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

September 11, 2023, 2:00 – 3:00 pm
Zoom

Welcome –

FDA MDUFA Performance — Actions through June 30, 2023

- Report on decision goals for 3rd Quarter FY 2023
- Status of Paused IVD Submissions

Guidance Development

Registration and Listing

Qualitative Update on Finances – 3rd Quarter FY 2023

- User fee receipts through the 3rd Quarter FY 2023
- Funding for Non-NEST Organizations (if applicable)

Annual Hiring Goals Update

TAP pilot progress

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CDRH Performance Data ----
Actions through 30 June 2023

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
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

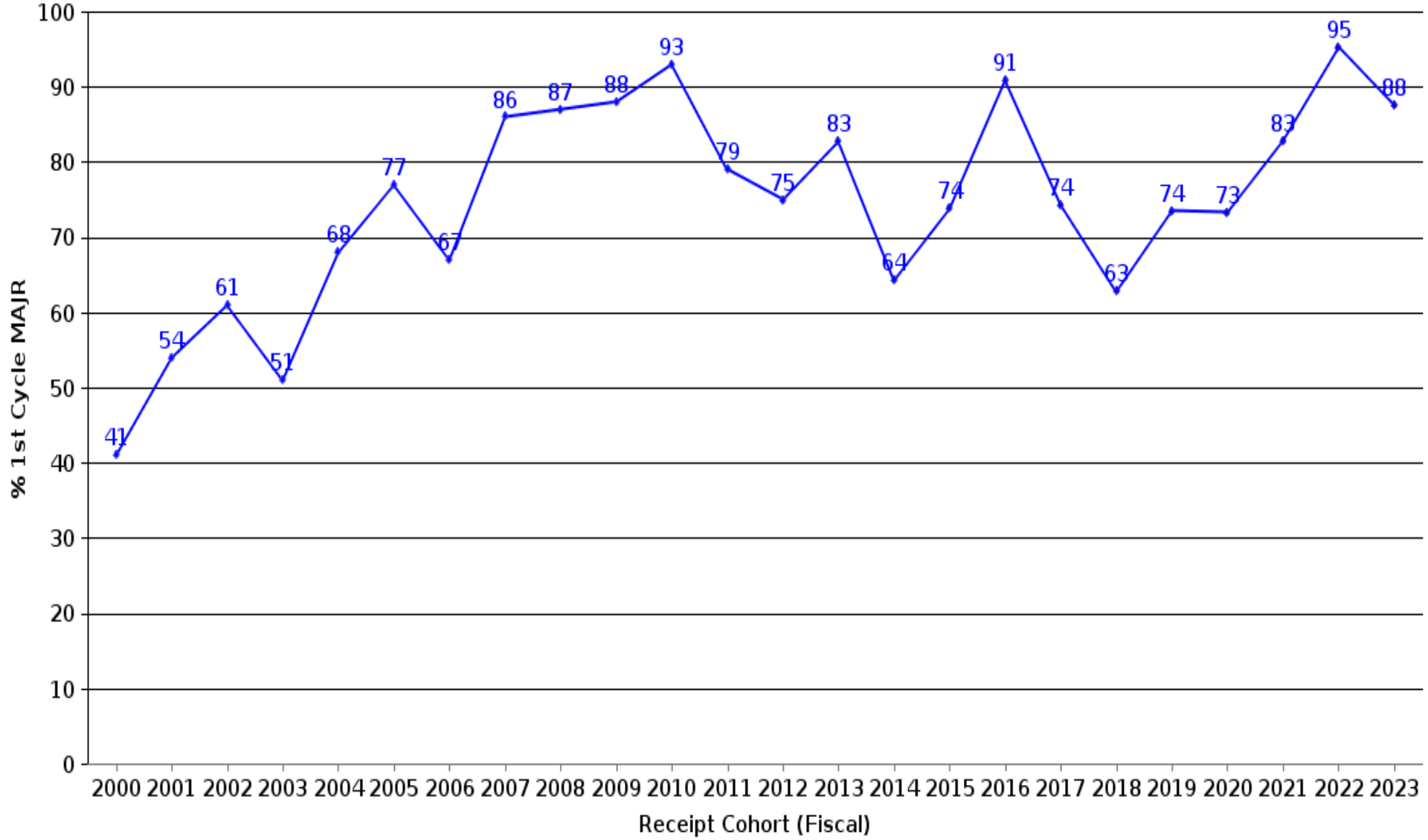
OHT8: Office of Radiological Health

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

PMAs

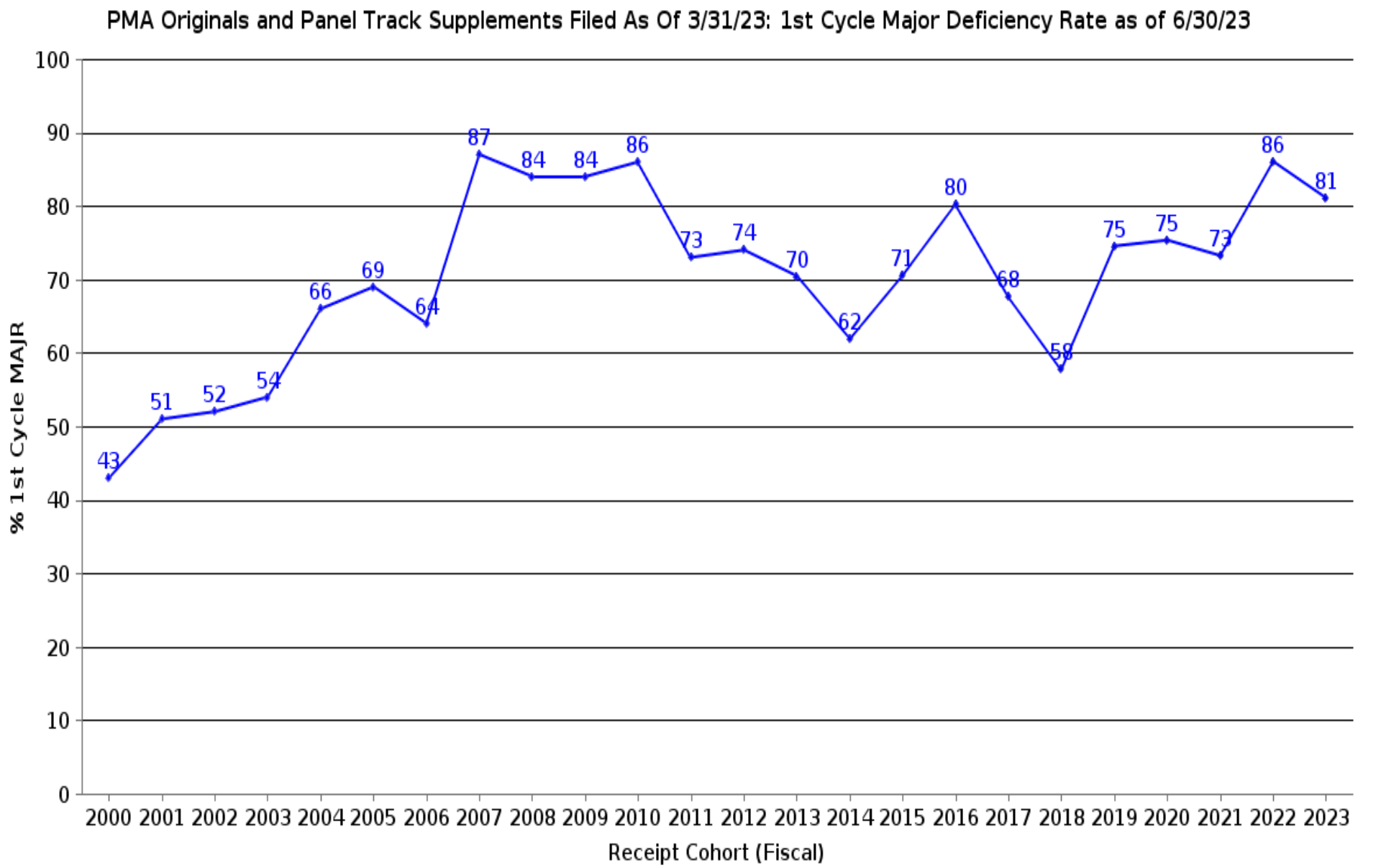
Q3 FY 2023

PMA Originals Filed As Of 3/31/23: 1st Cycle Major Deficiency Rate as of 6/30/23



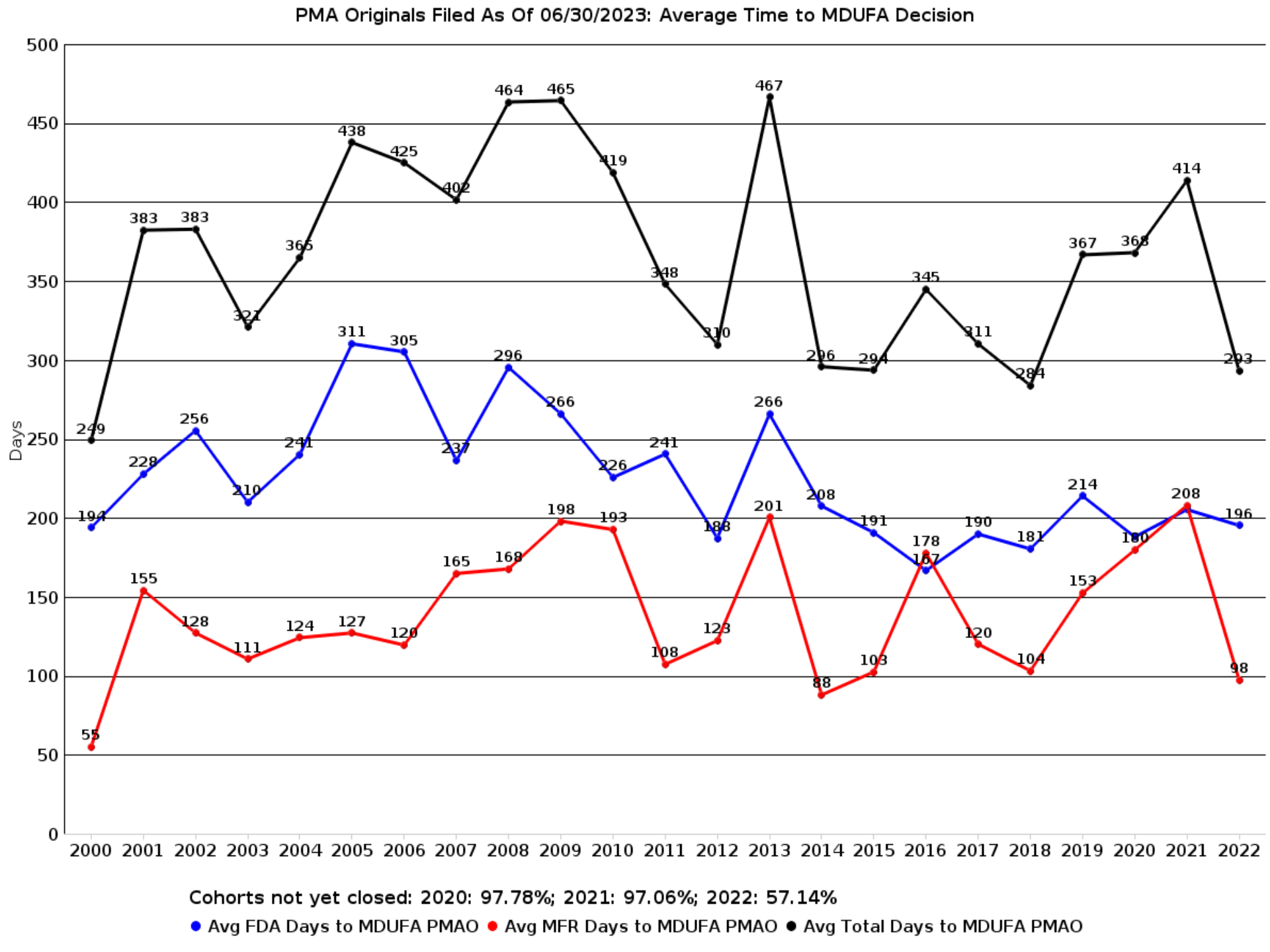
Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 3/31/23.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

♦ % 1st Cycle MAJR PMAO

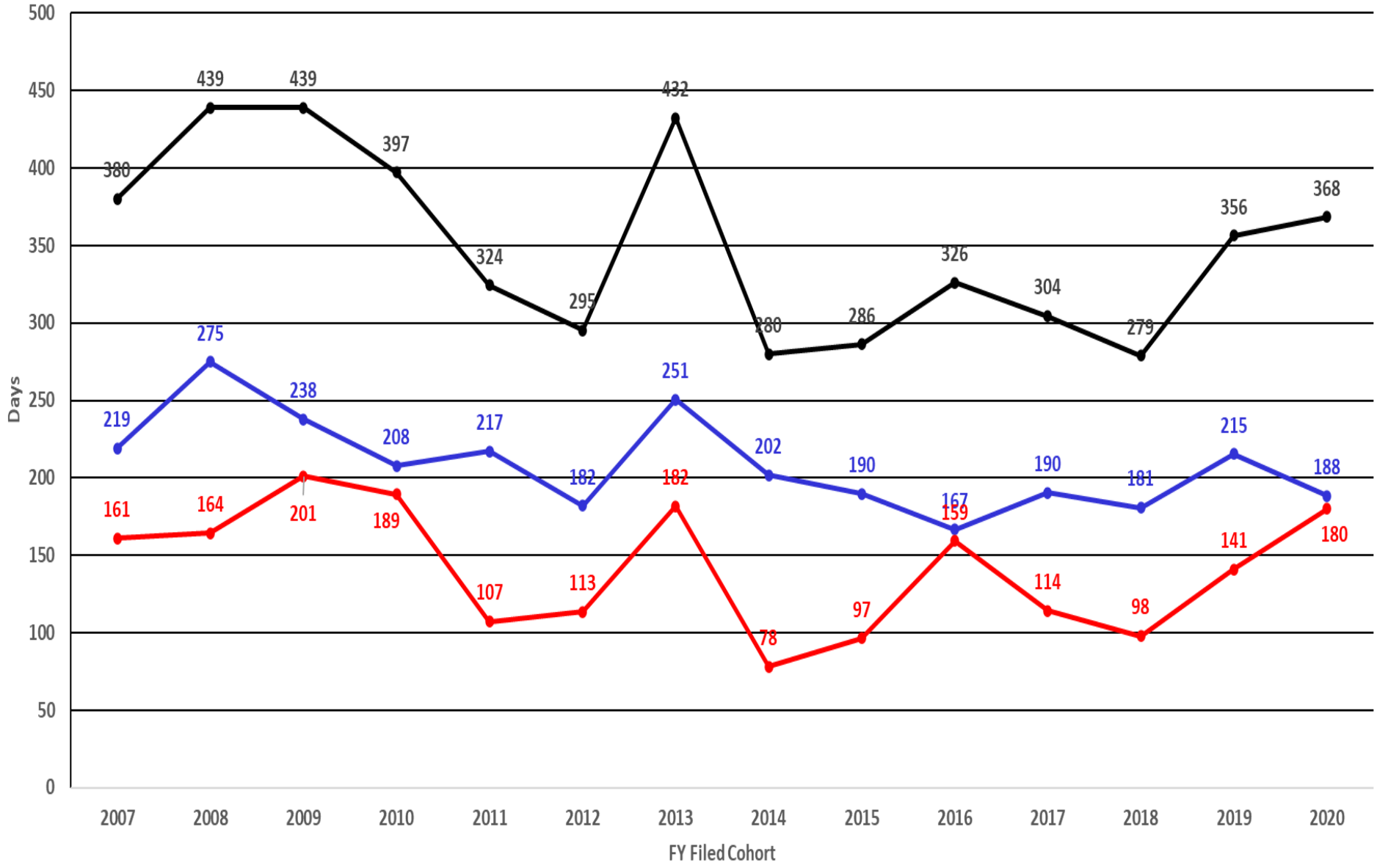


Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 3/31/23. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

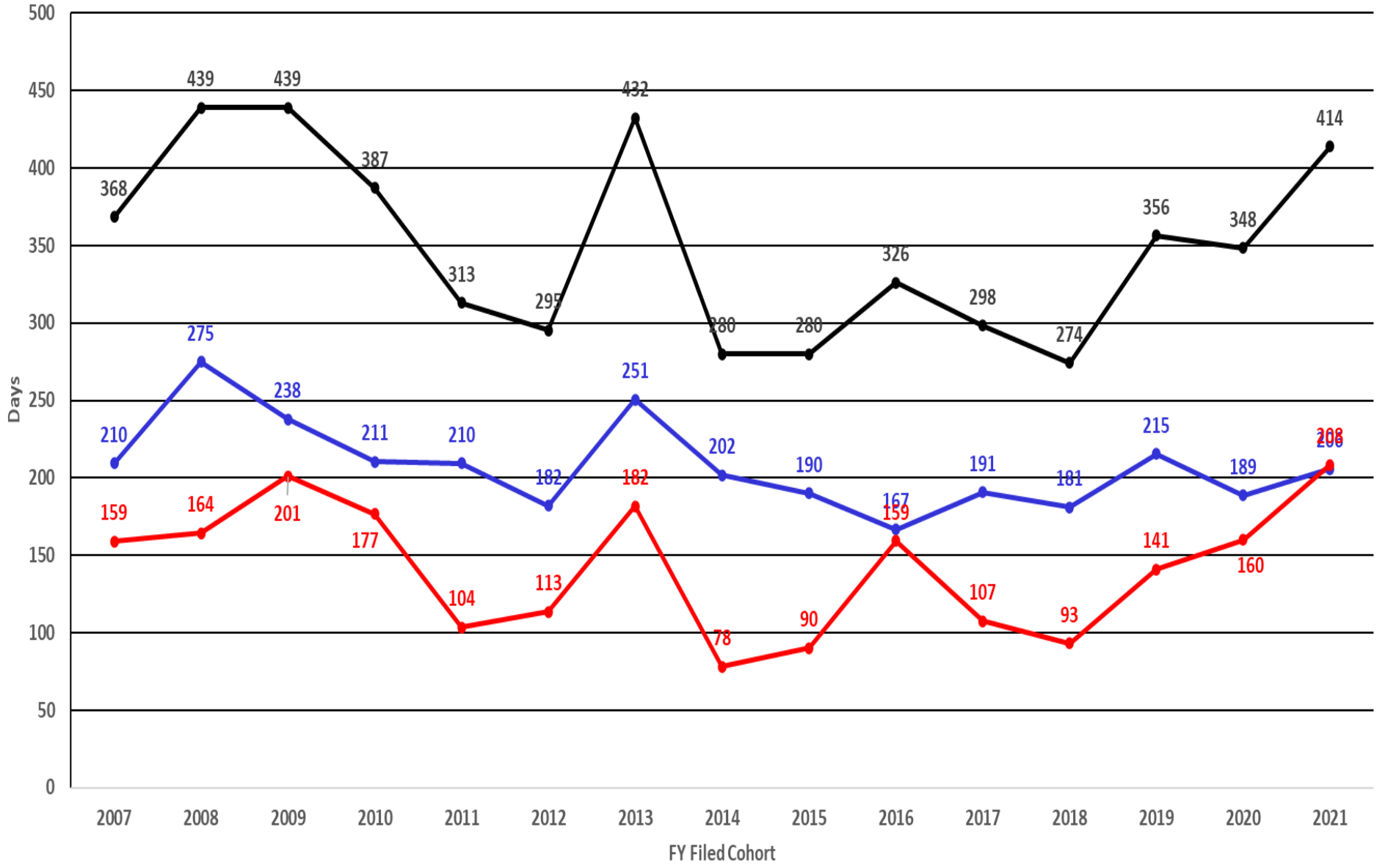
♦ % 1st Cycle MAJR PMAO/PTS


PMA Originals Filed As Of 06/30/2023: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
249 383 383 321 365 438 425 402 464 465 419 348 310 467 296 294 345 311 284 367 368 414 293
194 228 256 210 241 311 305 237 296 266 226 241 188 266 208 191 167 190 181 214 180 208 196
55 155 128 111 124 127 120 165 168 198 193 108 123 201 88 103 178 120 104 153 180 208 98
Cohorts not yet closed: 2020: 97.78%; 2021: 97.06%; 2022: 57.14%
Avg FDA Days to MDUFA PMAO
Avg MFR Days to MDUFA PMAO
Avg Total Days to MDUFA PMAO

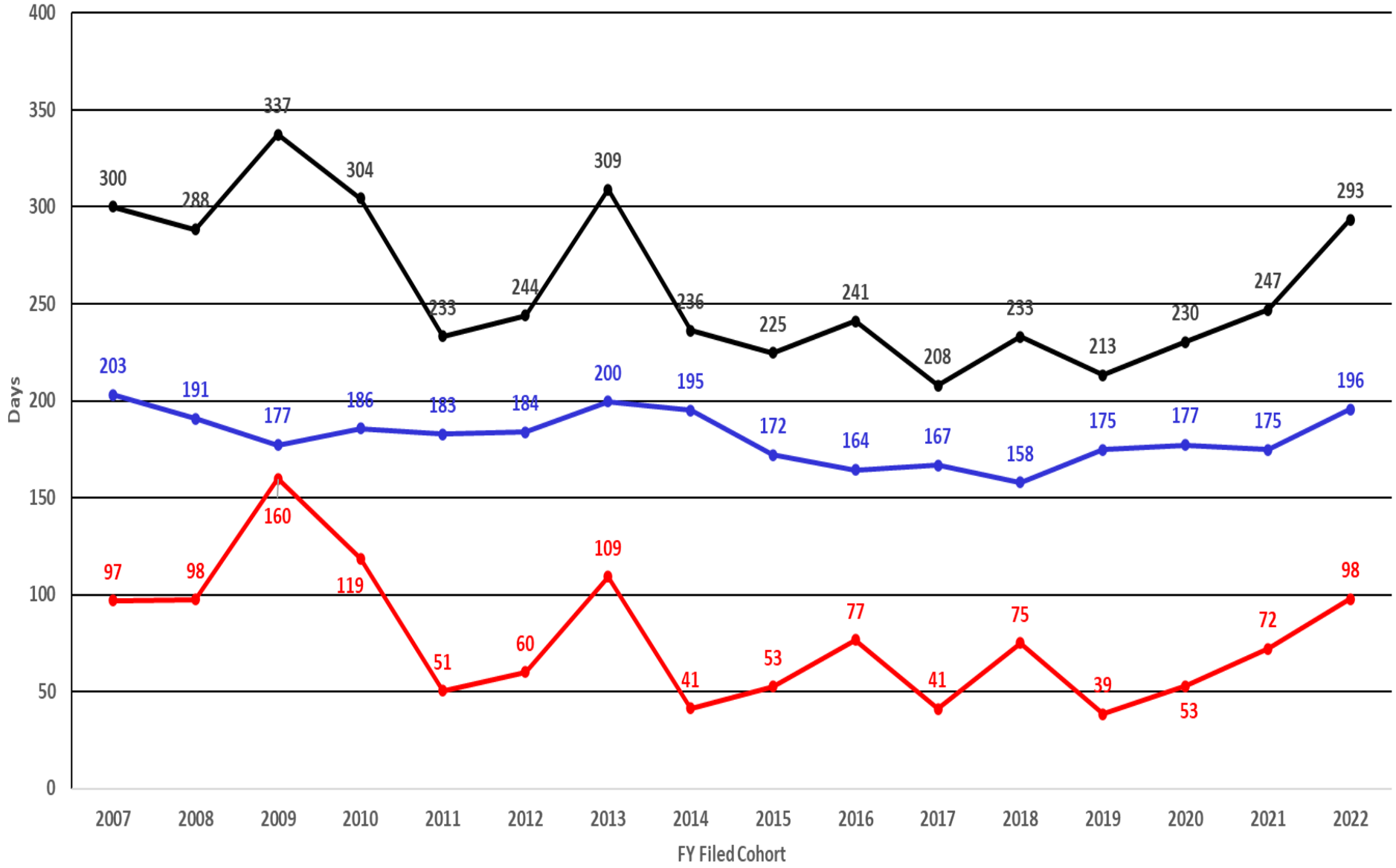
PMA Originals Filed as of 6/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 97.8% Closure

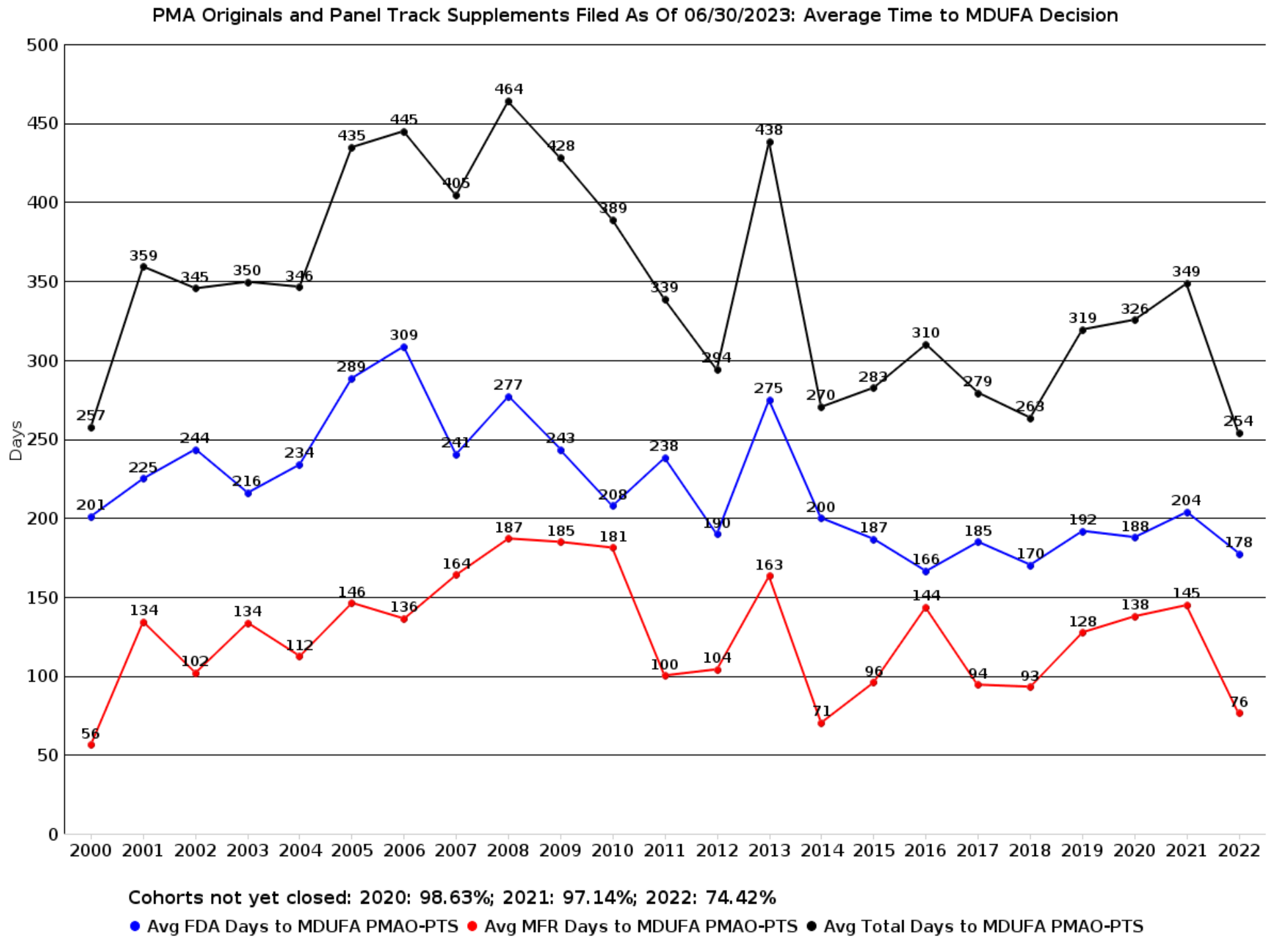


PMA Originals Filed as of 6/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 97.1% Closure

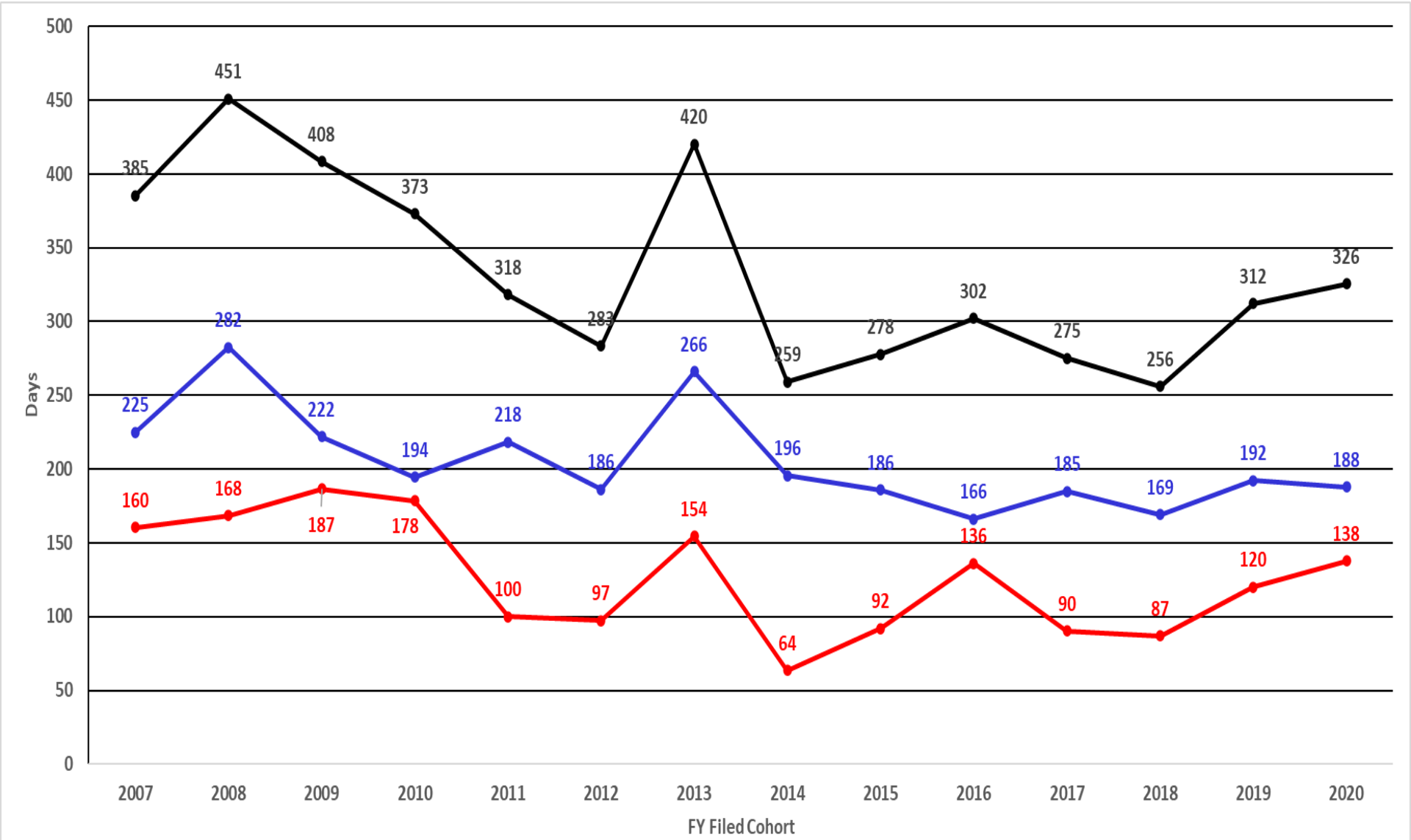


PMA Originals Filed as of 6/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 57.1% Closure

