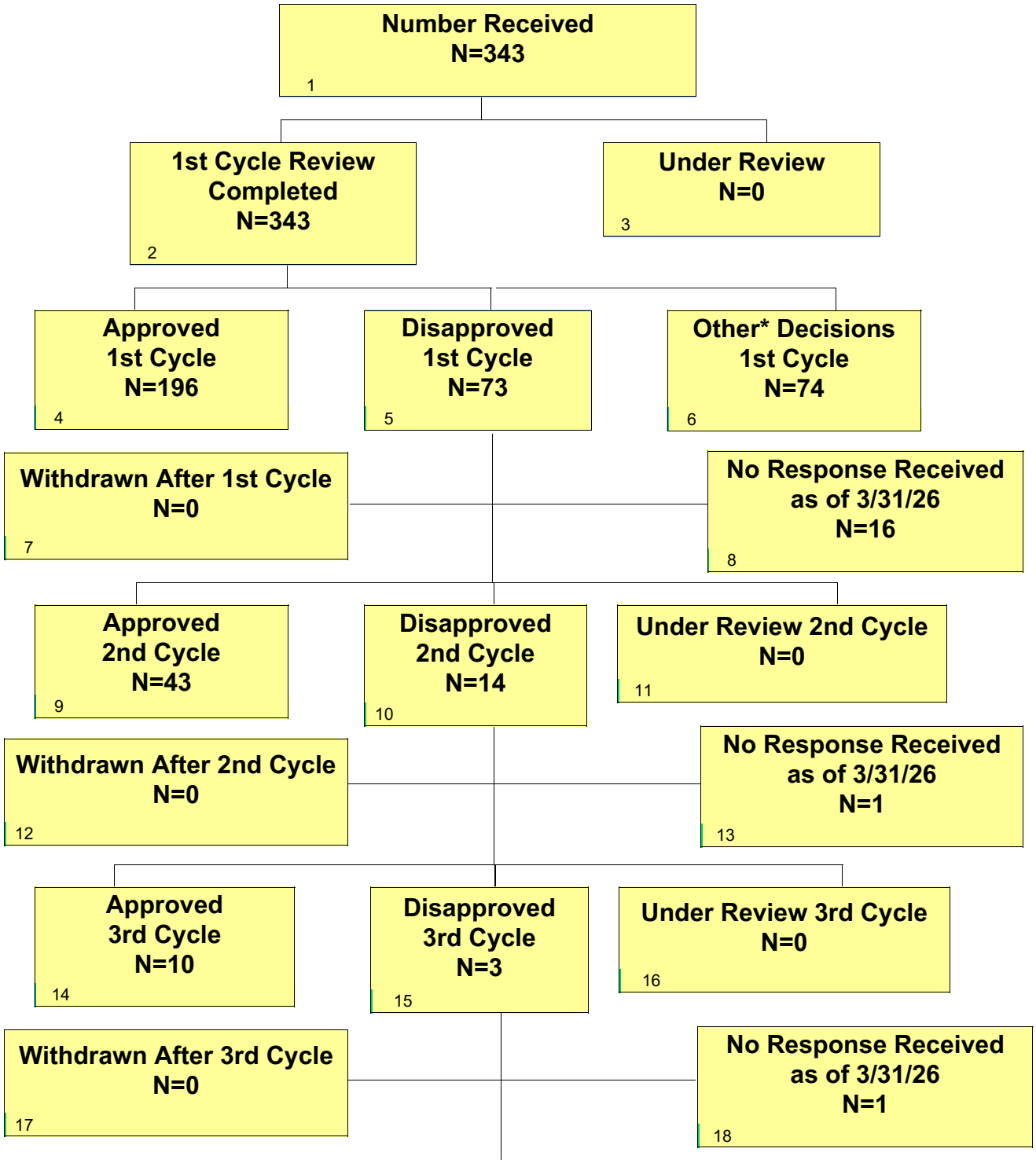
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5	4	2	1	
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00	45.25	60.50	37.00	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	206	214	214	63	
Meeting Minutes Submitted Within 15 Days of Meeting	159	173	188	47	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	3	
Meeting Minutes Past 15 Days of Meeting	44	38	25	11	
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	3	1	2	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.18%	80.84%	87.85%	78.33%	

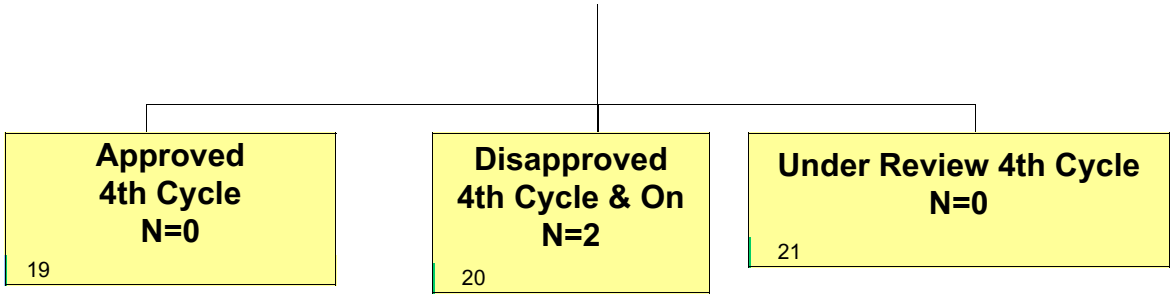
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 3/31/26

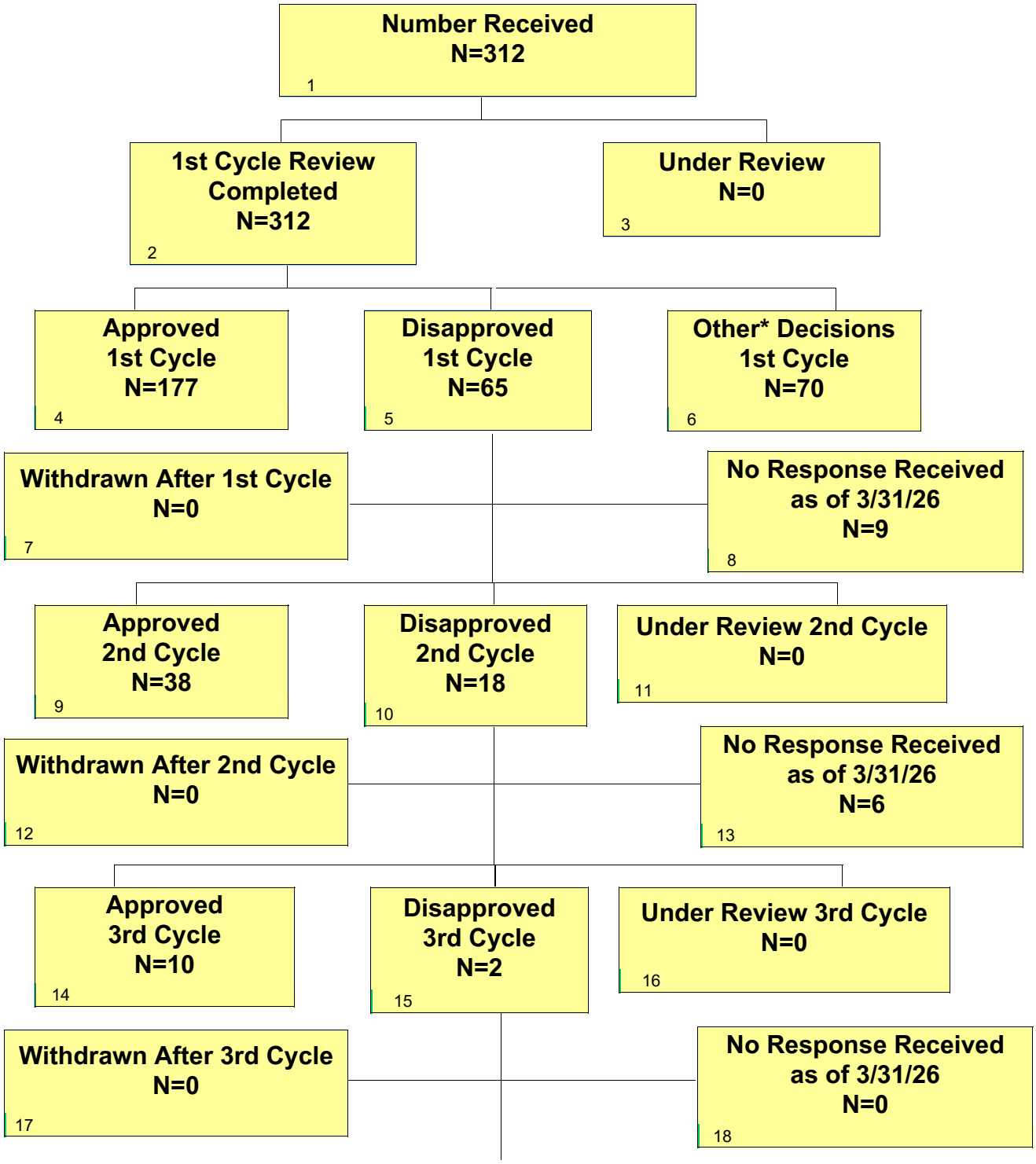


*** Other decisions include withdrawn (N=11), withdrawn and converted (N=51), RTA (N=0), nonsignificant risk device (N=10), exempt (N=0), product jurisdiction pending (N=1), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 3/31/26

