Individuals using assistive technology may not be able to fully access the information contained in this document. For assistance, please call 1(800) 638-2041 or (301) 796-7100 or send an email to CDRH's Division of Industry and Consumer Education (DICE). Please include "**508 Accommodation**" and the **title of the document** in the subject line of your e-mail.

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

**May 10, 2023, 2:00 – 3:00 pm**
**Zoom**

**Welcome –**

**FDA MDUFA Performance — Actions through March 31, 2023**

- Report on decision goals for 2nd Quarter FY 2023
- Status of Paused IVD Submissions

**Guidance Development**

**Registration and Listing**

**Qualitative Update on Finances – 2nd Quarter FY 2023**

- User fee receipts through the 2nd Quarter FY 2023
- Funding for Non-NEST Organizations (if applicable)

**Annual Hiring Goals Update**

**ASCA Program**

**TAP pilot progress**

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

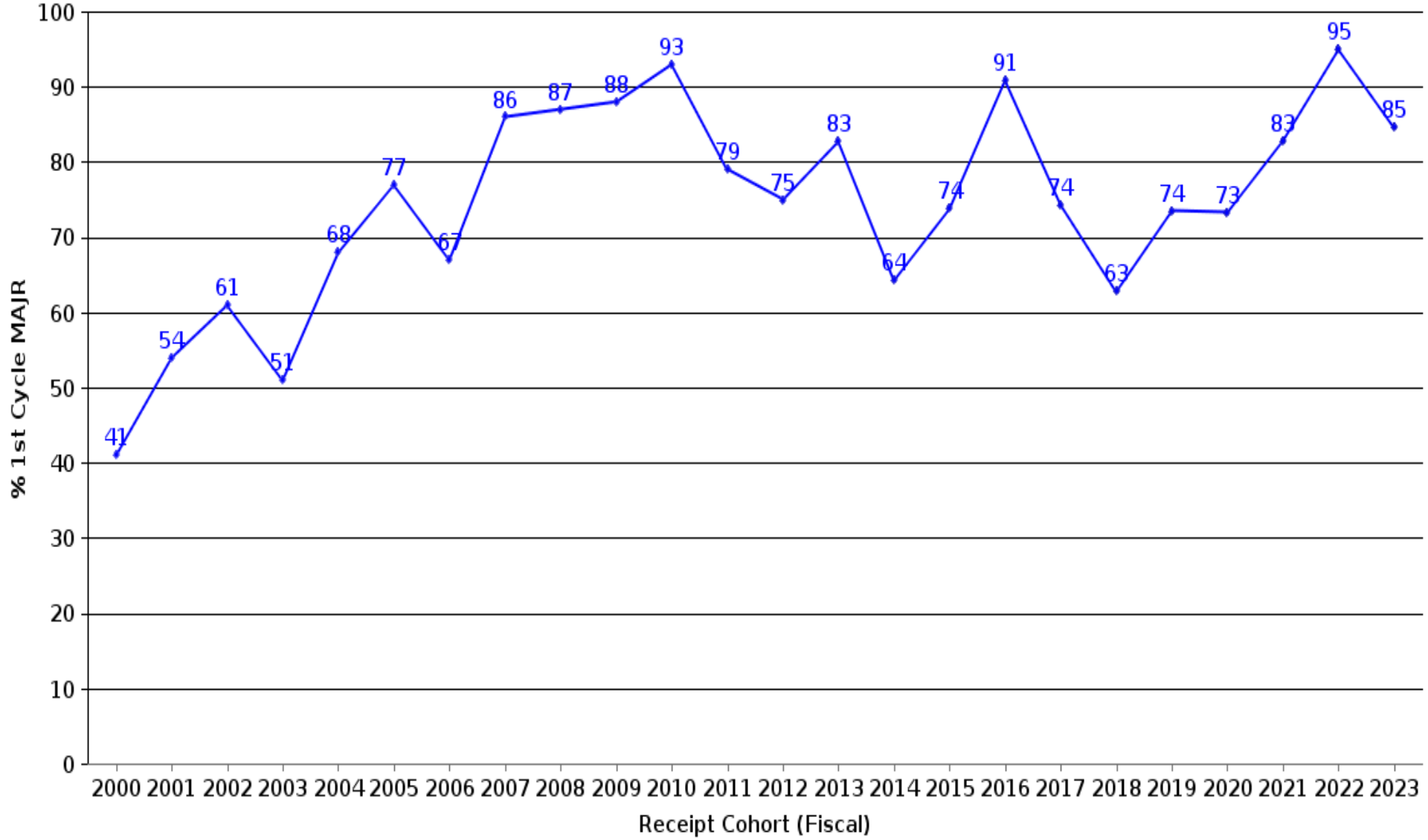
OHT8: Office of Radiological Health

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

# PMAs

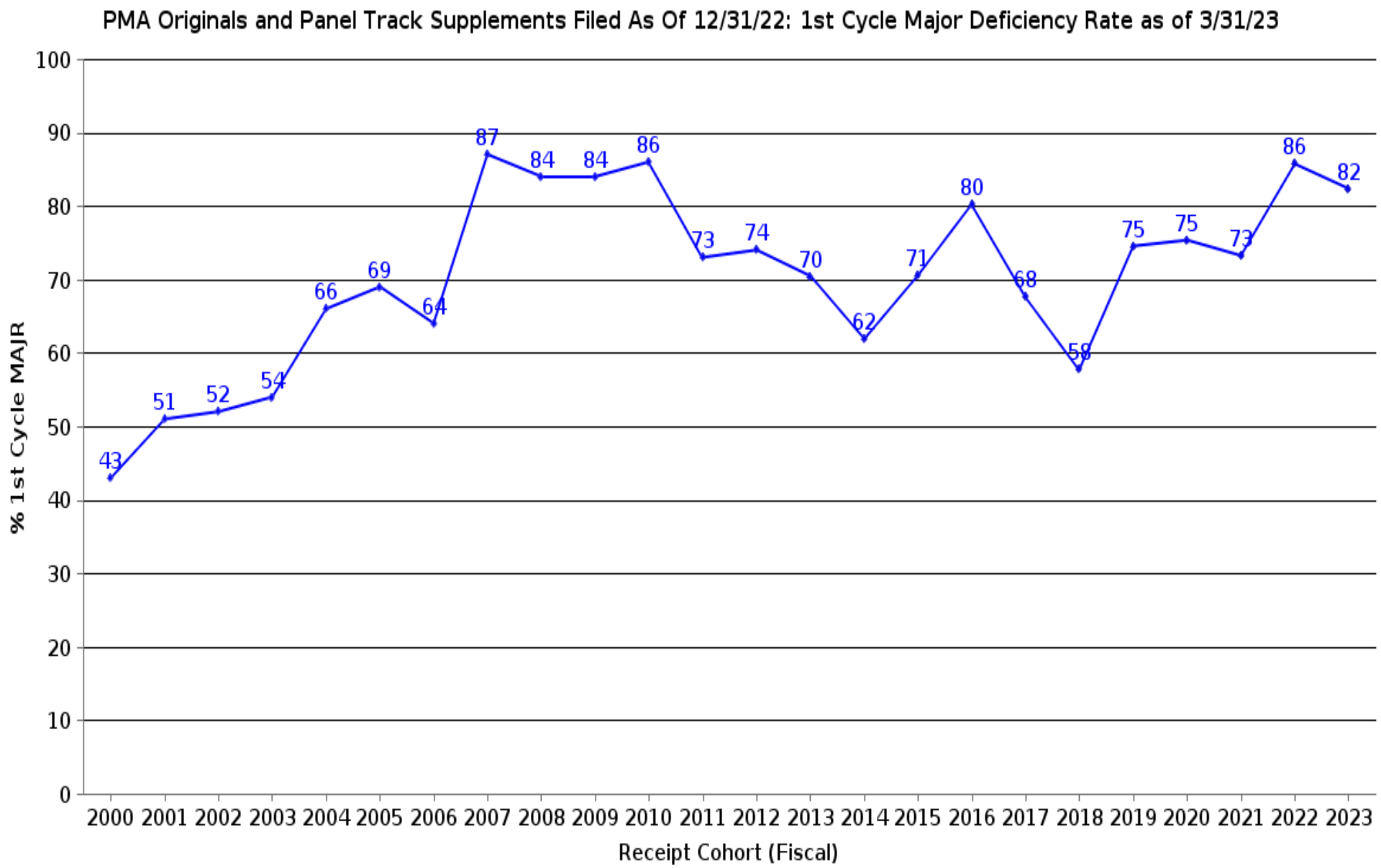
## Q2FY2023

# PMA Originals Filed As Of 12/31/22: 1st Cycle Major Deficiency Rate as of 3/31/23



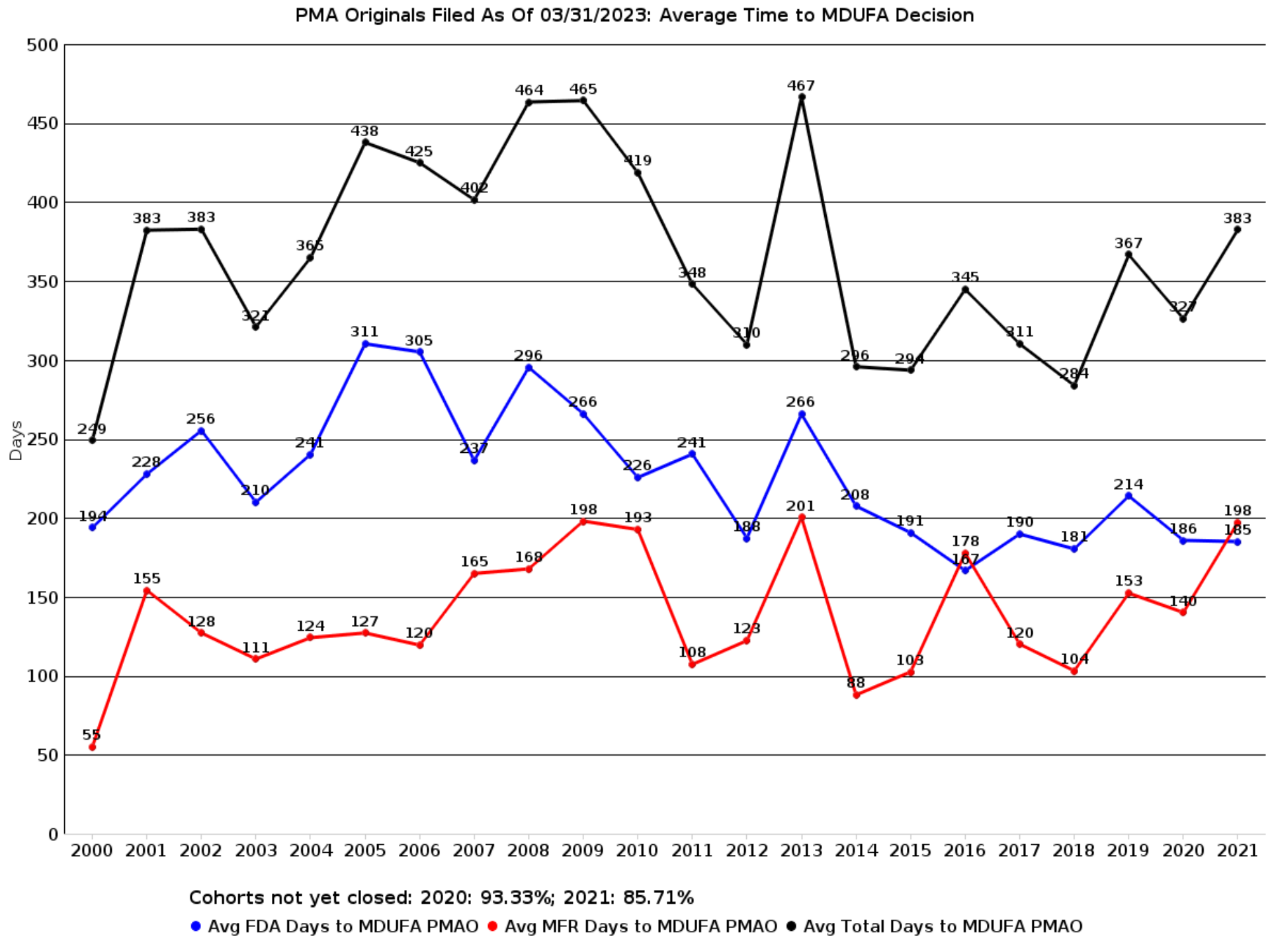

Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 12/31/22.
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