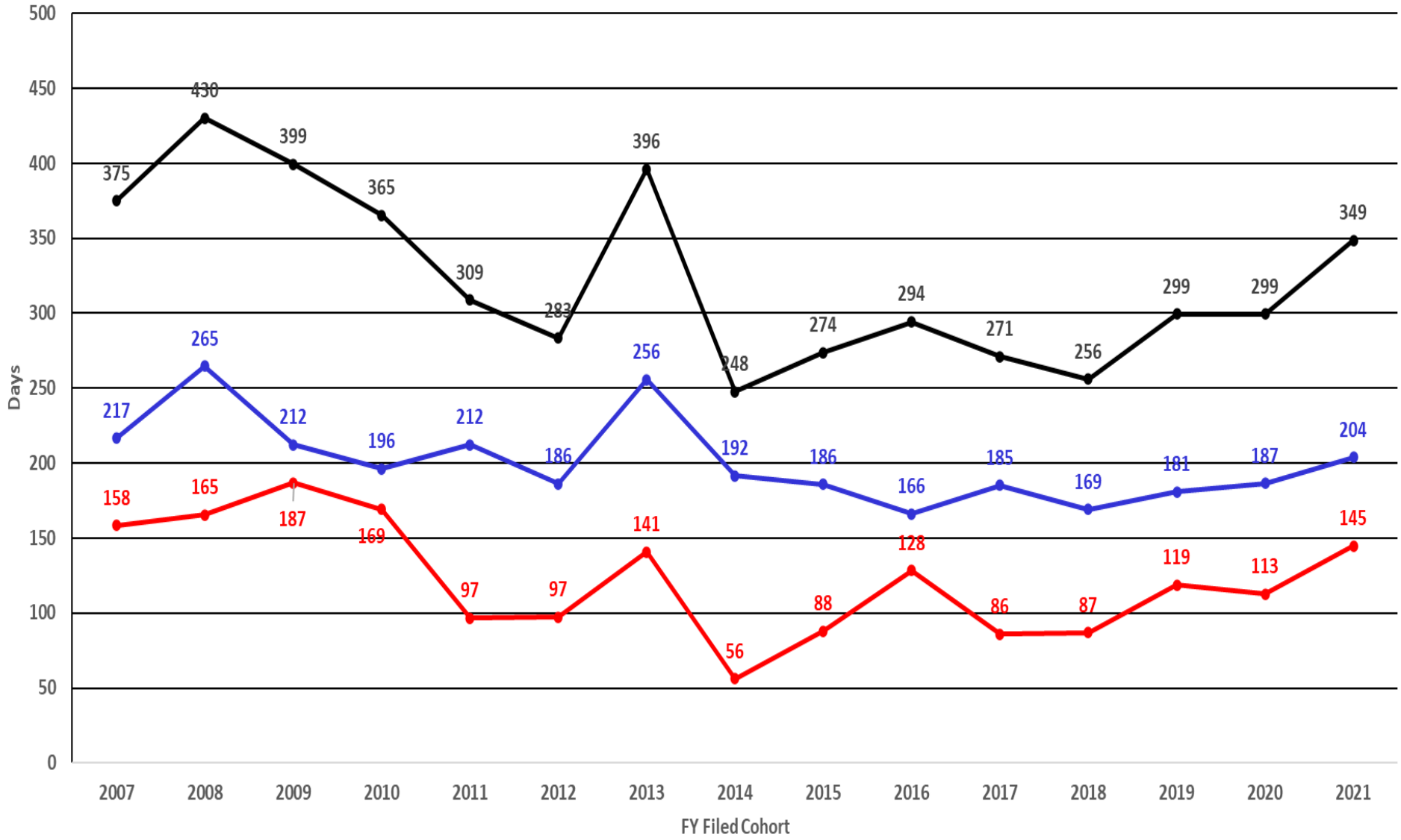



PMA Originals and Panel Track Supplements Filed As Of 06/30/2023: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
257 359 345 350 346 435 445 405 464 428 389 339 294 438 270 283 310 279 263 319 326 349 254
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 188 204 178
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 93 128 138 145 76
Cohorts not yet closed: 2020: 98.63%; 2021: 97.14%; 2022: 74.42%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

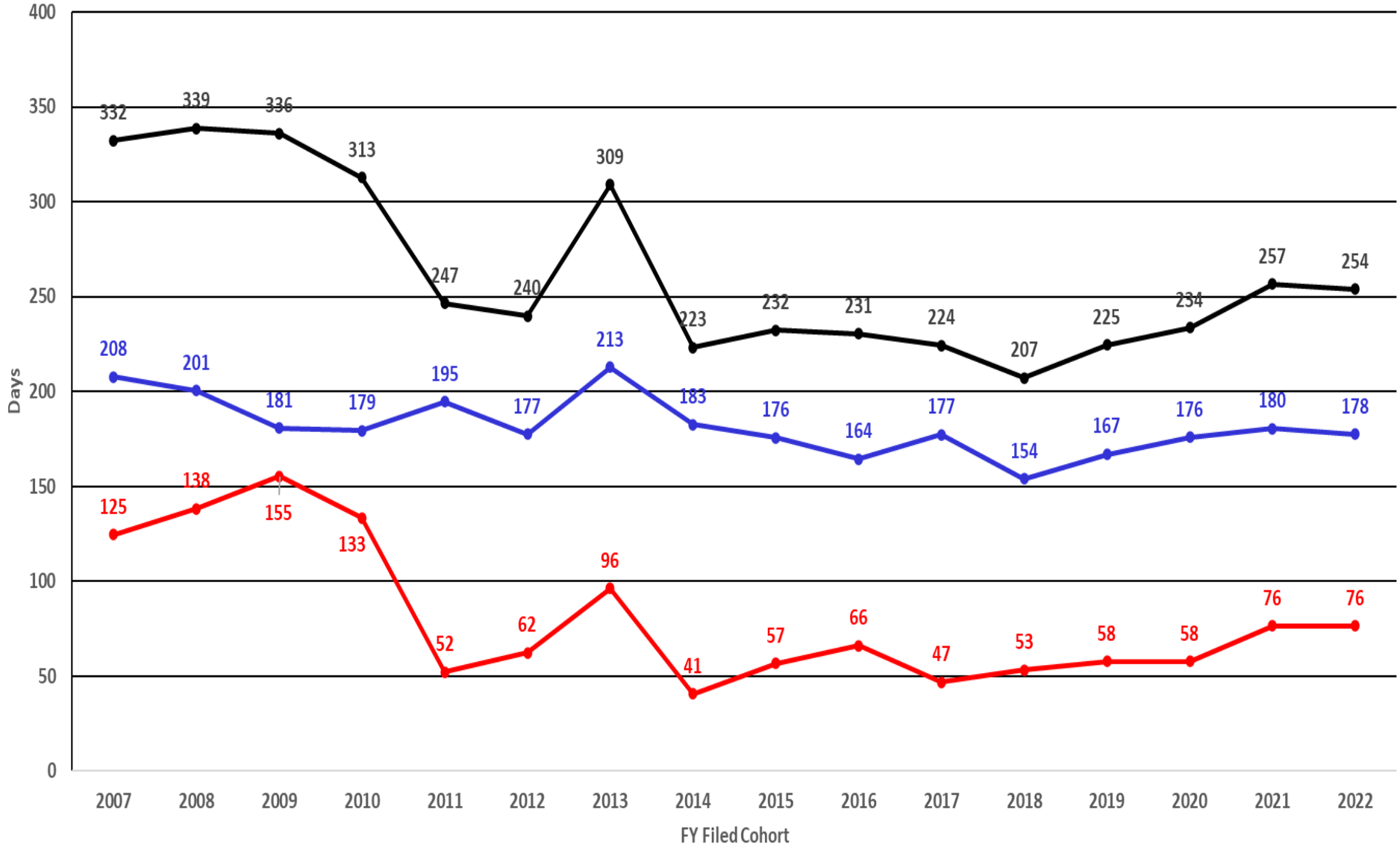
PMA Originals and Panel Track Supplements Filed as of 6/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 98.6% Closure

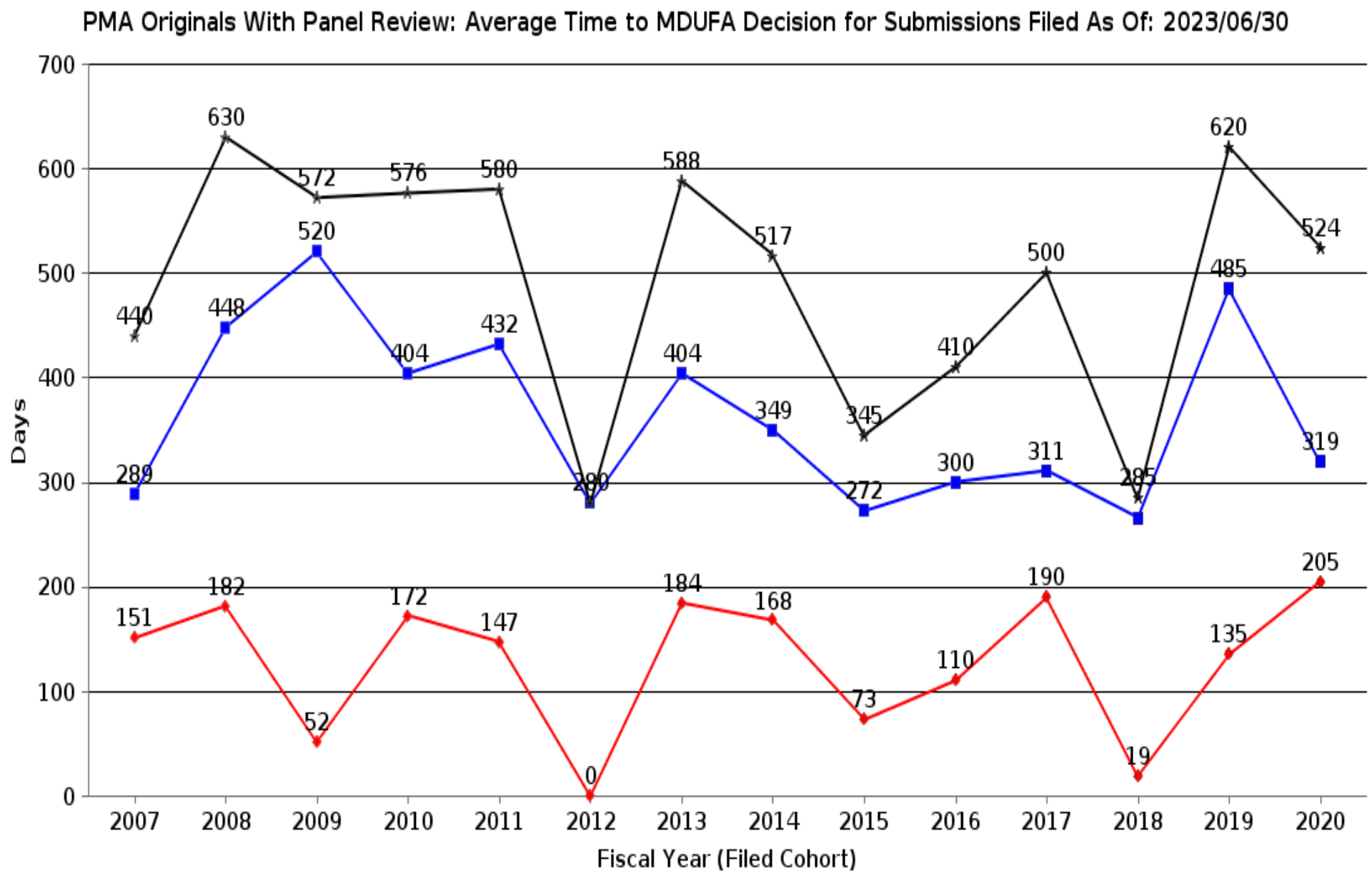


PMA Originals and Panel Track Supplements Filed as of 6/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 97.1% Closure



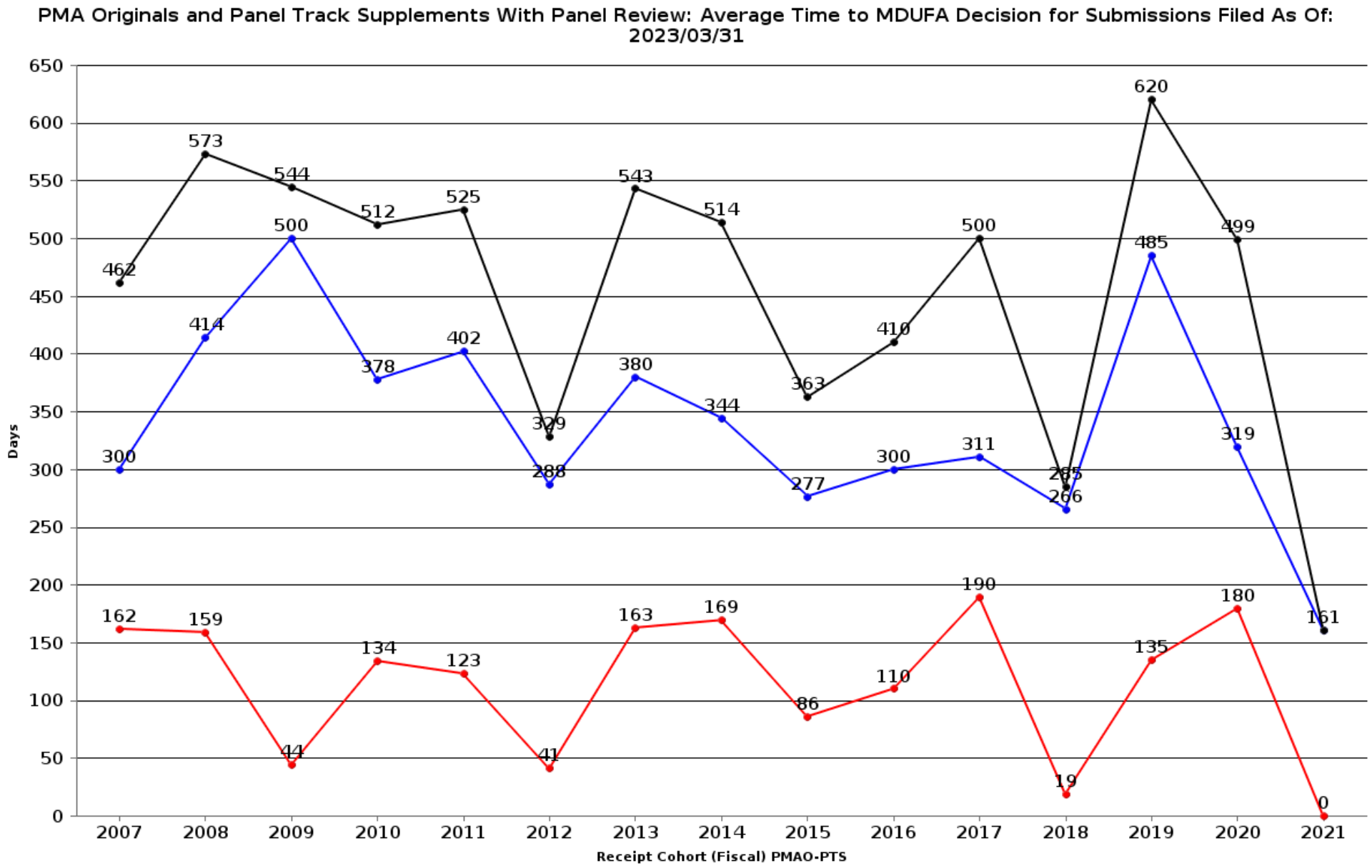
PMA Originals and Panel Track Supplements Filed as of 6/30/2023: Average Time to MDUFA Decision
Comparison of Cohorts at 74.4% Closure





Numbers Filed/Closed: 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

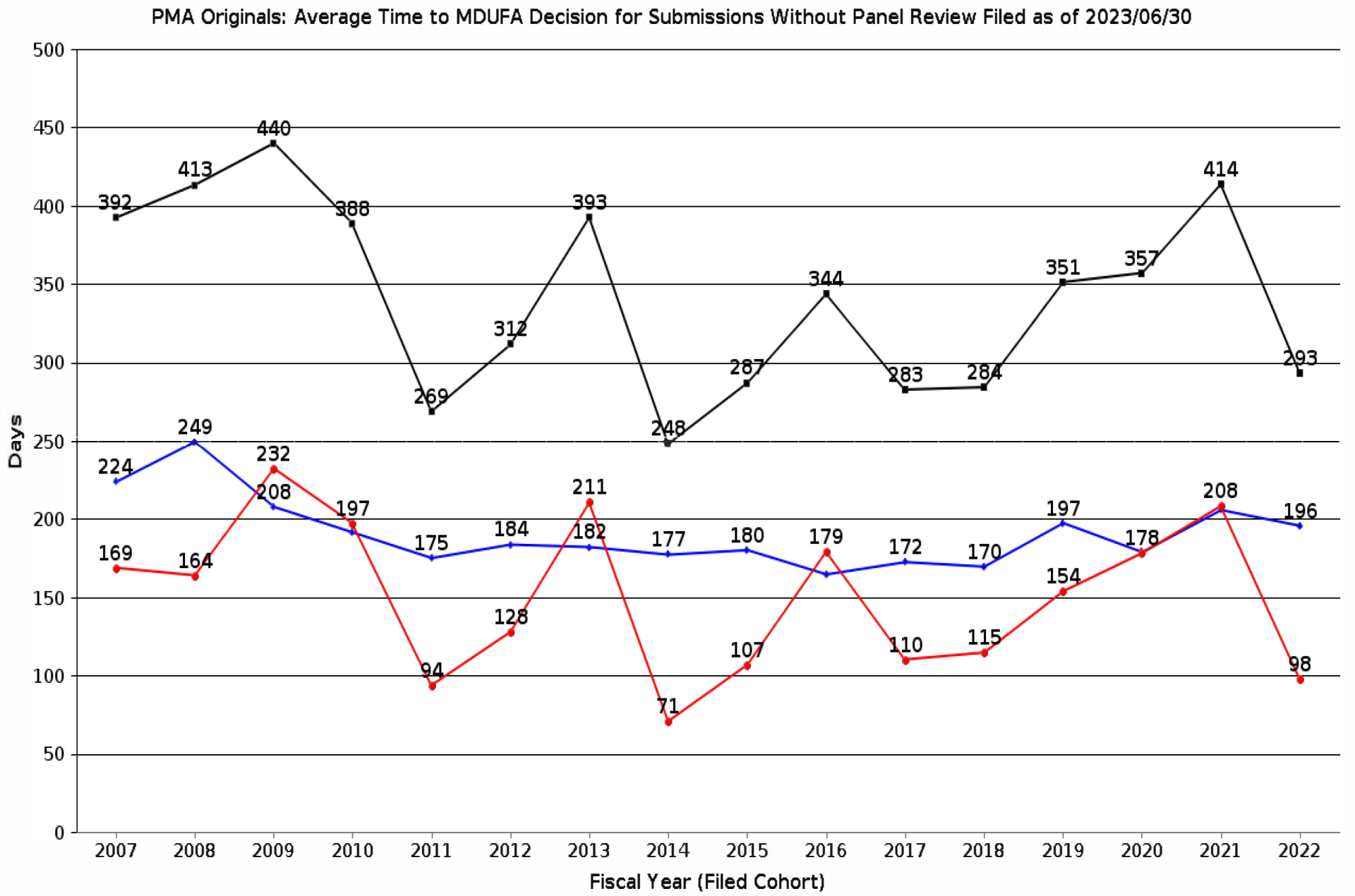
■ Avg FDA Days to MDUFA Decision PMAO ♦ Avg MFR Days to MDUFA Decision PMAO ★ Avg Total Days to MDUFA Decision PMAO

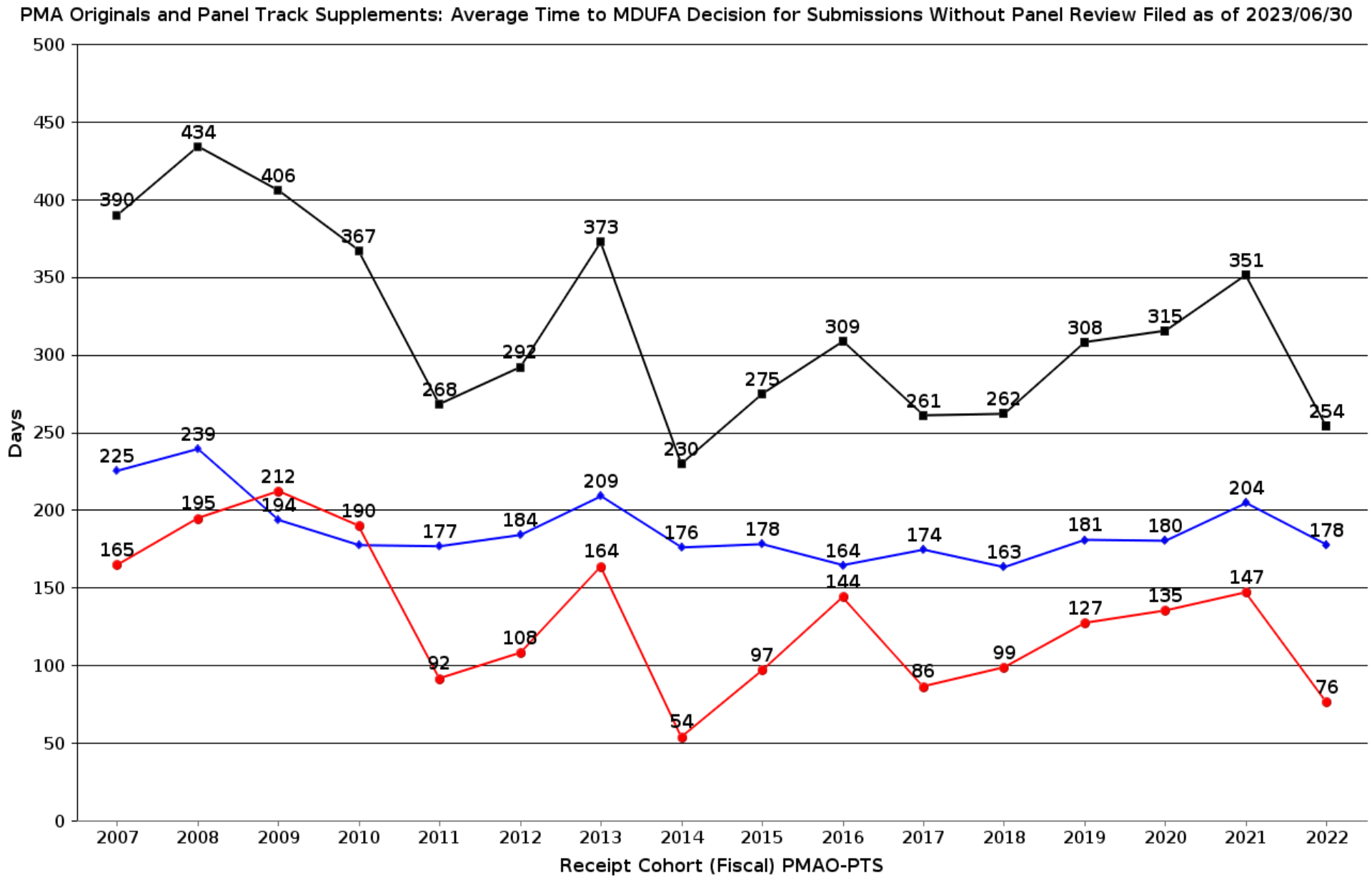


Numbers Filed/Closed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; +2012 = 2/2; 2013 = 17/17;+ 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/1

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

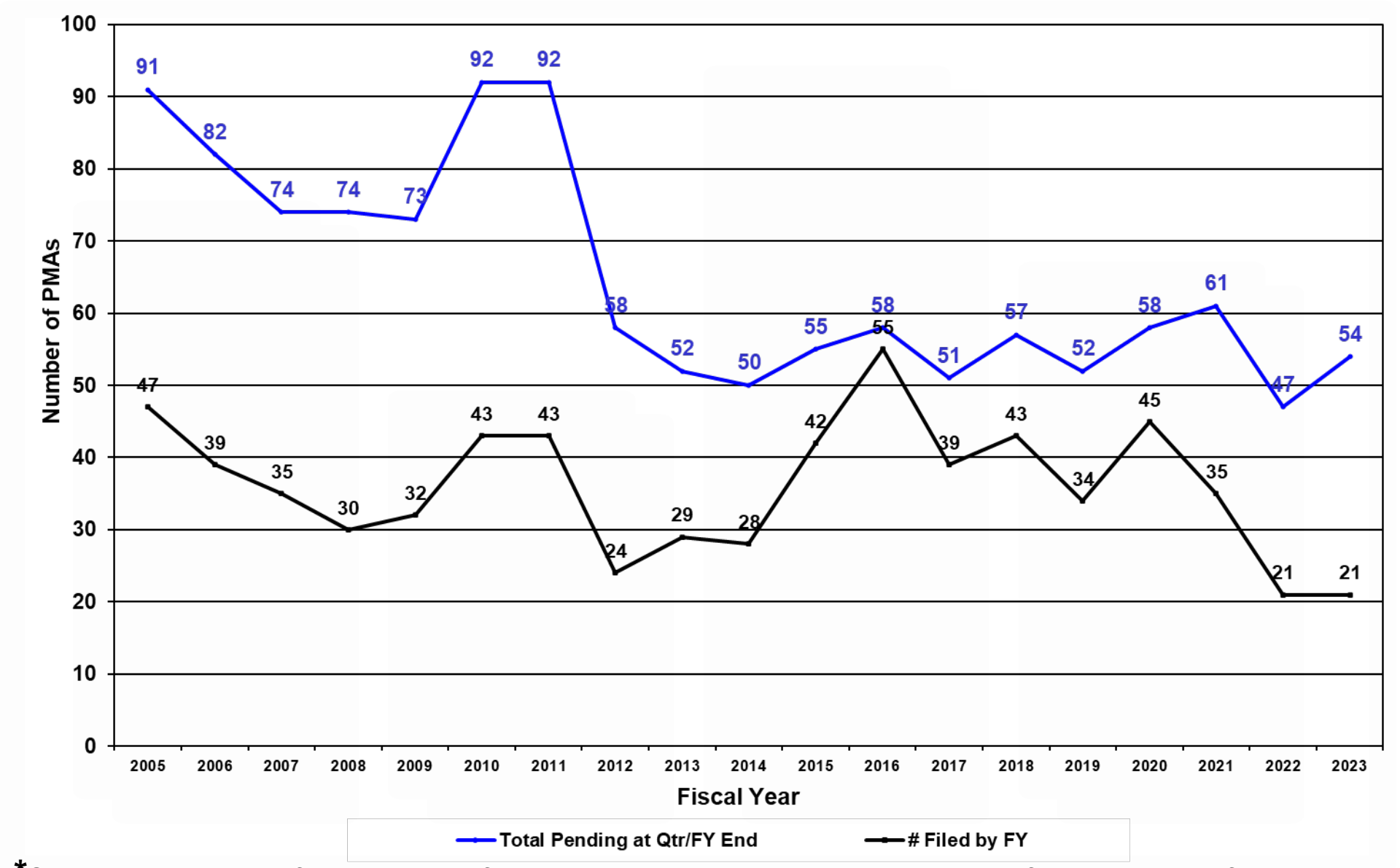
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.