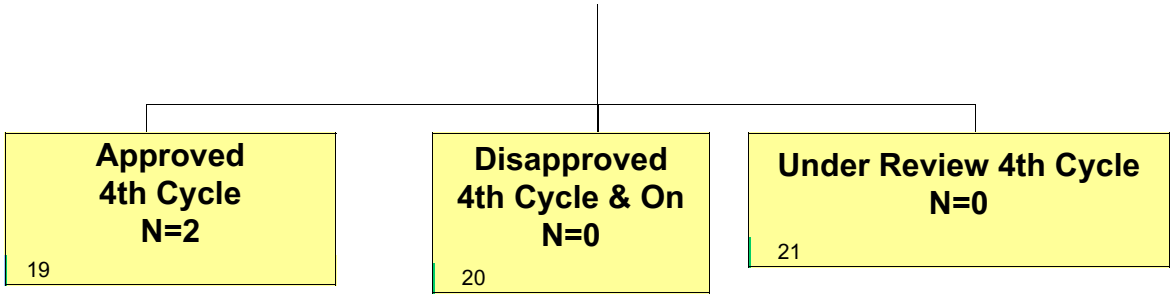


CDRH IDEs - FY 2024
as of 3/31/26

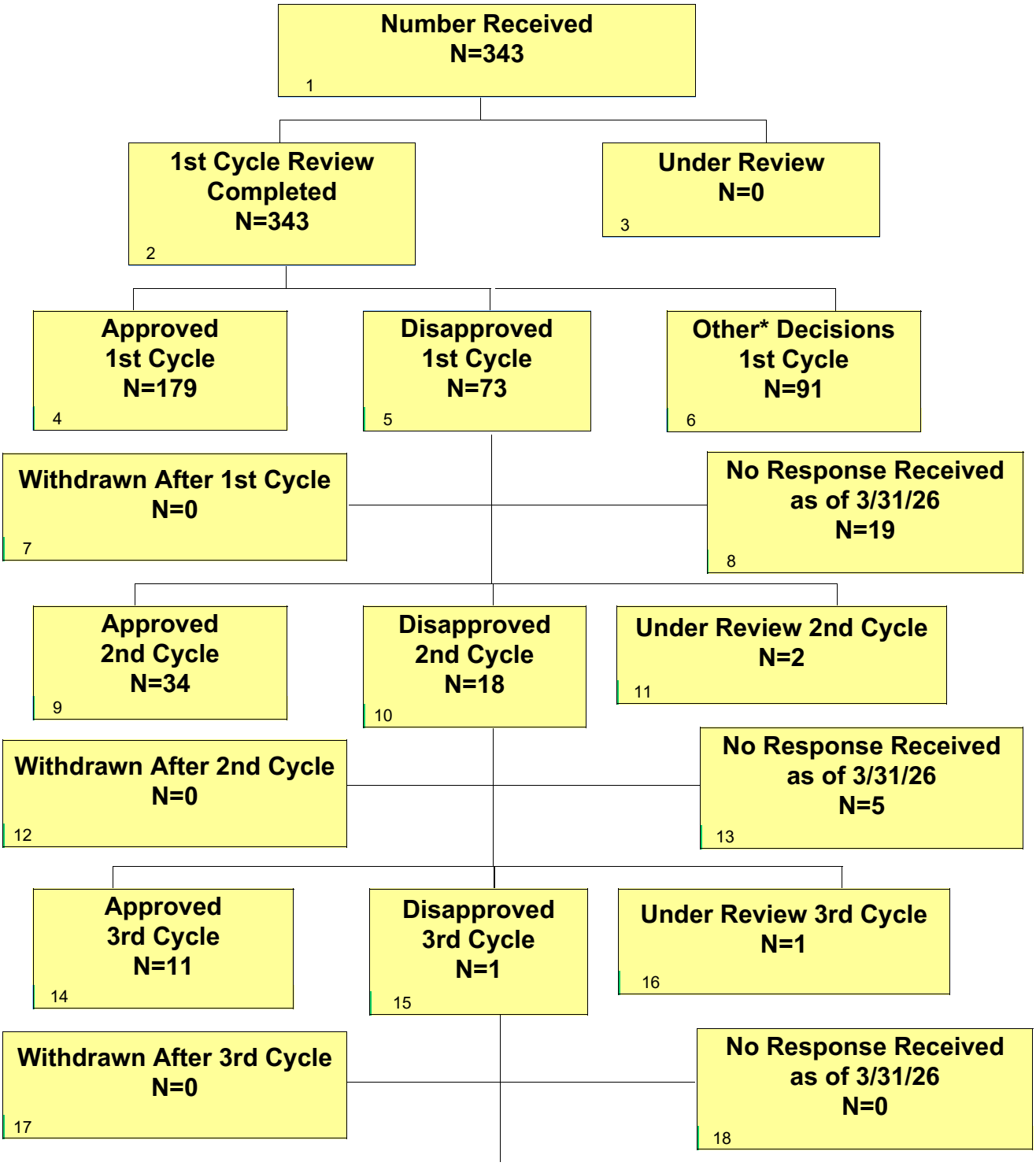


*** Other decisions include withdrawn (N=10), withdrawn and converted (N=35), RTA (N=0), nonsignificant risk device (N=16), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=9), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2024
as of 3/31/26



CDRH IDEs - FY 2025
as of 3/31/26



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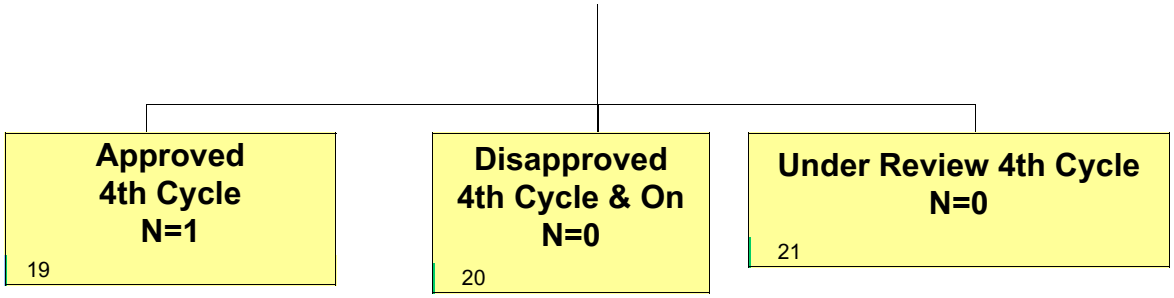
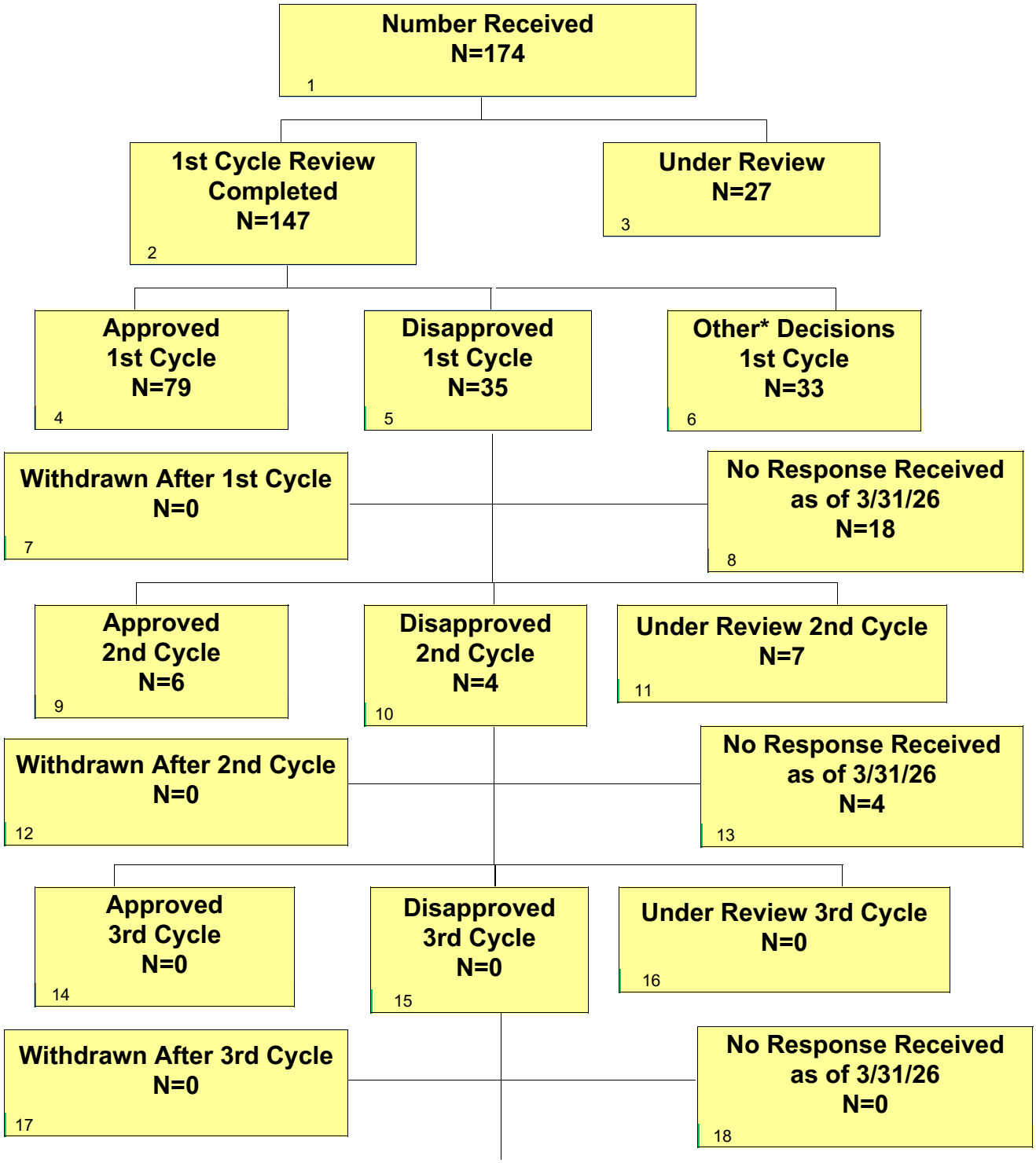
CDRH IDEs - FY 2025
as of 3/31/26