♦ % 1st Cycle MAJR PMAO

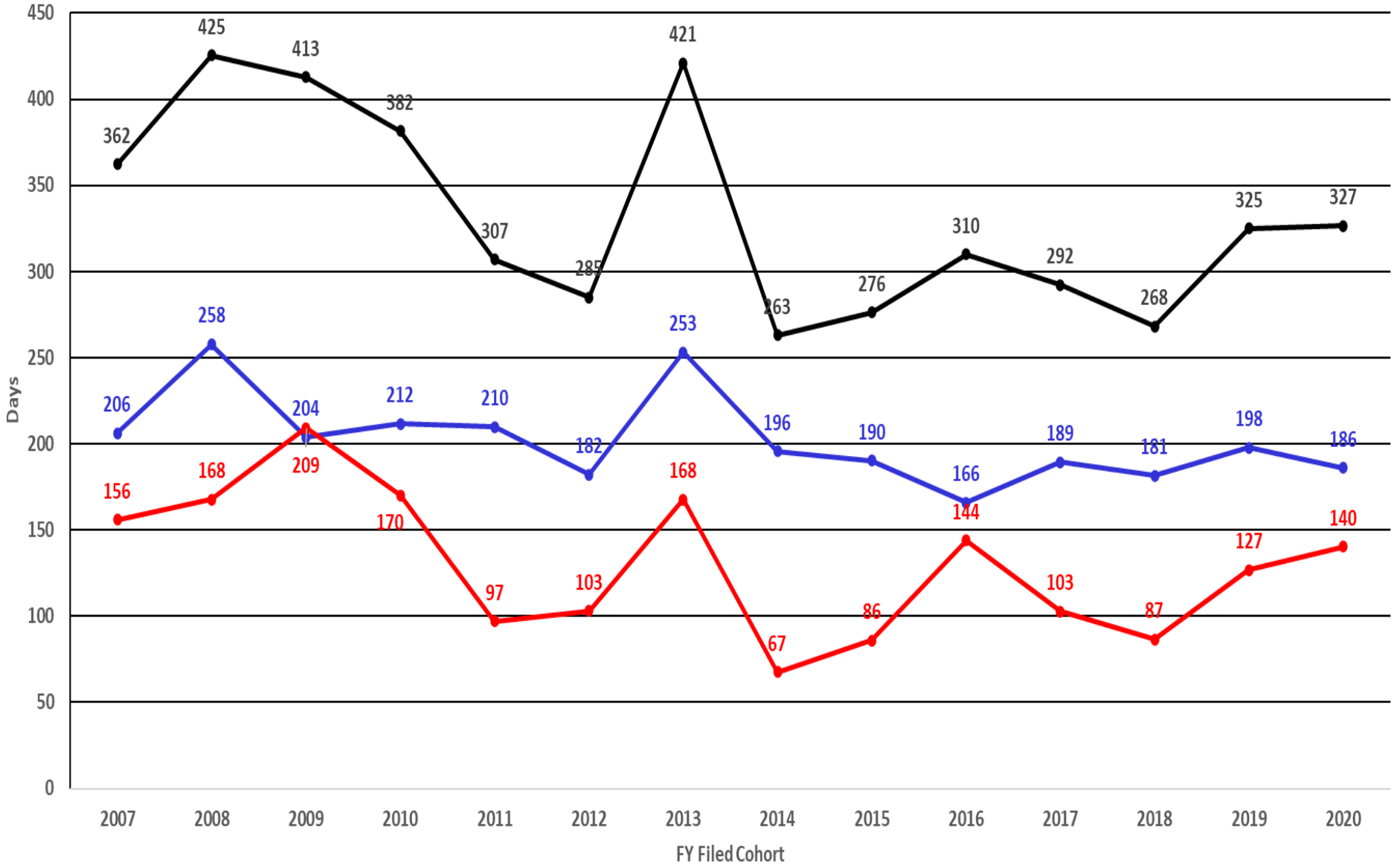



Data are based upon the number of submissions that received a major deficiency letter on the 1st review cycle, calculated as a percentage of the number of submissions with a completed 1st review cycle, for submissions rec'd, accepted & filed as of 12/31/22. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

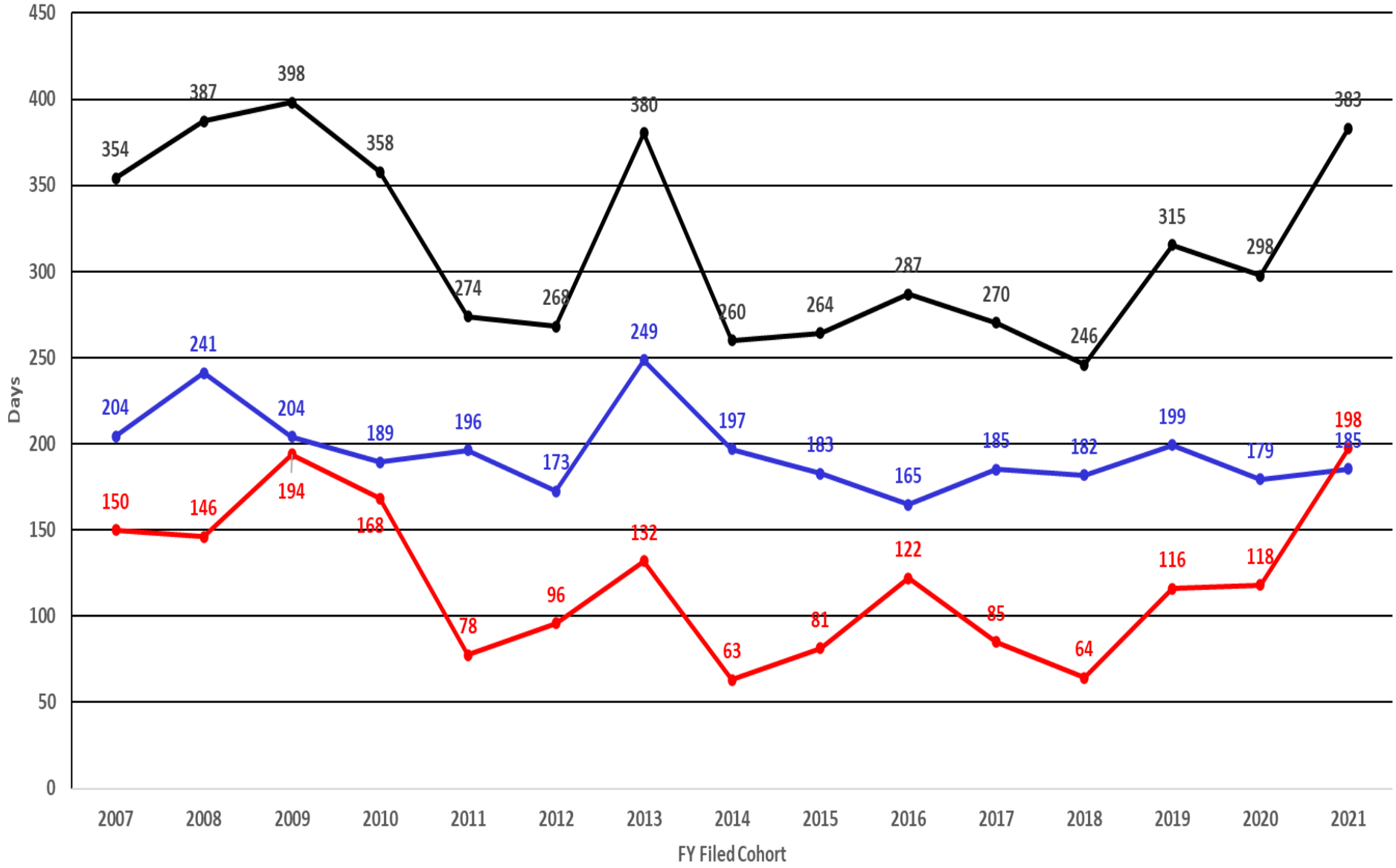
♦ % 1st Cycle MAJR PMAO/PTS

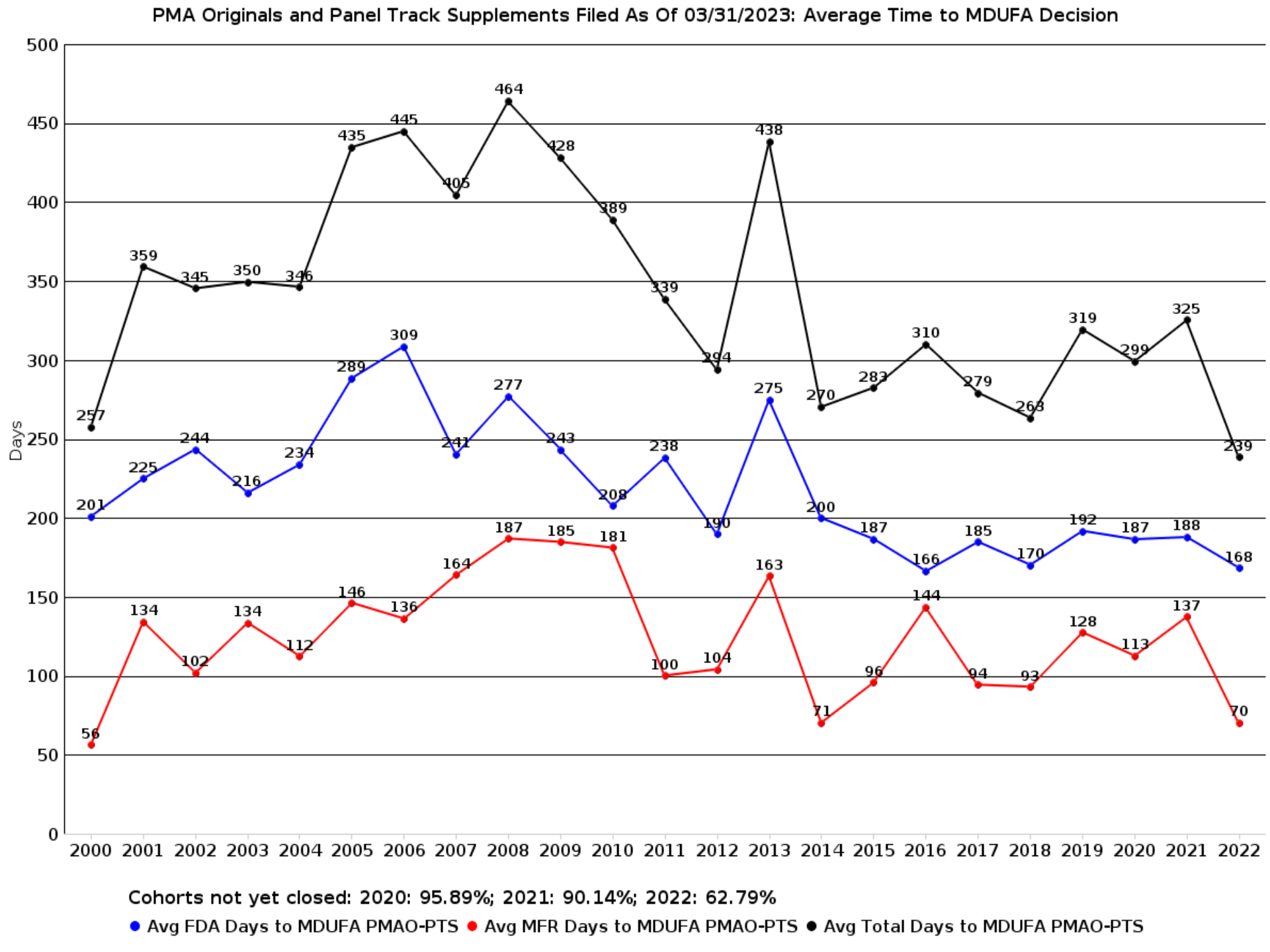

PMA Originals Filed As Of 03/31/2023: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021
249 383 383 321 365 438 425 402 464 465 419 348 310 467 296 294 345 311 284 367 327 383
194 228 256 210 241 311 305 237 296 266 226 241 188 266 208 191 178 190 181 214 186 185
55 155 128 111 124 127 120 165 168 198 193 108 123 201 88 103 167 120 104 153 140 198
Cohorts not yet closed: 2020: 93.33%; 2021: 85.71%
Avg FDA Days to MDUFA PMAO
Avg MFR Days to MDUFA PMAO
Avg Total Days to MDUFA PMAO