PMA Originals: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2023/06/30
Days
Fiscal Year (Filed Cohort)
2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
0 50 100 150 200 250 300 350 400 450 500
392 413 440 388 269 312 393 248 287 344 283 284 351 357 414 293
224 249 208 197 175 184 182 177 180 165 172 170 197 178 208 196
169 164 232 197 94 128 211 71 107 179 110 115 154 178 208 98
Numbers Filed/Closed: 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 = 42/41; 2021 = 42/33; 2022 =21/12
Avg FDA Days to MDUFA Decision PMAO
Avg MFR Days to MDUFA Decision PMAO
Avg Total Days to MDUFA Decision PMAO



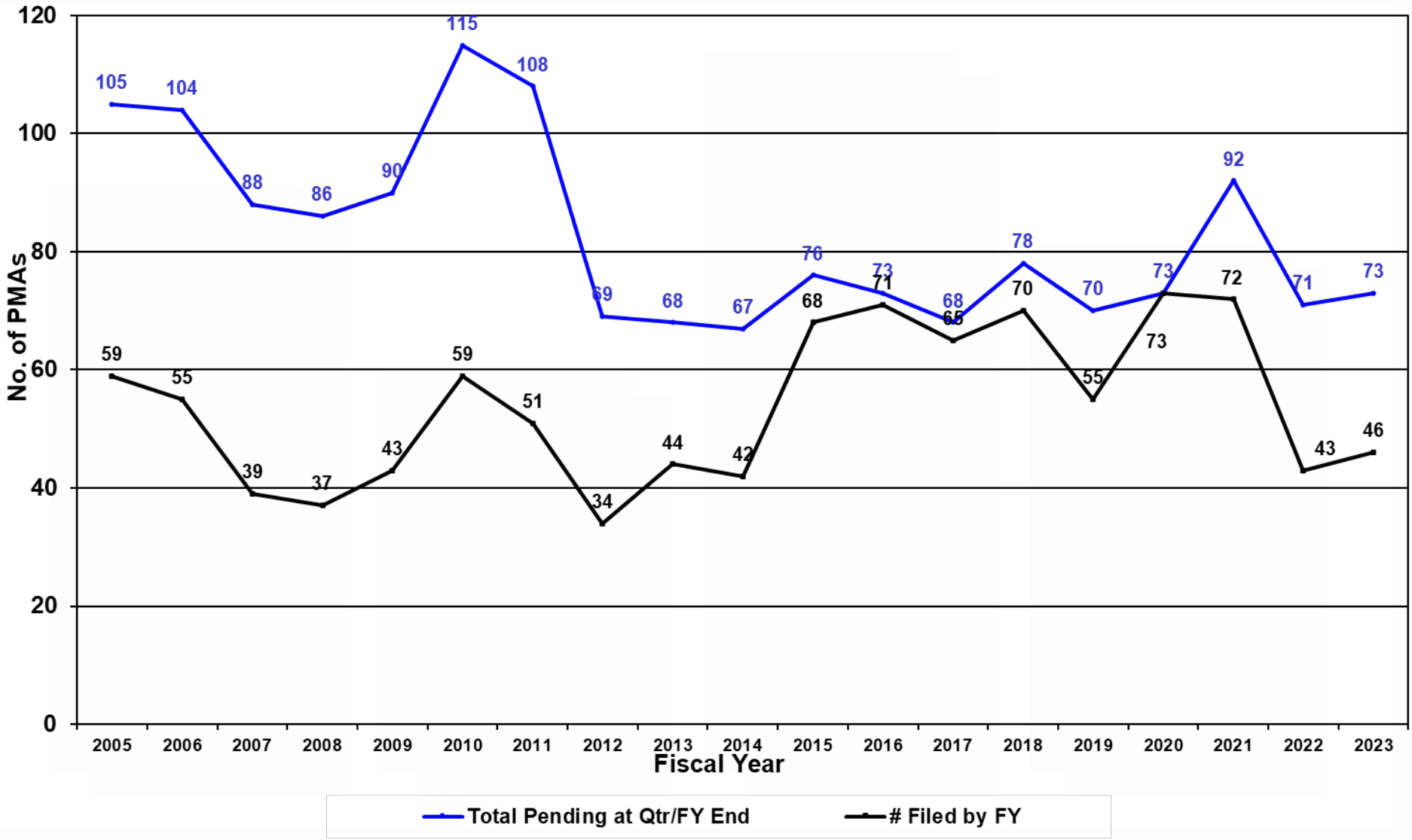
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year

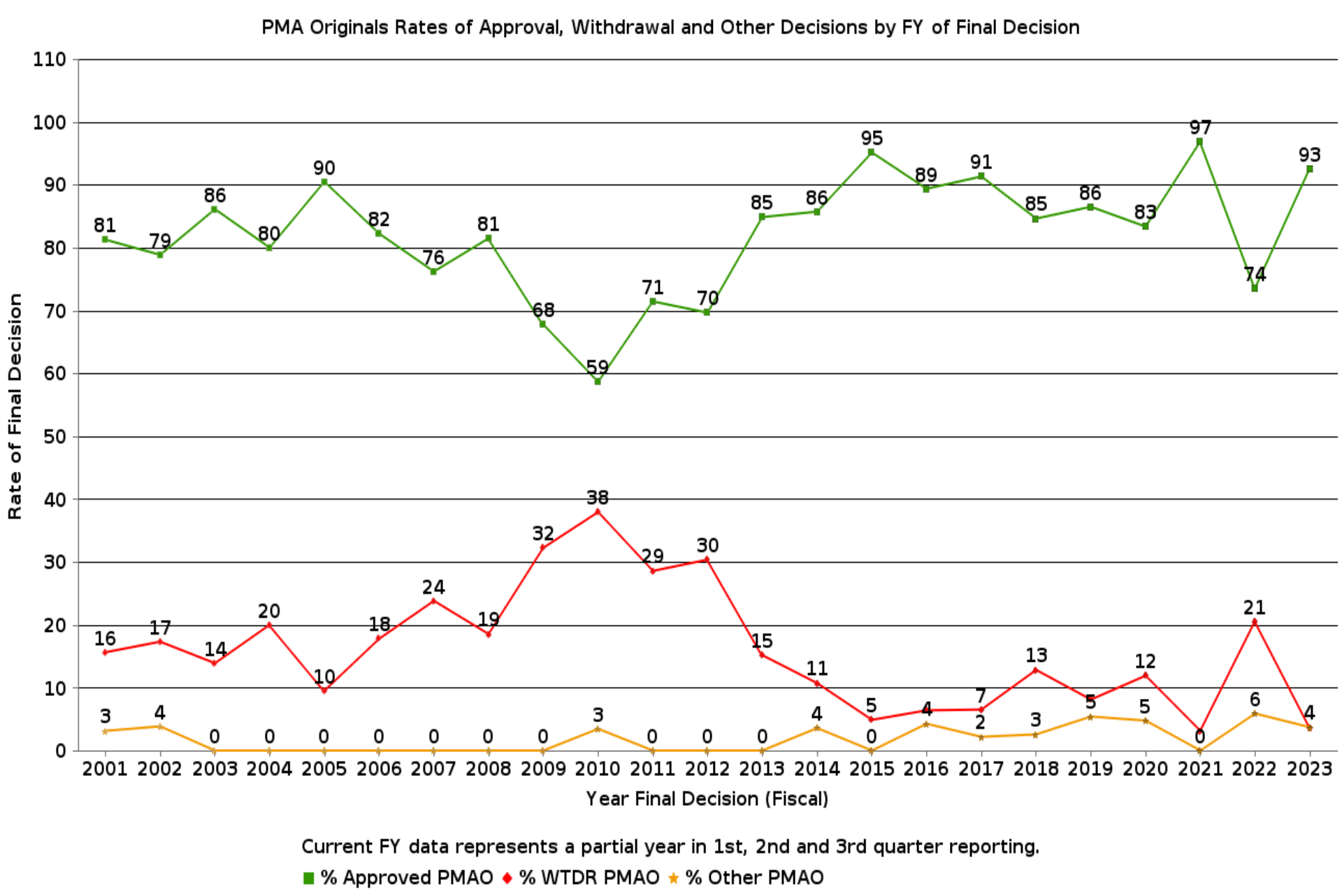


*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

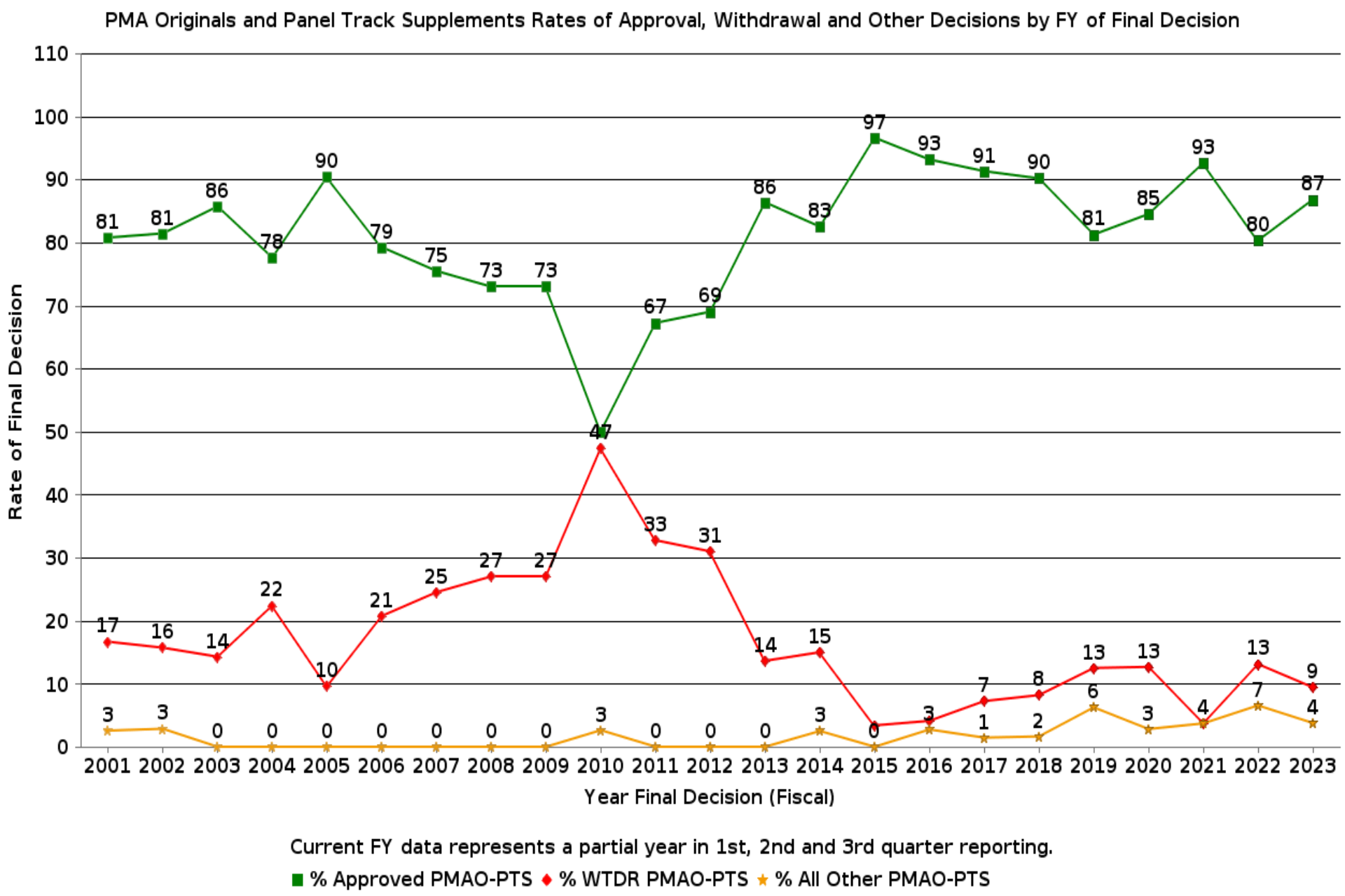
PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year



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

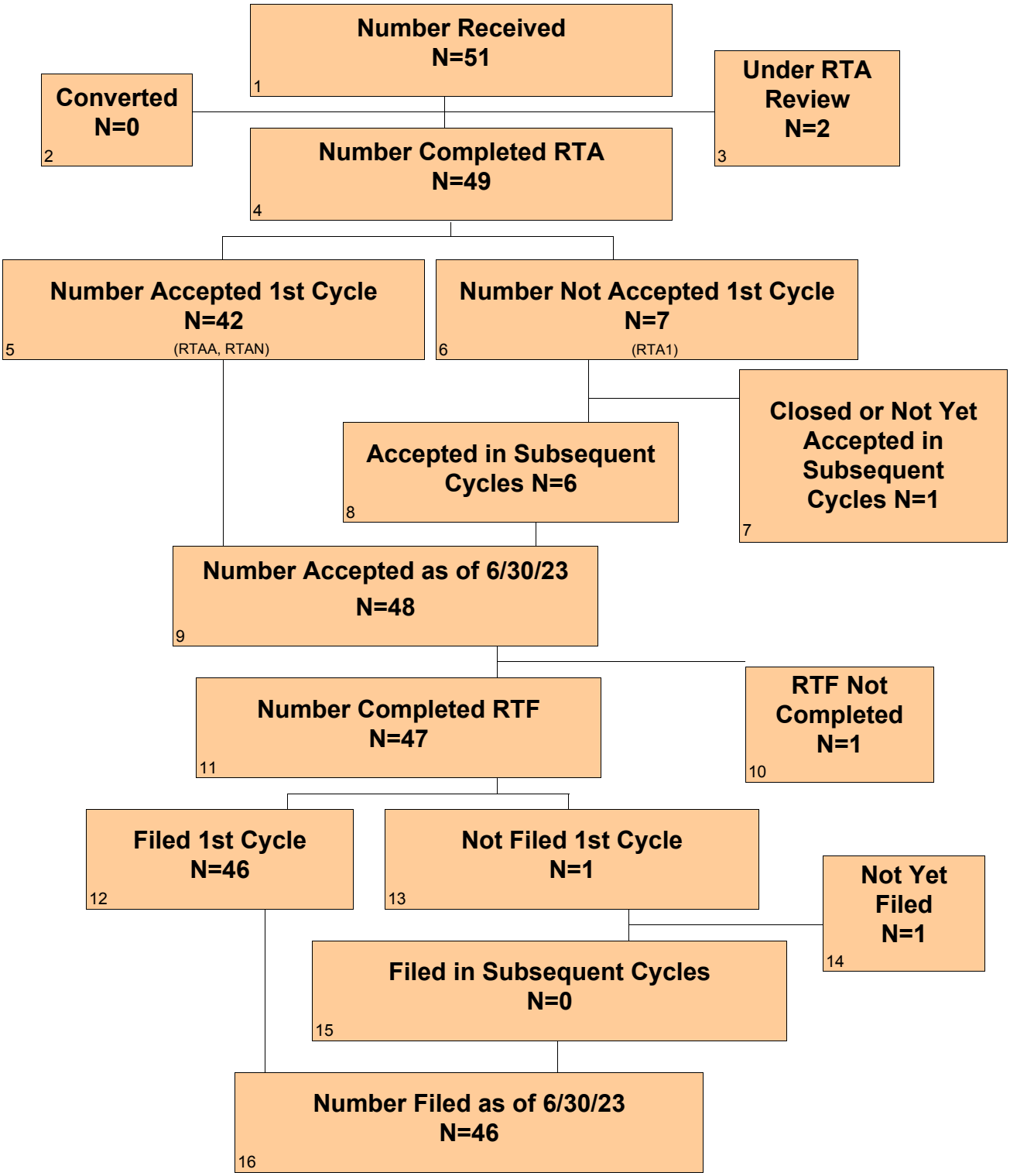


Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions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

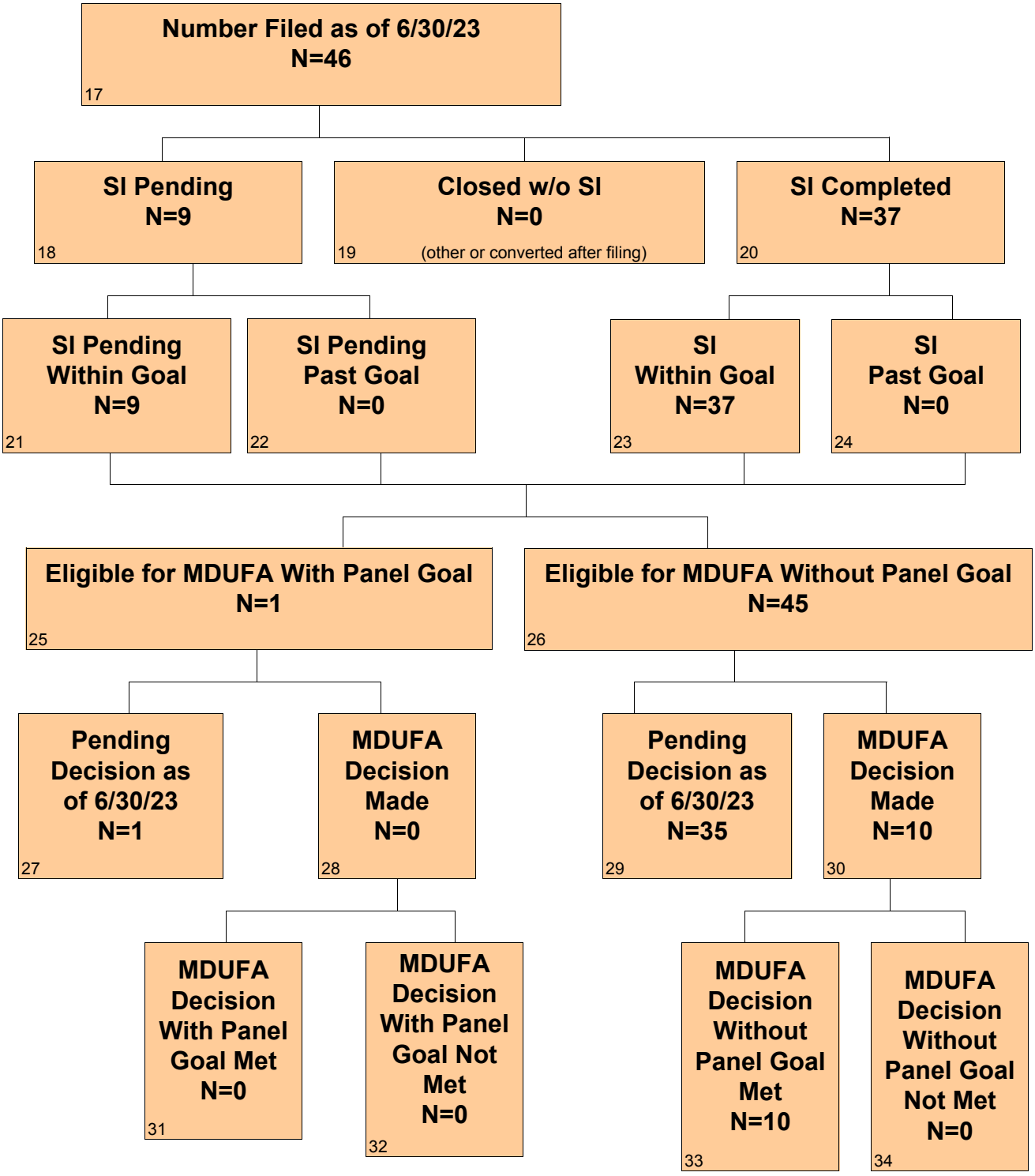


Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/23



CDRH PMA Original and Panel Track Supplements - FY 2023 as of 6/30/23 Continued



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

Table 1.1 CDRH - PMA Original and Panel-Track Supplements - Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	51				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	42				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	2				
Number Not Accepted for Filing Review on First Cycle	7				
Rate of Submissions Not Accepted for Filing Review on First Cycle	14.29%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	51				
Number Accepted	42				
Completed RTF	47				
Number Not Filed	1				
Rate of Submissions Not Filed	2.13%				

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	46				
SI Goal Met	37				
SI Goal Not Met	0				
SI Pending Within Goal	9				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	37				
Average Number of FDA Days to Substantive Interaction	88.86				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 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	45				
Non-MDUFA Decision	0				
MDUFA Decision	10				
MDUFA Decision Goal Met	10				
PMAs Pending MDUFA Decision	35				
PMAs Pending MDUFA Decision Past Goal	1				
Current Performance Percent Goal Met	90.91%				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA Decision	10				
Average FDA Days to MDUFA Decision	177.00				
20th Percentile FDA Days to MDUFA Decision	177				
40th Percentile FDA Days to MDUFA Decision	179				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	21.10				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	8				
60th Percentile Industry Days to MDUFA Decision	22				
80th Percentile Industry Days to MDUFA Decision	42				
Maximum Industry Days to MDUFA Decision	59				
Average Total Days to MDUFA Decision	198.10				
20th Percentile Total Days to MDUFA Decision	180				
40th Percentile Total Days to MDUFA Decision	187				
60th Percentile Total Days to MDUFA Decision	199				
80th Percentile Total Days to MDUFA Decision	221				
Maximum Total Days to MDUFA Decision	239				

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	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	45				
Number with MDUFA Decision	10				
Number of Withdrawal	0				
Number of Not Approvable	1				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	10.00%				

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	1				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	1				
Mean FDA Days for Submissions that Missed the Goal	190.00				
Mean Industry Days for Submissions that Missed the Goal	57.00				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	5				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	4				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

***Includes submission that went to panel**

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

Performance Metric	FY 2023 90% Within 320 FDA Days	FY 2024 90% Within 320 FDA Days	FY 2025 90% Within 320 FDA Days	FY 2026 90% Within 320 FDA Days	FY 2027 90% Within 320 FDA Days
Number of PMAs Filed	8				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	7				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

***Includes submission that went to panel**

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	6				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	1				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	5				
Rate of Submissions Not Accepted for Filing Review on First Cycle	83.33%				

***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	6				
Number Accepted	1				
Completed RTF	5				
Number Not Filed	0				
Rate of Submissions Not Filed	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	5				
SI Goal Met	4				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interactions	4				
Average Number of FDA Days to Substantive Interaction	90.00				
20th Percentile FDA Days to Substantive Interaction	90				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 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	5				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	4				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023 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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	1				
Average FDA Days to MDUFA Decision	180.00				
20th Percentile FDA Days to MDUFA Decision	180				
40th Percentile FDA Days to MDUFA Decision	180				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	52.00				
20th Percentile Industry Days to MDUFA Decision	52				
40th Percentile Industry Days to MDUFA Decision	52				
60th Percentile Industry Days to MDUFA Decision	52				
80th Percentile Industry Days to MDUFA Decision	52				
Maximum Industry Days to MDUFA Decision	52				
Average Total Days to MDUFA Decision	232.00				
20th Percentile Total Days to MDUFA Decision	232				
40th Percentile Total Days to MDUFA Decision	232				
60th Percentile Total Days to MDUFA Decision	232				
80th Percentile Total Days to MDUFA Decision	232				
Maximum Total Days to MDUFA Decision	232				

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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	5				
Number with MDUFA Decision	1				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	0.00%				

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

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

Table 1.11 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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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	13				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	12				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	1				
Rate of Submissions Not Accepted for Filing Review on First Cycle	7.69%				

***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	13				
Number Accepted	12				
Completed RTF	13				
Number Not Filed	0				
Rate of Submissions Not Filed	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	13				
SI Goal Met	12				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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	12				
Average Number of FDA Days to Substantive Interaction	88.75				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 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	12				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Goal Met	4				
PMAs Pending MDUFA Decision	8				
PMAs Pending MDUFA Decision Past Goal	1				
Current Performance Percent Goal Met	80.00%				

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

Performance Metric	FY 2023 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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	1				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	4				
Average FDA Days to MDUFA Decision	175.25				
20th Percentile FDA Days to MDUFA Decision	172				
40th Percentile FDA Days to MDUFA Decision	178				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	18.25				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	3				
60th Percentile Industry Days to MDUFA Decision	11				
80th Percentile Industry Days to MDUFA Decision	32				
Maximum Industry Days to MDUFA Decision	59				
Average Total Days to MDUFA Decision	193.50				
20th Percentile Total Days to MDUFA Decision	173				
40th Percentile Total Days to MDUFA Decision	182				
60th Percentile Total Days to MDUFA Decision	190				
80th Percentile Total Days to MDUFA Decision	211				
Maximum Total Days to MDUFA Decision	239				

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	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	12				
Number with MDUFA Decision	4				
Number of Withdrawal	0				
Number of Not Approvable	1				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	25.00%				

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	1				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.11 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	1				
Mean FDA Days for Submissions that Missed the Goal	190.00				
Mean Industry Days for Submissions that Missed the Goal	57.00				

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

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

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

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	2				
Average Number of FDA Days to Substantive Interaction	87.50				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	87				
60th Percentile FDA Days to Substantive Interaction	88				
80th Percentile FDA Days to Substantive Interaction	88				
Maximum FDA Days to Substantive Interaction	88				

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	2				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	1				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	1				
Average FDA Days to MDUFA Decision	172.00				
20th Percentile FDA Days to MDUFA Decision	172				
40th Percentile FDA Days to MDUFA Decision	172				
60th Percentile FDA Days to MDUFA Decision	172				
80th Percentile FDA Days to MDUFA Decision	172				
Maximum FDA Days to MDUFA Decision	172				
Average Industry Days to MDUFA Decision	28.00				
20th Percentile Industry Days to MDUFA Decision	28				
40th Percentile Industry Days to MDUFA Decision	28				
60th Percentile Industry Days to MDUFA Decision	28				
80th Percentile Industry Days to MDUFA Decision	28				
Maximum Industry Days to MDUFA Decision	28				
Average Total Days to MDUFA Decision	200.00				
20th Percentile Total Days to MDUFA Decision	200				
40th Percentile Total Days to MDUFA Decision	200				
60th Percentile Total Days to MDUFA Decision	200				
80th Percentile Total Days to MDUFA Decision	200				
Maximum Total Days to MDUFA Decision	200				

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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	2				
Number with MDUFA Decision	1				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	0.00%				

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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.11 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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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	8				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	8				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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	8				
Number Accepted	8				
Completed RTF	8				
Number Not Filed	0				
Rate of Submissions Not Filed	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	8				
SI Goal Met	5				
SI Goal Not Met	0				
SI Pending Within Goal	3				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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	5				
Average Number of FDA Days to Substantive Interaction	90.00				
20th Percentile FDA Days to Substantive Interaction	90				
40th Percentile FDA Days to Substantive Interaction	90				
60th Percentile FDA Days to Substantive Interaction	90				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

Table 1.5 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	8				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Goal Met	2				
PMAs Pending MDUFA Decision	6				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023 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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	2				
Average FDA Days to MDUFA Decision	179.00				
20th Percentile FDA Days to MDUFA Decision	178				
40th Percentile FDA Days to MDUFA Decision	179				
60th Percentile FDA Days to MDUFA Decision	179				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	20.00				
20th Percentile Industry Days to MDUFA Decision	8				
40th Percentile Industry Days to MDUFA Decision	16				
60th Percentile Industry Days to MDUFA Decision	24				
80th Percentile Industry Days to MDUFA Decision	32				
Maximum Industry Days to MDUFA Decision	40				
Average Total Days to MDUFA Decision	199.00				
20th Percentile Total Days to MDUFA Decision	188				
40th Percentile Total Days to MDUFA Decision	195				
60th Percentile Total Days to MDUFA Decision	203				
80th Percentile Total Days to MDUFA Decision	210				
Maximum Total Days to MDUFA Decision	218				

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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	8				
Number with MDUFA Decision	2				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	0.00%				

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

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

Table 1.11 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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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	3				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	2				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	1				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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	3				
Number Accepted	2				
Completed RTF	2				
Number Not Filed	0				
Rate of Submissions Not Filed	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	2				
SI Goal Met	1				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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

Table 1.5 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	2				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	2				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	0				
Average FDA Days to MDUFA Decision	0.00				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	0.00				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	0.00				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	2				
Number with MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.10 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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.11 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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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	3				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	2				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	1				
Rate of Submissions Not Accepted for Filing Review on First Cycle	33.33%				

***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	3				
Number Accepted	2				
Completed RTF	3				
Number Not Filed	0				
Rate of Submissions Not Filed	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	3				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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	2				
Average Number of FDA Days to Substantive Interaction	87.50				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	87				
60th Percentile FDA Days to Substantive Interaction	88				
80th Percentile FDA Days to Substantive Interaction	88				
Maximum FDA Days to Substantive Interaction	88				

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

Performance Metric	FY 2023 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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	3				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	0				
Average FDA Days to MDUFA Decision	0.00				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	0.00				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	0.00				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	3				
Number with MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.10 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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.11 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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	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	15				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	15				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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	15				
Number Accepted	15				
Completed RTF	14				
Number Not Filed	1				
Rate of Submissions Not Filed	7.14%				

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	13				
SI Goal Met	11				
SI Goal Not Met	0				
SI Pending Within Goal	2				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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	11				
Average Number of FDA Days to Substantive Interaction	88.45				
20th Percentile FDA Days to Substantive Interaction	87				
40th Percentile FDA Days to Substantive Interaction	89				
60th Percentile FDA Days to Substantive Interaction	89				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	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	13				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Goal Met	2				
PMAs Pending MDUFA Decision	11				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023 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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	2				
Average FDA Days to MDUFA Decision	179.50				
20th Percentile FDA Days to MDUFA Decision	179				
40th Percentile FDA Days to MDUFA Decision	179				
60th Percentile FDA Days to MDUFA Decision	180				
80th Percentile FDA Days to MDUFA Decision	180				
Maximum FDA Days to MDUFA Decision	180				
Average Industry Days to MDUFA Decision	9.00				
20th Percentile Industry Days to MDUFA Decision	4				
40th Percentile Industry Days to MDUFA Decision	7				
60th Percentile Industry Days to MDUFA Decision	11				
80th Percentile Industry Days to MDUFA Decision	14				
Maximum Industry Days to MDUFA Decision	18				
Average Total Days to MDUFA Decision	188.50				
20th Percentile Total Days to MDUFA Decision	183				
40th Percentile Total Days to MDUFA Decision	187				
60th Percentile Total Days to MDUFA Decision	190				
80th Percentile Total Days to MDUFA Decision	194				
Maximum Total Days to MDUFA Decision	198				

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	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	13				
Number with MDUFA Decision	2				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	0.00%				

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

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

Table 1.11 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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	5				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	4				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	8				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
PMAs Pending MDUFA Decision	7				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

***Includes submission that went to panel**

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0				
Number Closed Before First RTA Action	0				
Number Accepted First RTA Review	0				
Number Without a First Cycle RTA Review and > 15 Days Since Date Received*	0				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	0				
Number Not Accepted for Filing Review on First Cycle	0				
Rate of Submissions Not Accepted for Filing Review on First Cycle	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				
Number Accepted	0				
Completed RTF	0				
Number Not Filed	0				
Rate of Submissions Not Filed	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				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

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

Table 1.5 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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
PMAs Pending MDUFA Decision	0				
PMAs Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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				
Average FDA Days to MDUFA Decision	0.00				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	0.00				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	0.00				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Number with MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.10 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				
Number With MDUFA Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

Table 1.11 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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Goal Met	N/A				
PMAs Pending MDUFA Decision	N/A				
PMAs Pending MDUFA Decision Past Goal	N/A				
Current Performance Percent Goal Met	N/A				