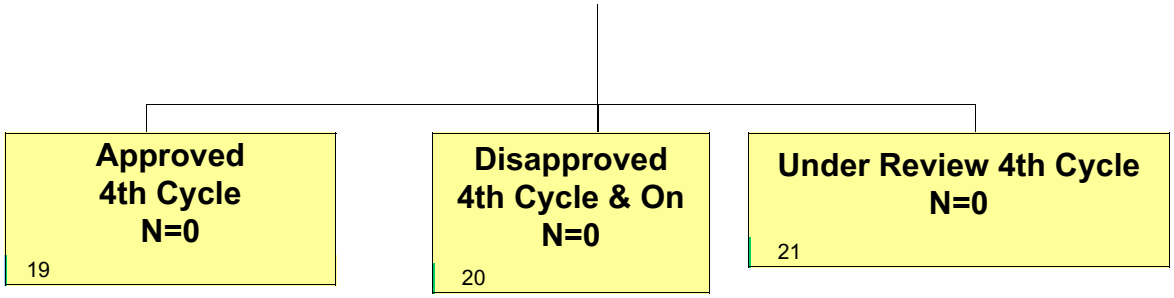


CDRH IDEs - FY 2026
as of 3/31/26



*** Other decisions include withdrawn (N=8), withdrawn and converted (N=19), RTA (N=0), nonsignificant risk device (N=4), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2026
as of 3/31/26



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	343	312	343	174	
Average Number of Cycles to IDE Approval or Conditional Approval	1.28	1.39	1.26	1.07	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.28	0.28	0.26	0.07	

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	18	
Average Number of Cycles to IDE Approval or Conditional Approval	1.39	1.21	1.63	1.17	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.39	0.21	0.63	0.17	

Table 10.1 OHT2 - Office of Cardiovascular Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	82	69	41	
Average Number of Cycles to IDE Approval or Conditional Approval	1.48	1.40	1.42	1.21	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.48	0.40	0.42	0.21	

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	19	
Average Number of Cycles to IDE Approval or Conditional Approval	1.31	1.31	1.15	1.15	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.31	0.31	0.15	0.15	

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	20	
Average Number of Cycles to IDE Approval or Conditional Approval	1.13	1.00	1.04	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.13	0.00	0.04	0.00	

Table 10.1 OHT5 - Office of Neurological and Physical Medicine Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	74	63	85	35	
Average Number of Cycles to IDE Approval or Conditional Approval	1.24	1.41	1.30	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.24	0.41	0.30	0.00	

Table 10.1 OHT6 - Office of Orthopedic Devices
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	26	23	17	7	
Average Number of Cycles to IDE Approval or Conditional Approval	1.33	1.27	1.67	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.33	0.27	0.67	0.00	

Table 10.1 OHT7 - Office of In Vitro Diagnostics
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	46	43	51	29	
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00	0.00	0.00	

Table 10.1 OHT8 - Office of Radiological Health
IDE MDUFA V Decision Performance Goal

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of IDEs Received	8	11	7	5	
Average Number of Cycles to IDE Approval or Conditional Approval	1.40	1.25	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.40	0.25	0.00	0.00	

Section 11 CLIA Waiver Annual Metrics

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

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

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

Section 13 TAP Center Level Metrics

Table 13.1 CDRH - TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		31	81	28	
Closed before Teleconference		0	0	2	
Teleconferences Held		31	81	25	
Teleconferences Held Within 14 Days		30	78	21	
Teleconferences Pending		0	0	1	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		96.77%	96.30%	84.00%	

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	7	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		3	12	7	
Written Feedback Provided Within 21 Days		3	10	5	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		100.00%	83.33%	71.43%	

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	47	
Closed before Written Feedback		0	1	0	
Written Feedback Provided		44	66	33	
Written Feedback Provided Within 40 Days		44	64	29	
Written Feedback Pending		0	0	14	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	96.97%	87.88%	

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	27	
Enrollment Requests Accepted		40	49	14	
Enrollment Requests Not Accepted		7	4	9	
Enrollment Requests Withdrawn Before Decision		0	1	0	
Enrollment Requests Pending		0	0	4	

Section 13 TAP Documents - Office Level Metric

Table 13.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	2	1	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	2	1	
Teleconferences Held Within 14 Days		0	2	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	0.00%	

Table 13.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	4	
Written Feedback Provided Within 21 Days		0	0	2	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	50.00%	

Table 13.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

Table 13.4 - OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
TAP Pilot Enrollment Data

Table 13.4 - TAP Pilot Enrollment Data	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	2	1	
Enrollment Requests Accepted		0	2	1	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Table 13.1 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		21	34	10	
Closed before Teleconference		0	0	1	
Teleconferences Held		21	34	8	
Teleconferences Held Within 14 Days		20	32	7	
Teleconferences Pending		0	0	1	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		95.24%	94.12%	87.50%	

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	4	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		3	6	4	
Written Feedback Provided Within 21 Days		3	4	2	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		100.00%	66.67%	50.00%	

Table 13.3 OHT2 - Office of Cardiovascular Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		34	39	23	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		34	39	17	
Written Feedback Provided Within 40 Days		34	39	14	
Written Feedback Pending		0	0	6	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	100.00%	82.35%	

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	7	
Enrollment Requests Accepted		16	13	4	
Enrollment Requests Not Accepted		5	1	2	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	1	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Table 13.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0	0	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	0	0	
Teleconferences Held Within 14 Days		0	0	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	N/A	N/A	

Table 13.2 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

Table 13.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

Table 13.4 - OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		1	2	1	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		1	2	1	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Table 13.1 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0	0	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	0	0	
Teleconferences Held Within 14 Days		0	0	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	N/A	N/A	

Table 13.2 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

Table 13.3 OHT4 - Office of Surgical and Infection Control Devices
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

Table 13.4 - OHT4 - Office of Surgical and Infection Control Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	0	0	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Table 13.1 OHT5 - Office of Neurological and Physical Medicine Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		10	35	13	
Closed before Teleconference		0	0	1	
Teleconferences Held		10	35	12	
Teleconferences Held Within 14 Days		10	34	10	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		100.00%	97.14%	83.33%	

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	1	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	6	1	
Written Feedback Provided Within 21 Days		0	6	1	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	100.00%	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	13	
Closed before Written Feedback		0	1	0	
Written Feedback Provided		10	20	7	
Written Feedback Provided Within 40 Days		10	18	6	
Written Feedback Pending		0	0	6	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		100.00%	90.00%	85.71%	

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	5	
Enrollment Requests Accepted		24	12	2	
Enrollment Requests Not Accepted		1	0	2	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	1	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Table 13.1 OHT6 - Office of Orthopedic Devices
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	9	3	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	9	3	
Teleconferences Held Within 14 Days		0	9	3	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	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	2	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	2	
Written Feedback Provided Within 21 Days		0	0	2	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	100.00%	

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	10	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	4	8	
Written Feedback Provided Within 40 Days		0	4	8	
Written Feedback Pending		0	0	2	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	100.00%	100.00%	

Table 13.4 - OHT6 - Office of Orthopedic Devices
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	15	7	
Enrollment Requests Accepted		0	15	4	
Enrollment Requests Not Accepted		0	0	2	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	1	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Table 13.1 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	0	0	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	0	0	
Teleconferences Held Within 14 Days		0	0	0	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	N/A	N/A	

Table 13.2 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Biocompatibility/Sterility) Performance Goal