# PMA Originals Filed as of 3/31/2023: Average Time to MDUFA Decision
# Comparison of Cohorts at 93.3% Closure

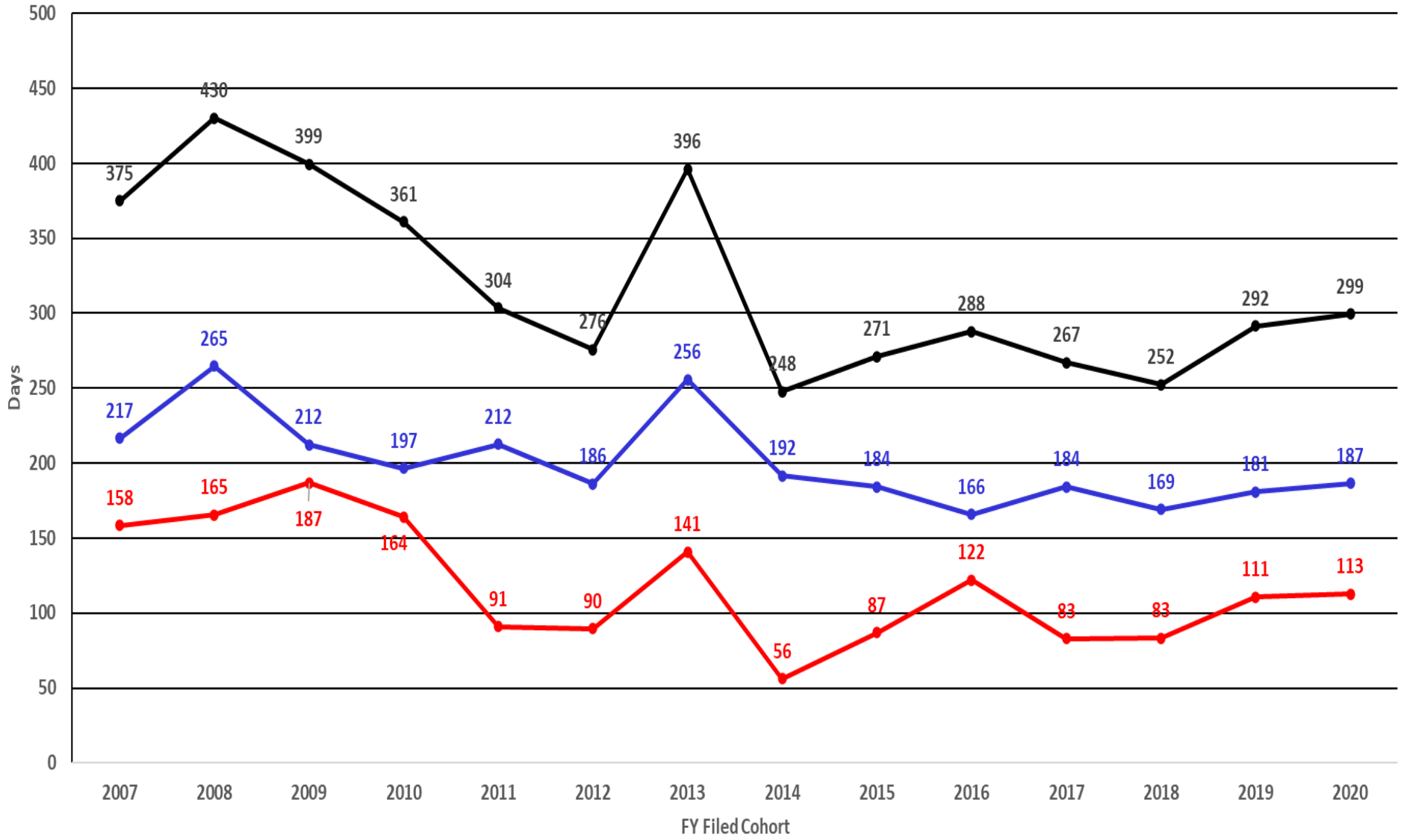


# PMA Originals Filed as of 12/31/2022: Average Time to MDUFA Decision
# Comparison of Cohorts at 85.7% Closure

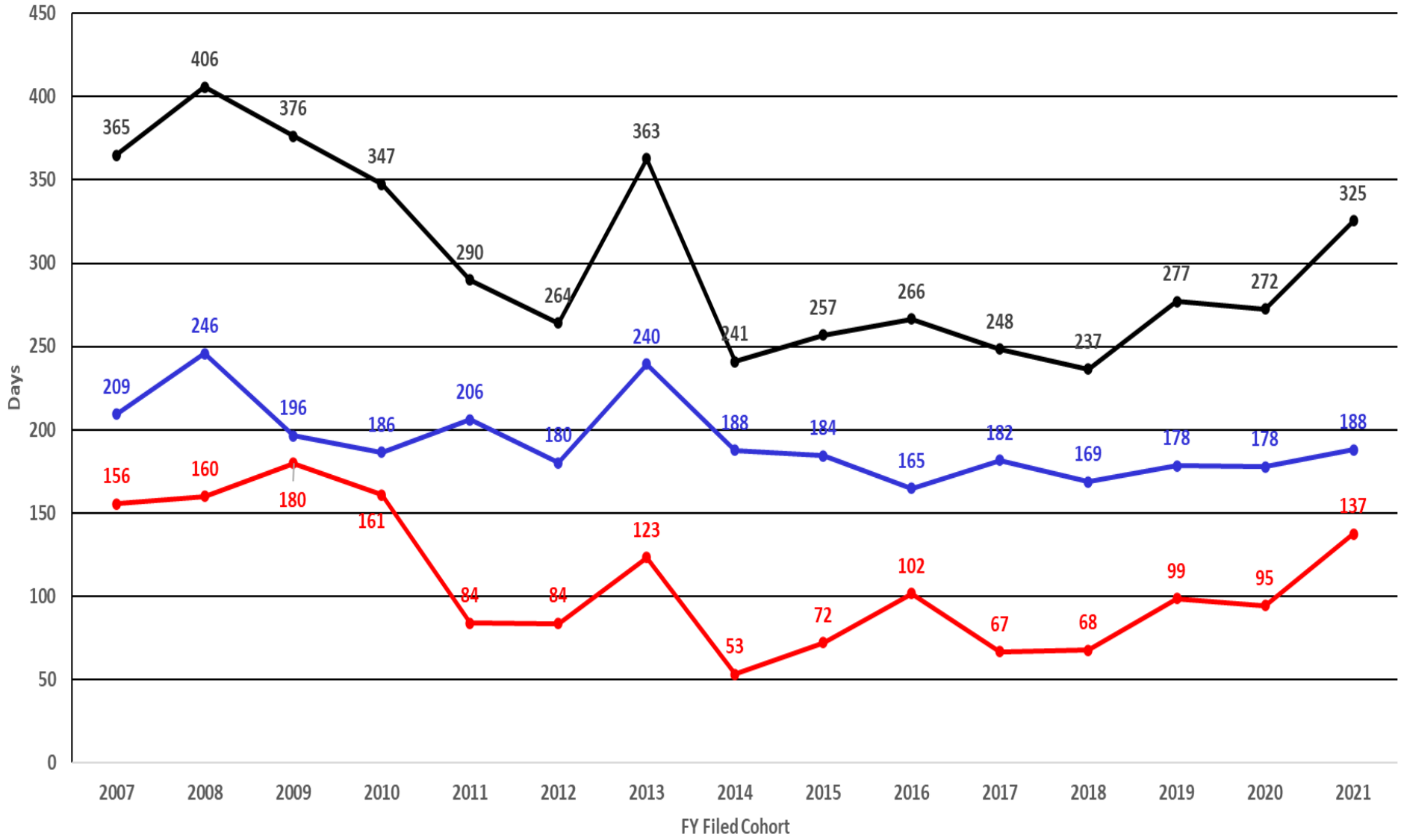



PMA Originals and Panel Track Supplements Filed As Of 03/31/2023: Average Time to MDUFA Decision
Days
500
450
400
350
300
250
200
150
100
50
0
2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022
257 359 345 350 346 435 445 405 464 428 389 339 294 438 270 283 310 279 263 319 299 325 239
201 225 244 216 234 289 309 241 277 243 208 238 190 275 200 187 166 185 170 192 187 188 168
56 134 102 134 112 146 136 164 187 185 181 100 104 163 71 96 144 94 93 128 113 137 70
Cohorts not yet closed: 2020: 95.89%; 2021: 90.14%; 2022: 62.79%
Avg FDA Days to MDUFA PMAO-PTS
Avg MFR Days to MDUFA PMAO-PTS
Avg Total Days to MDUFA PMAO-PTS