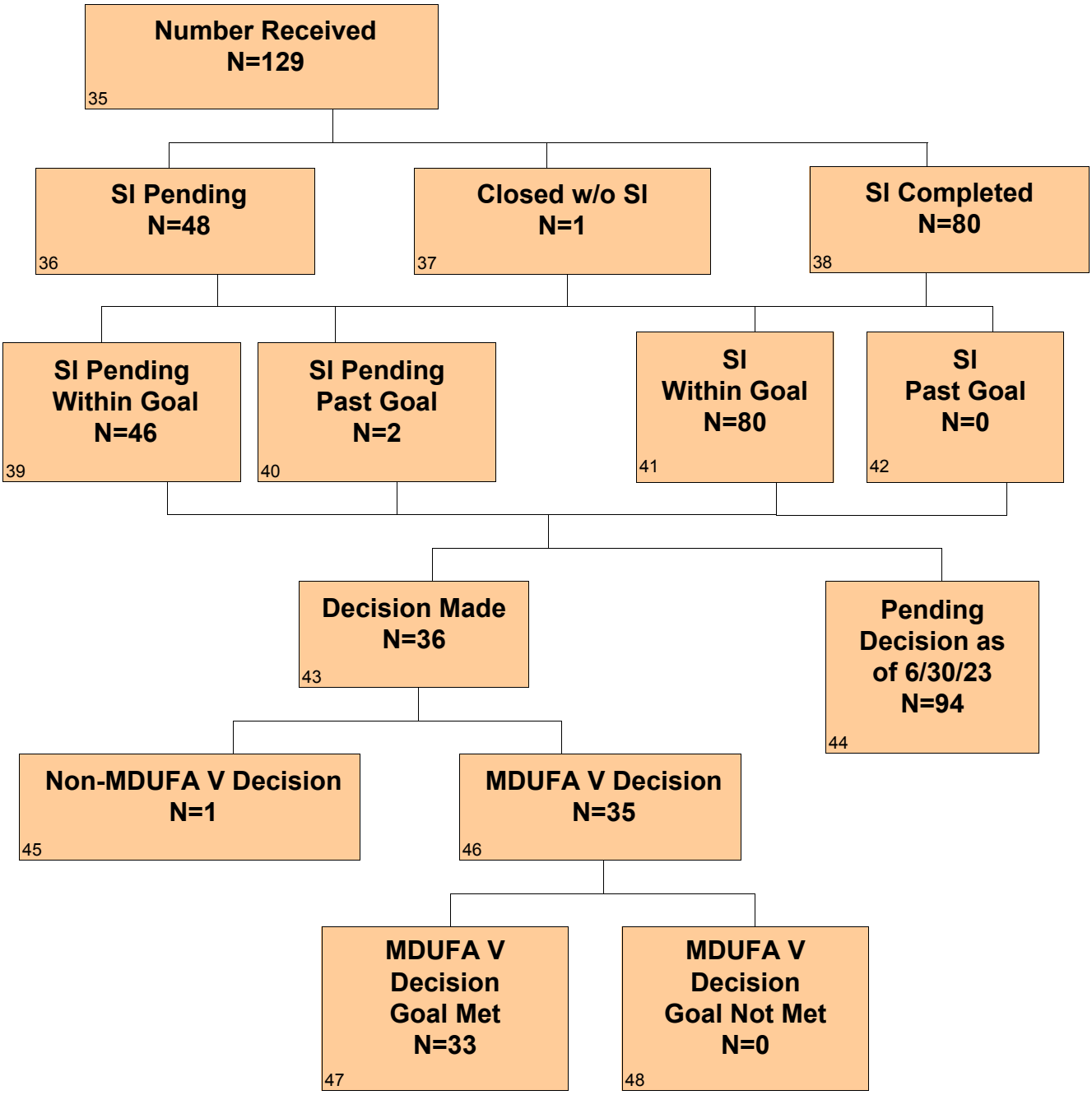
***Includes submission that went to panel**

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

***Includes submission that went to panel**

CDRH PMA 180 Day Supplements - FY 2023 as of 6/30/23



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	129				
SI Goal Met	80				
SI Goal Not Met	0				
SI Pending Within Goal	46				
SI Pending Past Goal	2				
Closed Without SI	1				
Current SI Performance Percent Goal Met	97.56%				

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	129				
Non-MDUFA Decision	1				
MDUFA Decision	35				
MDUFA Decision Goal Met	35				
Supplements Pending MDUFA Decision	93				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	129				
Number with MDUFA Decision	33				
Number of Not Approvable	0				
Rate of Not Approvable	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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	11				
SI Goal Met	6				
SI Goal Not Met	0				
SI Pending Within Goal	5				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	11				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Goal Met	2				
Supplements Pending MDUFA Decision	9				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	11				
Number with MDUFA Decision	2				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	47				
SI Goal Met	32				
SI Goal Not Met	0				
SI Pending Within Goal	14				
SI Pending Past Goal	1				
Closed Without SI	0				
Current SI Performance Percent Goal Met	96.97%				

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	47				
Non-MDUFA Decision	0				
MDUFA Decision	21				
MDUFA Decision Goal Met	21				
Supplements Pending MDUFA Decision	26				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	47				
Number with MDUFA Decision	19				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	15				
SI Goal Met	10				
SI Goal Not Met	0				
SI Pending Within Goal	4				
SI Pending Past Goal	1				
Closed Without SI	0				
Current SI Performance Percent Goal Met	90.91%				

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	15				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Goal Met	4				
Supplements Pending MDUFA Decision	11				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	15				
Number with MDUFA Decision	4				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	6				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	4				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023 95% Within 180 FDA Days	FY 2024 95% Within 180 FDA Days	FY 2025 95% Within 180 FDA Days	FY 2026 95% Within 180 FDA Days	FY 2027 95% Within 180 FDA Days
Supplements Received	6				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	6				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	6				
Number with MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	15				
SI Goal Met	9				
SI Goal Not Met	0				
SI Pending Within Goal	6				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	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	15				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
Supplements Pending MDUFA Decision	14				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	15				
Number with MDUFA Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	8				
SI Goal Met	4				
SI Goal Not Met	0				
SI Pending Within Goal	4				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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	8				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
Supplements Pending MDUFA Decision	7				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	8				
Number with MDUFA Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	27				
SI Goal Met	17				
SI Goal Not Met	0				
SI Pending Within Goal	9				
SI Pending Past Goal	0				
Closed Without SI	1				
Current SI Performance Percent Goal Met	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	27				
Non-MDUFA Decision	1				
MDUFA Decision	6				
MDUFA Decision Goal Met	6				
Supplements Pending MDUFA Decision	20				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	27				
Number with MDUFA Decision	6				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	0				
SI Goal Met	0				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	N/A				

Table 2.2 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	0				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Goal Met	0				
Supplements Pending MDUFA Decision	0				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	N/A				

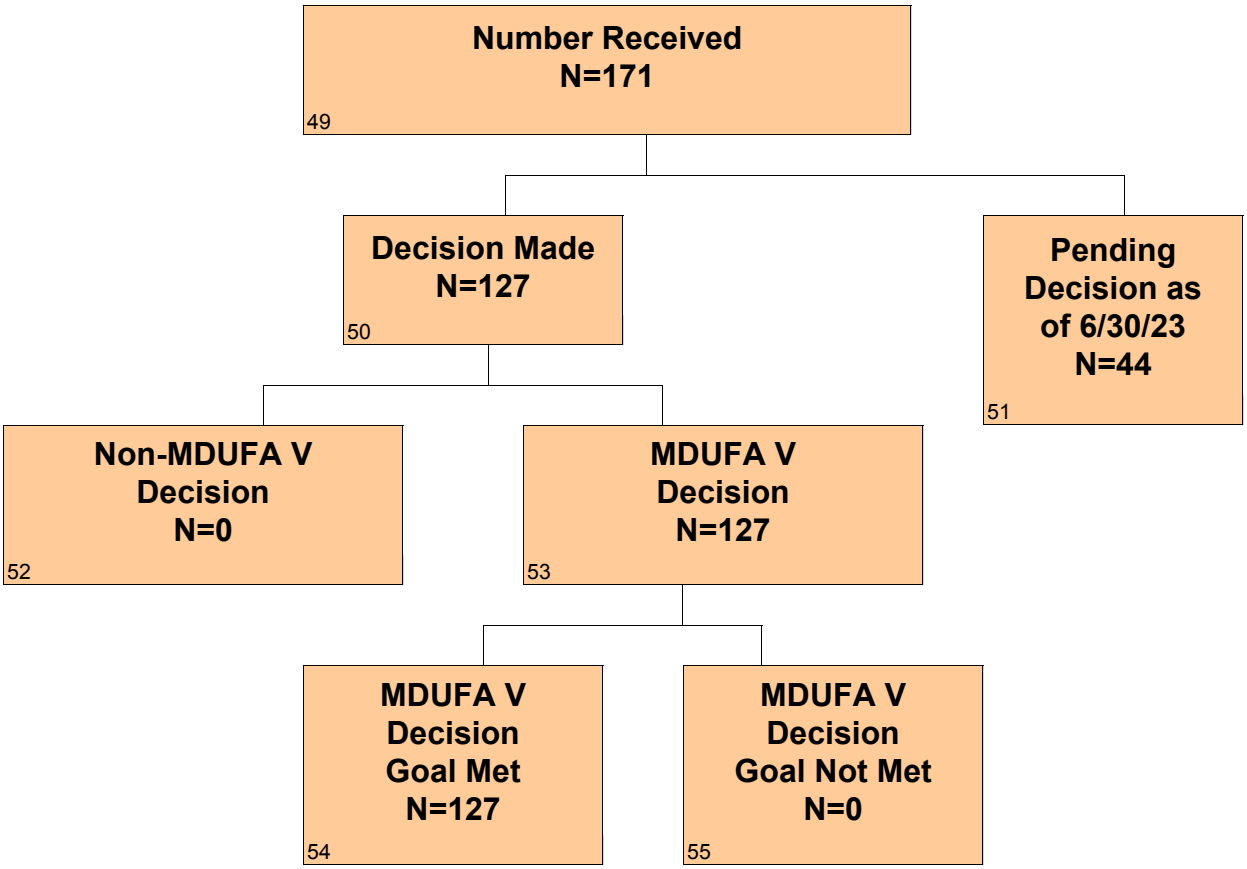
Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	0				
Number with MDUFA Decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	N/A				

CDRH PMA Real Time Supplements - FY 2023 as of 6/30/23



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	171				
Non-MDUFA Decision	0				
MDUFA Decision	127				
MDUFA Decision Goal Met	127				
Supplements Pending MDUFA Decision	44				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	171				
Number With MDUFA Decision	127				
Number of Not Approvable	3				
Rate of Not Approvable	2.36%				

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

Section 3 PMA Real-Time Supplements - Office Level Metric

Table 3.1 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	17				
Non-MDUFA Decision	0				
MDUFA Decision	11				
MDUFA Decision Goal Met	11				
Supplements Pending MDUFA Decision	6				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	17				
Number With MDUFA Decision	11				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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	110				
Non-MDUFA Decision	0				
MDUFA Decision	86				
MDUFA Decision Goal Met	86				
Supplements Pending MDUFA Decision	24				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	110				
Number With MDUFA Decision	86				
Number of Not Approvable	1				
Rate of Not Approvable	1.16%				

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

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	12				
Non-MDUFA Decision	0				
MDUFA Decision	8				
MDUFA Decision Goal Met	8				
Supplements Pending MDUFA Decision	4				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	12				
Number With MDUFA Decision	8				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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	5				
Non-MDUFA Decision	0				
MDUFA Decision	4				
MDUFA Decision Goal Met	4				
Supplements Pending MDUFA Decision	1				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	5				
Number With MDUFA Decision	4				
Number of Not Approvable	2				
Rate of Not Approvable	50.00%				

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

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	6				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Goal Met	2				
Supplements Pending MDUFA Decision	4				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	6				
Number With MDUFA Decision	2				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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

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	2				
Number With MDUFA Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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	18				
Non-MDUFA Decision	0				
MDUFA Decision	14				
MDUFA Decision Goal Met	14				
Supplements Pending MDUFA Decision	4				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	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	18				
Number With MDUFA Decision	14				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

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

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	1				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Goal Met	1				
Supplements Pending MDUFA Decision	0				
Supplements Pending MDUFA Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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	1				
Number With MDUFA Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2022 and March 31, 2023.

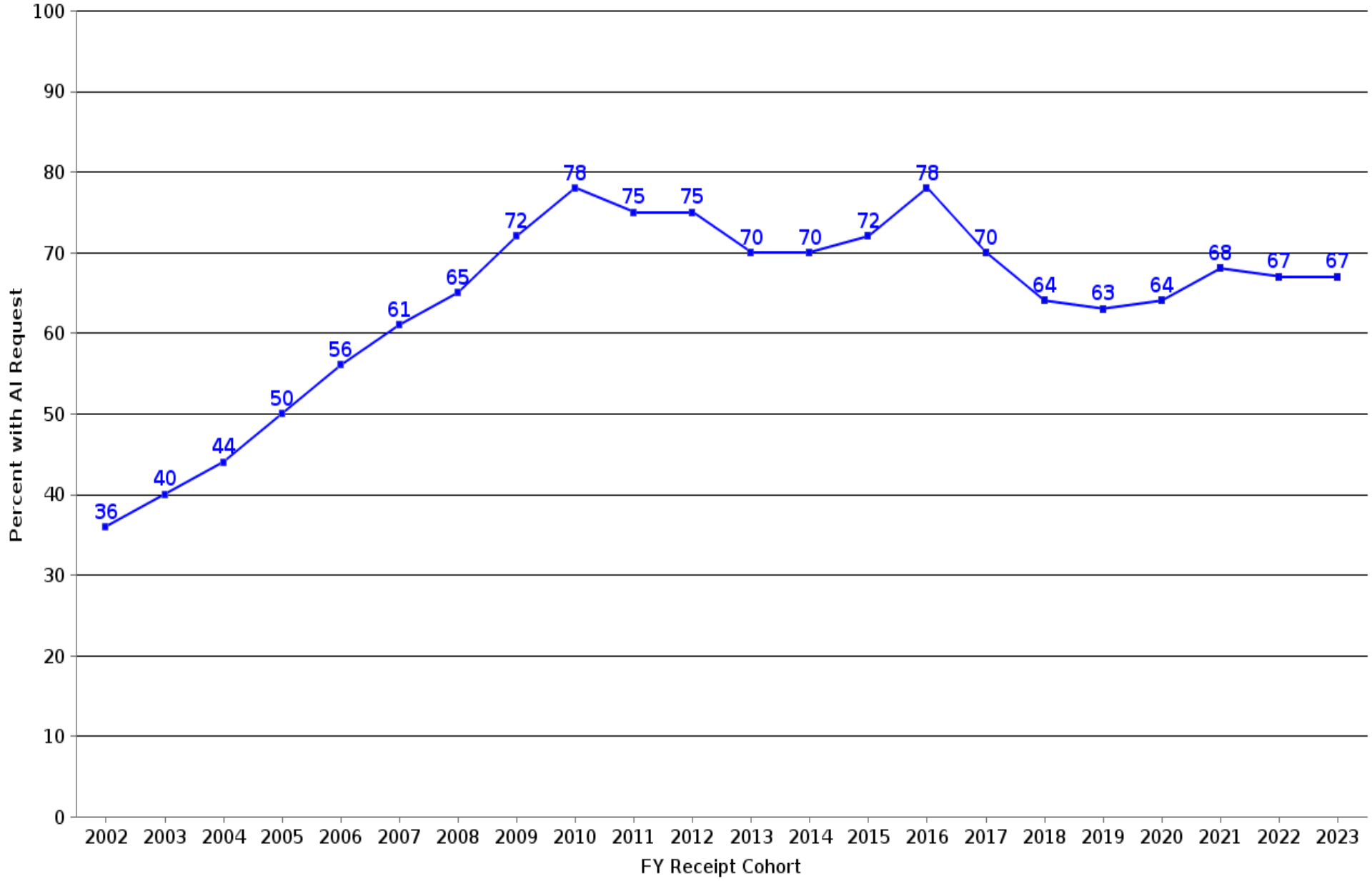
Section 5 PMA Annual Metrics and Goals

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

510(k)s

Q3 FY 2023

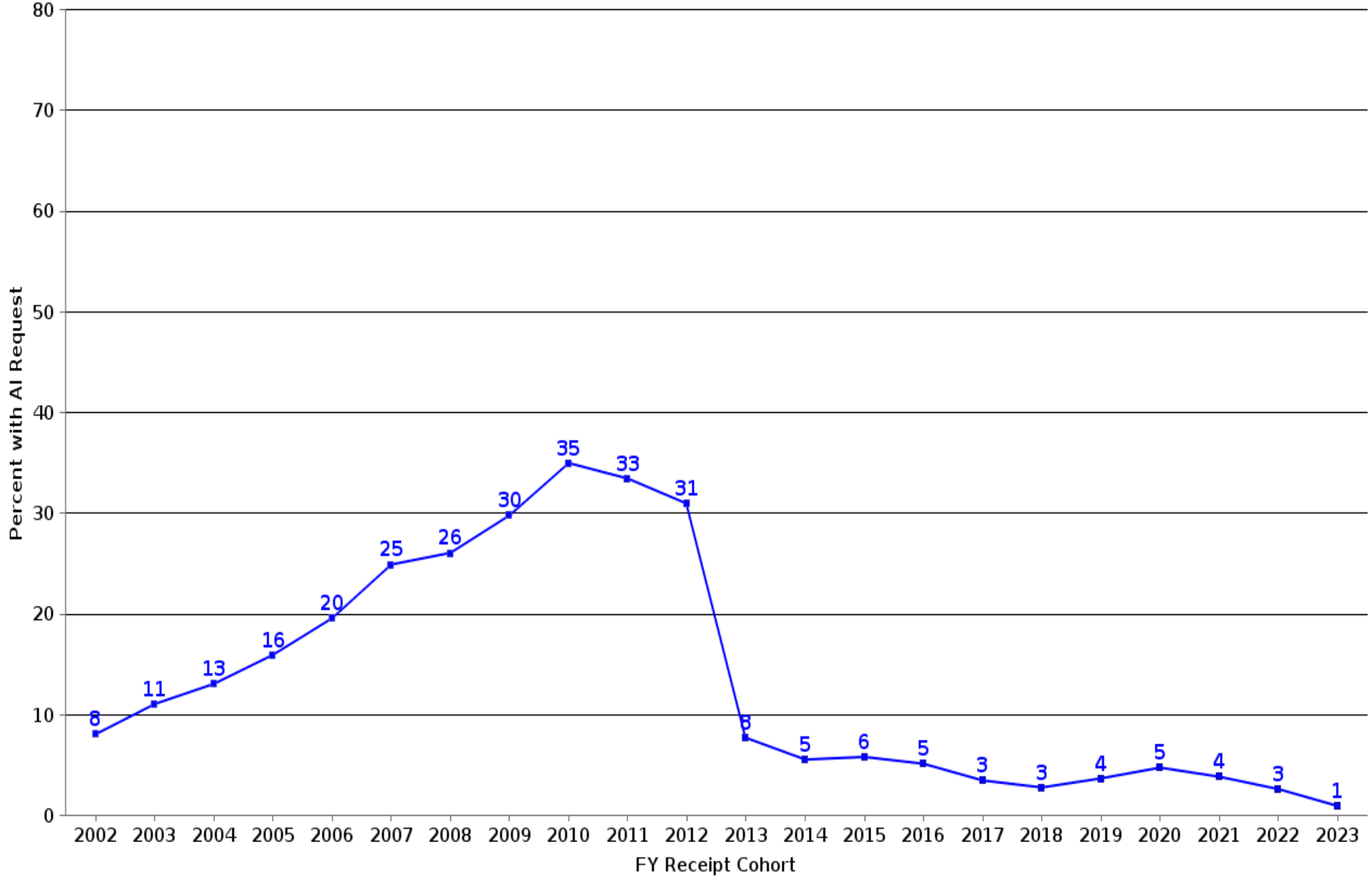
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 4/30/23

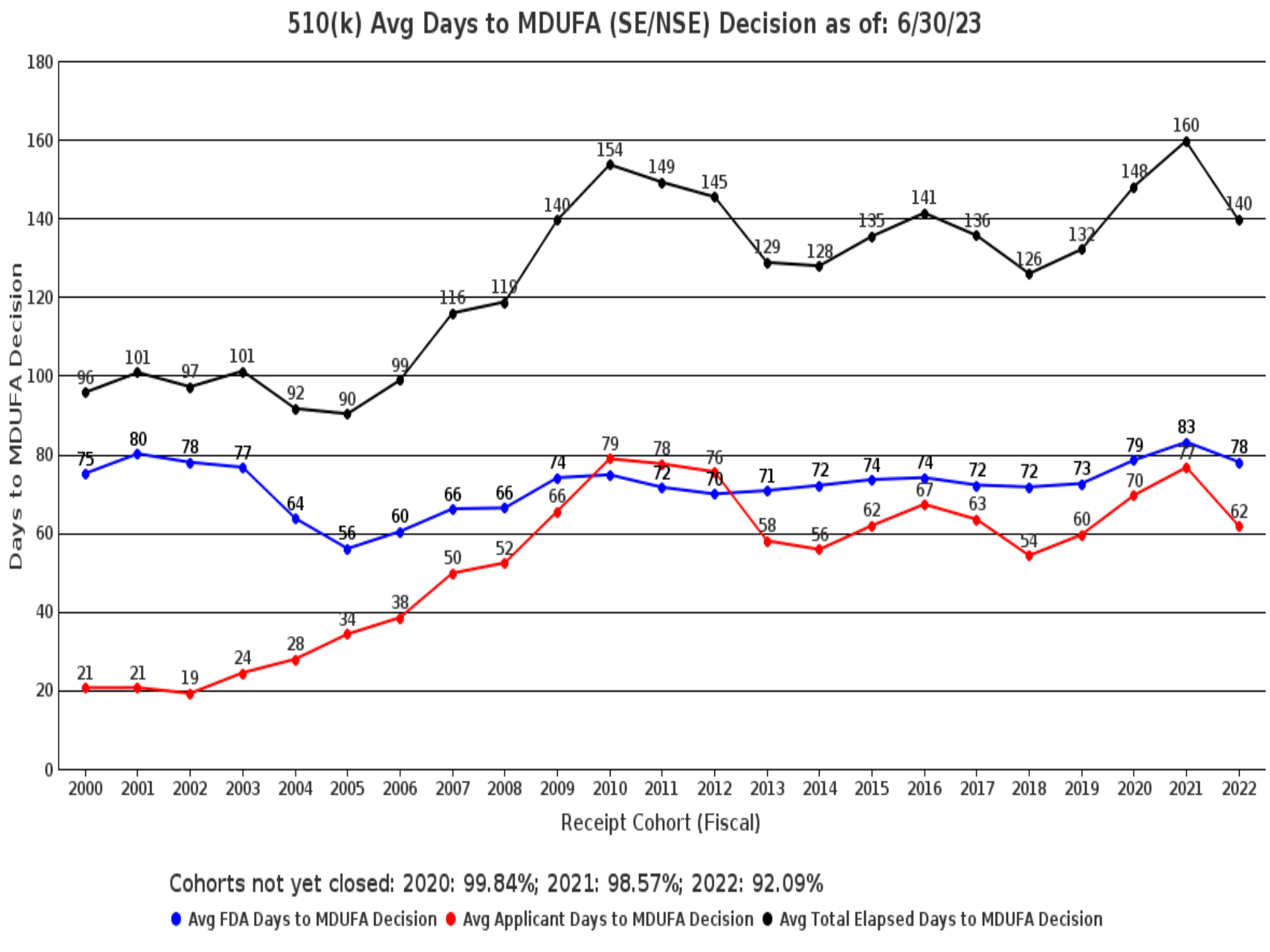
■ % with 1st Cycle AI Request

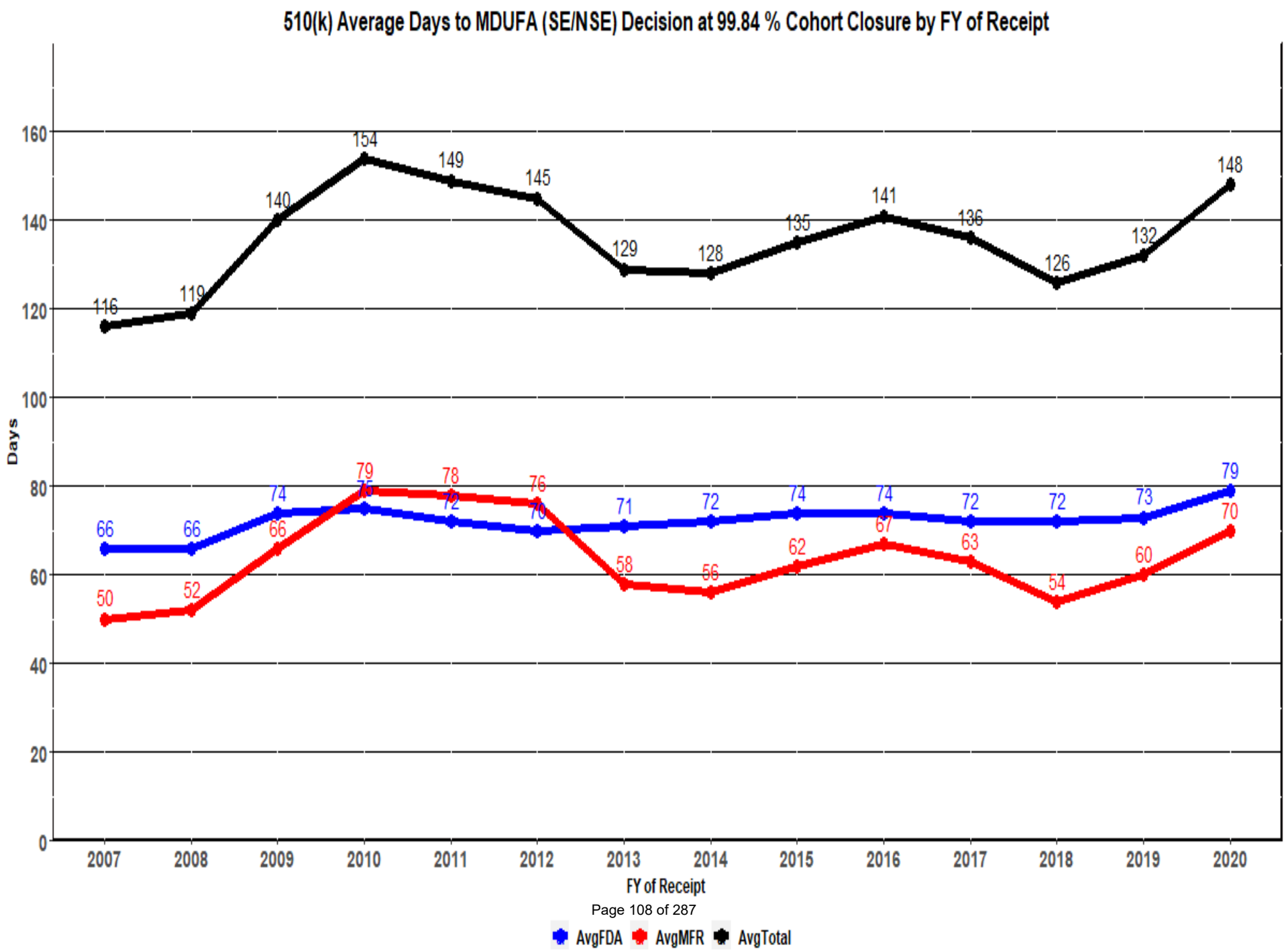
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 11/30/22