Performance Metric: 90% within 21 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

Table 13.3 OHT7 - Office of In Vitro Diagnostics
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	0	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 40 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	N/A	N/A	

Table 13.4 - OHT7 - Office of In Vitro Diagnostics
TAP Pilot Enrollment Data

	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Enrollment Requests Received		0	0	0	
Enrollment Requests Accepted		0	0	0	
Enrollment Requests Not Accepted		0	0	0	
Enrollment Requests Withdrawn Before Decision		0	0	0	
Enrollment Requests Pending*		0	0	0	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Table 13.1 OHT8 - Office of Radiological Health
TAP MDUFA V Teleconference Engagement Performance Goal

Performance Metric: 90% within 14 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Teleconferences Requested		0	1	1	
Closed before Teleconference		0	0	0	
Teleconferences Held		0	1	1	
Teleconferences Held Within 14 Days		0	1	1	
Teleconferences Pending		0	0	0	
Teleconferences Pending Over 14 Days		0	0	0	
Current Performance Percent Within 14 Days		N/A	100.00%	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	0	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	0	0	
Written Feedback Provided Within 21 Days		0	0	0	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 21 Days		0	0	0	
Current Performance Percent Within 21 Days		N/A	N/A	N/A	

Table 13.3 OHT8 - Office of Radiological Health
TAP MDUFA V Written Feedback (Other) Performance Goal

Performance Metric: 90% within 40 Days	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Written Feedback Requested		0	3	1	
Closed before Written Feedback		0	0	0	
Written Feedback Provided		0	3	1	
Written Feedback Provided Within 40 Days		0	3	1	
Written Feedback Pending		0	0	0	
Written Feedback Pending Over 40 Days		0	0	0	
Current Performance Percent Within 40 Days		N/A	100.00%	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	6	
Enrollment Requests Accepted		0	7	3	
Enrollment Requests Not Accepted		0	1	2	
Enrollment Requests Withdrawn Before Decision		0	1	0	
Enrollment Requests Pending*		0	0	1	

*Pending enrollment requests are reported under the OHT to which they will be assigned if accepted.

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

Table 1.1 and Tables 1.1.x PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Closed Before First RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a First Cycle RTA Review and > 15 Days Since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Filing Review on First Cycle	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

Table 1.2 and Tables 1.2.x PMA Originals and Panel Track Supplements – Filing Review Decision - Definitions

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Accepted	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAN decision in the first RTA review cycle entered by reviewer.
3	Completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of Submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

Table 1.3 and Tables 1.3.x **PMA Originals and Panel Track Supplements Substantive Interaction Performance Goal - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under review with no SI past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 1.4 and Tables 1.4.x PMA Originals and Panel Track Supplements Substantive Interaction Metric – Time to Substantive Interaction - Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average Number of FDA Days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20th Percentile FDA Days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA Days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA Days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA Days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA Days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 1.5 and Tables 1.5.x PMA Originals and Panel-Track Supplements (Without Panel Review) MDUFA V Decision Performance Goal - Definitions

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.6 and Tables 1.6.x PMA Originals and Panel Track Supplements (With Panel Review) MDUFA V Decision Performance Goal - Definitions

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.7 and Tables 1.7.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 1.8 and Tables 1.8.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number With MDUFA Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 1.9 and Tables 1.9.x PMA Originals and Panel Track Supplements (Without Panel Review) MDUFA V Performance Metric – Rates of Withdrawal, Not Approvable and Deleted - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number With MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

Table 1.10 and Tables 1.10.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Rate of Withdrawal, Not Approvable and Deleted - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number With MDUFA Decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawal	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawal	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

Table 1.11 and Tables 1.11.x PMA Originals and Panel Track Supplements (Without Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Table 1.12 and Tables 1.12.x PMA Originals and Panel Track Supplements (With Panel Review) Performance Metric – Submissions Missing Performance Goal - Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Tables 1.13 and Tables 1.13.x LDT PMA Originals and Panel-Track Supplements MDUFA V Metric* - Definitions

#	Measure	Description
1	Number of PMAs Filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decision	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decision	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements MDUFA V Metric* - Definitions

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA Decisions	Submissions filed (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA Decisions	Submissions filed (line 1) and closed with a MDUFA decision.
4	MDUFA Decisions Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs Pending MDUFA Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA decision or final decision.
6	PMAs Pending MDUFA Decision Past Goal	Number of submissions pending MDUFA Decision (line 5) past goal. These submissions already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA Decisions made on time (line 4) divided by the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goal – Definitions

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed Without SI	Number of submissions that are closed with a MDUFA (other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA Decision	Supplements received (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements Pending MDUFA Decision	Number of supplements received (line 1) that do not have a MDUFA decision or a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 2.3 and Tables 2.3.x PMA 180 Day Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

Table 2.4 and Tables 2.4.x PMA 180 Day Supplements MDUFA V Performance Metric – Submissions Missing Performance Goal – Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA V decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x PMA Real Time Supplements MDUFA V Decision Performance Goal – Definitions

#	Measure	Description
1	Supplements Received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA Decision	Supplements received in this fiscal year (line 1) and closed with a MDUFA decision.
4	MDUFA Decision Goal Met	Submissions with MDUFA decisions (line 3) within goal.
5	Supplements Pending MDUFA Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA decision and are not closed with a final decision.
6	Supplements Pending MDUFA Decision Past Goal	Number of supplements pending MDUFA Decision (line 5) past goal. These supplements already failed the MDUFA review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA Decisions made on time (line 4) divided by the total number of supplements with MDUFA Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 3.2 and Tables 3.2.x PMA Real Time Supplements MDUFA V Performance Metric – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number With MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

Table 3.3 and Tables 3.3.x PMA Real Time PMA Supplements MDUFA V Performance Metric – Submissions Missing Performance Goal – Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA Days for Submissions that Missed Goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed Goal	Mean industry days for supplements that missed the goal (line 1).

Section 5 PMA Annual Metrics and Goals

Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements(No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

Table 5.2 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number With a Decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY Closed	Number with a decision (line 2) divided by Number Filed (line 1).

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

#	Measure	Description
1	Number With a MDUFA Decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number With a MDUFA Decision After Trimming the Upper and Lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA V decision and 5% of submissions with the highest number of Total Days to MDUFA V decision.
3	Three-Year Rolling Average Total Time to MDUFA Decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

Section 6 510(k) MDUFA V Performance (Quarterly Data Exclude Third Party Review)

Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed Before First RTA or TS Action	Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action.
3	Number Accepted or Passed TS on First Cycle	Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle.
4	Number Without a RTA or TS Review and > 15 Days Since Date Received	Number Received (line 1) that did not receive an RTA or TS decision in the 1st 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 15th 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	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 6.4 and Tables 6.4.x 510(k) MDUFA V Decision Performance Goal– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA Decision	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA Decisions (line 3) and pending submissions that have missed the MDUFA goal (line 6).

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA V Decision– Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days to MDUFA V decision.

Table 6.6 and Tables 6.6.x 510(k) MDUFA V Performance Metric - Rates of SE, NSE, Withdrawal, and Delete Decision– Definitions

#	Measure	Description
1	510(k) Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Number with MDUFA Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

Table 6.7 and Tables 6.7.x 510(k) Performance Metric – Submissions Missing Performance Goal – Definitions

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA V Decision Metric– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of LDT submissions with MDUFA decision (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA Decision over 90 FDA days	Number of LDT submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA decision within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA Decision (line 3) and pending LDT submissions that already missed the MDUFA goal (line 6).

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric– Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA decision (not SE or NSE).
3	MDUFA Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA V decision (SE or NSE).
4	MDUFA Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA Decision (line 5) for more than 90 FDA Days. These submissions already missed the MDUFA V review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA Decision within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA Decision (line 3) and pending non-LDT IVD submissions that already missed the MDUFA goal (line 6).

Section 7 510(k) Annual General Metrics (Annual data includes Third Party reviews)

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

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA/TS review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

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

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Currently Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA V decision and the 2% of submissions with the highest number of Total Days to MDUFA decision.
7	Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

Table 7.3 CDRH - 510(k) Third Party Performance – Definitions

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90th Percentile FDA Days to MDUFA Decision	The 90th percentile of FDA days to MDUFA decision on 3rd 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 1st 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 15th day of that cycle.
6	Number Not Accepted or Failed TS on First Cycle	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" (RTA1/TSIC) decision in the first RTA/TS review cycle.
7	Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	Number Not Accepted or Failed TS on First Cycle (line 6) expressed as a percentage of the sum of the Number Accepted or Passed TS on First Cycle (line 3), Number Without a RTA or TS Review and <= 15 Days Since Date Received (line 4), and Number Not Accepted or Failed TS on First Cycle (line 6).

Tables 8.2 and Tables 8.2.x De Novo MDUFA V Decision Performance Goal– Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted or passed via the RTA/TS process as of quarter end date (RTAA, RTAN, RTAW, RTAS, TSOK, TSRN). For brevity, we refer to this as "accepted" in subsequent De Novo definitions.
2	Non-MDUFA Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA Decisions	Number of submissions accepted (line 1) and closed with a MDUFA decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA Decisions within 150 FDA Days	Number of submissions with MDUFA decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA V Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA Decision (line 5) for more than 150 FDA Days. These submissions have missed the MDUFA review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA Decisions (line 3) and pending submissions that already have missed the MDUFA goal (line 6).