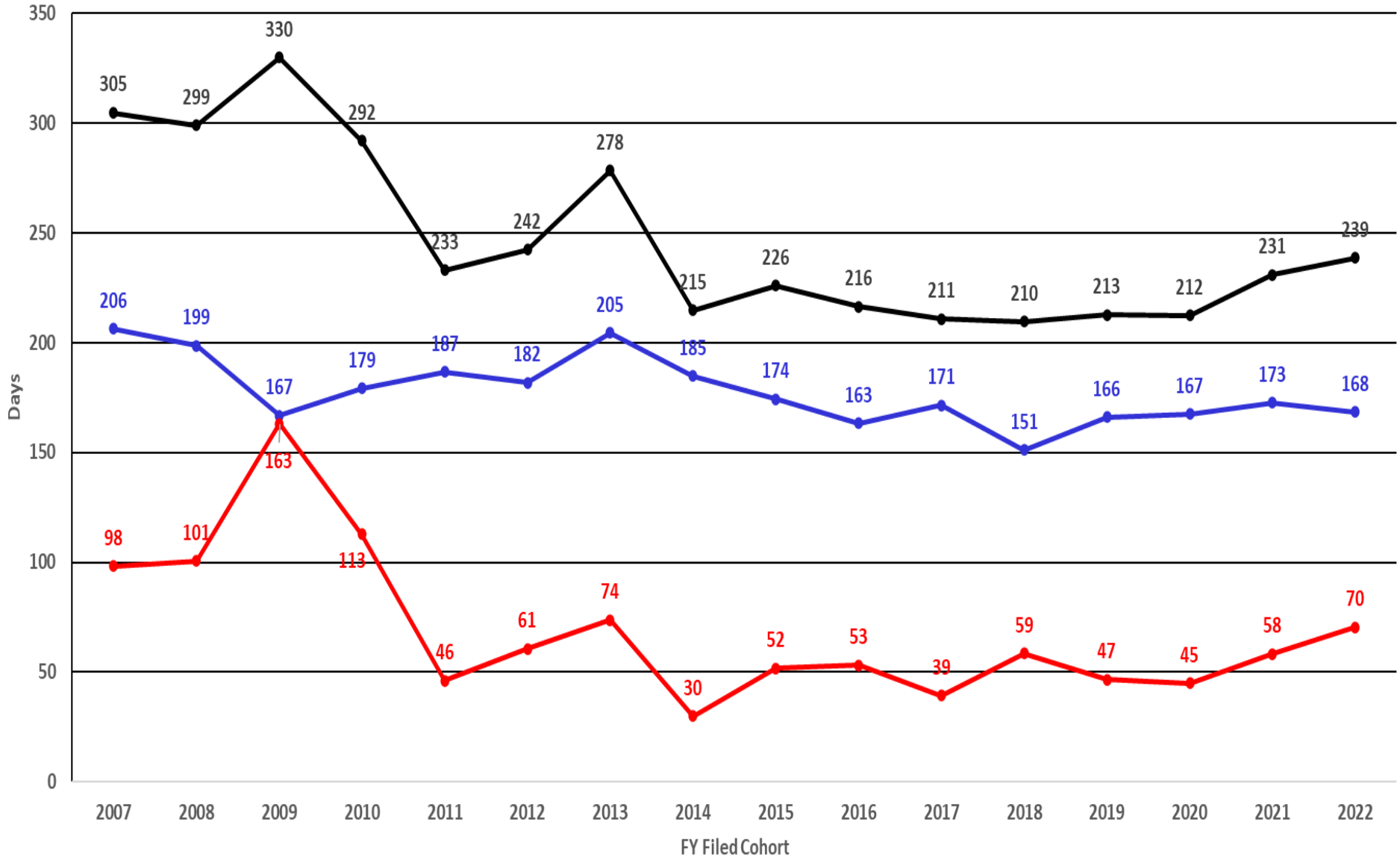
# PMA Originals and Panel Track Supplements Filed as of 3/31/2023: Average Time to MDUFA Decision
# Comparison of Cohorts at 95.89% Closure

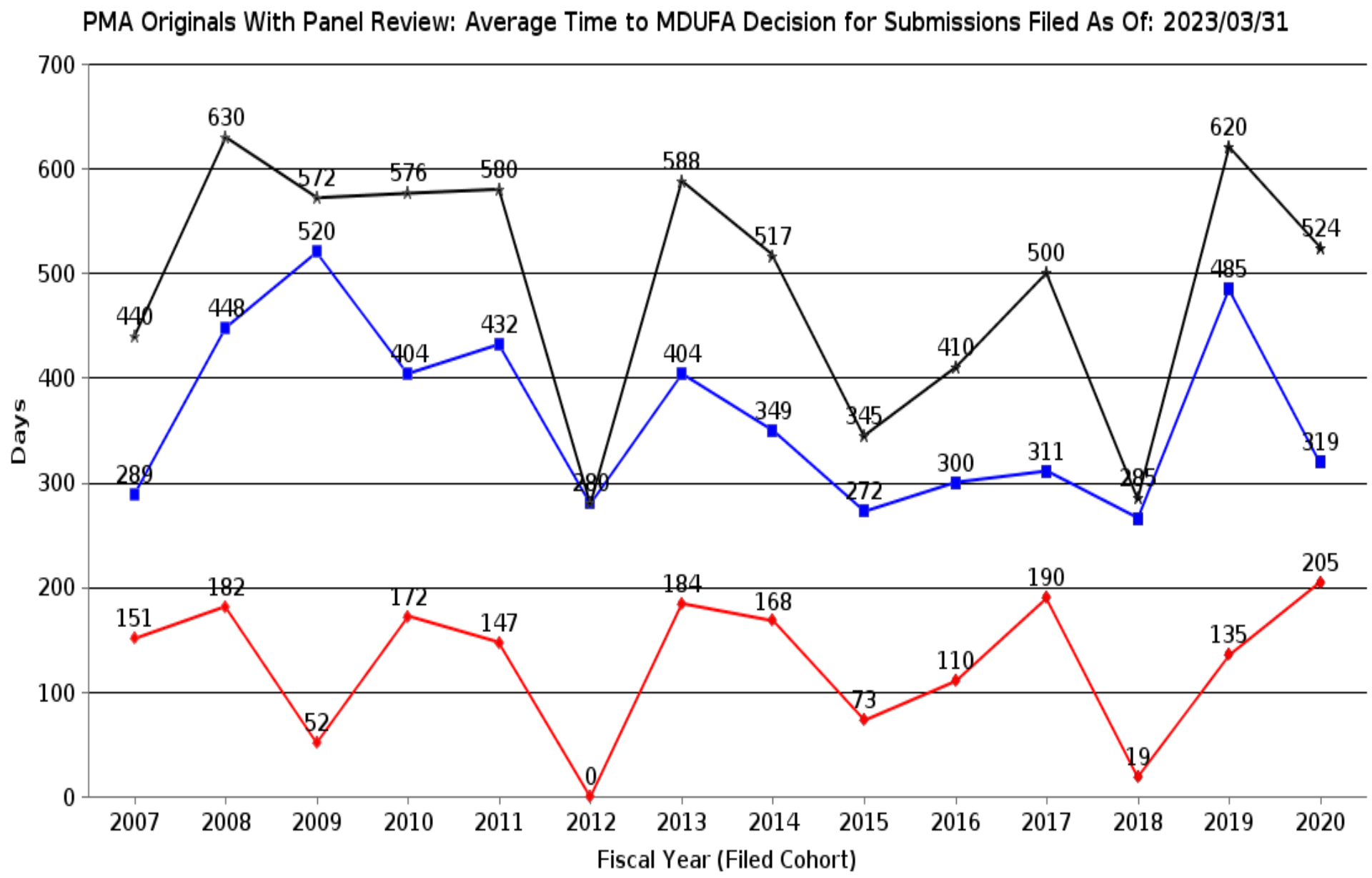


# PMA Originals and Panel Track Supplements Filed as of 3/31/2023: Average Time to MDUFA Decision
# Comparison of Cohorts at 90.1% Closure



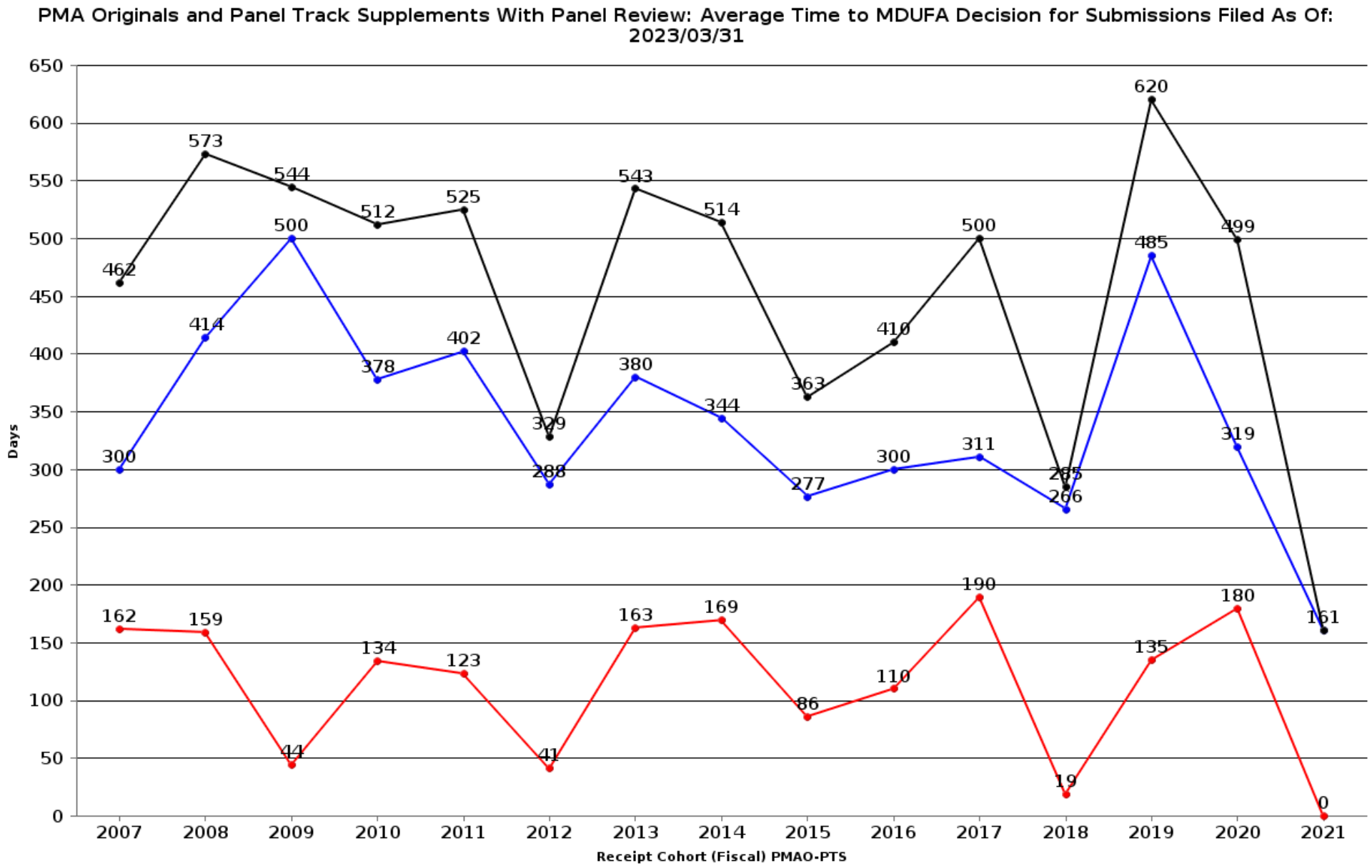
# PMA Originals and Panel Track Supplements Filed as of 3/31/2023: Average Time to MDUFA Decision
## Comparison of Cohorts at 62.8% Closure