■ % with 2nd Cycle AI Request


510(k) Avg Days to MDUFA (SE/NSE) Decision as of: 6/30/23
Days to MDUFA Decision
Receipt Cohort (Fiscal)
Cohorts not yet closed: 2020: 99.84%; 2021: 98.57%; 2022: 92.09%
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 99.84 % 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
FY of Receipt
116
119
140
154
149
145
129
128
135
141
136
126
132
148
66
66
74
75
72
70
71
72
74
74
72
72
73
79
50
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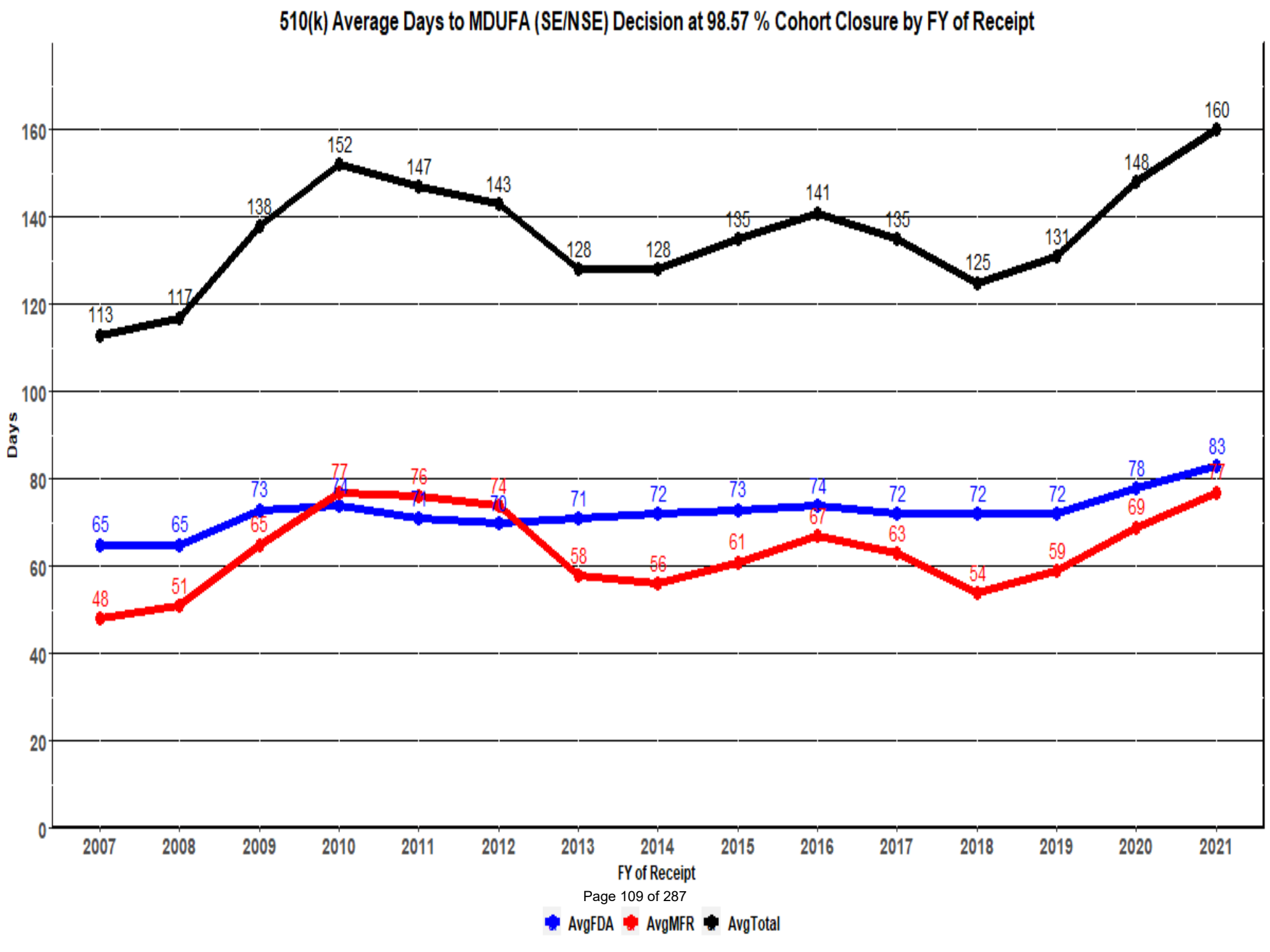
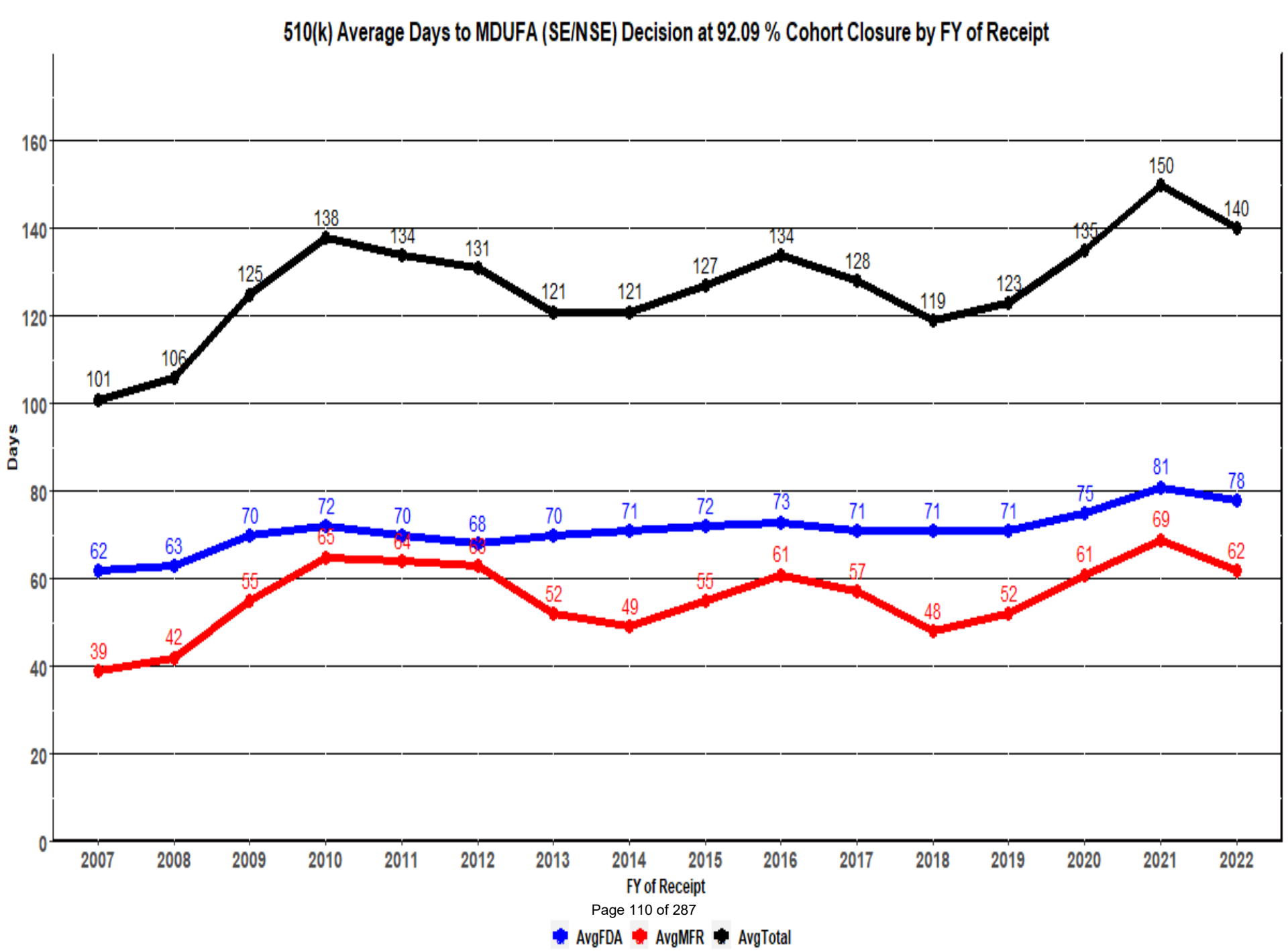
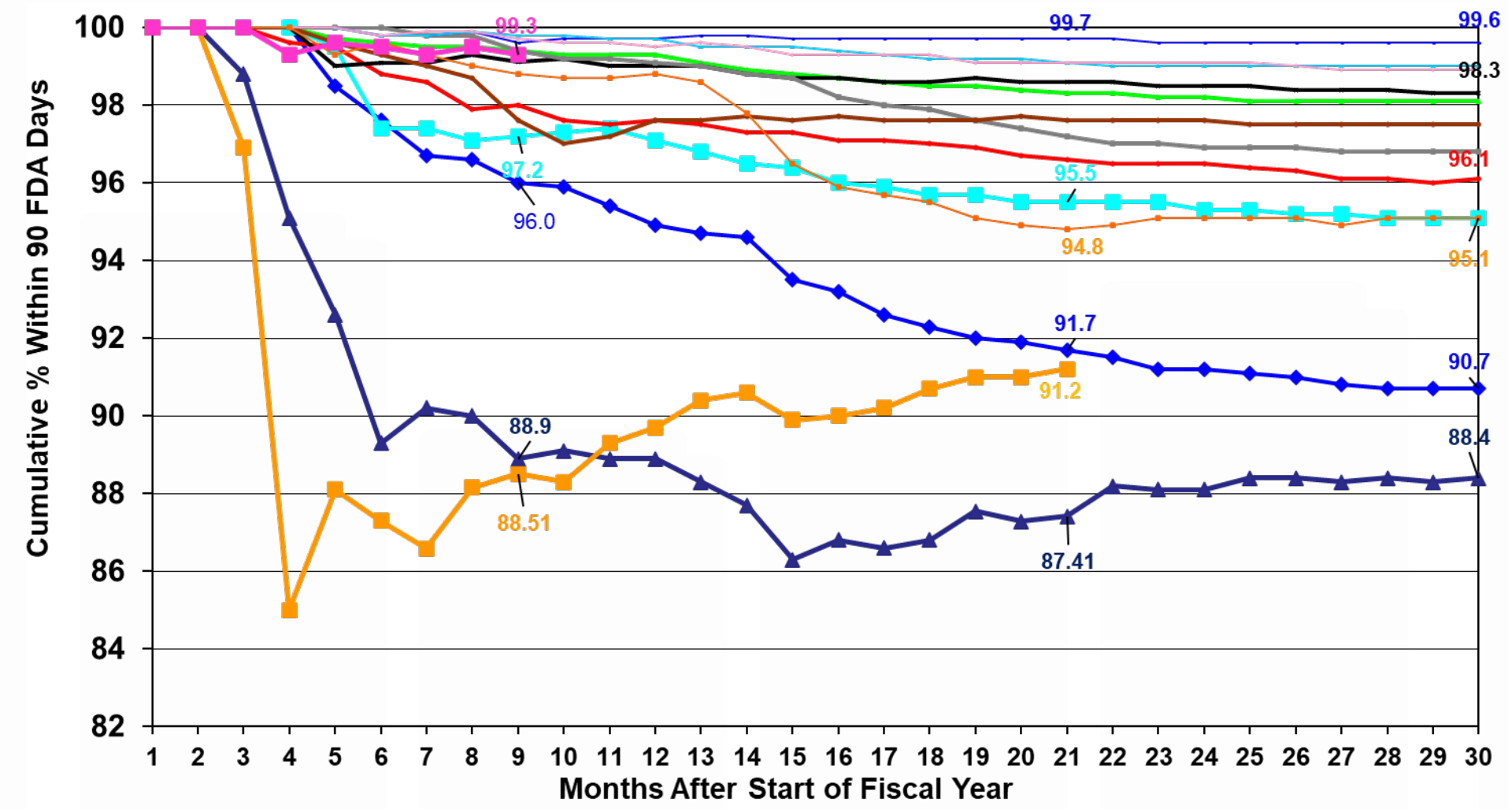
78
76
58
56
62
67
63
54
60
70
AvgFDA
AvgMFR
AvgTotal


510(k) Average Days to MDUFA (SE/NSE) Decision at 98.57 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
AvgFDA
AvgMFR
AvgTotal

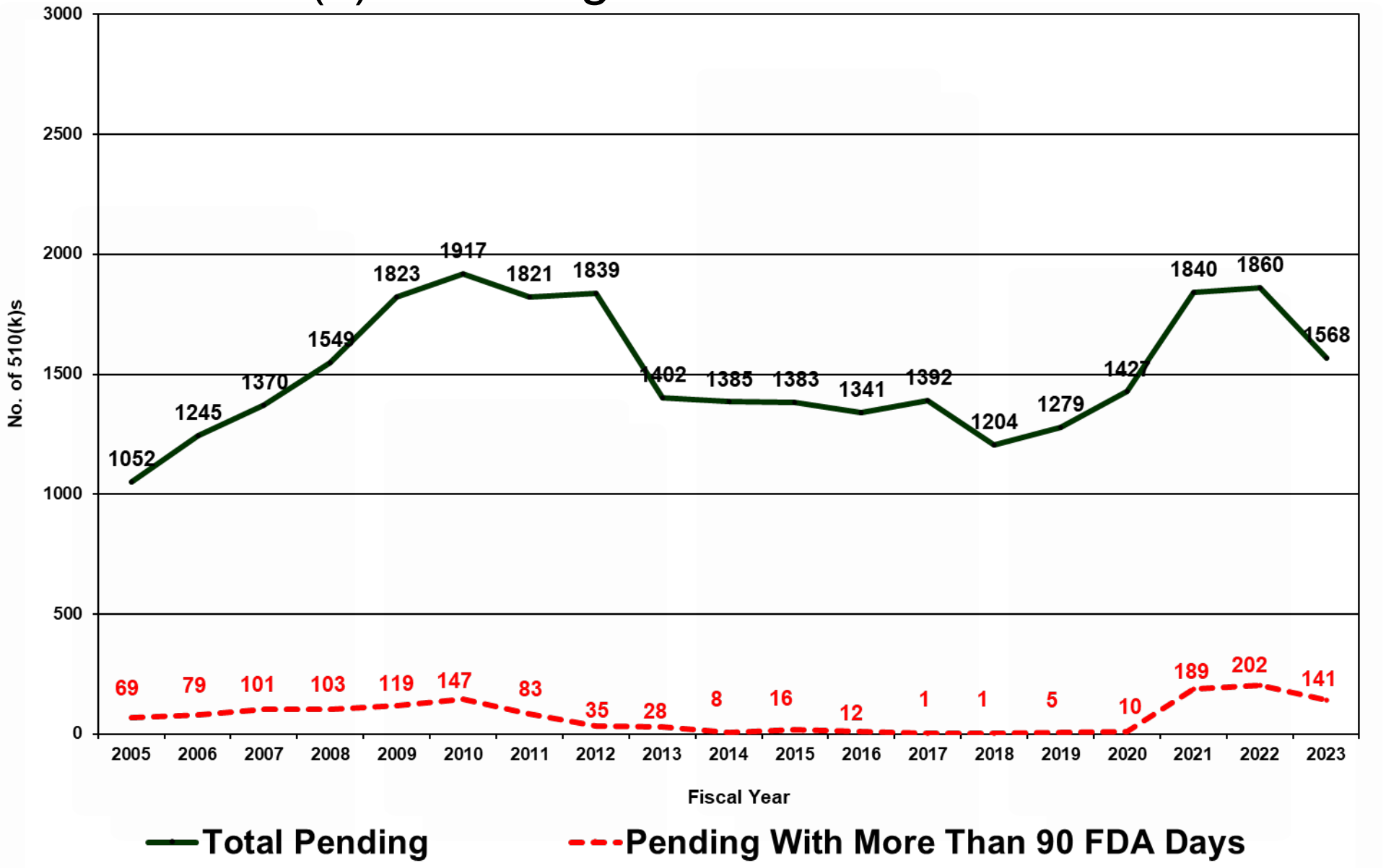

510(k) Average Days to MDUFA (SE/NSE) Decision at 92.09 % Cohort Closure by FY of Receipt
Days
FY of Receipt
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
AvgFDA
AvgMFR
AvgTotal

Trend in 510(k) MDUFA Decision Goal Performance

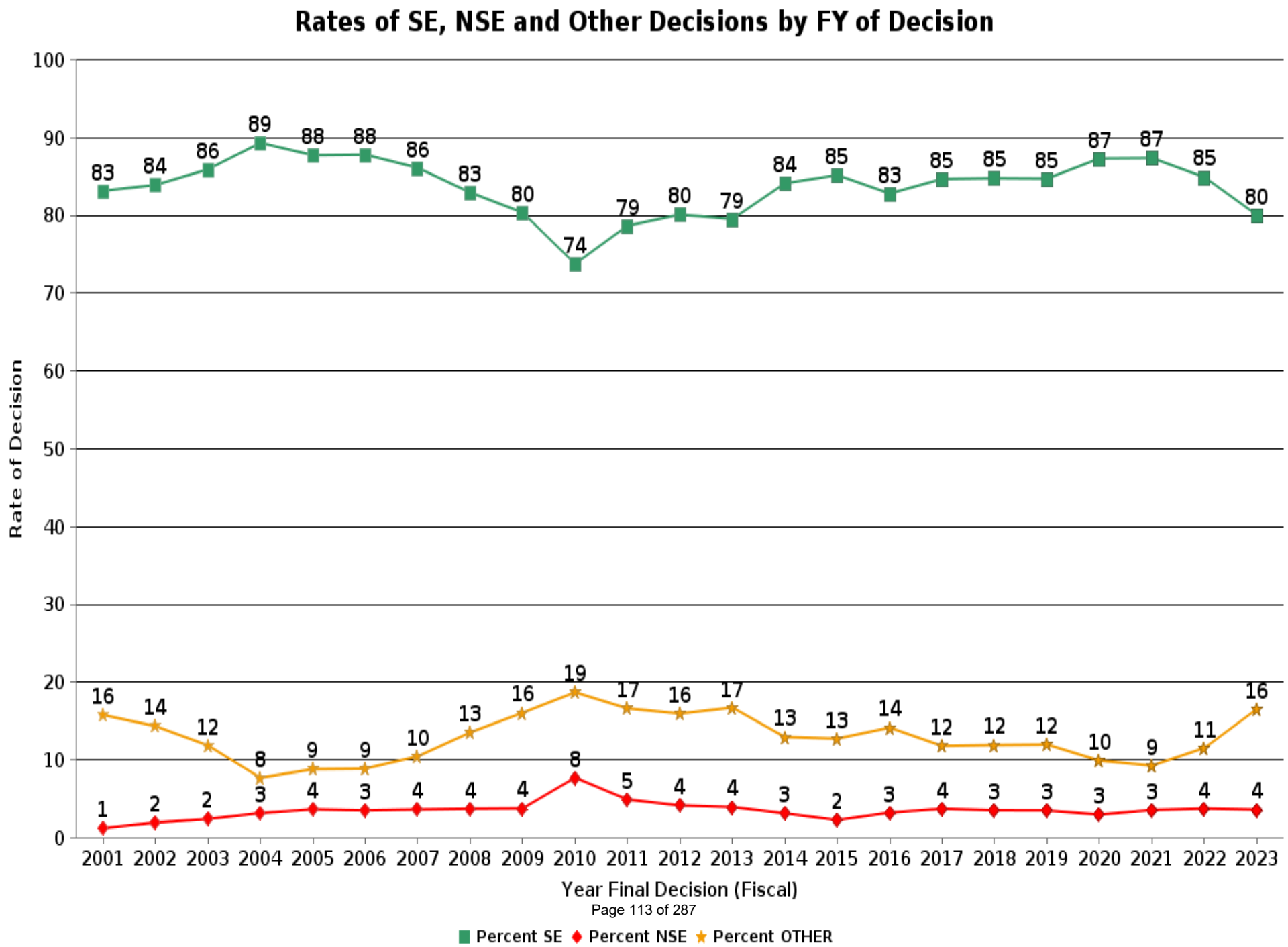
Comparison of FY10 – FY23 Receipt Cohorts



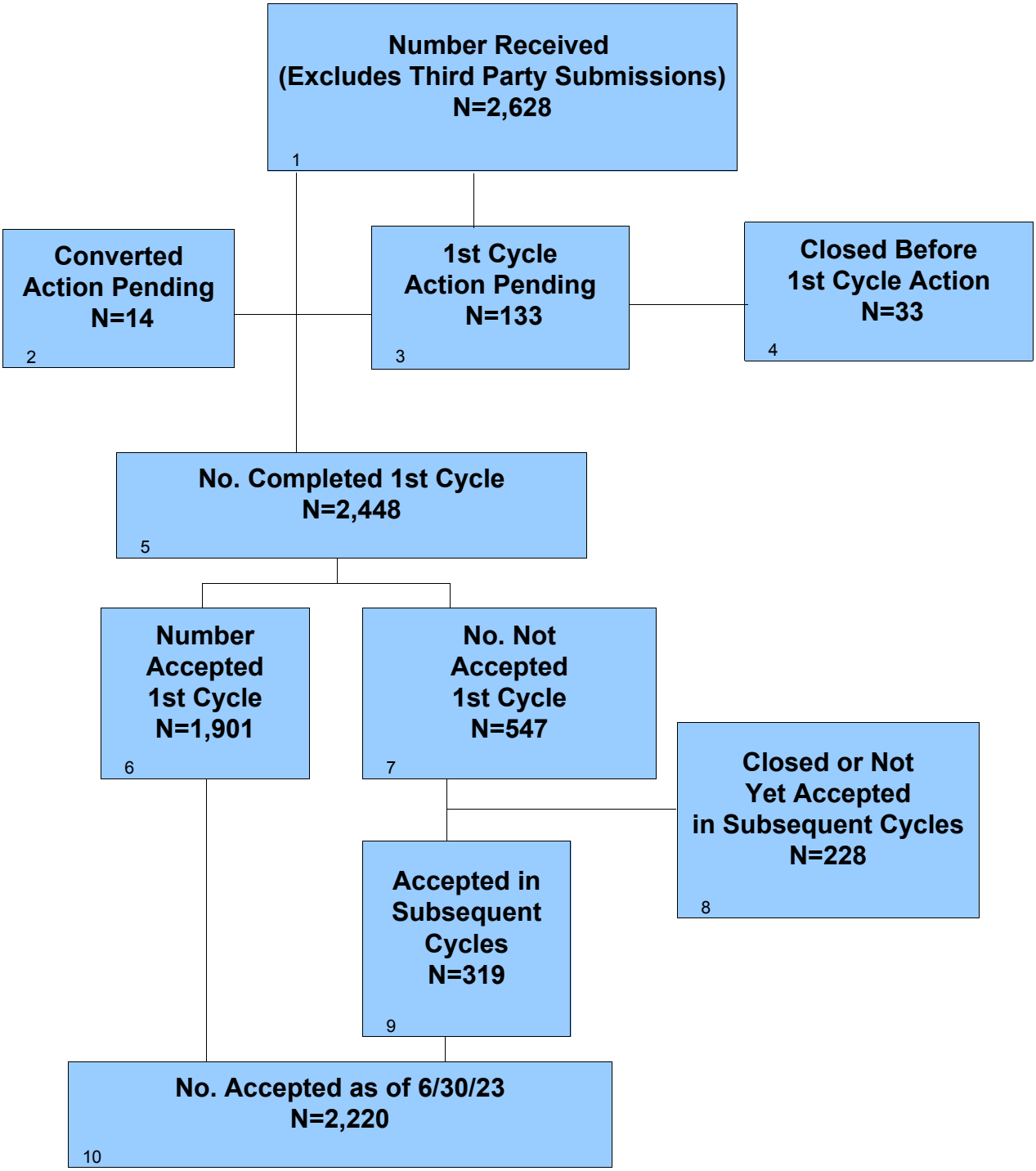
510(k)s Pending at End of Quarter/Year



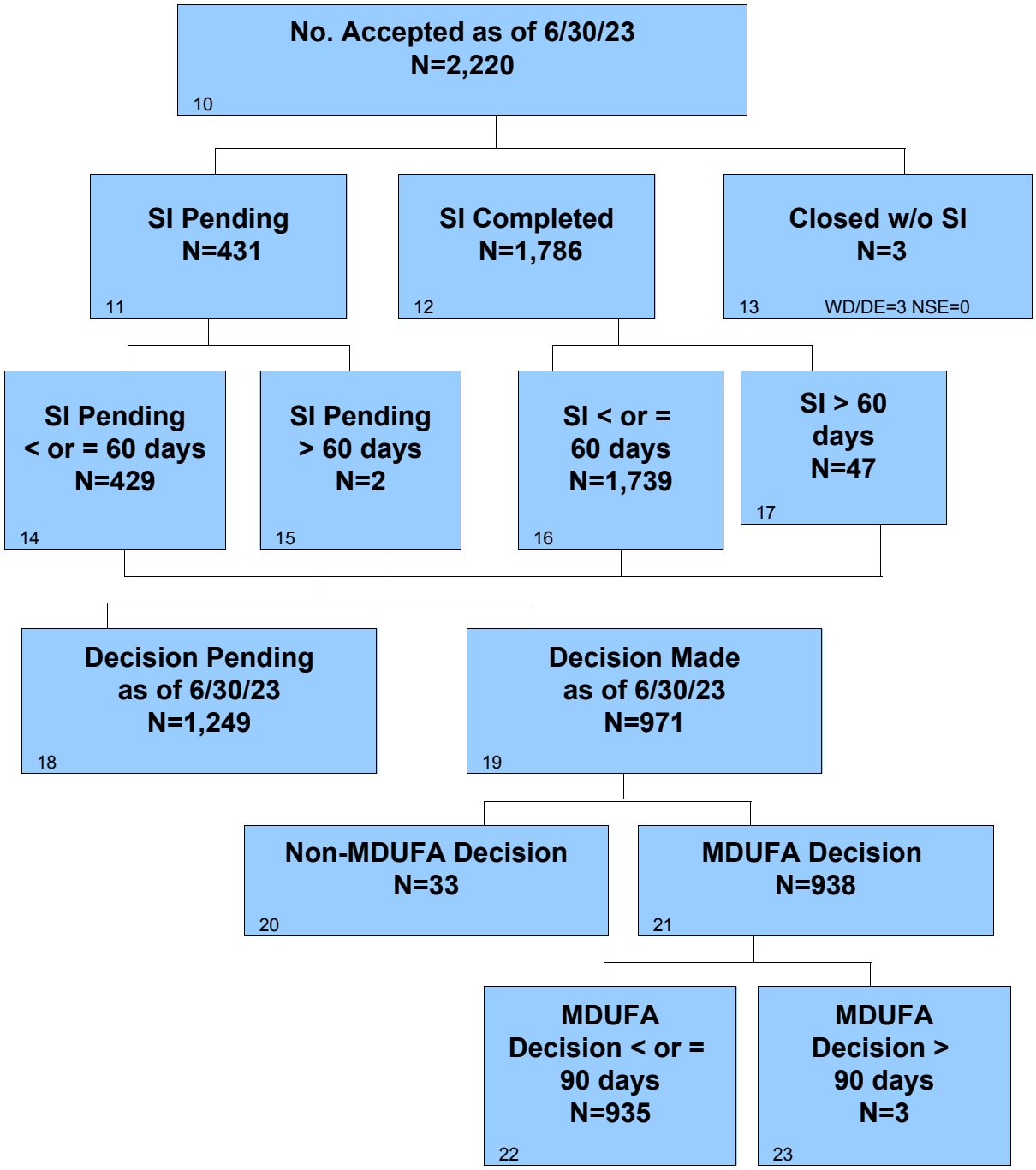
"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


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 80
16 14 12 8 9 9 10 13 16 19 17 16 17 13 13 14 12 12 12 10 9 11 16
1 2 2 3 4 3 4 4 4 8 5 4 4 3 2 3 4 3 3 3 3 4 4
2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023
Year Final Decision (Fiscal)
Percent SE
Percent NSE
Percent OTHER

CDRH 510(k)s - FY 2023
as of 6/30/23



CDRH 510(k)s - FY 2023
as of 6/30/23 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	2,628				
Closed Before First RTA or TS Action [1]	33				
Number Accepted or Passed TS on First Cycle [2]	1,887				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	14				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	147				
Number Not Accepted or Failed TS on First Cycle [2]	547				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	22.34%				

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	2,220				
Deleted or Withdrawn Prior to SI	3				
SI Within 60 FDA Days	1,739				
SI Over 60 FDA Days	47				
SI Pending Within 60 FDA Days	429				
SI Pending Over 60 FDA Days	2				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	97.26%				

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	1,786				
Average Number of FDA Days to Substantive Interaction	51.68				
20th Percentile FDA Days to Substantive Interaction	44				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	58				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	212				

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	2,220				
Non-MDUFA V Decision	33				
MDUFA V Decision (SE/NSE)	938				
MDUFA V Decision Within 90 FDA Days	935				
510(k)s Pending MDUFA V Decision	1,249				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	4				
Current Performance Percent Within 90 FDA Days	99.26%				

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	1.41				
Number With MDUFA V Decision	938				
Average Number of FDA Days to MDUFA V Decision	63.71				
20th Percentile FDA Days to MDUFA V Decision	30				
40th Percentile FDA Days to MDUFA V Decision	58				
60th Percentile FDA Days to MDUFA V Decision	84				
80th Percentile FDA Days to MDUFA V Decision	89				
Maximum FDA Days to MDUFA V Decision	93				
Average Number of Industry Days to MDUFA V Decision	18.94				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	3				
80th Percentile Industry Days to MDUFA V Decision	40				
Maximum Industry Days to MDUFA V Decision	179				
Average Number of Total Days to MDUFA V Decision	82.65				
20th Percentile Total Days to MDUFA V Decision	30				
40th Percentile Total Days to MDUFA V Decision	59				
60th Percentile Total Days to MDUFA V Decision	89				
80th Percentile Total Days to MDUFA V Decision	122				
Maximum Total Days to MDUFA V Decision	269				

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	2,220				
Number With MDUFA V Decision	938				
Number of SE Decision	928				
Number of NSE Decision	10				
Number of Withdrawal	27				
Number of Deleted	4				
Rate of SE Decision	98.93%				
Rate of NSE Decision	1.07%				
Rate of Withdrawal	1.22%				
Rate of Deleted	0.18%				

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	3				
Mean FDA Days for Submissions that Missed the Goal	92.00				
Mean Industry Days for Submissions that Missed the Goal	48.33				

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	1				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	1				
MDUFA V Decision Within 90 FDA Days	1				
510(k)s Pending MDUFA V Decision	0				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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	160				
Non-MDUFA V Decision	7				
MDUFA V Decision (SE/NSE)	53				
MDUFA V Decision Within 90 FDA Days	53				
510(k)s Pending MDUFA V Decision	100				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	400				
Closed Before First RTA or TS Action [1]	3				
Number Accepted or Passed TS on First Cycle [2]	191				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	4				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	28				
Number Not Accepted or Failed TS on First Cycle [2]	174				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	47.15%				

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

Table 6.2 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	291				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	189				
SI Over 60 FDA Days	34				
SI Pending Within 60 FDA Days	68				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	84.75%				

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	223				
Average Number of FDA Days to Substantive Interaction	55.59				
20th Percentile FDA Days to Substantive Interaction	52				
40th Percentile FDA Days to Substantive Interaction	58				
60th Percentile FDA Days to Substantive Interaction	60				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	212				

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	291				
Non-MDUFA V Decision	2				
MDUFA V Decision (SE/NSE)	92				
MDUFA V Decision Within 90 FDA Days	92				
510(k)s Pending MDUFA V Decision	197				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	2				
Current Performance Percent Within 90 FDA Days	97.87%				

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	1.52				
Number With MDUFA V Decision	92				
Average Number of FDA Days to MDUFA V Decision	73.11				
20th Percentile FDA Days to MDUFA V Decision	57				
40th Percentile FDA Days to MDUFA V Decision	85				
60th Percentile FDA Days to MDUFA V Decision	88				
80th Percentile FDA Days to MDUFA V Decision	89				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	21.39				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	14				
80th Percentile Industry Days to MDUFA V Decision	42				
Maximum Industry Days to MDUFA V Decision	179				
Average Number of Total Days to MDUFA V Decision	94.50				
20th Percentile Total Days to MDUFA V Decision	58				
40th Percentile Total Days to MDUFA V Decision	87				
60th Percentile Total Days to MDUFA V Decision	103				
80th Percentile Total Days to MDUFA V Decision	129				
Maximum Total Days to MDUFA V Decision	269				

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	291				
Number With MDUFA V Decision	92				
Number of SE Decision	90				
Number of NSE Decision	2				
Number of Withdrawal	1				
Number of Deleted	1				
Rate of SE Decision	97.83%				
Rate of NSE Decision	2.17%				
Rate of Withdrawal	0.34%				
Rate of Deleted	0.34%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	267				
Closed Before First RTA or TS Action [1]	6				
Number Accepted or Passed TS on First Cycle [2]	225				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	5				
Number Not Accepted or Failed TS on First Cycle [2]	30				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	11.72%				

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	246				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	196				
SI Over 60 FDA Days	4				
SI Pending Within 60 FDA Days	46				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	98.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	200				
Average Number of FDA Days to Substantive Interaction	51.56				
20th Percentile FDA Days to Substantive Interaction	43				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	86				

Table 6.4 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	246				
Non-MDUFA V Decision	2				
MDUFA V Decision (SE/NSE)	106				
MDUFA V Decision Within 90 FDA Days	103				
510(k)s Pending MDUFA V Decision	138				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	97.17%				

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	1.50				
Number With MDUFA V Decision	106				
Average Number of FDA Days to MDUFA V Decision	65.09				
20th Percentile FDA Days to MDUFA V Decision	30				
40th Percentile FDA Days to MDUFA V Decision	58				
60th Percentile FDA Days to MDUFA V Decision	85				
80th Percentile FDA Days to MDUFA V Decision	89				
Maximum FDA Days to MDUFA V Decision	93				
Average Number of Industry Days to MDUFA V Decision	26.90				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	14				
80th Percentile Industry Days to MDUFA V Decision	59				
Maximum Industry Days to MDUFA V Decision	179				
Average Number of Total Days to MDUFA V Decision	91.99				
20th Percentile Total Days to MDUFA V Decision	30				
40th Percentile Total Days to MDUFA V Decision	60				
60th Percentile Total Days to MDUFA V Decision	101				
80th Percentile Total Days to MDUFA V Decision	139				
Maximum Total Days to MDUFA V Decision	238				