Table 8.3 and Tables 8.3.x De Novo Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for De Novos with a MDUFA decision (line 2).
2	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days to MDUFA decision.

Table 8.4 and Tables 8.4.x De Novo MDUFA V Performance Metrics - Rates of Grant, Decline, Withdrawal and Delete Decision – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA V Decisions	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA decision (line 2).

Table 8.5 and Tables 8.5.x De Novo Performance Metrics – Submissions Missing Performance Goals – Definitions

#	Measure	Description
1	Number of Submissions that Mssed 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 (line7) 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)	Number of submissions accepted with a MDUFA action (line 3) plus the number of submissions accepted and pending a MDUFA action (line 5). 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.
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	20th Percentile FDA Days to Written Feedback	20th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
4	40th Percentile FDA Days to Written Feedback	40th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
5	60th Percentile FDA Days to Written Feedback	60th percentile FDA days to Written Feedback for Pre-Subs with MDUFA V Decision EMAL or EMFB (line 1).
6	80th Percentile FDA Days to Written Feedback	80th 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 (100th 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	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 11.3 CLIA Waiver (without Panel Review) MDUFA V Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 150 FDA Days	Number of submissions with MDUFA V decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 150 FDA days	Number of submissions pending MDUFA V Decision for more than 150 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA V Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.4 CLIA Waiver (with Panel Review) MDUFA V Decision Performance Goals) – Definitions

#	Measure	Description
1	Eligible for MDUFA V Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA V Decisions	Number of submissions closed with a non-MDUFA V decision (not Approved, Denied, or Withdrawn).
3	MDUFA V Decisions	Number of submissions closed with a MDUFA V decision (Approved, Denied, or Withdrawn).
4	MDUFA V Decisions within 320 FDA Days	Number of submissions with MDUFA V decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA V Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA V Decision over 320 FDA days	Number of submissions pending MDUFA V Decision for more than 320 FDA days. These submissions already failed the MDUFA V Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA V Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA V decisions (line 3) or that already failed the MDUFA V Decision goal (line 6).

Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA V Decision – Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA V Decision - Definitions

#	Measure	Description
1	Number with MDUFA V Decision	Number of submissions accepted in this fiscal year that had a MDUFA V decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA V Decision	Table shall show Average Days to MDUFA V decision as well as quintiles (20^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

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

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

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

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

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

Section 13 Total Product Life Cycle Advisory Program (TAP)

Table 13.1 TAP Teleconference Engagement Performance Goal – Definitions

#	Measure	Description
1	Teleconferences Requested	Number of Teleconferences requested
2	Closed before Teleconference	Number of Teleconferences Requested (line 1) that were closed with a final decision before Teleconference Held (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Teleconferences Held	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON))
4	Teleconferences Held Within 14 Days	Number of Teleconferences Requested (line 1) that had a final decision (e.g., "Teleconference Held" (TCON)) within 14 days
5	Teleconferences Pending	Number of Teleconferences Requested (line 1) that are under review without a final decision
6	Teleconferences Pending Over 14 Days	Number of Teleconferences Requested (line 1) that are under review without a final decision and where 14 days have elapsed.
7	Current Performance Percent Within 14 Days	Number of Teleconferences Held Within 14 Days (line 4) expressed as a percentage of the sum of the Teleconferences Held (line 3) and Teleconferences Pending Over 14 Days (line 6)

Table 13.2 TAP Written Feedback (Biocompatibility/Sterility) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on Biocompatibility and Sterility topics(s)
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 21 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 21 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 21 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 21 days have elapsed.
7	Current Performance Percent Within 21 Days	Number of Written Feedback Provided Within 21 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 21 Days (line 6)

Table 13.3 TAP Written Feedback (Other) Performance Goal – Definitions

#	Measure	Description
1	Written Feedback Requested	Number of Written Feedback Requested on topics(s) other than Biocompatibility and Sterility
2	Closed before Written Feedback	Number of Written Feedback Requested (line 1) that were closed with a final decision before Email reply (e.g., "Withdrawn by Sponsor/Applicant" (WTDR))
3	Written Feedback Provided	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL))
4	Written Feedback Provided Within 40 Days	Number of Written Feedback Requested (line 1) that had a final decision (e.g., "Email reply" (EMAL)) within 40 days
5	Written Feedback Pending	Number of Written Feedback Requested (line 1) that are under review without a final decision
6	Written Feedback Pending Over 40 Days	Number of Written Feedback Requested (line 1) that are under review without a final decision and where 40 days have elapsed.
7	Current Performance Percent Within 40 Days	Number of Written Feedback Provided Within 40 Days (line 4) expressed as a percentage of the sum of the Written Feedback Provided (line 3) and Written Feedback Pending Over 40 Days (line 6)

Table 13.4 TAP Pilot Enrollment Data– Definitions

#	Measure	Description
1	Enrollment Requests Received	Number of TAP Pilot Enrollment Requests received in the fiscal year.
2	Enrollment Requests Accepted	Number of TAP Pilot Enrollment Requests accepted in the fiscal year.
3	Enrollment Requests Not Accepted	Number of TAP Pilot Enrollment Requests not accepted in the fiscal year.
4	Enrollment Requests Pending	Number of TAP Pilot Enrollment Requests still under review.

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 31 March 2026

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	0	1	1	
Closed Before RTA Action	0	0	0	0	
Number with Accepted RTA Review	3	0	1	1	
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted for Filing Review	0	0	0	0	
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	0.00%	0.00%	

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

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

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

Substantive Interaction (SI) Goal	FY 2023 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	1	
SI Goal Met	3	0	1	1	
SI Goal Not Met	0	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	100.00%	N/A	100.00%	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	1	
Average Number of FDA Days to Substantive Interaction	88.33	0.00	90.00	90.00	
20th Percentile FDA Days to Substantive Interaction	87	0	90	90.00	
40th Percentile FDA Days to Substantive Interaction	88	0	90	90.00	
60th Percentile FDA Days to Substantive Interaction	88	0	90	90.00	
80th Percentile FDA Days to Substantive Interaction	89	0	90	90.00	
Maximum FDA Days to Substantive Interaction	90	0	90	90.00	

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	3	0	1	0	
Average FDA Days to MDUFA V Decision	177.00	0.00	142.00	0.00	
20th Percentile FDA Days to MDUFA V Decision	175	0	142	0	
40th Percentile FDA Days to MDUFA V Decision	178	0	142	0	
60th Percentile FDA Days to MDUFA V Decision	179	0	142	0	
80th Percentile FDA Days to MDUFA V Decision	180	0	142	0	
Maximum FDA Days to MDUFA V Decision	180	0	142	0	
Average Industry Days to MDUFA V Decision	0.00	0.00	62.00	0.00	
20th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
60th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
80th Percentile Industry Days to MDUFA V Decision	0	0	62	0	
Maximum Industry Days to MDUFA V Decision	0	0	62	0	
Average Total Days to MDUFA V Decision	177.00	0.00	204.00	0.00	
20th Percentile Total Days to MDUFA V Decision	175	0	204	0	
40th Percentile Total Days to MDUFA V Decision	178	0	204	0	
60th Percentile Total Days to MDUFA V Decision	179	0	204	0	
80th Percentile Total Days to MDUFA V Decision	180	0	204	0	
Maximum Total Days to MDUFA V Decision	180	0	204	0	

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

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

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

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

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

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

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2023 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	0	
SI Goal Met	2	5	8	0	
SI Goal Not Met	2	0	0	0	
SI Pending Within Goal	0	0	0	0	
SI Pending Past Goal	0	0	0	0	
Closed Without SI	0	0	0	0	
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023 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	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	4	5	6	0	
MDUFA V Decision Goal Met	3	5	6	0	
Supplements Pending MDUFA V Decision	0	0	2	0	
Supplements Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	75.00%	100.00%	100.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	4	5	8	0	
Number with MDUFA V Decision	4	5	6	0	
Number of Not Approvable	1	1	0	0	
Rate of Not Approvable	25.00%	20.00%	0.00%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1	0	0	0	
Mean FDA Days for Submissions that Missed the Goal	206.00	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	121.00	N/A	N/A	N/A	

Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
Supplements Received	3	2	2	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision	3	2	2	0	
MDUFA V Decision Goal Met	3	2	2	0	
Supplements Pending MDUFA V Decision	0	0	0	0	
Supplements Pending MDUFA V Decision Past Goal	0	0	0	0	
Current Performance Percent Goal Met	100%	100%	100%	N/A	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3	2	2	0	
Number With MDUFA V Decision	3	2	2	0	
Number of Not Approvable	0	0	0	0	
Rate of Not Approvable	0%	0%	0%	N/A	