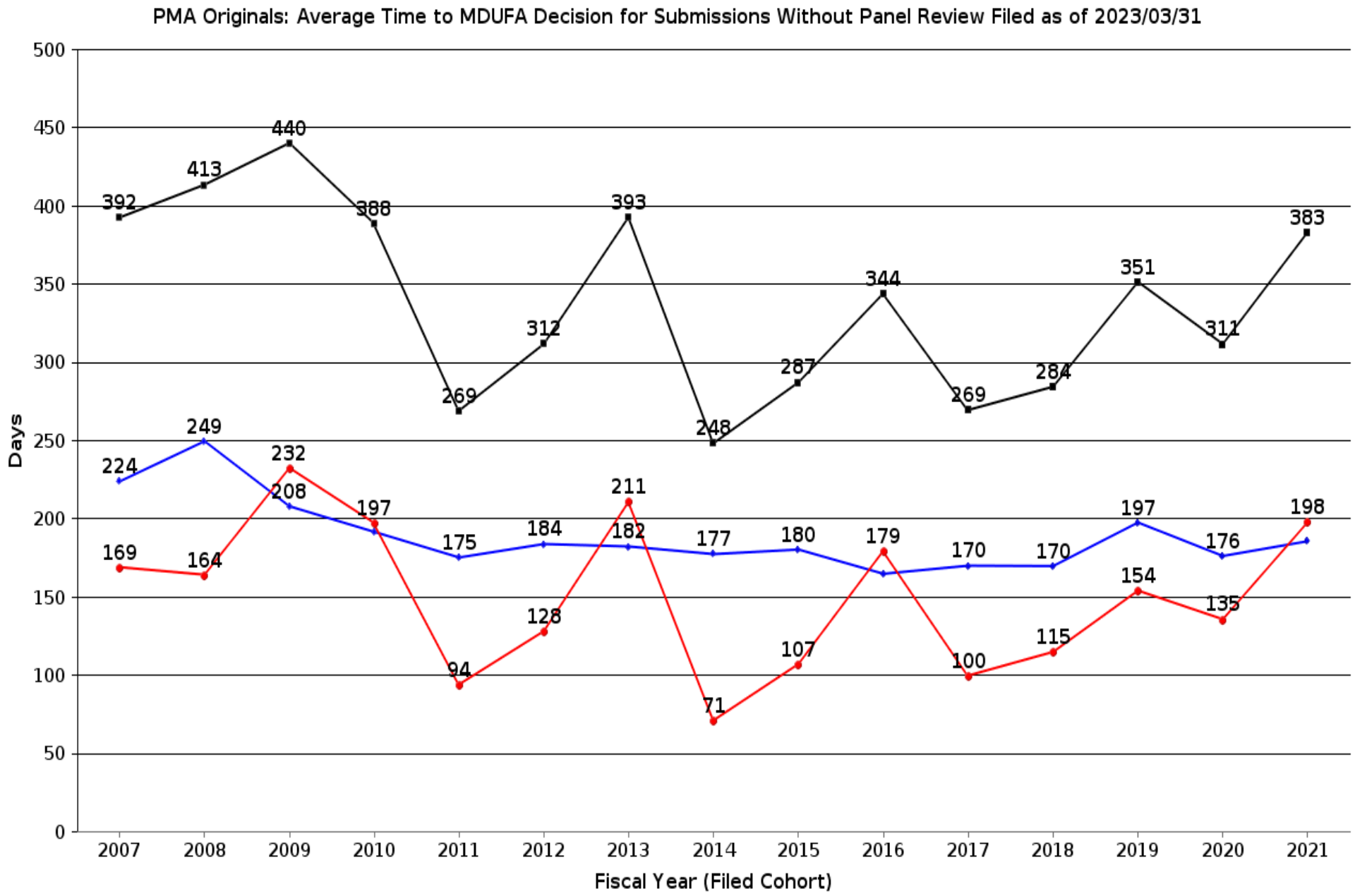

Numbers Filed/Closed: 2007 = 7/7; 2008 = 7/7; 2009 = 6/6; 2010 = 7/7; 2011 = 11/11; 2012 = 1/1; 2013 = 11/11; 2014 = 5/5; 2015 = 5/5; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 3/3

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



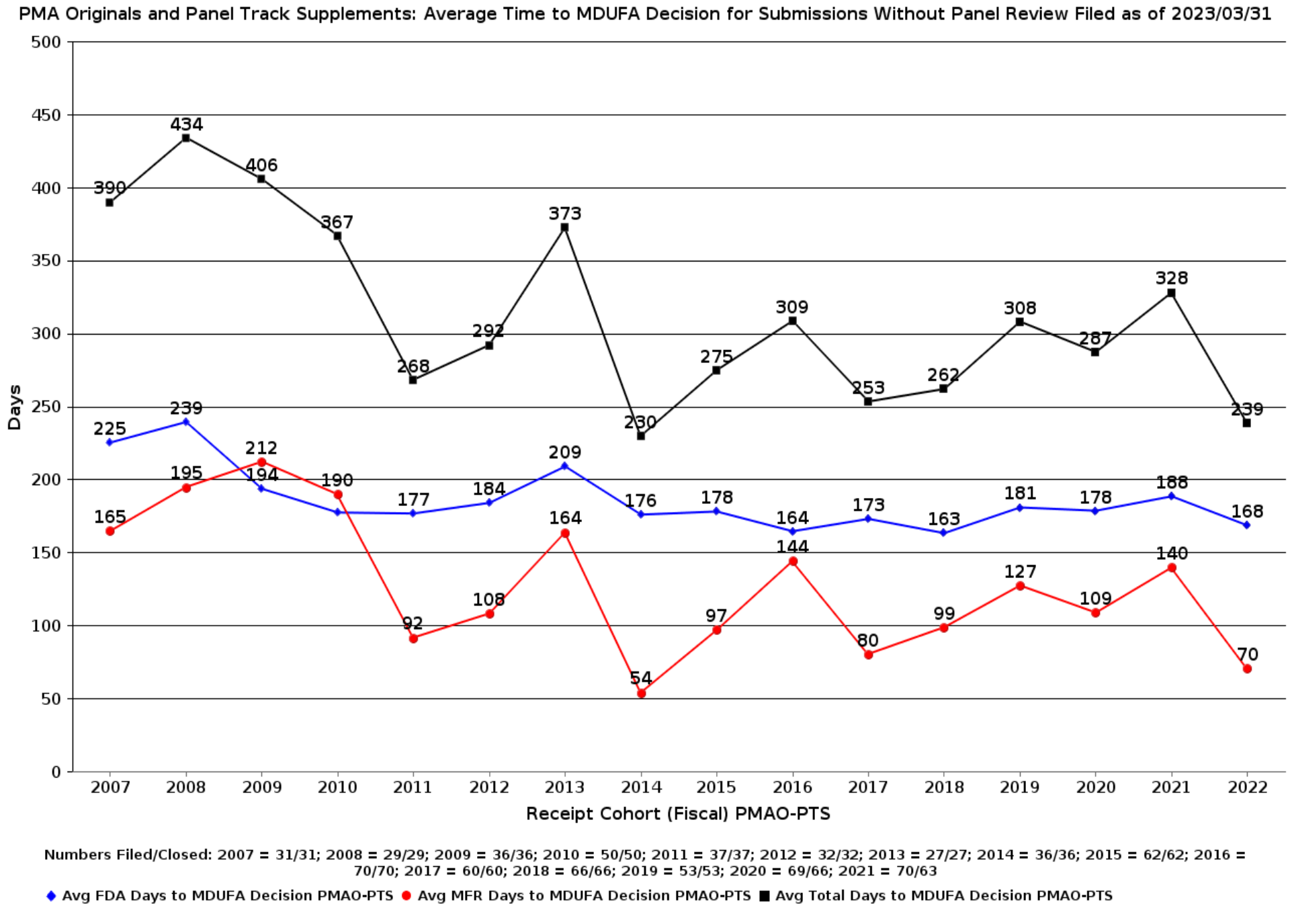



Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.



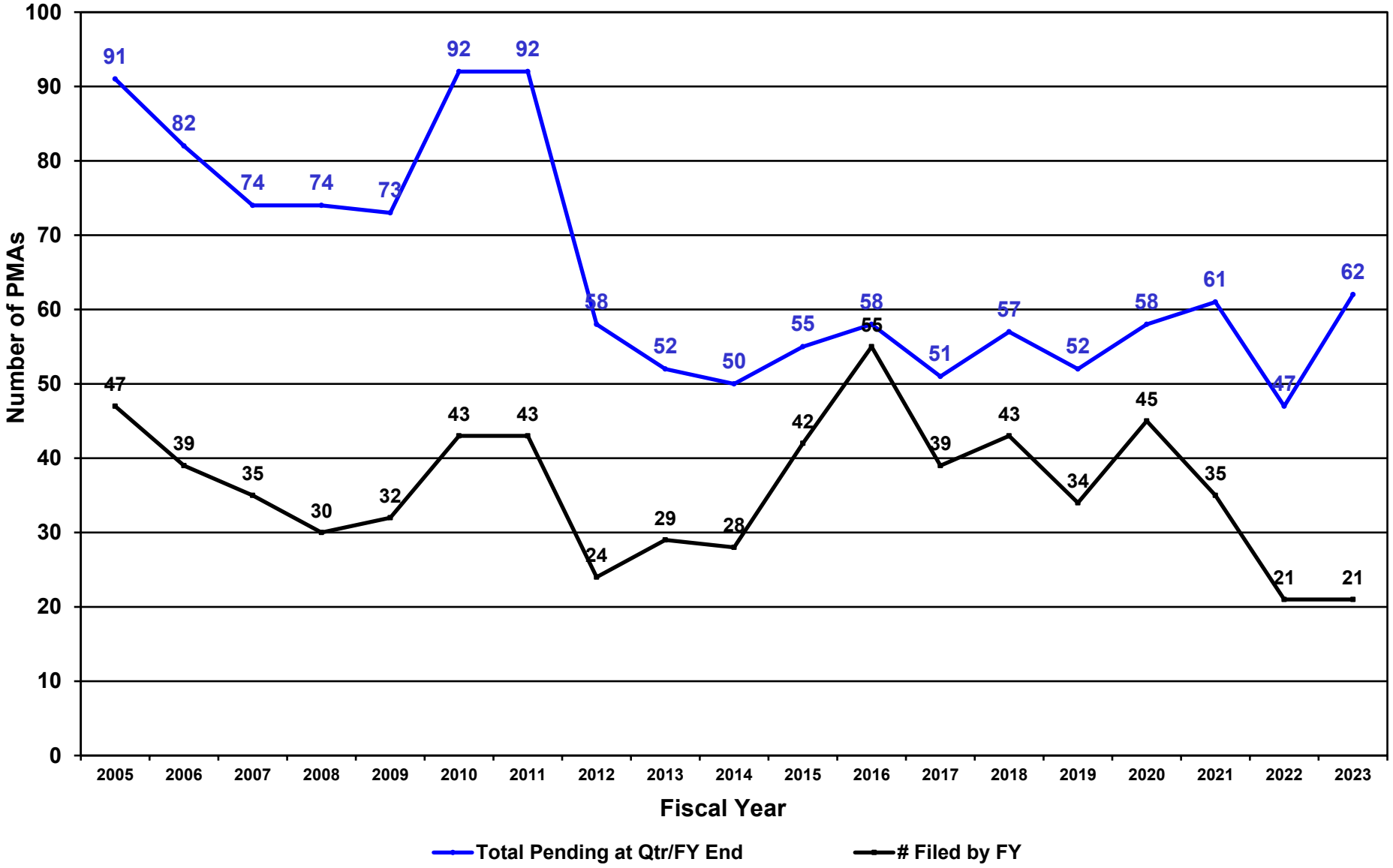

Numbers Filed/Closed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/39; 2021 = 42/30