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	246				
Number With MDUFA V Decision	106				
Number of SE Decision	103				
Number of NSE Decision	3				
Number of Withdrawal	2				
Number of Deleted	0				
Rate of SE Decision	97.17%				
Rate of NSE Decision	2.83%				
Rate of Withdrawal	0.81%				
Rate of Deleted	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	3				
Mean FDA Days for Submissions that Missed the Goal	92.00				
Mean Industry Days for Submissions that Missed the Goal	48.33				

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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	310				
Closed Before First RTA or TS Action [1]	3				
Number Accepted or Passed TS on First Cycle [2]	225				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	17				
Number Not Accepted or Failed TS on First Cycle [2]	64				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	22.07%				

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 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	263				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	203				
SI Over 60 FDA Days	2				
SI Pending Within 60 FDA Days	58				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	99.02%				

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	205				
Average Number of FDA Days to Substantive Interaction	53.65				
20th Percentile FDA Days to Substantive Interaction	53				
40th Percentile FDA Days to Substantive Interaction	58				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	61				

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	263				
Non-MDUFA V Decision	4				
MDUFA V Decision (SE/NSE)	81				
MDUFA V Decision Within 90 FDA Days	81				
510(k)s Pending MDUFA V Decision	178				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.48				
Number With MDUFA V Decision	81				
Average Number of FDA Days to MDUFA V Decision	65.91				
20th Percentile FDA Days to MDUFA V Decision	30				
40th Percentile FDA Days to MDUFA V Decision	59				
60th Percentile FDA Days to MDUFA V Decision	86				
80th Percentile FDA Days to MDUFA V Decision	89				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	24.69				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	9				
80th Percentile Industry Days to MDUFA V Decision	58				
Maximum Industry Days to MDUFA V Decision	153				
Average Number of Total Days to MDUFA V Decision	90.60				
20th Percentile Total Days to MDUFA V Decision	30				
40th Percentile Total Days to MDUFA V Decision	66				
60th Percentile Total Days to MDUFA V Decision	90				
80th Percentile Total Days to MDUFA V Decision	140				
Maximum Total Days to MDUFA V Decision	243				

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	263				
Number With MDUFA V Decision	81				
Number of SE Decision	79				
Number of NSE Decision	2				
Number of Withdrawal	4				
Number of Deleted	0				
Rate of SE Decision	97.53%				
Rate of NSE Decision	2.47%				
Rate of Withdrawal	1.52%				
Rate of Deleted	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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	442				
Closed Before First RTA or TS Action [1]	6				
Number Accepted or Passed TS on First Cycle [2]	323				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	25				
Number Not Accepted or Failed TS on First Cycle [2]	88				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	21.41%				

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	377				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	312				
SI Over 60 FDA Days	2				
SI Pending Within 60 FDA Days	61				
SI Pending Over 60 FDA Days	2				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	98.73%				

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	314				
Average Number of FDA Days to Substantive Interaction	51.14				
20th Percentile FDA Days to Substantive Interaction	42				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	58				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	71				

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	377				
Non-MDUFA V Decision	5				
MDUFA V Decision (SE/NSE)	189				
MDUFA V Decision Within 90 FDA Days	189				
510(k)s Pending MDUFA V Decision	183				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1				
Current Performance Percent Within 90 FDA Days	99.47%				

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	1.42				
Number With MDUFA V Decision	189				
Average Number of FDA Days to MDUFA V Decision	66.51				
20th Percentile FDA Days to MDUFA V Decision	52				
40th Percentile FDA Days to MDUFA V Decision	59				
60th Percentile FDA Days to MDUFA V Decision	83				
80th Percentile FDA Days to MDUFA V Decision	88				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	16.85				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	4				
80th Percentile Industry Days to MDUFA V Decision	30				
Maximum Industry Days to MDUFA V Decision	169				
Average Number of Total Days to MDUFA V Decision	83.37				
20th Percentile Total Days to MDUFA V Decision	55				
40th Percentile Total Days to MDUFA V Decision	67				
60th Percentile Total Days to MDUFA V Decision	87				
80th Percentile Total Days to MDUFA V Decision	114				
Maximum Total Days to MDUFA V Decision	258				

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	377				
Number With MDUFA V Decision	189				
Number of SE Decision	189				
Number of NSE Decision	0				
Number of Withdrawal	5				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	1.33%				
Rate of Deleted	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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	210				
Closed Before First RTA or TS Action [1]	3				
Number Accepted or Passed TS on First Cycle [2]	139				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	13				
Number Not Accepted or Failed TS on First Cycle [2]	54				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	27.84%				

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	167				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	128				
SI Over 60 FDA Days	5				
SI Pending Within 60 FDA Days	34				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	96.24%				

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	133				
Average Number of FDA Days to Substantive Interaction	53.40				
20th Percentile FDA Days to Substantive Interaction	49				
40th Percentile FDA Days to Substantive Interaction	58				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	80				

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	167				
Non-MDUFA V Decision	3				
MDUFA V Decision (SE/NSE)	66				
MDUFA V Decision Within 90 FDA Days	66				
510(k)s Pending MDUFA V Decision	98				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	1				
Current Performance Percent Within 90 FDA Days	98.51%				

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	1.48				
Number With MDUFA V Decision	66				
Average Number of FDA Days to MDUFA V Decision	66.71				
20th Percentile FDA Days to MDUFA V Decision	30				
40th Percentile FDA Days to MDUFA V Decision	59				
60th Percentile FDA Days to MDUFA V Decision	88				
80th Percentile FDA Days to MDUFA V Decision	90				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	28.24				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	26				
80th Percentile Industry Days to MDUFA V Decision	63				
Maximum Industry Days to MDUFA V Decision	121				
Average Number of Total Days to MDUFA V Decision	94.95				
20th Percentile Total Days to MDUFA V Decision	30				
40th Percentile Total Days to MDUFA V Decision	84				
60th Percentile Total Days to MDUFA V Decision	97				
80th Percentile Total Days to MDUFA V Decision	145				
Maximum Total Days to MDUFA V Decision	209				

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	167				
Number With MDUFA V Decision	66				
Number of SE Decision	63				
Number of NSE Decision	3				
Number of Withdrawal	1				
Number of Deleted	1				
Rate of SE Decision	95.45%				
Rate of NSE Decision	4.55%				
Rate of Withdrawal	0.60%				
Rate of Deleted	0.60%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	486				
Closed Before First RTA or TS Action [1]	6				
Number Accepted or Passed TS on First Cycle [2]	360				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	1				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	38				
Number Not Accepted or Failed TS on First Cycle [2]	81				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	18.33%				

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 (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	417				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	345				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	72				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	345				
Average Number of FDA Days to Substantive Interaction	50.09				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	55				
60th Percentile FDA Days to Substantive Interaction	58				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 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	417				
Non-MDUFA V Decision	6				
MDUFA V Decision (SE/NSE)	210				
MDUFA V Decision Within 90 FDA Days	210				
510(k)s Pending MDUFA V Decision	201				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.27				
Number With MDUFA V Decision	210				
Average Number of FDA Days to MDUFA V Decision	58.08				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	55				
60th Percentile FDA Days to MDUFA V Decision	60				
80th Percentile FDA Days to MDUFA V Decision	87				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	9.56				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	11				
Maximum Industry Days to MDUFA V Decision	116				
Average Number of Total Days to MDUFA V Decision	67.64				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	56				
60th Percentile Total Days to MDUFA V Decision	66				
80th Percentile Total Days to MDUFA V Decision	94				
Maximum Total Days to MDUFA V Decision	206				

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	417				
Number With MDUFA V Decision	210				
Number of SE Decision	210				
Number of NSE Decision	0				
Number of Withdrawal	6				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	1.44%				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance Percent Within 90 FDA Days	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	189				
Closed Before First RTA or TS Action [1]	4				
Number Accepted or Passed TS on First Cycle [2]	147				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	4				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	7				
Number Not Accepted or Failed TS on First Cycle [2]	27				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	15.17%				

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

Table 6.2 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	161				
Deleted or Withdrawn Prior to SI	3				
SI Within 60 FDA Days	127				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	31				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	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	127				
Average Number of FDA Days to Substantive Interaction	51.72				
20th Percentile FDA Days to Substantive Interaction	44				
40th Percentile FDA Days to Substantive Interaction	56				
60th Percentile FDA Days to Substantive Interaction	59				
80th Percentile FDA Days to Substantive Interaction	60				
Maximum FDA Days to Substantive Interaction	60				

Table 6.4 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	161				
Non-MDUFA V Decision	7				
MDUFA V Decision (SE/NSE)	54				
MDUFA V Decision Within 90 FDA Days	54				
510(k)s Pending MDUFA V Decision	100				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.11				
Number With MDUFA V Decision	54				
Average Number of FDA Days to MDUFA V Decision	57.59				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	54				
60th Percentile FDA Days to MDUFA V Decision	68				
80th Percentile FDA Days to MDUFA V Decision	88				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	10.43				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	0				
Maximum Industry Days to MDUFA V Decision	163				
Average Number of Total Days to MDUFA V Decision	68.02				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	54				
60th Percentile Total Days to MDUFA V Decision	68				
80th Percentile Total Days to MDUFA V Decision	90				
Maximum Total Days to MDUFA V Decision	253				

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	161				
Number With MDUFA V Decision	54				
Number of SE Decision	54				
Number of NSE Decision	0				
Number of Withdrawal	6				
Number of Deleted	1				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	3.73%				
Rate of Deleted	0.62%				

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

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	160				
Non-MDUFA V Decision	7				
MDUFA V Decision (SE/NSE)	53				
MDUFA V Decision Within 90 FDA Days	53				
510(k)s Pending MDUFA V Decision	100				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	324				
Closed Before First RTA or TS Action [1]	2				
Number Accepted or Passed TS on First Cycle [2]	277				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	2				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	14				
Number Not Accepted or Failed TS on First Cycle [2]	29				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	9.42%				

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	298				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	239				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	59				
SI Pending Over 60 FDA Days	0				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Substantive Interaction	239				
Average Number of FDA Days to Substantive Interaction	48.50				
20th Percentile FDA Days to Substantive Interaction	30				
40th Percentile FDA Days to Substantive Interaction	51				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

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	298				
Non-MDUFA V Decision	4				
MDUFA V Decision (SE/NSE)	140				
MDUFA V Decision Within 90 FDA Days	140				
510(k)s Pending MDUFA V Decision	154				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.51				
Number With MDUFA V Decision	140				
Average Number of FDA Days to MDUFA V Decision	60.79				
20th Percentile FDA Days to MDUFA V Decision	29				
40th Percentile FDA Days to MDUFA V Decision	56				
60th Percentile FDA Days to MDUFA V Decision	80				
80th Percentile FDA Days to MDUFA V Decision	87				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	23.77				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	16				
80th Percentile Industry Days to MDUFA V Decision	48				
Maximum Industry Days to MDUFA V Decision	145				
Average Number of Total Days to MDUFA V Decision	84.56				
20th Percentile Total Days to MDUFA V Decision	29				
40th Percentile Total Days to MDUFA V Decision	57				
60th Percentile Total Days to MDUFA V Decision	98				
80th Percentile Total Days to MDUFA V Decision	130				
Maximum Total Days to MDUFA V Decision	233				

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	298				
Number With MDUFA V Decision	140				
Number of SE Decision	140				
Number of NSE Decision	0				
Number of Withdrawal	2				
Number of Deleted	1				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.67%				
Rate of Deleted	0.34%				

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

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

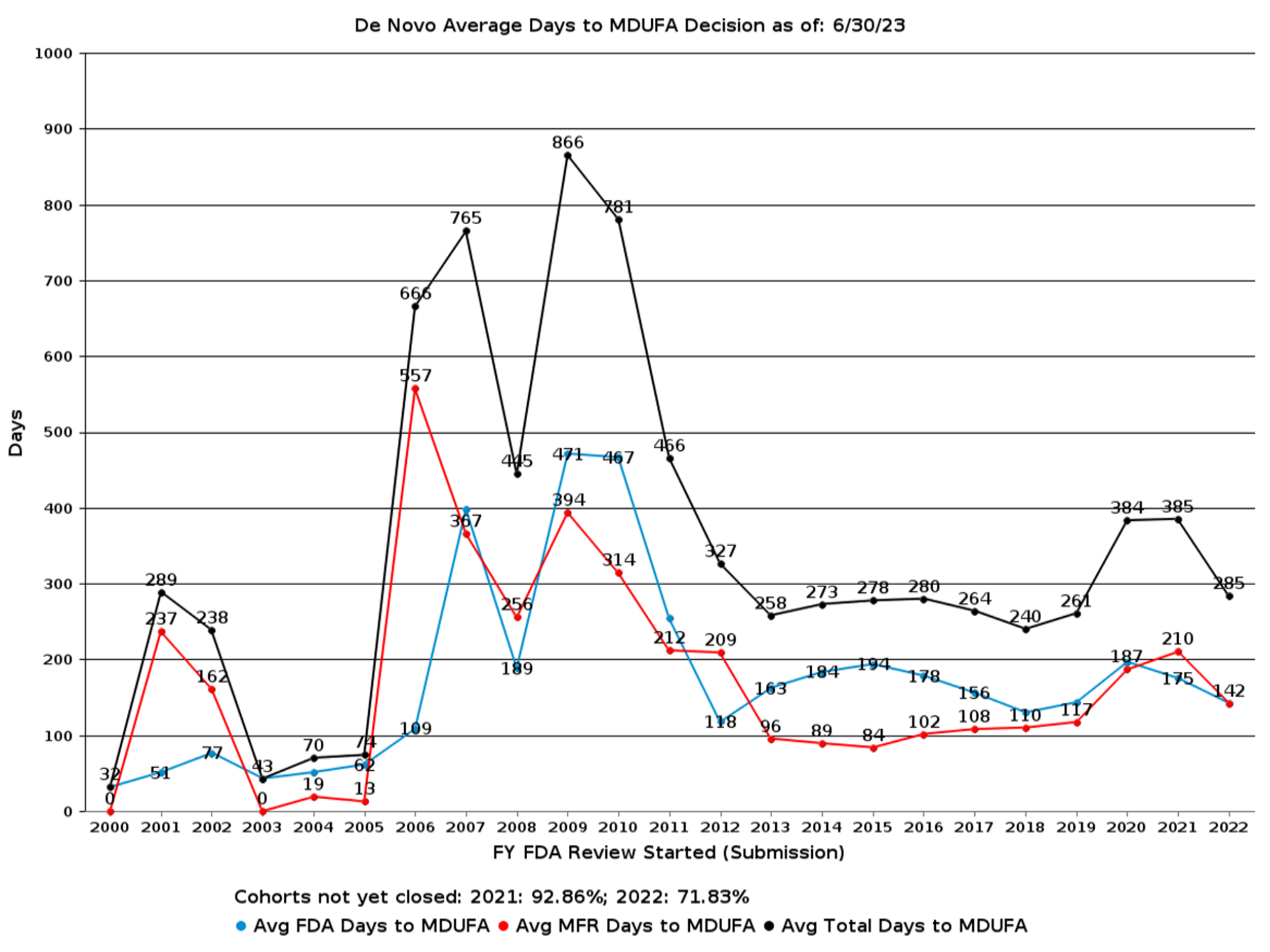
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
510(k)s Accepted	N/A				
Non-MDUFA V Decision	N/A				
MDUFA V Decision (SE/NSE)	N/A				
MDUFA V Decision Within 90 FDA Days	N/A				
510(k)s Pending MDUFA V Decision	N/A				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	N/A				
Current Performance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

Section 7 510(k) Annual General Metrics

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

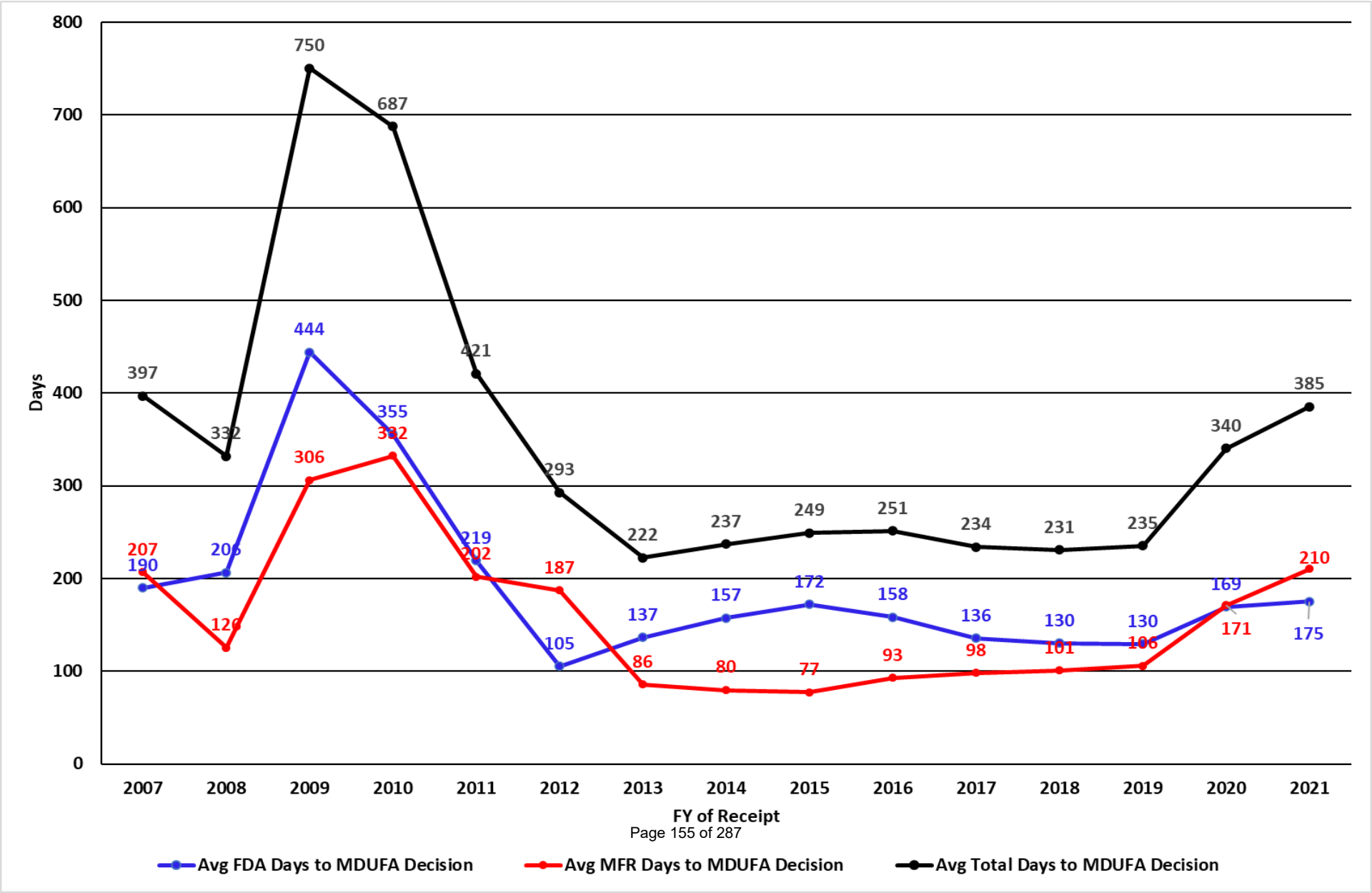
De Novos

Q3 FY 2023


De Novo Average Days to MDUFA Decision as of: 6/30/23
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2021: 92.86%; 2022: 71.83%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

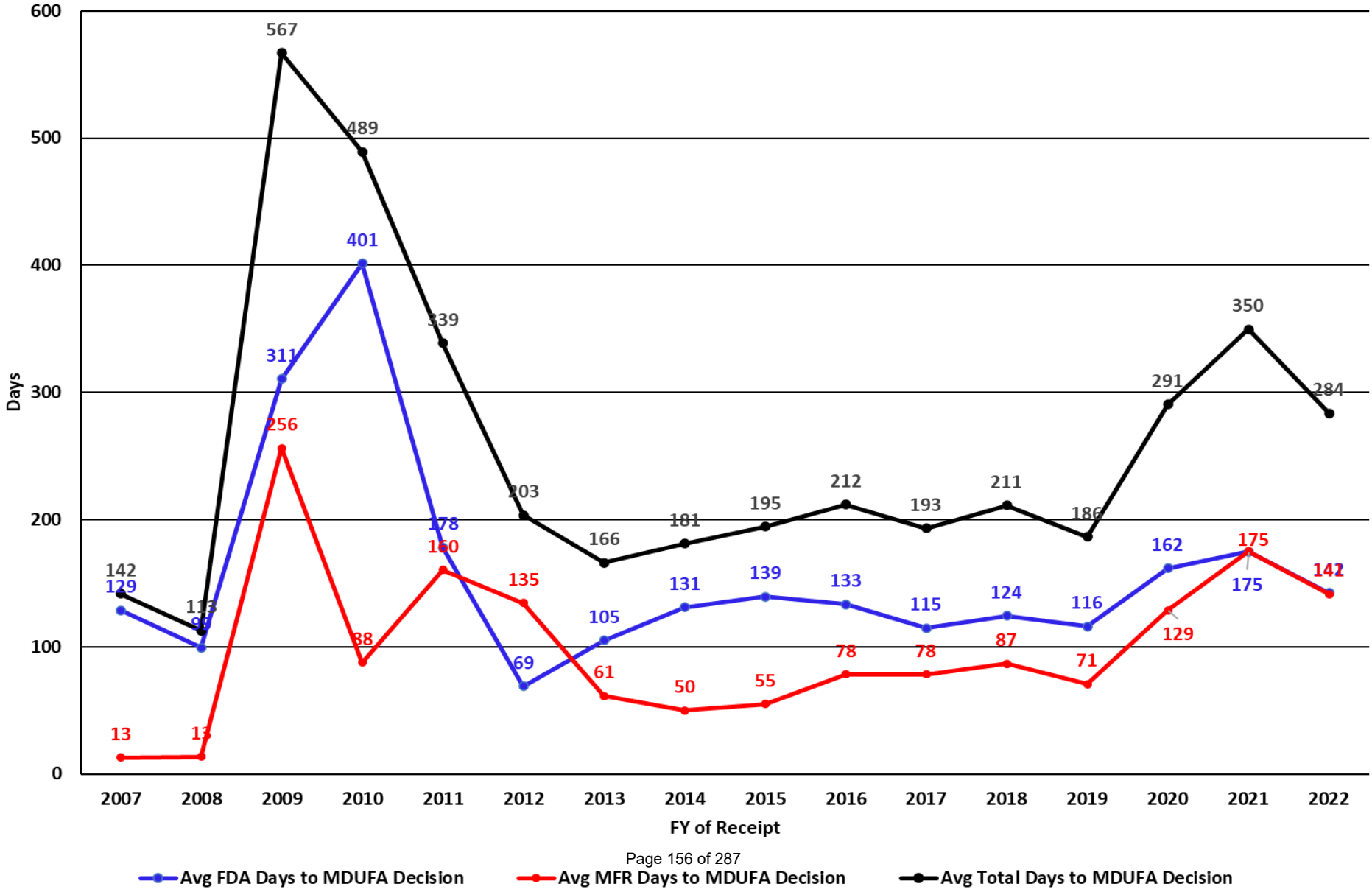
Average Time to MDUFA Decision: De Novos

(92.9% closure comparison)

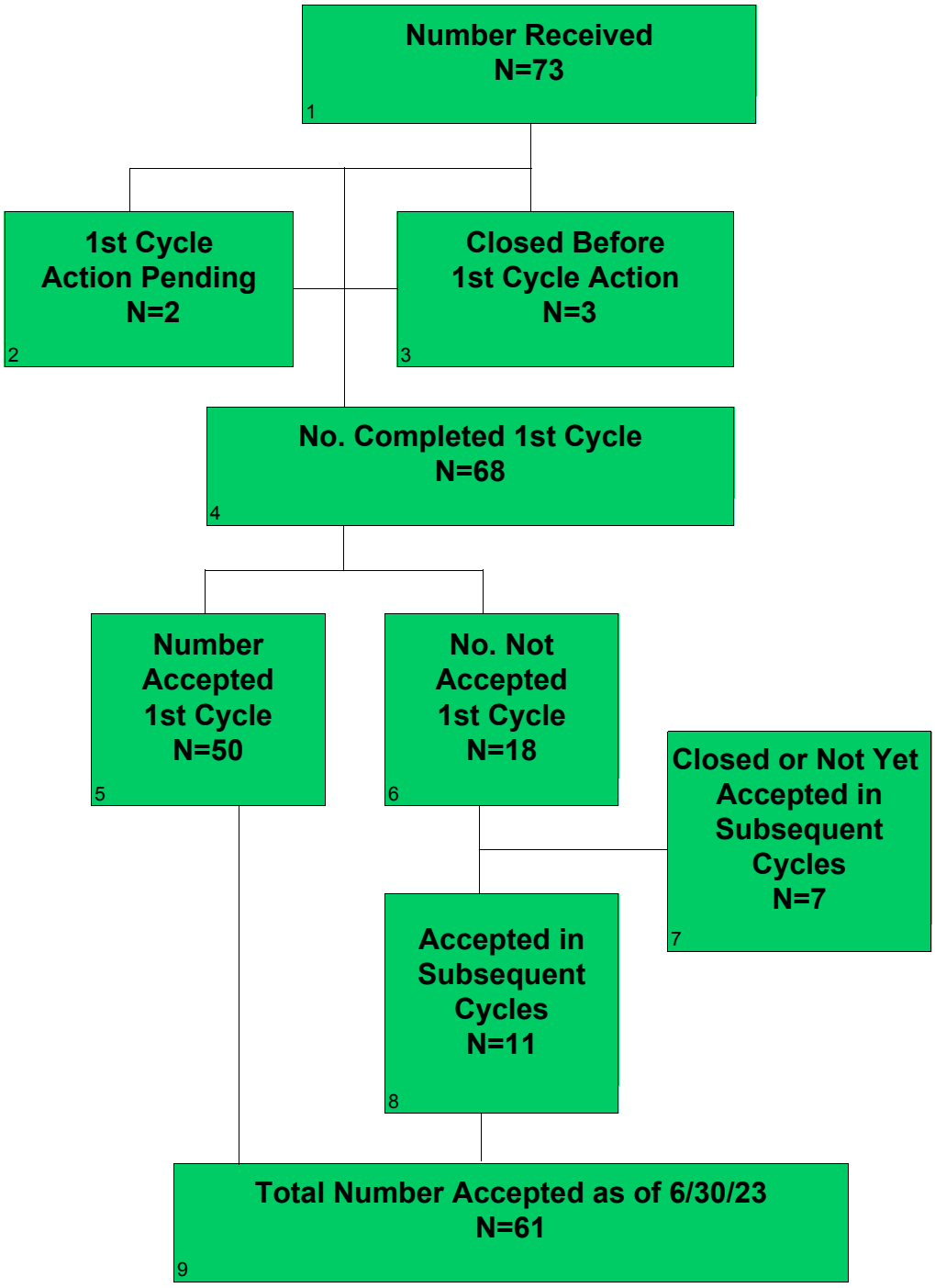


Average Time to MDUFA Decision: De Novos

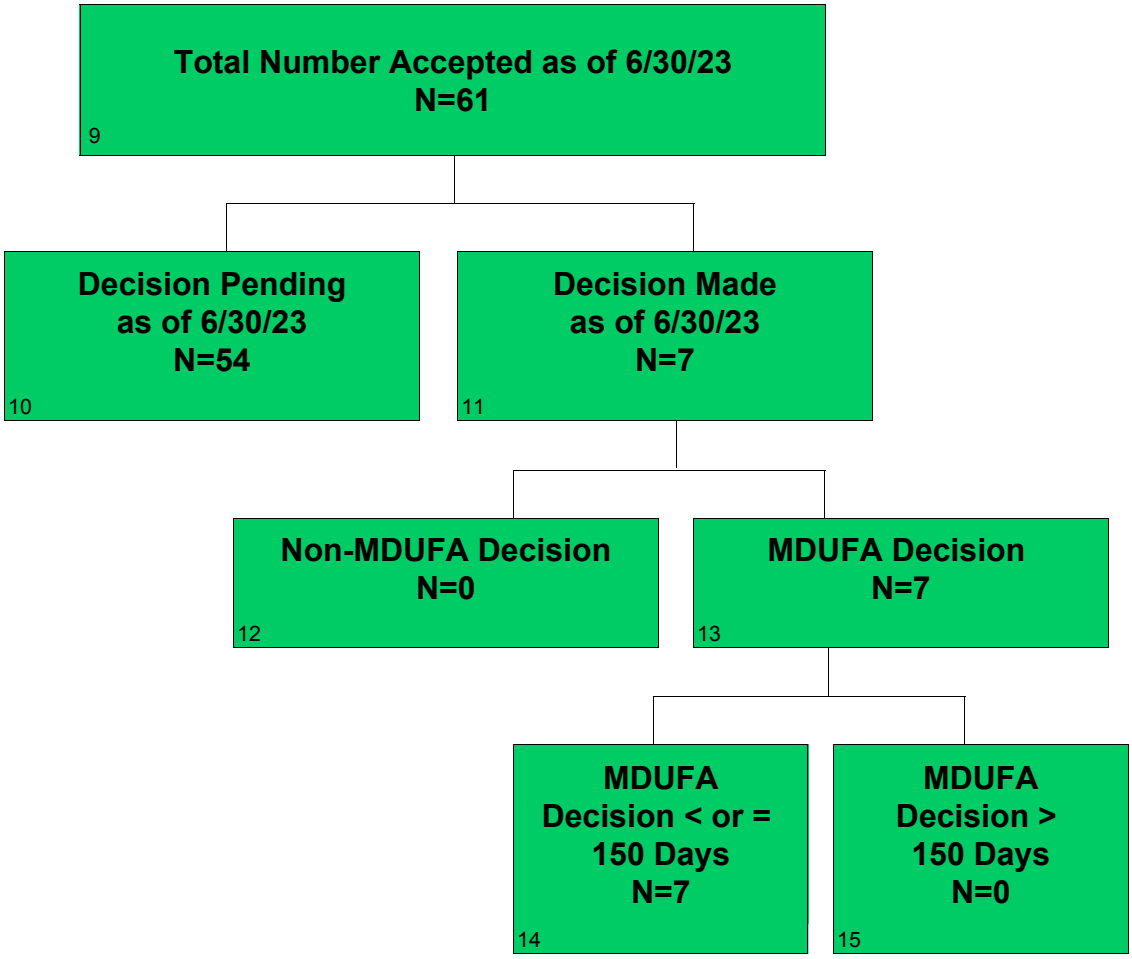
(71.8% closure comparison)