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

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

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	41	33	52	20	
Closed Before First RTA or TS Action [1]	0	4	2	0	
Number Accepted or Passed TS on First Cycle [2]	30	25	40	12	
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	0	0	1	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0	0	0	2	
Number Not Accepted or Failed TS on First Cycle [2]	11	4	9	6	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	26.83%	13.79%	18.00%	33.33%	

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	46	18	
Deleted or Withdrawn Prior to SI	0	0	0	0	
SI Within 60 FDA Days	37	29	44	10	
SI Over 60 FDA Days	2	0	1	1	
SI Pending Within 60 FDA Days	0	0	1	7	
SI Pending Over 60 FDA Days	0	0	0	0	
510(k)s NSE Without SI	0	0	0	0	
Current SI Performance Percent Within 60 FDA Days	94.87%	100.00%	97.78%	90.91%	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	39	29	45	11	
Average Number of FDA Days to Substantive Interaction	55.53	56.79	51.64	59.45	
20th Percentile FDA Days to Substantive Interaction	51	56	46	57	
40th Percentile FDA Days to Substantive Interaction	56	57	57	58	
60th Percentile FDA Days to Substantive Interaction	59	58	59	59	
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	
Maximum FDA Days to Substantive Interaction	90	60	62	73	

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	46	18	
Non-MDUFA V Decision	3	3	3	0	
MDUFA V Decision (SE/NSE)	36	26	36	6	
MDUFA V Decision Within 90 FDA Days	36	26	36	6	
510(k)s Pending MDUFA V Decision	0	0	7	12	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	

Table 6.5 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	1.53	1.67	
Number With MDUFA V Decision	36	26	36	6	
Average Number of FDA Days to MDUFA V Decision	77.33	80.08	71.19	84.00	
20th Percentile FDA Days to MDUFA V Decision	69	73	29	81	
40th Percentile FDA Days to MDUFA V Decision	84	86	80	82	
60th Percentile FDA Days to MDUFA V Decision	89	87	86	90	
80th Percentile FDA Days to MDUFA V Decision	90	89	88	90	
Maximum FDA Days to MDUFA V Decision	90	90	90	90	
Average Number of Industry Days to MDUFA V Decision	48.92	82.12	55.06	15.50	
20th Percentile Industry Days to MDUFA V Decision	0	0	0	0	
40th Percentile Industry Days to MDUFA V Decision	0	0	0	9	
60th Percentile Industry Days to MDUFA V Decision	0	102	34	20	
80th Percentile Industry Days to MDUFA V Decision	115	180	153	22	
Maximum Industry Days to MDUFA V Decision	315	207	193	42	
Average Number of Total Days to MDUFA V Decision	126.25	162.19	126.25	99.50	
20th Percentile Total Days to MDUFA V Decision	81	79	52	90	
40th Percentile Total Days to MDUFA V Decision	88	90	85	91	
60th Percentile Total Days to MDUFA V Decision	90	188	122	101	
80th Percentile Total Days to MDUFA V Decision	90	266	234	112	
Maximum Total Days to MDUFA V Decision	375	288	270	113	

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	46	18	
Number With MDUFA V Decision	36	26	36	6	
Number of SE Decision	35	20	30	6	
Number of NSE Decision	1	6	6	0	
Number of Withdrawal	2	1	1	0	
Number of Deleted	1	2	2	0	
Rate of SE Decision	97.22%	76.92%	83.33%	100.00%	
Rate of NSE Decision	2.78%	23.08%	16.67%	0.00%	
Rate of Withdrawal	5.13%	3.45%	2.17%	0.00%	
Rate of Deleted	2.56%	6.90%	4.35%	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	0	
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	

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

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

Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA V Decision Metric

Performance Metric	FY 2023 95% Within 90 FDA Days	FY 2024 95% Within 90 FDA Days	FY 2025 95% Within 90 FDA Days	FY 2026 95% Within 90 FDA Days	FY 2027 95% Within 90 FDA Days
510(k)s Accepted	7	4	3	0	
Non-MDUFA V Decision	0	0	0	0	
MDUFA V Decision (SE/NSE)	7	4	3	0	
MDUFA V Decision Within 90 FDA Days	7	4	3	0	
510(k)s Pending MDUFA V Decision	0	0	0	0	
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0	0	0	0	
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	N/A	

Section 8 De Novo Center Level Metrics

Table 8.1 CBER - De Novo Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	1	0	1	0	
Closed Before First RTA or TS Action	0	0	0	0	
Number Accepted or Passed TS on First Cycle	0	0	1	0	
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0	0	0	0	
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0	0	0	0	
Number Not Accepted or Failed TS on First Cycle	1	0	0	0	
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	100.00%	N/A	0.00%	N/A	

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

Table 8.2 CBER - De Novo MDUFA V Decision Performance Goal

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

Table 8.3 CBER - De Novo Time to MDUFA V Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00	0.00	0.00	0.00	
Number With MDUFA Decision	1	0	0	0	
Average FDA Days to MDUFA Decision	75.00	0.00	0.00	0.00	
20th Percentile FDA Days to MDUFA Decision	75	0	0	0	
40th Percentile FDA Days to MDUFA Decision	75	0	0	0	
60th Percentile FDA Days to MDUFA Decision	75	0	0	0	
80th Percentile FDA Days to MDUFA Decision	75	0	0	0	
Maximum FDA Days to MDUFA Decision	75	0	0	0	
Average Industry Days to MDUFA Decision	177.00	0.00	0.00	0.00	
20th Percentile Industry Days to MDUFA Decision	177	0	0	0	
40th Percentile Industry Days to MDUFA Decision	177	0	0	0	
60th Percentile Industry Days to MDUFA Decision	177	0	0	0	
80th Percentile Industry Days to MDUFA Decision	177	0	0	0	
Maximum Industry Days to MDUFA Decision	177	0	0	0	
Average Total Days to MDUFA Decision	252.00	0.00	0.00	0.00	
20th Percentile Total Days to MDUFA Decision	252	0	0	0	
40th Percentile Total Days to MDUFA Decision	252	0	0	0	
60th Percentile Total Days to MDUFA Decision	252	0	0	0	
80th Percentile Total Days to MDUFA Decision	252	0	0	0	
Maximum Total Days to MDUFA Decision	252	0	0	0	

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	1	0	1	0	
Number With MDUFA Decision	1	0	0	0	
Number With Granted Decision	0	0	0	0	
Number With Declined Decision	1	0	0	0	
Number of Withdrawal	0	0	1	0	
Number of Deleted	0	0	0	0	
Rate of Granted Decision	0.00%	N/A	0.00%	N/A	
Rate of Declined Decision	100.00%	N/A	0.00%	N/A	
Rate of Withdrawal	0.00%	N/A	100.00%	N/A	
Rate of Deleted	0.00%	N/A	0.00%	N/A	

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

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

Table 8.6 CBER - LDT De Novo MDUFA V Decision Metrics

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

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

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	68	62	75	42	
Interactions for Breakthrough Designated Products & Products Included in STeP	3	1	4	2	
Number Closed Before First RTA Action	7	1	1	1	
Number Accepted First RTA Cycle [1]	59	60	74	39	
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	2	0	0	0	
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0	0	0	2	
Number Not Accepted First RTA Cycle	0	1	0	0	
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.00%	1.64%	0.00%	0.00%	

1. This includes RTAA actions and submissions considered accepted upon receipt.

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

Table 9.2 CBER - MDUFA V Pre-Sub Performance Goals

Performance Metric	MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2023 90% / 75% Within MDUFA Goal [1]	FY 2024 90% / 80% Within MDUFA Goal [2]	FY 2025 90% Within MDUFA Goal	FY 2026 90% Within MDUFA Goal	FY 2027 90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	61	61	74	39	
Number with Non-MDUFA Action [3]	3	0	0	0	
Number with MDUFA Action	58	61	74	23	
Written Feedback Provided Within Goal	55	61	74	23	
Number Pending MDUFA Action	0	0	0	16	
Pending MDUFA Action Past Goal	0	0	0	0	
Number in MDUFA Cohort (up to max 4300)[4]	58	61	74	39	
Current Performance Percent Within Goal	94.83%	100.00%	100.00%	100.00%	

1. In FY 2023, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 3585, or 75% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 3585 or more.

2. In FY 2024, the MDUFA Goal will be 90% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is fewer than 4060, or 80% of Pre-Subs in the MDUFA Cohort if the MDUFA Cohort is 4060 or more.

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

4. If the Pre-Sub MDUFA goal is met for FY 2023, the maximum number of submissions subject to the goal will escalate to 4700 Pre-Subs in FYs 2025, 2026, and 2027. If the Pre-Sub MDUFA goal is met for FY 2024, the maximum number of submissions subject to the goal will escalate to 4800 Pre-Subs in FY 2026 and FY 2027. If the Pre-Sub MDUFA goal is met for FY 2025, the goal will not be subject to a maximum number of submissions in FY 2027.