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



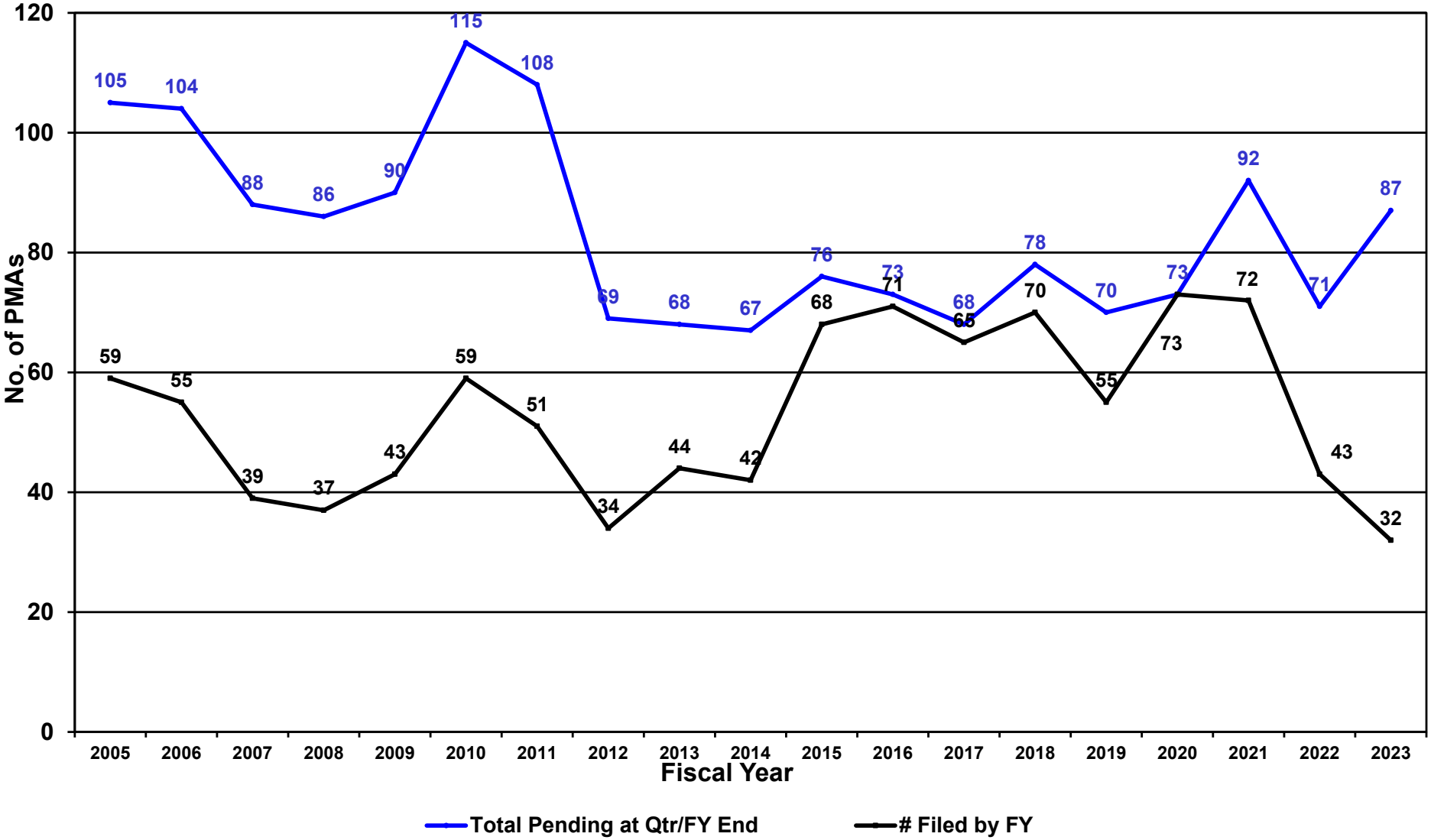

Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

# PMA Originals Pending* at End of Quarter/Year

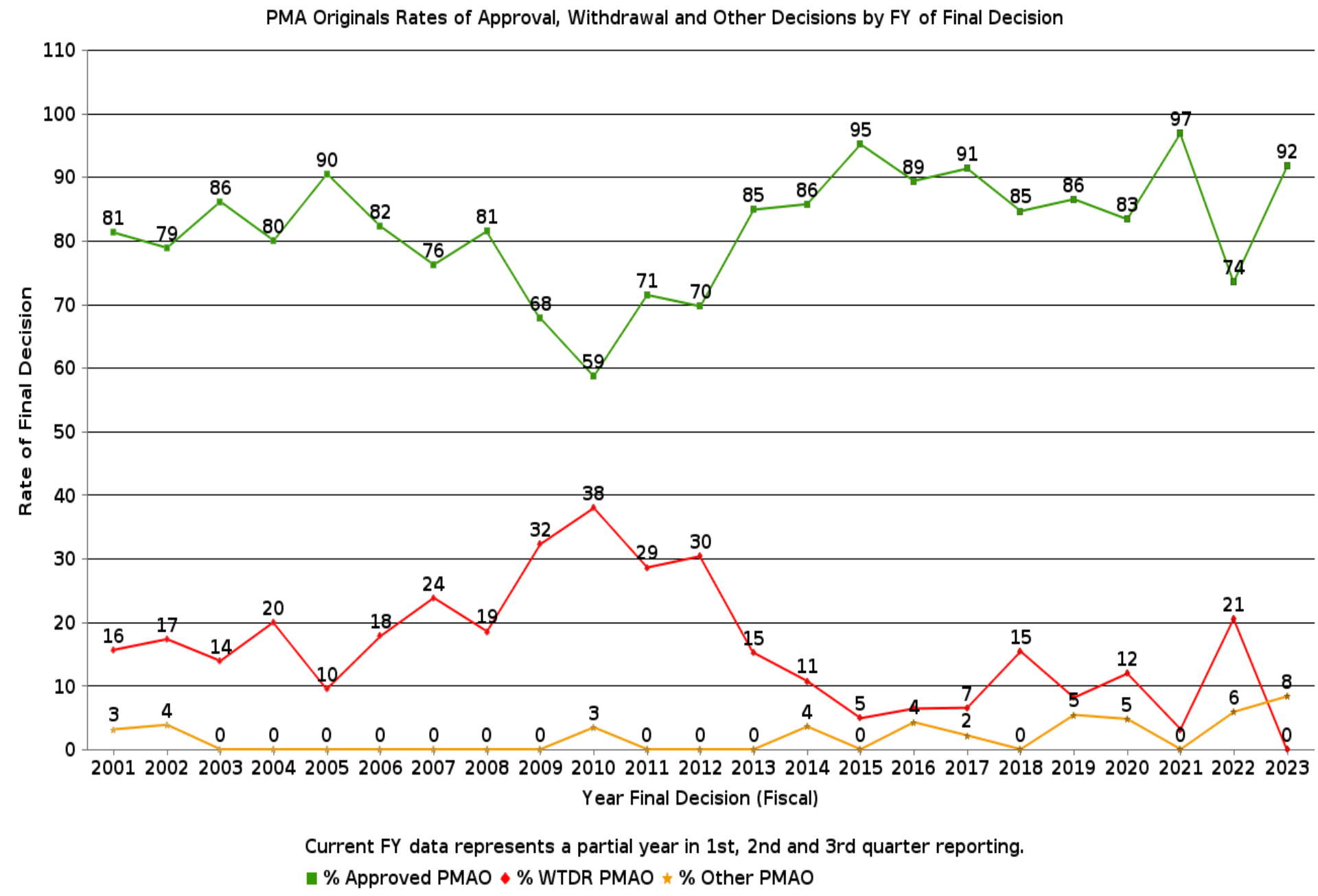



*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year.

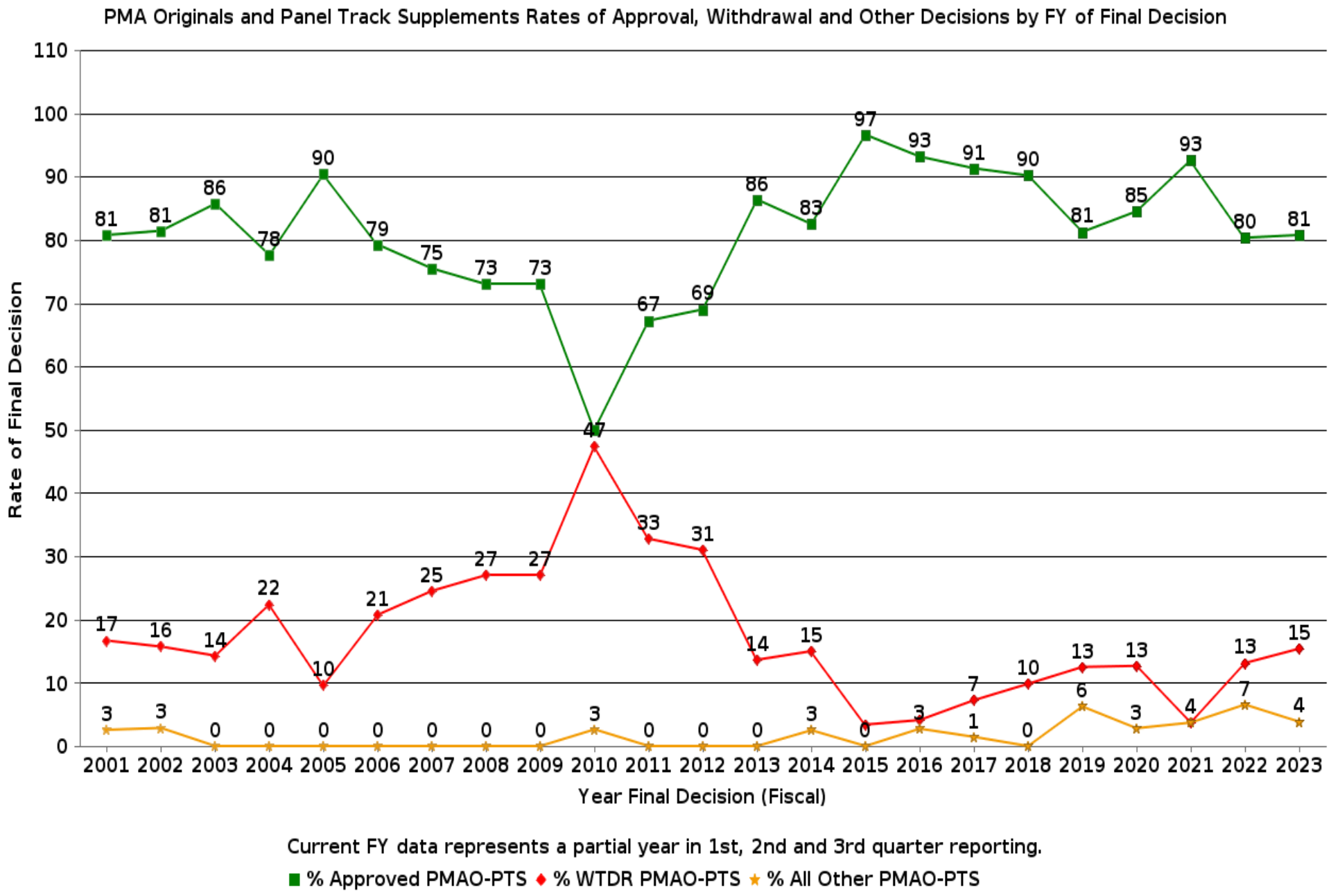
# PMA Originals and Panel Track Supplements Pending* at End of Quarter/Year




*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.