CDRH De Novo - FY 2023
as of 6/30/23



CDRH De Novo - FY 2023
as of 6/30/23 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	73				
Closed Before First RTA or TS Action	3				
Number Accepted or Passed TS on First Cycle	50				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	2				
Number Not Accepted or Failed TS on First Cycle	18				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	26.47%				

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

Table 8.2 CDRH - De Novo MDUFA V Decision Performance Goal

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	61				
Non-MDUFA Decision	0				
MDUFA Decision	7				
MDUFA Decision Within 150 FDA Days	7				
De Novos Pending MDUFA Decision	54				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	1.29				
Number With MDUFA Decision	7				
Average FDA Days to MDUFA Decision	122.71				
20th Percentile FDA Days to MDUFA Decision	82				
40th Percentile FDA Days to MDUFA Decision	137				
60th Percentile FDA Days to MDUFA Decision	148				
80th Percentile FDA Days to MDUFA Decision	150				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	44.71				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	8				
60th Percentile Industry Days to MDUFA Decision	24				
80th Percentile Industry Days to MDUFA Decision	72				
Maximum Industry Days to MDUFA Decision	183				
Average Total Days to MDUFA Decision	167.43				
20th Percentile Total Days to MDUFA Decision	134				
40th Percentile Total Days to MDUFA Decision	148				
60th Percentile Total Days to MDUFA Decision	161				
80th Percentile Total Days to MDUFA Decision	219				
Maximum Total Days to MDUFA Decision	253				

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	61				
Number With MDUFA Decision	7				
Number With Granted Decision	3				
Number With Declined Decision	1				
Number of Withdrawal	2				
Number of Deleted	1				
Rate of Granted Decision	42.86%				
Rate of Declined Decision	14.29%				
Rate of Withdrawal	28.57%				
Rate of Deleted	14.29%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	1				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	13				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Within 150 FDA Days	2				
De Novos Pending MDUFA Decision	11				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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	11				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	5				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	6				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	54.55%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	10				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	10				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	N/A				
Number With MDUFA Decision	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	10				
Number With MDUFA Decision	0				
Number With Granted Decision	0				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	N/A				
Rate of Declined Decision	N/A				
Rate of Withdrawal	N/A				
Rate of Deleted	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	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	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	9				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	8				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	1				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	11.11%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	8				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Within 150 FDA Days	1				
De Novos Pending MDUFA Decision	7				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	1.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00				
Number With MDUFA Decision	1				
Average FDA Days to MDUFA Decision	70.00				
20th Percentile FDA Days to MDUFA Decision	70				
40th Percentile FDA Days to MDUFA Decision	70				
60th Percentile FDA Days to MDUFA Decision	70				
80th Percentile FDA Days to MDUFA Decision	70				
Maximum FDA Days to MDUFA Decision	70				
Average Industry Days to MDUFA Decision	183.00				
20th Percentile Industry Days to MDUFA Decision	183				
40th Percentile Industry Days to MDUFA Decision	183				
60th Percentile Industry Days to MDUFA Decision	183				
80th Percentile Industry Days to MDUFA Decision	183				
Maximum Industry Days to MDUFA Decision	183				
Average Total Days to MDUFA Decision	253.00				
20th Percentile Total Days to MDUFA Decision	253				
40th Percentile Total Days to MDUFA Decision	253				
60th Percentile Total Days to MDUFA Decision	253				
80th Percentile Total Days to MDUFA Decision	253				
Maximum Total Days to MDUFA Decision	253				

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	8				
Number With MDUFA Decision	1				
Number With Granted Decision	0				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	1				
Rate of Granted Decision	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	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	8				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	7				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	1				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	12.50%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	8				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Within 150 FDA Days	1				
De Novos Pending MDUFA Decision	7				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	1.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00				
Number With MDUFA Decision	1				
Average FDA Days to MDUFA Decision	148.00				
20th Percentile FDA Days to MDUFA Decision	148				
40th Percentile FDA Days to MDUFA Decision	148				
60th Percentile FDA Days to MDUFA Decision	148				
80th Percentile FDA Days to MDUFA Decision	148				
Maximum FDA Days to MDUFA Decision	148				
Average Industry Days to MDUFA Decision	83.00				
20th Percentile Industry Days to MDUFA Decision	83				
40th Percentile Industry Days to MDUFA Decision	83				
60th Percentile Industry Days to MDUFA Decision	83				
80th Percentile Industry Days to MDUFA Decision	83				
Maximum Industry Days to MDUFA Decision	83				
Average Total Days to MDUFA Decision	231.00				
20th Percentile Total Days to MDUFA Decision	231				
40th Percentile Total Days to MDUFA Decision	231				
60th Percentile Total Days to MDUFA Decision	231				
80th Percentile Total Days to MDUFA Decision	231				
Maximum Total Days to MDUFA Decision	231				

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	8				
Number With MDUFA Decision	1				
Number With Granted Decision	1				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	100.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	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	16				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	8				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	7				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	46.67%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	11				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Within 150 FDA Days	1				
De Novos Pending MDUFA Decision	10				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	1.00%				

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	1.00				
Number With MDUFA Decision	1				
Average FDA Days to MDUFA Decision	150.00				
20th Percentile FDA Days to MDUFA Decision	150				
40th Percentile FDA Days to MDUFA Decision	150				
60th Percentile FDA Days to MDUFA Decision	150				
80th Percentile FDA Days to MDUFA Decision	150				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	150.00				
20th Percentile Total Days to MDUFA Decision	150				
40th Percentile Total Days to MDUFA Decision	150				
60th Percentile Total Days to MDUFA Decision	150				
80th Percentile Total Days to MDUFA Decision	150				
Maximum Total Days to MDUFA Decision	150				

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	11				
Number With MDUFA Decision	1				
Number With Granted Decision	1				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	100.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	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	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	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	7				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	3				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	1				
Number Not Accepted or Failed TS on First Cycle	2				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	40.00%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	5				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Within 150 FDA Days	1				
De Novos Pending MDUFA Decision	4				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	1.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	2.00				
Number With MDUFA Decision	1				
Average FDA Days to MDUFA Decision	150.00				
20th Percentile FDA Days to MDUFA Decision	150				
40th Percentile FDA Days to MDUFA Decision	150				
60th Percentile FDA Days to MDUFA Decision	150				
80th Percentile FDA Days to MDUFA Decision	150				
Maximum FDA Days to MDUFA Decision	150				
Average Industry Days to MDUFA Decision	19.00				
20th Percentile Industry Days to MDUFA Decision	19				
40th Percentile Industry Days to MDUFA Decision	19				
60th Percentile Industry Days to MDUFA Decision	19				
80th Percentile Industry Days to MDUFA Decision	19				
Maximum Industry Days to MDUFA Decision	19				
Average Total Days to MDUFA Decision	169.00				
20th Percentile Total Days to MDUFA Decision	169				
40th Percentile Total Days to MDUFA Decision	169				
60th Percentile Total Days to MDUFA Decision	169				
80th Percentile Total Days to MDUFA Decision	169				
Maximum Total Days to MDUFA Decision	169				

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	5				
Number With MDUFA Decision	1				
Number With Granted Decision	1				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	100.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	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	2				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	2				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	0				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	0.00%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	2				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	2				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	N/A				
Number With MDUFA Decision	0				
Average FDA Days to MDUFA Decision	N/A				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	N/A				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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	2				
Number With MDUFA Decision	0				
Number With Granted Decision	0				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	N/A				
Rate of Declined Decision	N/A				
Rate of Withdrawal	N/A				
Rate of Deleted	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				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance Percent Within 150 FDA Days	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	17				
Closed Before First RTA or TS Action	1				
Number Accepted or Passed TS on First Cycle	14				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	1				
Number Not Accepted or Failed TS on First Cycle	1				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	6.67%				

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	14				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Within 150 FDA Days	2				
De Novos Pending MDUFA Decision	12				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	1.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Average Review Cycles	1.00				
Number With MDUFA Decision	2				
Average FDA Days to MDUFA Decision	139.00				
20th Percentile FDA Days to MDUFA Decision	134				
40th Percentile FDA Days to MDUFA Decision	137				
60th Percentile FDA Days to MDUFA Decision	141				
80th Percentile FDA Days to MDUFA Decision	144				
Maximum FDA Days to MDUFA Decision	147				
Average Industry Days to MDUFA Decision	N/A				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	139.00				
20th Percentile Total Days to MDUFA Decision	134				
40th Percentile Total Days to MDUFA Decision	137				
60th Percentile Total Days to MDUFA Decision	141				
80th Percentile Total Days to MDUFA Decision	144				
Maximum Total Days to MDUFA Decision	147				

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	14				
Number With MDUFA Decision	2				
Number With Granted Decision	0				
Number With Declined Decision	1				
Number of Withdrawal	1				
Number of Deleted	0				
Rate of Granted Decision	0.00%				
Rate of Declined Decision	50.00%				
Rate of Withdrawal	50.00%				
Rate of Deleted	0.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Submissions that Missed the Goal	0				
Mean FDA Days for Submissions That Missed the Goal	N/A				
Mean Industry Days for Submissions That Missed the Goal	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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA IV Decision	1				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	N/A				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	13				
Non-MDUFA Decision	0				
MDUFA Decision	2				
MDUFA Decision Within 150 FDA Days	2				
De Novos Pending MDUFA IV Decision	11				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	100.00%				

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

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

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

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

Performance Metric	FY 2023 70% Within 150 FDA Days	FY 2024 70% Within 150 FDA Days	FY 2025 70% Within 150 FDA Days	FY 2026 70% Within 150 FDA Days	FY 2027 70% Within 150 FDA Days
De Novos Accepted	3				
Non-MDUFA Decision	0				
MDUFA Decision	1				
MDUFA Decision Within 150 FDA Days	1				
De Novos Pending MDUFA Decision	2				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	1.00%				

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	1.00				
Number With MDUFA Decision	1				
Average FDA Days to MDUFA Decision	63.00				
20th Percentile FDA Days to MDUFA Decision	63				
40th Percentile FDA Days to MDUFA Decision	63				
60th Percentile FDA Days to MDUFA Decision	63				
80th Percentile FDA Days to MDUFA Decision	63				
Maximum FDA Days to MDUFA Decision	63				
Average Industry Days to MDUFA Decision	28.00				
20th Percentile Industry Days to MDUFA Decision	28				
40th Percentile Industry Days to MDUFA Decision	28				
60th Percentile Industry Days to MDUFA Decision	28				
80th Percentile Industry Days to MDUFA Decision	28				
Maximum Industry Days to MDUFA Decision	28				
Average Total Days to MDUFA Decision	91.00				
20th Percentile Total Days to MDUFA Decision	91				
40th Percentile Total Days to MDUFA Decision	91				
60th Percentile Total Days to MDUFA Decision	91				
80th Percentile Total Days to MDUFA Decision	91				
Maximum Total Days to MDUFA Decision	91				

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	3				
Number With MDUFA Decision	1				
Number With Granted Decision	0				
Number With Declined Decision	0				
Number of Withdrawal	1				
Number of Deleted	0				
Rate of Granted Decision	0.00%				
Rate of Declined Decision	0.00%				
Rate of Withdrawal	100.00%				
Rate of Deleted	0.00%				

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

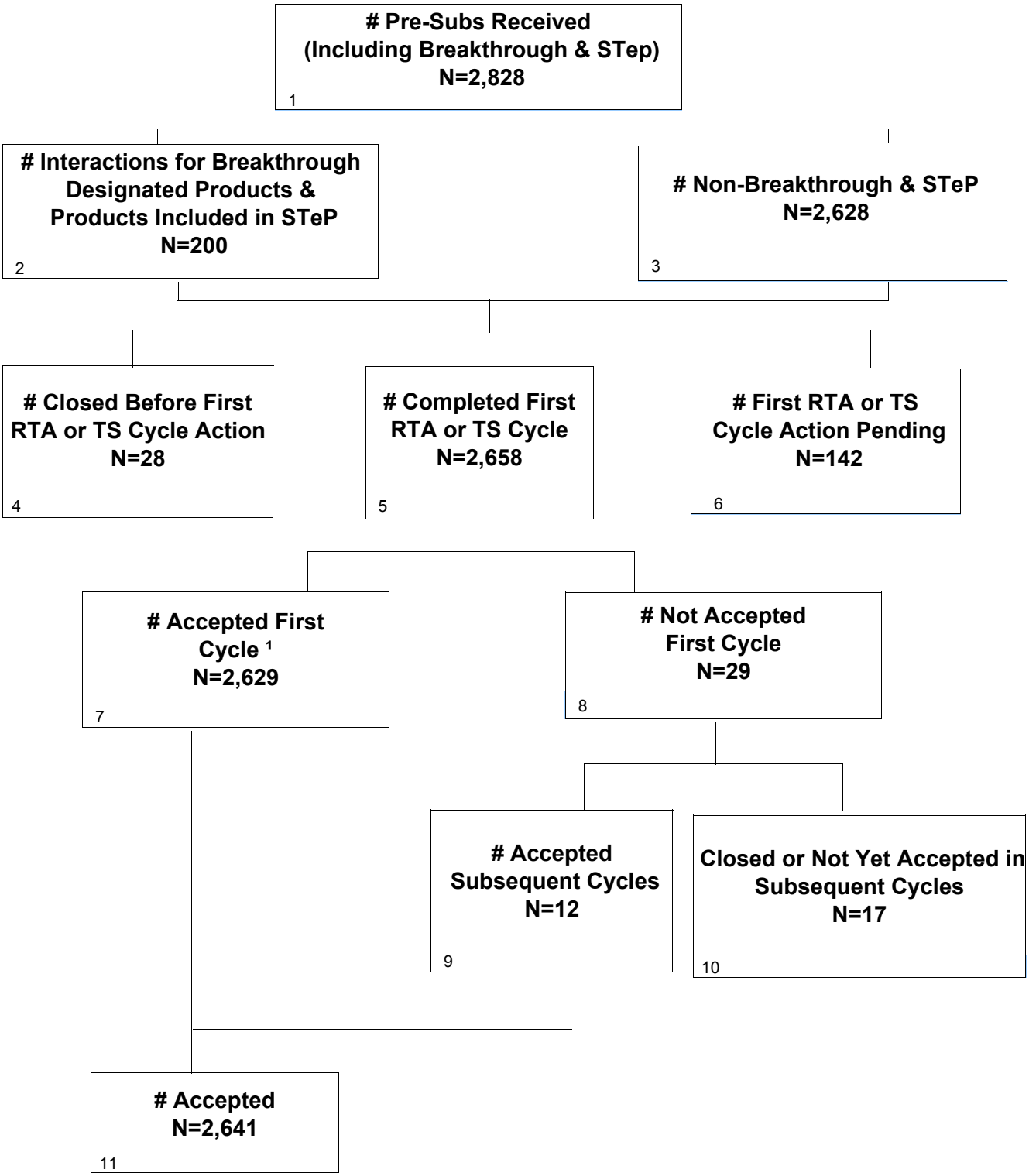
Table 8.6 OHT8 - Office of Radiological Health
LDT De Novo MDUFA V Metrics

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

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

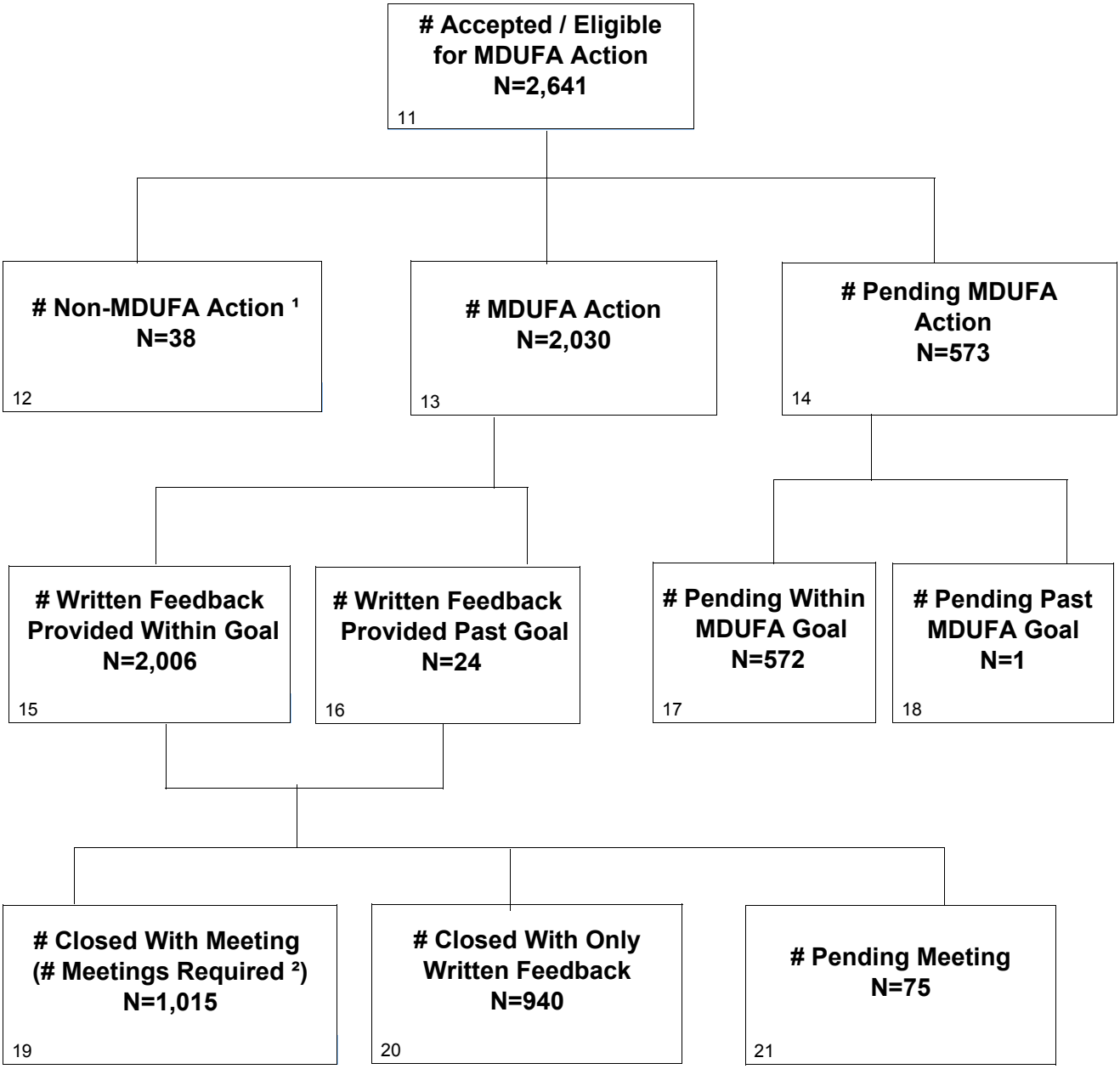
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
De Novos Accepted	N/A				
Non-MDUFA Decision	N/A				
MDUFA Decision	N/A				
MDUFA Decision Within 150 FDA Days	N/A				
De Novos Pending MDUFA IV Decision	N/A				
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A				
Current Performance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

CDRH Pre-Sub - FY 2023
as of 6/30/23



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 6/30/23 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	2,828				
Interactions for Breakthrough Designated Products & Products Included in STeP	200				
Number Closed Before First RTA Action	28				
Number Accepted First RTA Cycle [1]	2,550				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	79				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	142				
Number Not Accepted First RTA Cycle	29				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.09%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	2,641				
Number with Non-MDUFA Action [3]	38				
Number with MDUFA Action	2,030				
Written Feedback Provided Within Goal	2,006				
Number Pending MDUFA Action	573				
Pending MDUFA Action Past Goal	1				
Number in MDUFA Cohort (up to max 4300)[4]	2,603				
Current Performance Percent Within Goal	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 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	2,030				
Average FDA Days to Written Feedback	61.34				
20th Percentile FDA Days to Written Feedback	55				
40th Percentile FDA Days to Written Feedback	63				
60th Percentile FDA Days to Written Feedback	67				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	141				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	85				
Average Days to Scheduling for Meetings Scheduled After Day 30	40.94				

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]	1,014				
Meeting Minutes Submitted Within 15 Days of Meeting	713				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	48				
Meeting Minutes Past 15 Days of Meeting	214				
Meeting Minutes Not Submitted and >15 Days Since Meeting	39				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	73.81%				

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	322				
Interactions for Breakthrough Designated Products & Products Included in STeP	14				
Number Closed Before First RTA Action	3				
Number Accepted First RTA Cycle [1]	286				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	9				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	20				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.34%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	296				
Number with Non-MDUFA Action [3]	9				
Number with MDUFA Action	226				
Written Feedback Provided Within Goal	218				
Number Pending MDUFA Action	61				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	287				
Current Performance Percent Within Goal	96.46%				

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

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

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

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

Table 9.3 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	226				
Average FDA Days to Written Feedback	65.46				
20th Percentile FDA Days to Written Feedback	62				
40th Percentile FDA Days to Written Feedback	65				
60th Percentile FDA Days to Written Feedback	69				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	141				

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	18				
Average Days to Scheduling for Meetings Scheduled After Day 30	44.17				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Required [1]	127				
Meeting Minutes Submitted Within 15 Days of Meeting	85				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	8				
Meeting Minutes Past 15 Days of Meeting	26				
Meeting Minutes Not Submitted and >15 Days Since Meeting	8				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%				

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	542				
Interactions for Breakthrough Designated Products & Products Included in STeP	56				
Number Closed Before First RTA Action	4				
Number Accepted First RTA Cycle [1]	497				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	8				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	29				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.79%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	509				
Number with Non-MDUFA Action [3]	1				
Number with MDUFA Action	407				
Written Feedback Provided Within Goal	397				
Number Pending MDUFA Action	101				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	508				
Current Performance Percent Within Goal	97.54%				

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	407				
Average FDA Days to Written Feedback	58.08				
20th Percentile FDA Days to Written Feedback	47				
40th Percentile FDA Days to Written Feedback	59				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	69				
Maximum FDA Days to Written Feedback	83				

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	22				
Average Days to Scheduling for Meetings Scheduled After Day 30	40.36				

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]	218				
Meeting Minutes Submitted Within 15 Days of Meeting	155				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	11				
Meeting Minutes Past 15 Days of Meeting	44				
Meeting Minutes Not Submitted and >15 Days Since Meeting	8				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.88%				

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	325				
Interactions for Breakthrough Designated Products & Products Included in STeP	28				
Number Closed Before First RTA Action	2				
Number Accepted First RTA Cycle [1]	299				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	8				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	12				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.29%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	310				
Number with Non-MDUFA Action [3]	8				
Number with MDUFA Action	230				
Written Feedback Provided Within Goal	229				
Number Pending MDUFA Action	72				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	302				
Current Performance Percent Within Goal	99.57%				

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	230				
Average FDA Days to Written Feedback	61.22				
20th Percentile FDA Days to Written Feedback	55				
40th Percentile FDA Days to Written Feedback	63				
60th Percentile FDA Days to Written Feedback	66				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	78				

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	4				
Average Days to Scheduling for Meetings Scheduled After Day 30	49.50				

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]	119				
Meeting Minutes Submitted Within 15 Days of Meeting	91				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	1				
Meeting Minutes Past 15 Days of Meeting	23				
Meeting Minutes Not Submitted and >15 Days Since Meeting	4				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	77.12%				

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	268				
Interactions for Breakthrough Designated Products & Products Included in STeP	14				
Number Closed Before First RTA Action	3				
Number Accepted First RTA Cycle [1]	240				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	16				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.61%				

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

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

Table 9.2 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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	246				
Number with Non-MDUFA Action [3]	6				
Number with MDUFA Action	186				
Written Feedback Provided Within Goal	186				
Number Pending MDUFA Action	54				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	240				
Current Performance Percent Within Goal	100.00%				

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

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

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

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

Table 9.3 OHT4 - Office of Surgical and Infection Control Devices
MDUFA V Pre-Sub Time to Written Feedback Sent (for Pre-Subs in the MDUFA Cohort)

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	186				
Average FDA Days to Written Feedback	59.13				
20th Percentile FDA Days to Written Feedback	50				
40th Percentile FDA Days to Written Feedback	60				
60th Percentile FDA Days to Written Feedback	65				
80th Percentile FDA Days to Written Feedback	69				
Maximum FDA Days to Written Feedback	70				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	8				
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25				

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]	96				
Meeting Minutes Submitted Within 15 Days of Meeting	68				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	7				
Meeting Minutes Past 15 Days of Meeting	16				
Meeting Minutes Not Submitted and >15 Days Since Meeting	5				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	76.40%				

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	290				
Interactions for Breakthrough Designated Products & Products Included in STeP	29				
Number Closed Before First RTA Action	4				
Number Accepted First RTA Cycle [1]	258				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	12				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	12				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.46%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	272				
Number with Non-MDUFA Action [3]	4				
Number with MDUFA Action	200				
Written Feedback Provided Within Goal	199				
Number Pending MDUFA Action	68				
Pending MDUFA Action Past Goal	1				
Number in MDUFA Cohort (up to max 4300)[4]	268				
Current Performance Percent Within Goal	99.00%				

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	200				
Average FDA Days to Written Feedback	65.74				
20th Percentile FDA Days to Written Feedback	64				
40th Percentile FDA Days to Written Feedback	67				
60th Percentile FDA Days to Written Feedback	70				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	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	19				
Average Days to Scheduling for Meetings Scheduled After Day 30	37.63				

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]	124				
Meeting Minutes Submitted Within 15 Days of Meeting	80				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	36				
Meeting Minutes Not Submitted and >15 Days Since Meeting	6				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	65.57%				

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	223				
Interactions for Breakthrough Designated Products & Products Included in STeP	32				
Number Closed Before First RTA Action	5				
Number Accepted First RTA Cycle [1]	203				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	8				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	4				
Number Not Accepted First RTA Cycle	3				
Rate of Submissions Not Accepted for Review on First RTA Cycle	1.40%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	212				
Number with Non-MDUFA Action [3]	5				
Number with MDUFA Action	167				
Written Feedback Provided Within Goal	166				
Number Pending MDUFA Action	40				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	207				
Current Performance Percent Within Goal	99.40%				

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	167				
Average FDA Days to Written Feedback	58.23				
20th Percentile FDA Days to Written Feedback	46				
40th Percentile FDA Days to Written Feedback	57				
60th Percentile FDA Days to Written Feedback	63				
80th Percentile FDA Days to Written Feedback	68				
Maximum FDA Days to Written Feedback	91				

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	2				
Average Days to Scheduling for Meetings Scheduled After Day 30	50.00				

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]	70				
Meeting Minutes Submitted Within 15 Days of Meeting	51				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	2				
Meeting Minutes Past 15 Days of Meeting	14				
Meeting Minutes Not Submitted and >15 Days Since Meeting	3				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.00%				

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

Table 9.1 OHT7 - Office of In Vitro Diagnostics
Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	657				
Interactions for Breakthrough Designated Products & Products Included in STeP	25				
Number Closed Before First RTA Action	6				
Number Accepted First RTA Cycle [1]	587				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	24				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	38				
Number Not Accepted First RTA Cycle	2				
Rate of Submissions Not Accepted for Review on First RTA Cycle	0.33%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	611				
Number with Non-MDUFA Action [3]	3				
Number with MDUFA Action	468				
Written Feedback Provided Within Goal	465				
Number Pending MDUFA Action	140				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	608				
Current Performance Percent Within Goal	99.36%				

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	468				
Average FDA Days to Written Feedback	62.90				
20th Percentile FDA Days to Written Feedback	59				
40th Percentile FDA Days to Written Feedback	65				
60th Percentile FDA Days to Written Feedback	69				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	75				

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	7				
Average Days to Scheduling for Meetings Scheduled After Day 30	42.57				

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]	146				
Meeting Minutes Submitted Within 15 Days of Meeting	100				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	12				
Meeting Minutes Past 15 Days of Meeting	32				
Meeting Minutes Not Submitted and >15 Days Since Meeting	2				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.63%				

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	201				
Interactions for Breakthrough Designated Products & Products Included in STeP	2				
Number Closed Before First RTA Action	1				
Number Accepted First RTA Cycle [1]	180				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	5				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	11				
Number Not Accepted First RTA Cycle	4				
Rate of Submissions Not Accepted for Review on First RTA Cycle	2.12%				

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	FY 2024	FY 2025	FY 2026	FY 2027
	90% / 75% Within MDUFA Goal [1]	90% / 80% Within MDUFA Goal [2]	90% Within MDUFA Goal	90% Within MDUFA Goal	90% Within MDUFA Goal
Number Accepted / Eligible for MDUFA Action	185				
Number with Non-MDUFA Action [3]	2				
Number with MDUFA Action	146				
Written Feedback Provided Within Goal	146				
Number Pending MDUFA Action	37				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	183				
Current Performance Percent Within Goal	100.00%				

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

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with Written Feedback Sent	146				
Average FDA Days to Written Feedback	59.59				
20th Percentile FDA Days to Written Feedback	53				
40th Percentile FDA Days to Written Feedback	59				
60th Percentile FDA Days to Written Feedback	64				
80th Percentile FDA Days to Written Feedback	66				
Maximum FDA Days to Written Feedback	70				