Table 9.3 CBER – MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	58	61	74	23	
Average FDA Days to Written Feedback	59.38	60.79	60.49	59.26	
20th Percentile FDA Days to Written Feedback	55	54	55	57	
40th Percentile FDA Days to Written Feedback	60	61	60	61	
60th Percentile FDA Days to Written Feedback	64	65	65	65	
80th Percentile FDA Days to Written Feedback	69	69	68	66	
Maximum FDA Days to Written Feedback	72	70	70	69	

Table 9.4 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Scheduling (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	0	0	0	0	
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00	0.00	0.00	

Table 9.5 CBER - MDUFA V Pre-Sub Performance Metrics - Meeting Minutes (Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	24	31	23	10	
Meeting Minutes Submitted Within 15 Days of Meeting	21	26	20	8	
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	
Meeting Minutes Past 15 Days of Meeting	3	5	3	1	
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	0	0	0	
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	87.50%	83.87%	86.96%	88.89%	

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	5	
Average Number of Cycles to IDE Approval or Conditional Approval	1.07	1.07	1.00	1.00	
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.07	0.06	0.00	0.00	

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

Medical Devices

Guidance Documents

Pursuant to the MDUFA V Commitment Letter,[1] the table below includes all FDA guidance documents issued in FY 2026 related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA V Commitment Letter are indicated as such.[2] The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).[3] Guidance documents are listed by the quarter in which they were issued and are provided in a cumulative format for FY 2026.

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2026

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-selecting-developing-or-modifying-fit-purpose-clinical-outcome	10/22/2025	Yes	Yes	Section 3002 of the 21st Century Cures Act	No
2	Q1	Quality Management System Information for Certain Premarket Submission Reviews www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-management-system-information-certain-premarket-submission-reviews	10/27/2025	Yes	No	N/A	A-List
3	Q1	Menstrual Products - Performance Testing and Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/menstrual-products-performance-testing-and-labeling-recommendations	10/28/2025	Yes	No	No	A-List
4	Q1	Cross-Center Master Files: Where to Submit www.fda.gov/regulatory-information/search-fda-guidance-documents/cross-center-master-files-where-submit	11/25/2025	Yes	No	N/A	No

[1] www.fda.gov/media/158308/download.
[2] CDRH provides the annotation of "yes" for guidance's that are substantially related to the process. CDRH provides the annotation of "no" for guidance's that contain a minimal amount of guidance related to the process.
[3] CDRH Proposed Guidance Development | FDA

#	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	[4]eCopy Program for Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions	12/03/2025	Yes	No	N/A	No
6	Q1	Study of Sex Differences in the Clinical Evaluation of Medical Products www.fda.gov/regulatory-information/search-fda-guidance-documents/study-sex-differences-clinical-evaluation-medical-products	12/15/2025	Yes	No	N/A	No
7	Q1	Investigator Responsibilities – Safety Reporting for Investigational Drugs and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/investigator-responsibilities-safety-reporting-investigational-drugs-and-devices	12/15/2025	Yes	No	N/A	No
8	Q1	Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices	12/18/2025	Yes	Yes	Section 3629 of the Food and Drug Omnibus Reform Act (FDORA) & MDUFA V Commitment Letter V.F.	A-List
9	Q1	Processes and Practices Applicable to Bioresearch Monitoring Inspections www.fda.gov/regulatory-information/search-fda-guidance-documents/processes-and-practices-applicable-bioresearch-monitoring-inspections	12/19/2025	Yes	Yes	Section 3612 of the Food and Drug Omnibus Reform Act (FDORA)	No
10	Q2	[4]General Wellness: Policy for Low Risk Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices	01/06/2026	Yes	No	N/A	No
11	Q2	Minimal Residual Disease and Complete Response in Multiple Myeloma: Use as Endpoints to Support Accelerated Approval www.fda.gov/regulatory-information/search-fda-guidance-documents/minimal-residual-disease-and-complete-response-multiple-myeloma-use-endpoints-support-accelerated	01/21/2026	Yes	No	N/A	No

[4] This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2)

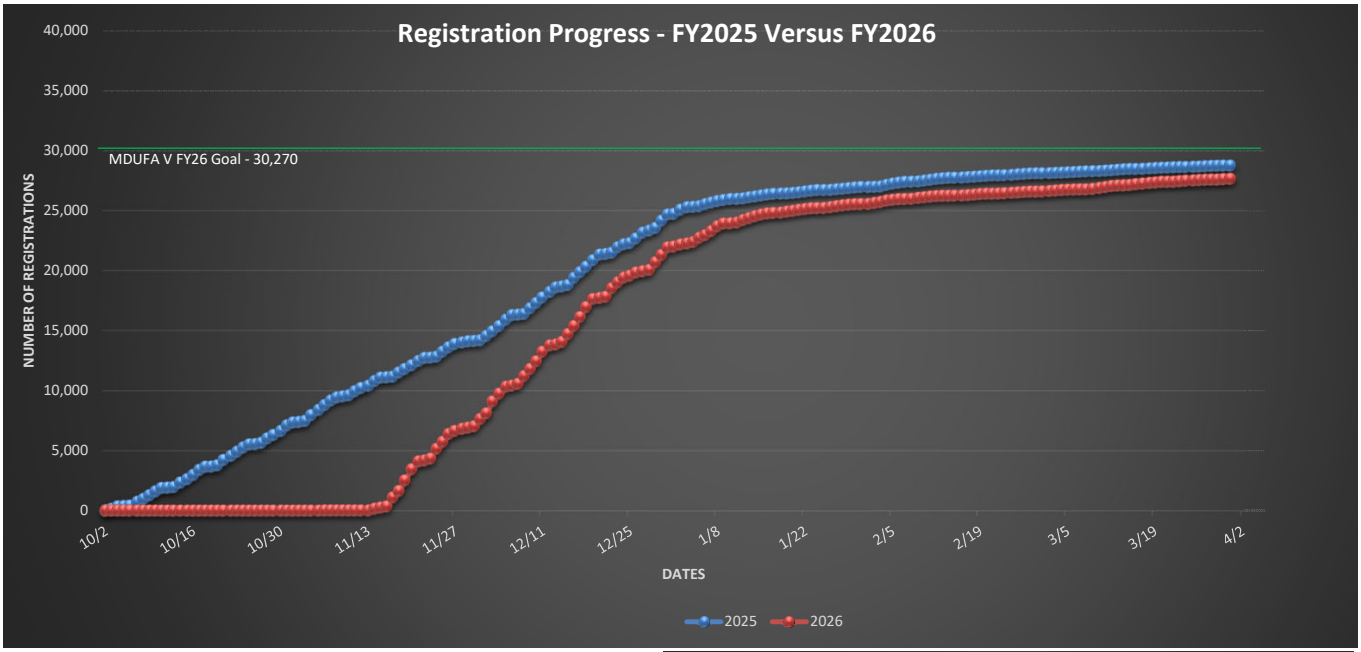
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
12	Q2	Cuffless Non-invasive Blood Pressure Measuring Devices – Clinical Performance Testing and Evaluation www.fda.gov/regulatory-information/search-fda-guidance-documents/cuffless-non-invasive-blood-pressure-measuring-devices-clinical-performance-testing-and-evaluation	01/23/2026	Yes	No	N/A	No
13	Q2	[4]Clinical Decision Support Software www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software	01/29/2026	Yes	No	N/A	No
14	Q2	[4]Computer Software Assurance for Production and Quality Management System Software www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-management-system-software	02/03/2026	No	No	N/A	No
15	Q2	[4]Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-management-system-considerations-and-content-premarket	02/03/2026	Yes	No	N/A	No
16	Q2	Medical Devices with Indications Associated with Weight Loss - Premarket Considerations www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-indications-associated-weight-loss-premarket-considerations	03/13/2026	Yes	No	N/A	B-List
17	Q2	[4]Pyrogen and Endotoxins Testing: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/pyrogen-and-endotoxins-testing-questions-and-answers	03/18/2026	Yes	No	N/A	No
18	Q2	Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle www.fda.gov/regulatory-information/search-fda-guidance-documents/incorporating-voluntary-patient-preference-information-over-total-product-life-cycle-0	03/30/2026	Yes	Yes	MDUFA V Commitment Letter V.E.	A-List