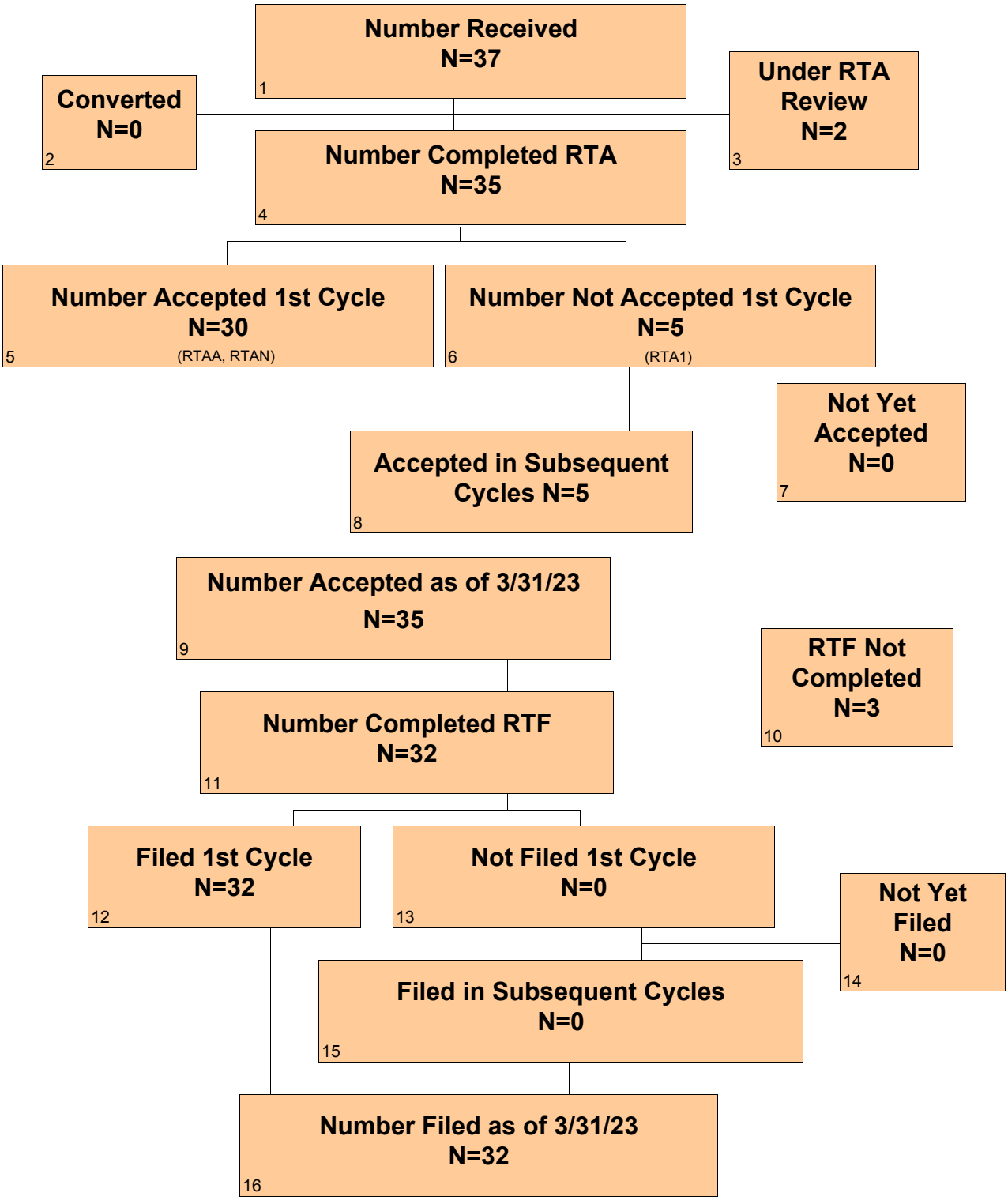



**Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions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

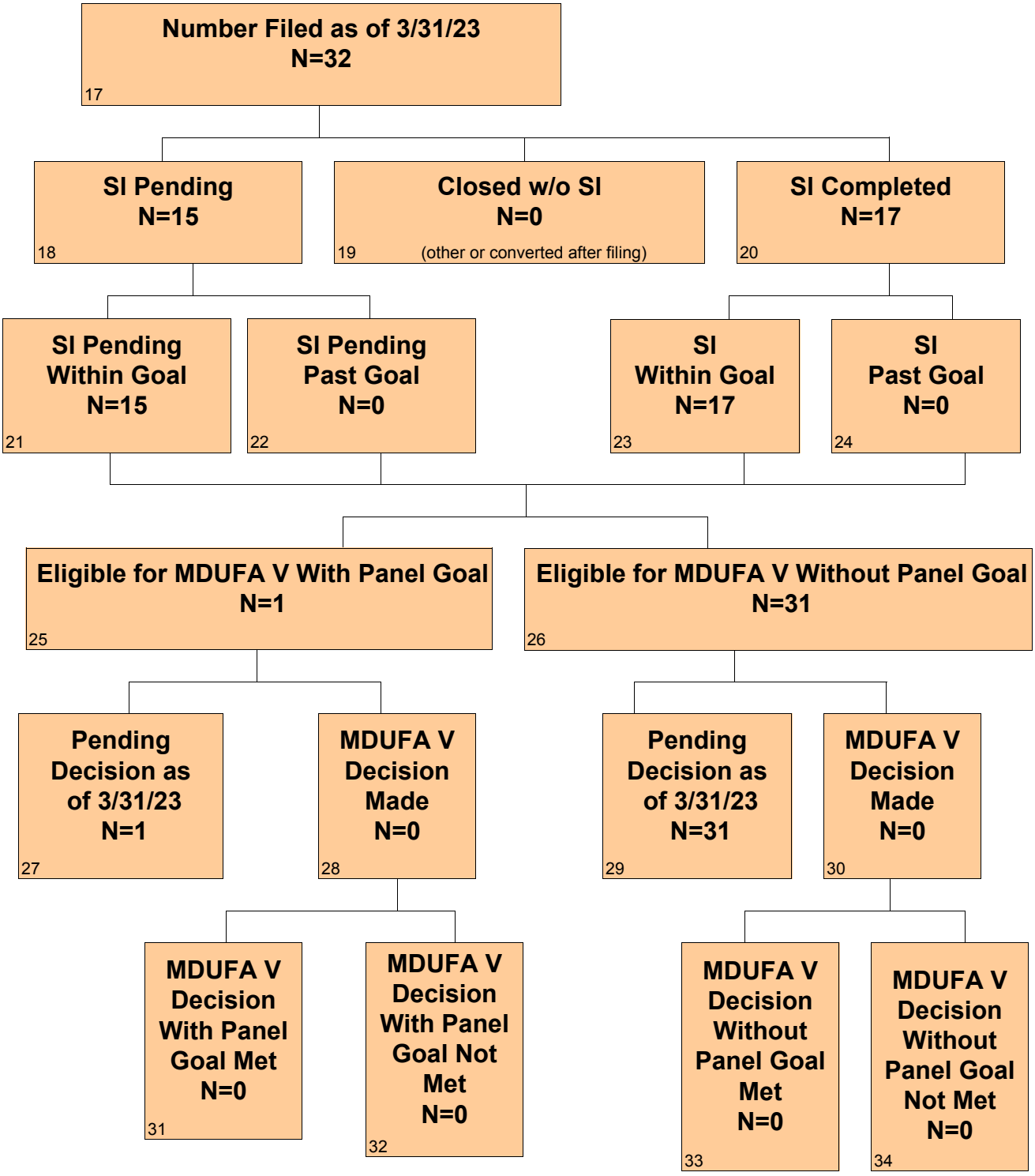



**Submissions deleted due to lack of response were counted as "withdrawals" prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as "withdrawals" from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered "other" decisions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

# CDRH PMA Original and Panel Track Supplements - FY 2023 as of 3/31/23



# CDRH PMA Original and Panel Track Supplements - FY 2023 as of 3/31/23 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 | 37 | | | | |
| Number Closed Before First RTA Action | 0 | | | | |
| Number Accepted First RTA Review | 30 | | | | |
| 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 | 5 | | | | |
| 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 | 37 | | | | |
| Number Accepted | 30 | | | | |
| Completed RTF | 32 | | | | |
| Number Not Filed | 0 | | | | |
| Rate of Submissions Not Filed | 0.00% | | | | |

### 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 | 32 | | | | |
| SI Goal Met | 17 | | | | |
| SI Goal Not Met | 0 | | | | |
| SI Pending Within Goal | 15 | | | | |
| 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 | 17 | | | | |
| Average Number of FDA Days to Substantive Interaction | 88.47 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 87 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 89 | | | | |
| 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 | 31 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| PMAs Pending MDUFA Decision | 31 | | | | |
| PMAs Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 90% Within 320 FDA Days | FY 2024 90% Within 320 FDA Days | FY 2025 90% Within 320 FDA Days | FY 2026 90% Within 320 FDA Days | FY 2027 90% Within 320 FDA Days |
|---|---|---|---|---|---|
| Number of PMAs Filed | 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 | 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 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** | 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 1.9 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 | 31 | | | | |
| 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 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 | 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

### 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 | 4 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| 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 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 | 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 | | | | |

***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 DevicePMA Original and Pane

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 5 | | | | |
| 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) | 1 | | | | |
| Number Not Accepted for Filing Review on First Cycle | 3 | | | | |
| Rate of Submissions Not Accepted for Filing Review on First Cycle | 75.00% | | | | |

***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 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 | 5 | | | | |
| Number Accepted | 1 | | | | |
| Completed RTF | 4 | | | | |
| 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 | 4 | | | | |
| SI Goal Met | 2 | | | | |
| 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 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 | 2 | | | | |
| 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 | 4 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| PMAs Pending MDUFA Decision | 4 | | | | |
| PMAs Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 90% Within 320 FDA Days | FY 2024 90% Within 320 FDA Days | FY 2025 90% Within 320 FDA Days | FY 2026 90% Within 320 FDA Days | FY 2027 90% Within 320 FDA Days |
|---|---|---|---|---|---|
| Number of PMAs Filed | 0 | | | | |
| 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 | 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 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** | 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 1.9 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 | 4 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 12 | | | | |
| Number Closed Before First RTA Action | 0 | | | | |
| Number Accepted First RTA Review | 10 | | | | |
| 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 | 1 | | | | |
| Rate of Submissions Not Accepted for Filing Review on First Cycle | 9.09% | | | | |

***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 | 12 | | | | |
| Number Accepted | 10 | | | | |
| Completed RTF | 11 | | | | |
| 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 | 11 | | | | |
| SI Goal Met | 8 | | | | |
| 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 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 | 8 | | | | |
| Average Number of FDA Days to Substantive Interaction | 88.13 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 85 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 89 | | | | |
| 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 | 10 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| PMAs Pending MDUFA Decision | 10 | | | | |
| PMAs Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 90% Within 320 FDA Days | FY 2024 90% Within 320 FDA Days | FY 2025 90% Within 320 FDA Days | FY 2026 90% Within 320 FDA Days | FY 2027 90% Within 320 FDA Days |
|---|---|---|---|---|---|
| Number of PMAs Filed | 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 | 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 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** | 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 1.9 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 | 10 | | | | |
| 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 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 | 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 2 | | | | |
| 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 | 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 | 2 | | | | |
| 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 | 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 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 | 1 | | | | |
| Average Number of FDA Days to Substantive Interaction | 88.00 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 88 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 88 | | | | |
| 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 | 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 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 | 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 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** | 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 1.9 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 | 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 5 | | | | |
| Number Closed Before First RTA Action | 0 | | | | |
| Number Accepted First RTA Review | 5 | | | | |
| 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 | 5 | | | | |
| Number Accepted | 5 | | | | |
| Completed RTF | 5 | | | | |
| 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 | 5 | | | | |
| SI Goal Met | 2 | | | | |
| 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 | 2 | | | | |
| 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 | 5 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| PMAs Pending MDUFA Decision | 5 | | | | |
| PMAs Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 90% Within 320 FDA Days | FY 2024 90% Within 320 FDA Days | FY 2025 90% Within 320 FDA Days | FY 2026 90% Within 320 FDA Days | FY 2027 90% Within 320 FDA Days |
|---|---|---|---|---|---|
| Number of PMAs Filed | 0 | | | | |
| 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 | 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 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** | 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 1.9 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 | 5 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 1 | | | | |
| 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 | 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 | 1 | | | | |
| Number Accepted | 1 | | | | |
| Completed RTF | 1 | | | | |
| 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 | 1 | | | | |
| SI Goal Met | 1 | | | | |
| 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 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 | 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 1.6 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** | 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 1.9 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 | 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 1.10 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 2 | | | | |
| 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 | 1 | | | | |
| Rate of Submissions Not Accepted for Filing Review on First Cycle | 50.00% | | | | |