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

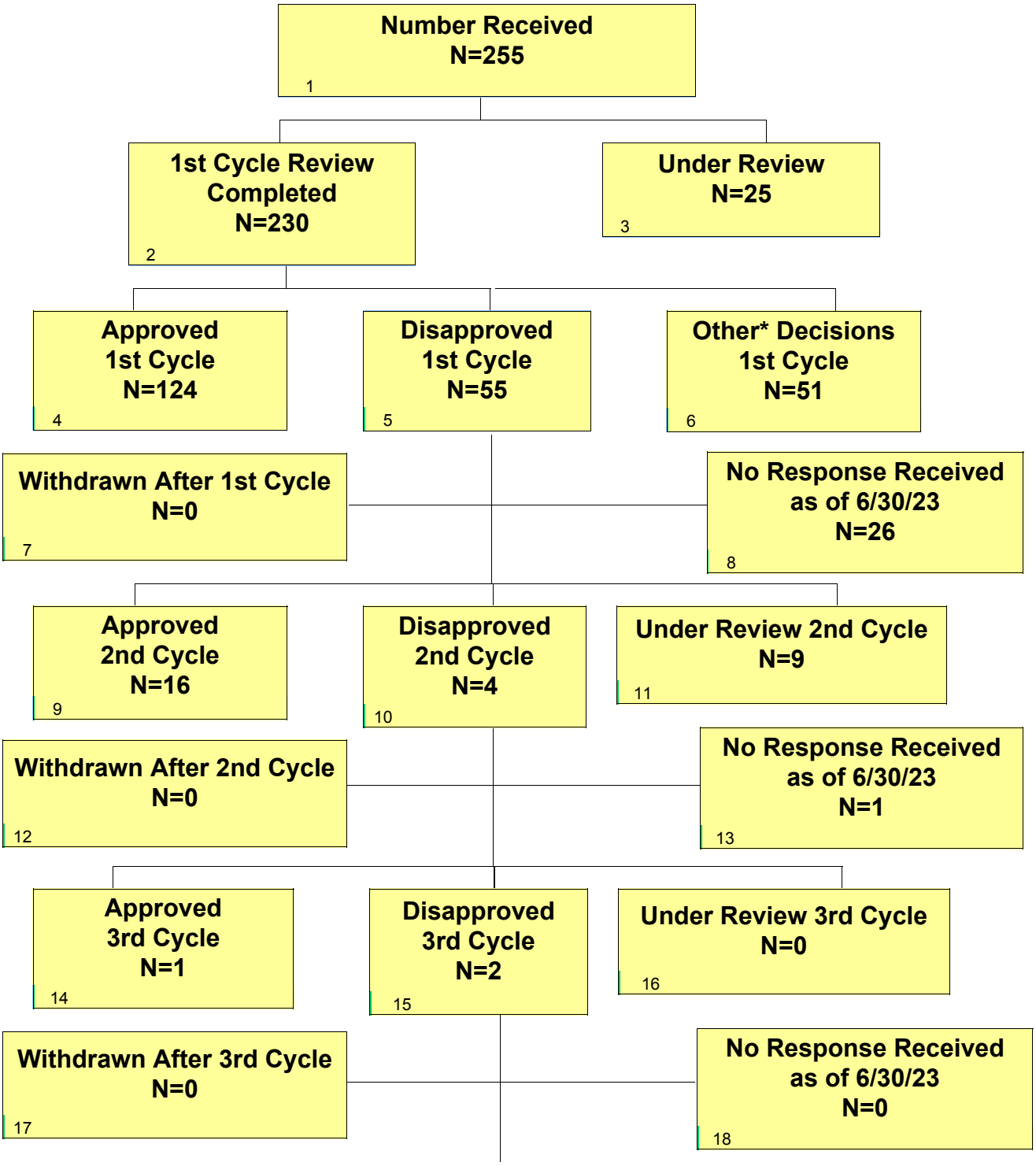
Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number of Meetings Not Scheduled By Day 30	5				
Average Days to Scheduling for Meetings Scheduled After Day 30	44.00				

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]	114				
Meeting Minutes Submitted Within 15 Days of Meeting	83				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	5				
Meeting Minutes Past 15 Days of Meeting	23				
Meeting Minutes Not Submitted and >15 Days Since Meeting	3				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	76.15%				

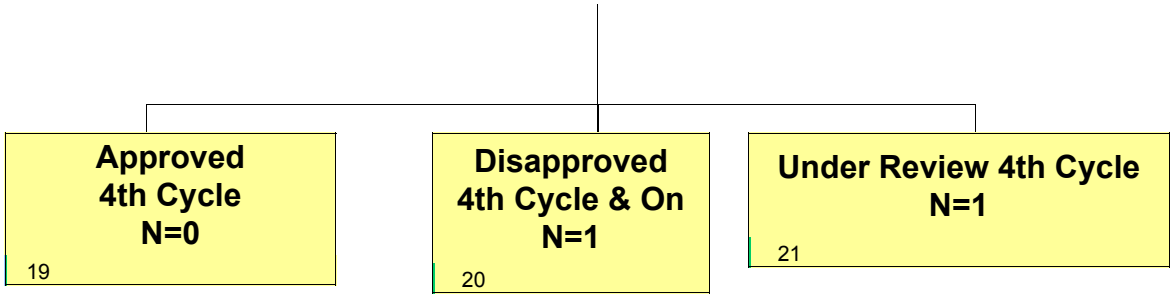
1. Number of meetings requested and then held after written feedback is provided.

CDRH IDEs - FY 2023
as of 6/30/23



*** Other decisions include withdrawn (N=9), withdrawn and converted (N=34), RTA (N=0), nonsignificant risk device (N=7), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=1), Basic Physiological Research (N=0).**

CDRH IDEs - FY 2023
as of 6/30/23



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	255				
Average Number of Cycles to IDE Approval or Conditional Approval	1.15				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.15				

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	28				
Average Number of Cycles to IDE Approval or Conditional Approval	1.14				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.14				

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	54				
Average Number of Cycles to IDE Approval or Conditional Approval	1.23				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.23				

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	25				
Average Number of Cycles to IDE Approval or Conditional Approval	1.38				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.38				

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	31				
Average Number of Cycles to IDE Approval or Conditional Approval	1.10				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.10				

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	57				
Average Number of Cycles to IDE Approval or Conditional Approval	1.12				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.12				

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	17				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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	35				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

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				
Average Number of Cycles to IDE Approval or Conditional Approval	1.50				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.50				

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.

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 submissions with MDUFA decision (line 3) made within 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.

Quarterly Update on
Medical Device Performance Goals
---- MDUFA V CBER Performance Data ----
Actions through 30 June 2023

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	2				
Closed Before RTA Action	0				
Number with Accepted RTA Review	2				
Number Without a RTA Review and > 15 Days Since Date Received	0				
Number Without a RTA Review and <= 15 Days Since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of Submissions Not Accepted for Filing Review	0.00%				

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	2				
Number Accepted	2				
Completed RTF	2				
Number Not Filed	0				
Rate of Submissions Not Filed	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	2				
SI Goal Met	2				
SI Goal Not Met	0				
SI Pending Within Goal	0				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	100.00%				

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	2				
Average Number of FDA Days to Substantive Interaction	89.00				
20th Percentile FDA Days to Substantive Interaction	88				
40th Percentile FDA Days to Substantive Interaction	89				
60th Percentile FDA Days to Substantive Interaction	89				
80th Percentile FDA Days to Substantive Interaction	90				
Maximum FDA Days to Substantive Interaction	90				

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

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

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number with MDUFA V Decision	1				
Average FDA Days to MDUFA V Decision	179.00				
20th Percentile FDA Days to MDUFA V Decision	179				
40th Percentile FDA Days to MDUFA V Decision	179				
60th Percentile FDA Days to MDUFA V Decision	179				
80th Percentile FDA Days to MDUFA V Decision	179				
Maximum FDA Days to MDUFA V Decision	179				
Average Industry Days to MDUFA V Decision	0.00				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	0				
Maximum Industry Days to MDUFA V Decision	0				
Average Total Days to MDUFA V Decision	179.00				
20th Percentile Total Days to MDUFA V Decision	179				
40th Percentile Total Days to MDUFA V Decision	179				
60th Percentile Total Days to MDUFA V Decision	179				
80th Percentile Total Days to MDUFA V Decision	179				
Maximum Total Days to MDUFA V Decision	179				

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

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Filed	2				
Number with MDUFA V Decision	1				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	0.00%				
Rate of Not Approvable	0.00%				

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				
Number With MDUFA V Decision	0				
Number of Withdrawal	0				
Number of Not Approvable	0				
Number of Deleted	0				
Rate of Withdrawal	N/A				
Rate of Not Approvable	N/A				

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

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

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

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

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

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

***Includes submission that went to panel**

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

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

***Includes submission that went to panel**

Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 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				
SI Goal Met	0				
SI Goal Not Met	2				
SI Pending Within Goal	1				
SI Pending Past Goal	0				
Closed Without SI	0				
Current SI Performance Percent Goal Met	0.00%				

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	3				
Non-MDUFA V Decision	0				
MDUFA V Decision	1				
MDUFA V Decision Goal Met	1				
Supplements Pending MDUFA V Decision	2				
Supplements Pending MDUFA V Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	3				
Number with MDUFA V Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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	0				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	2				
Non-MDUFA V Decision	0				
MDUFA V Decision	1				
MDUFA V Decision Goal Met	1				
Supplements Pending MDUFA V Decision	1				
Supplements Pending MDUFA V Decision Past Goal	0				
Current Performance Percent Goal Met	100.00%				

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	2				
Number With MDUFA V Decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0.00%				

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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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	29				
Closed Before First RTA or TS Action [1]	0				
Number Accepted or Passed TS on First Cycle [2]	22				
Number Without a RTA or TS Review and > 15 Days Since Date Received [3]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received [1]	0				
Number Not Accepted or Failed TS on First Cycle [2]	7				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2]	24.14%				

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

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	26				
Deleted or Withdrawn Prior to SI	0				
SI Within 60 FDA Days	21				
SI Over 60 FDA Days	0				
SI Pending Within 60 FDA Days	3				
SI Pending Over 60 FDA Days	2				
510(k)s NSE Without SI	0				
Current SI Performance Percent Within 60 FDA Days	91.30%				

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	21				
Average Number of FDA Days to Substantive Interaction	51.52				
20th Percentile FDA Days to Substantive Interaction	49				
40th Percentile FDA Days to Substantive Interaction	55				
60th Percentile FDA Days to Substantive Interaction	57				
80th Percentile FDA Days to Substantive Interaction	59				
Maximum FDA Days to Substantive Interaction	60				

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	26				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	13				
MDUFA V Decision Within 90 FDA Days	13				
510(k)s Pending MDUFA V Decision	13				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	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	1.15				
Number With MDUFA V Decision	13				
Average Number of FDA Days to MDUFA V Decision	72.54				
20th Percentile FDA Days to MDUFA V Decision	50				
40th Percentile FDA Days to MDUFA V Decision	81				
60th Percentile FDA Days to MDUFA V Decision	85				
80th Percentile FDA Days to MDUFA V Decision	90				
Maximum FDA Days to MDUFA V Decision	90				
Average Number of Industry Days to MDUFA V Decision	13.15				
20th Percentile Industry Days to MDUFA V Decision	0				
40th Percentile Industry Days to MDUFA V Decision	0				
60th Percentile Industry Days to MDUFA V Decision	0				
80th Percentile Industry Days to MDUFA V Decision	0				
Maximum Industry Days to MDUFA V Decision	115				
Average Number of Total Days to MDUFA V Decision	85.69				
20th Percentile Total Days to MDUFA V Decision	50				
40th Percentile Total Days to MDUFA V Decision	83				
60th Percentile Total Days to MDUFA V Decision	86				
80th Percentile Total Days to MDUFA V Decision	90				
Maximum Total Days to MDUFA V Decision	196				

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	26				
Number With MDUFA V Decision	13				
Number of SE Decision	13				
Number of NSE Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of SE Decision	100.00%				
Rate of NSE Decision	0.00%				
Rate of Withdrawal	0.00%				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	N/A				
Mean Industry Days for Submissions that Missed the Goal	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				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	0				
MDUFA V Decision Within 90 FDA Days	0				
510(k)s Pending MDUFA V Decision	0				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	N/A				

Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA 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				
Non-MDUFA V Decision	0				
MDUFA V Decision (SE/NSE)	2				
MDUFA V Decision Within 90 FDA Days	2				
510(k)s Pending MDUFA V Decision	5				
510(k)s Pending MDUFA V Decision Over 90 FDA Days	0				
Current Performance Percent Within 90 FDA Days	100.00%				

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				
Closed Before First RTA or TS Action	0				
Number Accepted or Passed TS on First Cycle	0				
Number Without a RTA or TS Review and > 15 Days Since Date Received [1]	0				
Number Without a RTA or TS Review and <= 15 Days Since Date Received	0				
Number Not Accepted or Failed TS on First Cycle	1				
Rate of Submissions Not Accepted for Review or Failed TS on First Cycle	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 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				
Non-MDUFA Decision	0				
MDUFA Decision	0				
MDUFA Decision Within 150 FDA Days	0				
De Novos Pending MDUFA Decision	1				
De Novos Pending MDUFA Decision Over 150 FDA Days	0				
Current Performance Percent Within 150 FDA Days	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	0.00				
Number With MDUFA Decision	0				
Average FDA Days to MDUFA Decision	0.00				
20th Percentile FDA Days to MDUFA Decision	0				
40th Percentile FDA Days to MDUFA Decision	0				
60th Percentile FDA Days to MDUFA Decision	0				
80th Percentile FDA Days to MDUFA Decision	0				
Maximum FDA Days to MDUFA Decision	0				
Average Industry Days to MDUFA Decision	0.00				
20th Percentile Industry Days to MDUFA Decision	0				
40th Percentile Industry Days to MDUFA Decision	0				
60th Percentile Industry Days to MDUFA Decision	0				
80th Percentile Industry Days to MDUFA Decision	0				
Maximum Industry Days to MDUFA Decision	0				
Average Total Days to MDUFA Decision	0.00				
20th Percentile Total Days to MDUFA Decision	0				
40th Percentile Total Days to MDUFA Decision	0				
60th Percentile Total Days to MDUFA Decision	0				
80th Percentile Total Days to MDUFA Decision	0				
Maximum Total Days to MDUFA Decision	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				
Number With MDUFA Decision	0				
Number With Granted Decision	0				
Number With Declined Decision	0				
Number of Withdrawal	0				
Number of Deleted	0				
Rate of Granted Decision	N/A				
Rate of Declined Decision	N/A				
Rate of Withdrawal	N/A				
Rate of Deleted	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				
Mean FDA Days for Submissions that Missed the Goal	0.00				
Mean Industry Days for Submissions that Missed the Goal	0.00				

Table 8.6 CBER - LDT De Novo MDUFA V Decision Metrics

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

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

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

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

Performance Metric	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
Number Received	48				
Interactions for Breakthrough Designated Products & Products Included in STeP	2				
Number Closed Before First RTA Action	7				
Number Accepted First RTA Cycle [1]	35				
Number Without First Cycle RTA Review and > 15 Days Since Date Received [2]	3				
Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending)	1				
Number Not Accepted First RTA Cycle	0				
Rate of Submissions Not Accepted for Review on First RTA Cycle	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	35				
Number with Non-MDUFA Action [3]	7				
Number with MDUFA Action	32				
Written Feedback Provided Within Goal	31				
Number Pending MDUFA Action	3				
Pending MDUFA Action Past Goal	0				
Number in MDUFA Cohort (up to max 4300)[4]	35				
Current Performance Percent Within Goal	96.88%				

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	31				
Average FDA Days to Written Feedback	59.87				
20th Percentile FDA Days to Written Feedback	54				
40th Percentile FDA Days to Written Feedback	60				
60th Percentile FDA Days to Written Feedback	63				
80th Percentile FDA Days to Written Feedback	70				
Maximum FDA Days to Written Feedback	72				

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				
Average Days to Scheduling for Meetings Scheduled After Day 30	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]	14				
Meeting Minutes Submitted Within 15 Days of Meeting	12				
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0				
Meeting Minutes Past 15 Days of Meeting	2				
Meeting Minutes Not Submitted and >15 Days Since Meeting	0				
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	85.71%				

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	19				
Average Number of Cycles to IDE Approval or Conditional Approval	1.00				
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00				

BLA

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

Guidance Documents

Pursuant to the MDUFA V Commitment Letter,[1] the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA 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]

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2023

#	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	[4]FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
2	Q1	[4]FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
3	Q1	[4]FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals	10/3/2022	Yes	No	N/A	No
4	Q1	[4]User Fees for 513(g) Requests for Information www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-513g-requests-information	10/5/2022	Yes	No	N/A	No

[1] www.fda.gov/media/158308/download.
[2] CDRH provides the annotation of "yes" for guidances that are substantially related to the process. CDRH provides the annotation of "no" for guidances that contain a minimal amount of guidance related to the process.
[3] www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2023-fy2023.
[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
5	Q1	[4]User Fees and Refunds for Premarket Notification Submissions (510(k)s) www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-notification-submissions-510ks	10/5/2022	Yes	No	N/A	No
6	Q1	[4]User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-premarket-approval-applications-and-device-biologics-license-applications	10/5/2022	Yes	No	N/A	No
7	Q1	[4]User Fees and Refunds for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-de-novo-classification-requests	10/5/2022	Yes	No	N/A	No
8	Q1	Procedures for Handling Post-Approval Studies Imposed by PMA Order www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-handling-post-approval-studies-imposed-pma-order	10/7/2022	Yes	No	N/A	A-List
9	Q1	Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-surveillance-under-section-522-federal-food-drug-and-cosmetic-act	10/7/2022	Yes	No	N/A	A-List
10	Q1	Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-breakthrough-devices-program-guidance-reducing-disparities-health-and-health-care	10/21/2022	Yes	No	N/A	A-List
11	Q1	[4]Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions	10/26/2022	Yes	Yes	MDUFA V Commitment Letter V.B.	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
12	Q1	Referencing the Definition of "Device" in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents www.fda.gov/regulatory-information/search-fda-guidance-documents/referencing-definition-device-federal-food-drug-and-cosmetic-act-guidance-regulatory-documents	11/14/2022	No	No	N/A	No
13	Q1	Voluntary Malfunction Summary Reporting (VMSR) Program for Manufacturers www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-malfunction-summary-reporting-vmsr-program-manufacturers	12/9/2022	Yes	No	N/A	A-List
14	Q1	Content of Human Factors Information in Medical Device Marketing Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions	12/9/2022	Yes	No	N/A	B-List
15	Q1	Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection (December 2022) www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-or-device-inspection-december	12/16/2022	No	No	N/A	No
16	Q2	[4]Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-evaluating-impact-viral-mutations-covid-19-tests-revised	1/12/2023	No	No	N/A	No
17	Q2	[4]Policy for Coronavirus Disease-2019 Tests (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-revised	1/12/2023	No	No	N/A	No
18	Q2	Photobiomodulation (PBM) Devices - Premarket Notification [510(k)] Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/photobiomodulation-pbm-devices-premarket-notification-510k-submissions	1/12/2023	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q2	Surveying, Leveling, and Alignment Laser Products www.fda.gov/regulatory-information/search-fda-guidance-documents/surveying-leveling-and-alignment-laser-products	1/31/2023	No	No	N/A	No
20	Q2	[4]Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-and-premarket-notification-510k-submissions-ultrasonic-diathermy-devices	2/21/2023	Yes	No	N/A	No
21	Q2	[4]Medical X-Ray Imaging Devices Conformance with IEC Standards www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards	2/21/2023	Yes	No	N/A	No
22	Q2	[4]Marketing Clearance of Diagnostic Ultrasound Systems and Transducers www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers	2/21/2023	Yes	No	N/A	No
23	Q2	[4]Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56) www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56	2/21/2023	No	No	N/A	No
24	Q2	[4]Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide www.fda.gov/regulatory-information/search-fda-guidance-documents/performance-standard-diagnostic-x-ray-systems-and-their-major-components-21cfr-102030-102031-102032	2/21/2023	No	No	N/A	No
25	Q2	[4]Guidance for Industry and Food and Drug Administration Staff - Assembler's Guide to Diagnostic X-Ray Equipment www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-food-and-drug-administration-staff-assemblers-guide-diagnostic-x-ray-equipment	2/21/2023	No	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
26	Q2	[4]Enforcement Policy for Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-shields-surgical-masks-and-respirators-during-coronavirus-disease-covid-19	3/13/2023	Yes	No	N/A	No
27	Q2	[4]Enforcement Policy for Face Masks and Barrier Face Coverings During the Coronavirus Disease (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-barrier-face-coverings-during-coronavirus-disease-covid-19-public	3/13/2023	Yes	No	N/A	No
28	Q2	Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-systems-electronic-records-and-electronic-signatures-clinical-investigations-questions	3/16/2023	No	No	N/A	No
29	Q2	Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease	3/27/2023	Yes	No	N/A	A-List
30	Q2	Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) Related to Coronavirus Disease 2019 (COVID-19) www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease	3/27/2023	Yes	No	N/A	A-List
31	Q2	Soft (Hydrophilic) Daily Wear Contact Lenses - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/soft-hydrophilic-daily-wear-contact-lenses-performance-criteria-safety-and-performance-based-pathway	3/28/2023	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
32	Q2	General Considerations for Animal Studies Intended to Evaluate Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/general-considerations-animal-studies-intended-evaluate-medical-devices	3/28/2023	Yes	No	N/A	No
33	Q2	Orthopedic Non-Spinal Bone Plates, Screws, and Washers - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-non-spinal-bone-plates-screws-and-washers-premarket-notification-510k-submissions	3/29/2023	Yes	No	N/A	No
34	Q2	[5]Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-refuse-accept-policy-cyber-devices-and-related-systems-under-section	3/30/2023	Yes	No	N/A	No
35	Q3	Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial	4/3/2023	Yes	Yes	MDUFA V Commitment Letter V.G.5	B-List
36	Q3	Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-focused-drug-development-incorporating-clinical-outcome-assessments-endpoints-regulatory	4/6/2023	Yes	Yes	Section 3002 of the 21st Century Cures Act	No
37	Q3	A Risk-Based Approach to Monitoring of Clinical Investigations Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/risk-based-approach-monitoring-clinical-investigations-questions-and-answers	4/12/2023	Yes	No	N/A	No

[5] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).

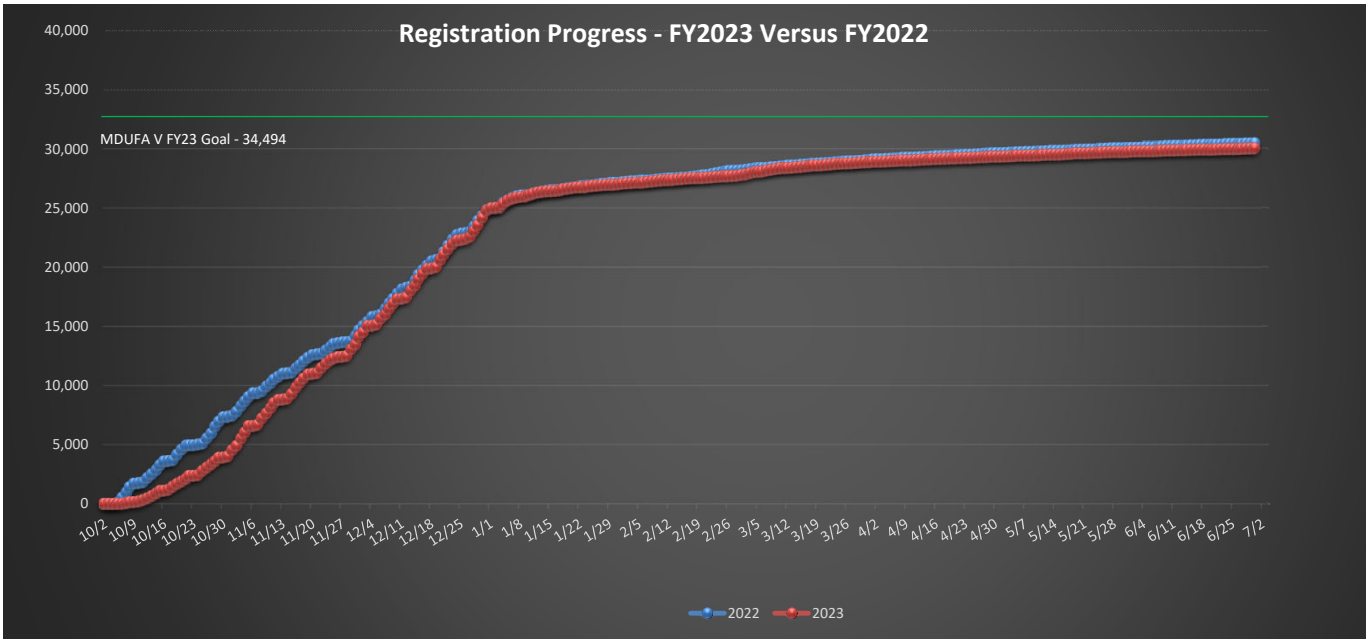
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
38	Q3	Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/peripheral-percutaneous-transluminal-angioplasty-pta-and-specialty-catheters-premarket-notification	4/14/2023	Yes	No	N/A	No
39	Q3	[4]Data Standards Catalog www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog	4/28/2023	Yes	No	N/A	No
40	Q3	Decentralized Clinical Trials for Drugs, Biological Products, and Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices	5/3/2023	Yes	Yes	Section 3606(a) of the Food and Drug Omnibus Reform Act (FDORA)	No
41	Q3	Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/use-whole-slide-imaging-nonclinical-toxicology-studies-questions-and-answers	5/25/2023	Yes	No	N/A	No
42	Q3	Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-performance-assessment-tissue-containment-systems-used-during-power-morcellation	5/26/2023	Yes	No	N/A	No
43	Q3	[4]Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program	6/2/2023	Yes	No	N/A	No
44	Q3	Content of Premarket Submissions for Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions	06/14/2023	Yes	Yes	MDUFA V Commitment Letter V.G.4.	A-List
45	Q3	Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program www.fda.gov/regulatory-information/search-fda-guidance-documents/oncology-drug-products-used-certain-in-vitro-diagnostic-tests-pilot-program	6/20/2023	Yes	No	N/A	No

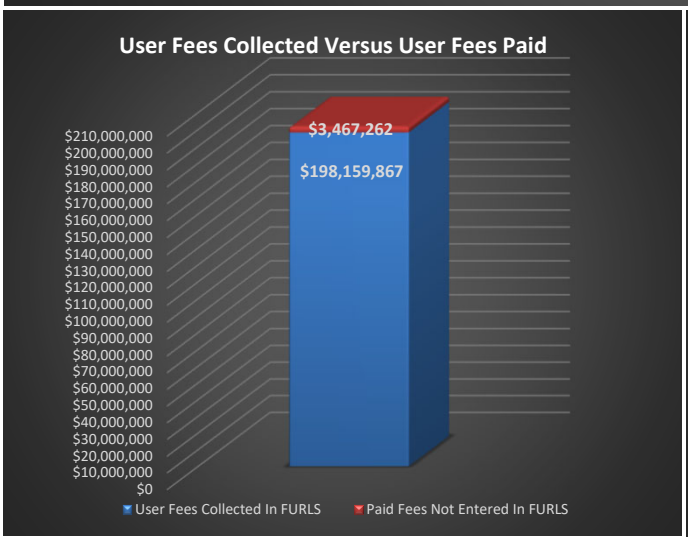
#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
46	Q3	Patient-Matched Guides to Orthopedic Implants www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-matched-guides-orthopedic-implants	6/28/2023	Yes	No	N/A	No

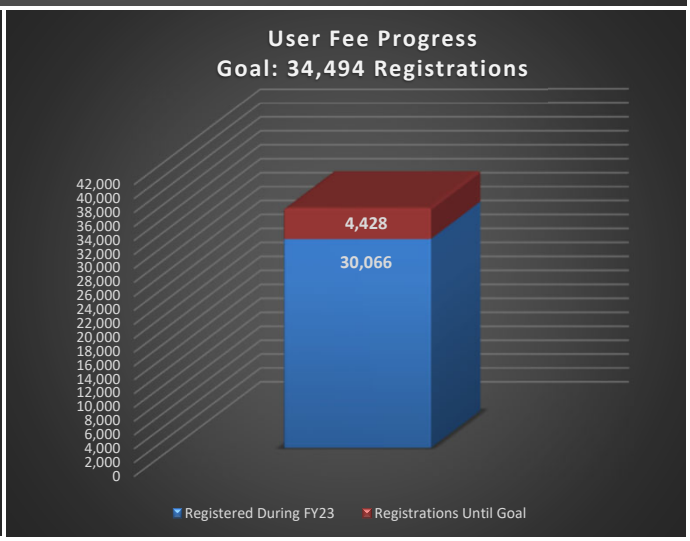
MDUFA V Registrations - 3rd Quarter Summary FY2023*

Current Active Registrations by Type	FY23 Q3			FY22 Year End Active Totals			FY23 vs End FY22
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	6,637	12,164	18,801	6,848	12,892	19,738	95.25%
Contract Manufacturer	1,233	1,847	3,080	1,234	1,798	3,032	101.58%
Contract Sterilizer	74	170	244	68	166	234	104.27%
Specification Developer	1,648	555	2,203	1,768	573	2,341	94.11%
Reprocessor of Single Use Devices	31	4	35	25	5	30	116.67%
U.S. Manufacturer of Export Only Devices	122	0	122	138	0	138	88.41%
Repackager/Relabeler	1,098	219	1,317	1,178	209	1,387	94.95%
Remanufacturer	13	9	22	22	10	32	68.75%
Foreign Exporter/Private Label Distributor		1,103	1,103		1,156	1,156	95.42%
Initial Importer	3,308		3,308	3,640		3,640	90.88%
Unknown	6	13	19	6	12	18	105.56%
Total:	**14,170**	**16,084**	**30,254**	**14,927**	**16,821**	**31,748**	**95.29%**

*Note: This data is current as of 6/30/2023







FY 2023 Medical Device User Fee Collections as of June 30, 2023 Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$198,430,162	-$357,580	$198,072,582		
Application Fees	$69,054,516	-$901,256	$68,153,260		
Total	**$267,484,678**	**-$1,258,835**	**$266,225,843**	**$324,777,000**	**82%**

Medical Device User Fee Collection History Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,281,779	$31,738,775	$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	$147,153,783	$137,774,923
	FY 2018	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
MD IV	$193,892,253	$208,670,231	$214,586,503	$275,072,612	$266,954,734
	FY 2023	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
MD V	$266,225,843				

MDUFA V Commitment Letter - VI. Performance Reports
2.12. Number of discretionary fee waivers or reductions granted by type of submission[1/]

CDRH Data 3rd Quarter FY 2023 by Submission type	# Waived	# Reduced
Full Fee applications[2/]	4	0
PMA	4	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	2	0
De Novo Classification	2	54
180-Day Supplements	2	10
Real-Time Supplements	1	22
510(k)s	41	1,293
30-day Notices /135 day supplements*	10	33
513(g)s	0	51
PMA Annual Report	0	14
Total	**62**	**1,477**

[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**