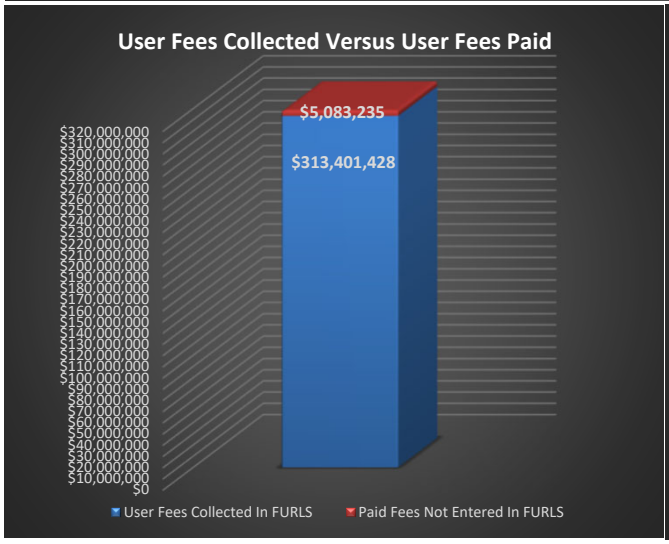
Registrations and Listings

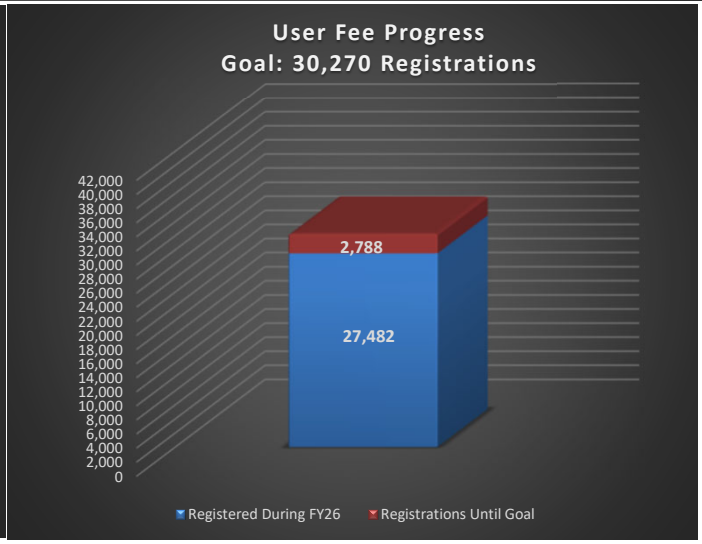
MDUFA V Registrations - 2nd Quarter Summary FY2026*

Current Max Activity Registrations by Type	FY26 Q2			FY25 Year End Active Totals			FY26 vs End of FY25
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,084	11,014	17,098	6,499	12,045	18,544	92.20%
Contract Manufacturer	1,174	2,021	3,195	1,267	2,101	3,368	94.86%
Contract Sterilizer	75	174	249	77	181	258	96.51%
Specification Developer	1,423	504	1,927	1,579	551	2,130	90.47%
Reprocessor of Single Use Devices	21	4	25	23	4	27	92.59%
U.S. Manufacturer of Export Only Devices	89	0	89	113	0	113	78.76%
Repackager/Relabeler	938	164	1,102	1,057	189	1,246	88.44%
Remanufacturer	7	4	11	15	8	23	47.83%
Foreign Exporter/Private Label Distributor		886	886		1,064	1,064	83.27%
Initial Importer	2,701		2,701	3,063		3,063	88.18%
Unknown	0	1	0	0	0	0	0.00%
Total:	**12,512**	**14,772**	**27,284**	**13,693**	**16,143**	**29,836**	91.45%

*Data is current as of 03/31/2026







Medical Device User Fee Collections

Q2 FY 2026 Medical Device User Fee Collections as of March 31, 2026 Excludes Unearned Revenue					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$313,455,342	-$319,844	$313,135,498		
Application Fees	$60,765,552	-$303,252	$60,462,300		
Total	**$374,220,894**	**-$623,096**	**$373,597,798**	**$478,165,880**	**78%**
Medical Device User Fee Collection History Excludes Unearned Revenue, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,281,779	$31,738,775	$34,425,417	$28,031,569
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,794,823	$56,962,602	$63,699,312	$69,720,145	$65,324,184
	FY 2013	**FY 2014**	**FY 2015**	**FY 2016**	**FY 2017**
MD III	$101,306,430	$122,346,416	$136,098,825	$147,165,318	$137,782,995
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,896,895	$208,692,116	$215,697,178	$275,338,627	$269,130,850
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$322,347,363	$340,209,427	$411,483,643	$373,597,798	

Number of Discretionary Fee Waivers or Reductions

MDUFA V Commitment Letter - VI. Performance Reports
2.12. Number of discretionary fee waivers or reductions granted by type of submission[1/]

CDRH Data 2nd Quarter FY 2026 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	0	0
PMA	8	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	6
De Novo Classification	0	0
180-Day Supplements	1	8
Real-Time Supplements	0	17
510(k)s	0	0
30-day Notices /135 day supplements*	7	40
513(g)s	0	0
PMA Annual Report		
Total	**8**	**0**

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

[2/] As specified in the MDUFA V Commitment Letter, BLAs, BLA efficacy supplements, and other CBER data will be reported annually.

***135-day supplements were initially received and paid as 30-day notices; totals are combinations of both cohorts**

The Accreditation Scheme for Conformity Assessment (ASCA) - MDUFA V Update

Eric Franca, Ph.D.
Director, Conformity Assessment Program

May 19, 2026

U.S. FOOD & DRUG ADMINISTRATION
Center for Devices and Radiological Health
Division of Standards and Conformity Assessment

1

Topics

- Update on Commitments
- ASCA 'By the Numbers'
- Other Program Updates

2

2

Commitment One

Transition from pilot to permanent program (due September 2023): Completed September 2023

- Announced the transition through email/social media comms
- Updated web pages
- Posted cover letters to final guidances that indicated the program's permanent status

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Commitment Two

Feasibility Report (due March 2024): Completed March 2024

- Published the ASCA Pilot Final report March 2024
- Concluded that the program is feasible and has value
- Combined the final report with the 2023 Annual Report

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Commitment Three

Training staff and supervisors (ongoing):

- Simplifying and streamlining reviewer support materials to make ASCA review even easier
- Immediate contact with reviewer upon receipt of ASCA submissions
- Real-time training provided to reviewers
- Ongoing training opportunities for CDRH and CBER review staff

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Commitment Four

Training test labs and reviewers (ongoing):

- Conducting routine meetings with test labs
- Formal training
- Guidance on how to conduct and report testing correctly
- Standing 'office hours' to field questions from labs

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Commitment Five

Annual Reports (ongoing):

- 2025 Annual Report published on time (**Completed Jan 2026**)
- 2026 Annual Report on track for January 2027 publication

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Commitment Six

Expansion and program improvements (no due date):

- Draft updates to guidances **published Sept 23, 2024**
- Draft-to-final guidance publication ongoing
- Added IEC 61326-2-6 for EMC to IVD (**2025**)
- Five additional biocompatibility methods included in draft guidance

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ASCA UPDATES

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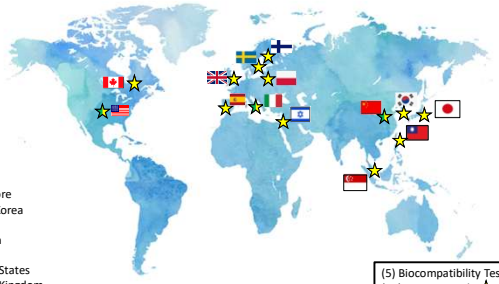
99 ASCA-Accredited Testing Laboratories Around the World

- Canada
- China
- Finland
- Israel
- Italy
- Japan
- Poland
- Singapore
- South Korea
- Spain
- Sweden
- Taiwan
- United States
- United Kingdom



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ASCA By the Numbers

(through Q2 FY 2026)

99 ASCA-accredited Testing Laboratories	200+ Manufacturers have used ASCA	40+ Manufacturers have used ASCA multiple times
277 Submissions with ASCA STRs	~88% ASCA STRs have not needed additional technical information	97% ASCA submissions for which FDA requested no complete test reports

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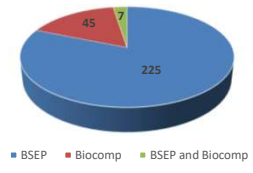
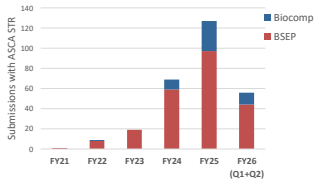
ASCA By the Numbers

Steady influx of ASCA STRs

Submissions with ASCA STRs



Submissions with ASCA STRs per FY



BSEP = Basic Safety and Essential Performance (e.g., IEC 60601 series)
Biocomp = Biocompatibility (e.g., ISO 10993 series and others)
STR = ASCA Summary Test Report

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What Do Reviewers Think?

Much **quicker** compared to a full test report review

No issues

Increased **confidence** in the test reports

Really **turned the submission around**

Easier to review

Fewer deficiencies

Helps **mitigate** the **risk** of data integrity issues

ASCA

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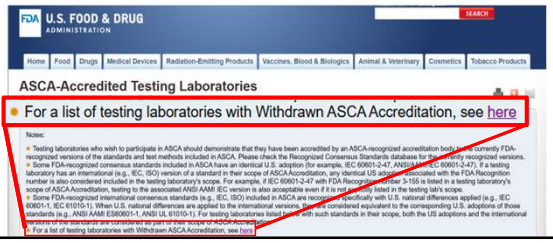
Additional Updates

- **Ensuring only high-quality labs are ASCA-accredited**
  - ASCA audits precipitated the withdrawal of *ASCA Accreditation* from multiple TLs
  - Withdrawn labs also explicitly listed (link)



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What Comes Next?

- Continue to promote the program
- Enhance training
- Continue auditing labs
- Exploring expansion
- Move guidances from draft to final
- Looking ahead to MDUFA VI

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QUESTIONS?

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