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

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 2 | | | | |
| Number Accepted | 1 | | | | |
| Completed RTF | 2 | | | | |
| 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 | 2 | | | | |
| SI Goal Met | 0 | | | | |
| 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 | N/A | | | | |

**Table 1.4 OHT6 - Office of Orthopedic Devices**
**PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Substantive Interactions | 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 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 | 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 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** | 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 1.9 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 | 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 10 | | | | |
| Number Closed Before First RTA Action | 0 | | | | |
| Number Accepted First RTA Review | 10 | | | | |
| 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 | 10 | | | | |
| Number Accepted | 10 | | | | |
| Completed RTF | 7 | | | | |
| Number Not Filed | 0 | | | | |
| Rate of Submissions Not Filed | 0.00% | | | | |

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

| Substantive Interaction (SI) Goal | FY 2023 95% SI Within 90 FDA Days | FY 2024 95% SI Within 90 FDA Days | FY 2025 95% SI Within 90 FDA Days | FY 2026 95% SI Within 90 FDA Days | FY 2027 95% SI Within 90 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 7 | | | | |
| SI Goal Met | 3 | | | | |
| 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 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 | 3 | | | | |
| Average Number of FDA Days to Substantive Interaction | 87.00 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 87 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 87 | | | | |
| 60th Percentile FDA Days to Substantive Interaction | 87 | | | | |
| 80th Percentile FDA Days to Substantive Interaction | 87 | | | | |
| Maximum FDA Days to Substantive Interaction | 87 | | | | |

**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 | 7 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| PMAs Pending MDUFA Decision | 7 | | | | |
| PMAs Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 90% Within 320 FDA Days | FY 2024 90% Within 320 FDA Days | FY 2025 90% Within 320 FDA Days | FY 2026 90% Within 320 FDA Days | FY 2027 90% Within 320 FDA Days |
|---|---|---|---|---|---|
| Number of PMAs Filed | 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 | 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 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** | 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 1.9 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 | 7 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 4 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| 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 | 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 | | | | |

***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** | 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 1.9 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | | | | |

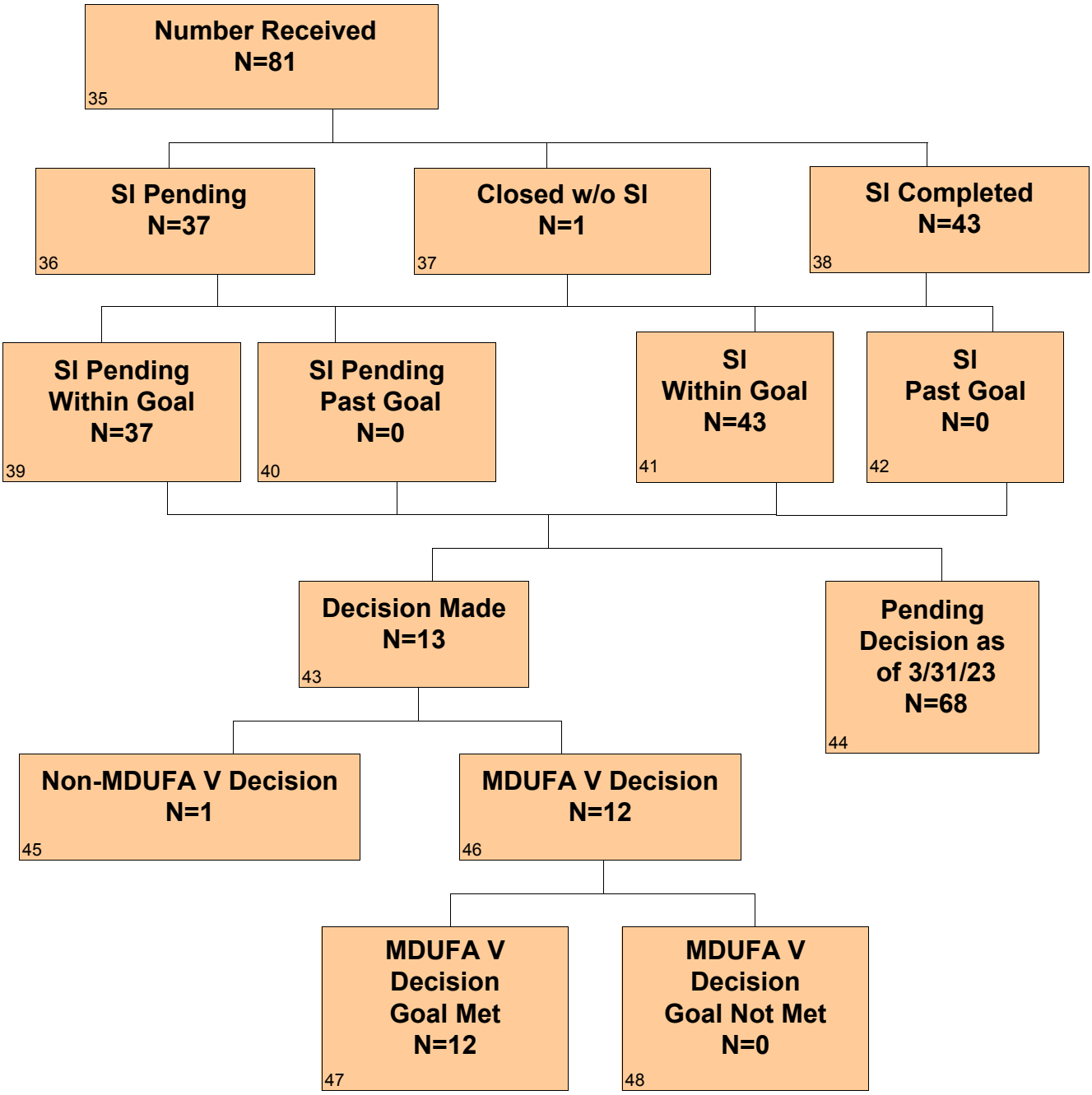
***Includes submission that went to panel**

**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 3/31/23



## 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 | 81 | | | | |
| SI Goal Met | 43 | | | | |
| SI Goal Not Met | 0 | | | | |
| SI Pending Within Goal | 37 | | | | |
| SI Pending Past Goal | 0 | | | | |
| Closed Without SI | 1 | | | | |
| Current SI Performance Percent Goal Met | 100.00% | | | | |

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

| Performance Metric | FY 2023 95% Within 180 FDA Days | FY 2024 95% Within 180 FDA Days | FY 2025 95% Within 180 FDA Days | FY 2026 95% Within 180 FDA Days | FY 2027 95% Within 180 FDA Days |
|---|---|---|---|---|---|
| Supplements Received | 81 | | | | |
| Non-MDUFA Decision | 1 | | | | |
| MDUFA Decision | 12 | | | | |
| MDUFA Decision Goal Met | 12 | | | | |
| Supplements Pending MDUFA Decision | 68 | | | | |
| 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 | 81 | | | | |
| Number with MDUFA Decision | 12 | | | | |
| 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

## Section 2 PMA 180-Day Supplements - Office Level Metric

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

| Substantive Interaction (SI) Goal | FY 2023 95% SI Within 90 FDA Days | FY 2024 95% SI Within 90 FDA Days | FY 2025 95% SI Within 90 FDA Days | FY 2026 95% SI Within 90 FDA Days | FY 2027 95% SI Within 90 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 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 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 | 5 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| Supplements Pending MDUFA Decision | 5 | | | | |
| Supplements Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 5 | | | | |
| Number with MDUFA Decision | 0 | | | | |
| Number of Not Approvable | 0 | | | | |
| Rate of Not Approvable | N/A | | | | |

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

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

**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 | 33 | | | | |
| SI Goal Met | 21 | | | | |
| SI Goal Not Met | 0 | | | | |
| SI Pending Within Goal | 12 | | | | |
| SI Pending Past Goal | 0 | | | | |
| Closed Without SI | 0 | | | | |
| Current SI Performance Percent Goal Met | 100.00% | | | | |

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

| Performance Metric | FY 2023 95% Within 180 FDA Days | FY 2024 95% Within 180 FDA Days | FY 2025 95% Within 180 FDA Days | FY 2026 95% Within 180 FDA Days | FY 2027 95% Within 180 FDA Days |
|---|---|---|---|---|---|
| Supplements Received | 33 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 10 | | | | |
| MDUFA Decision Goal Met | 10 | | | | |
| Supplements Pending MDUFA Decision | 23 | | | | |
| 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 | 33 | | | | |
| Number with MDUFA Decision | 10 | | | | |
| 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

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

| Substantive Interaction (SI) Goal | FY 2023 95% SI Within 90 FDA Days | FY 2024 95% SI Within 90 FDA Days | FY 2025 95% SI Within 90 FDA Days | FY 2026 95% SI Within 90 FDA Days | FY 2027 95% SI Within 90 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 11 | | | | |
| SI Goal Met | 4 | | | | |
| SI Goal Not Met | 0 | | | | |
| SI Pending Within Goal | 7 | | | | |
| SI Pending Past Goal | 0 | | | | |
| Closed Without SI | 0 | | | | |
| Current SI Performance Percent Goal Met | 100.00% | | | | |

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

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

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 11 | | | | |
| Number with MDUFA Decision | 0 | | | | |
| Number of Not Approvable | 0 | | | | |
| Rate of Not Approvable | N/A | | | | |

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

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

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

| Substantive Interaction (SI) Goal | FY 2023 95% SI Within 90 FDA Days | FY 2024 95% SI Within 90 FDA Days | FY 2025 95% SI Within 90 FDA Days | FY 2026 95% SI Within 90 FDA Days | FY 2027 95% SI Within 90 FDA Days |
|---|---|---|---|---|---|
| Eligible for SI | 2 | | | | |
| SI Goal Met | 0 | | | | |
| 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 | N/A | | | | |

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

| Performance Metric | FY 2023 95% Within 180 FDA Days | FY 2024 95% Within 180 FDA Days | FY 2025 95% Within 180 FDA Days | FY 2026 95% Within 180 FDA Days | FY 2027 95% Within 180 FDA Days |
|---|---|---|---|---|---|
| Supplements Received | 2 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| Supplements Pending MDUFA Decision | 2 | | | | |
| 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 | 2 | | | | |
| 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 9 | | | | |
| SI Goal Met | 6 | | | | |
| 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 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 | 9 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 1 | | | | |
| MDUFA Decision Goal Met | 1 | | | | |
| Supplements Pending MDUFA Decision | 8 | | | | |
| 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 | 9 | | | | |
| 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 3 | | | | |
| SI Goal Met | 0 | | | | |
| 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 | N/A | | | | |

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

| Performance Metric | FY 2023 95% Within 180 FDA Days | FY 2024 95% Within 180 FDA Days | FY 2025 95% Within 180 FDA Days | FY 2026 95% Within 180 FDA Days | FY 2027 95% Within 180 FDA Days |
|---|---|---|---|---|---|
| Supplements Received | 3 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| Supplements Pending MDUFA Decision | 3 | | | | |
| Supplements Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 3 | | | | |
| Number with MDUFA Decision | 0 | | | | |
| Number of Not Approvable | 0 | | | | |
| Rate of Not Approvable | N/A | | | | |

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

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

**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 | 18 | | | | |
| SI Goal Met | 8 | | | | |
| 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 | 18 | | | | |
| Non-MDUFA Decision | 1 | | | | |
| MDUFA Decision | 1 | | | | |
| MDUFA Decision Goal Met | 1 | | | | |
| Supplements Pending MDUFA Decision | 16 | | | | |
| 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 | 18 | | | | |
| Number with MDUFA Decision | 1 | | | | |
| 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | | | | |

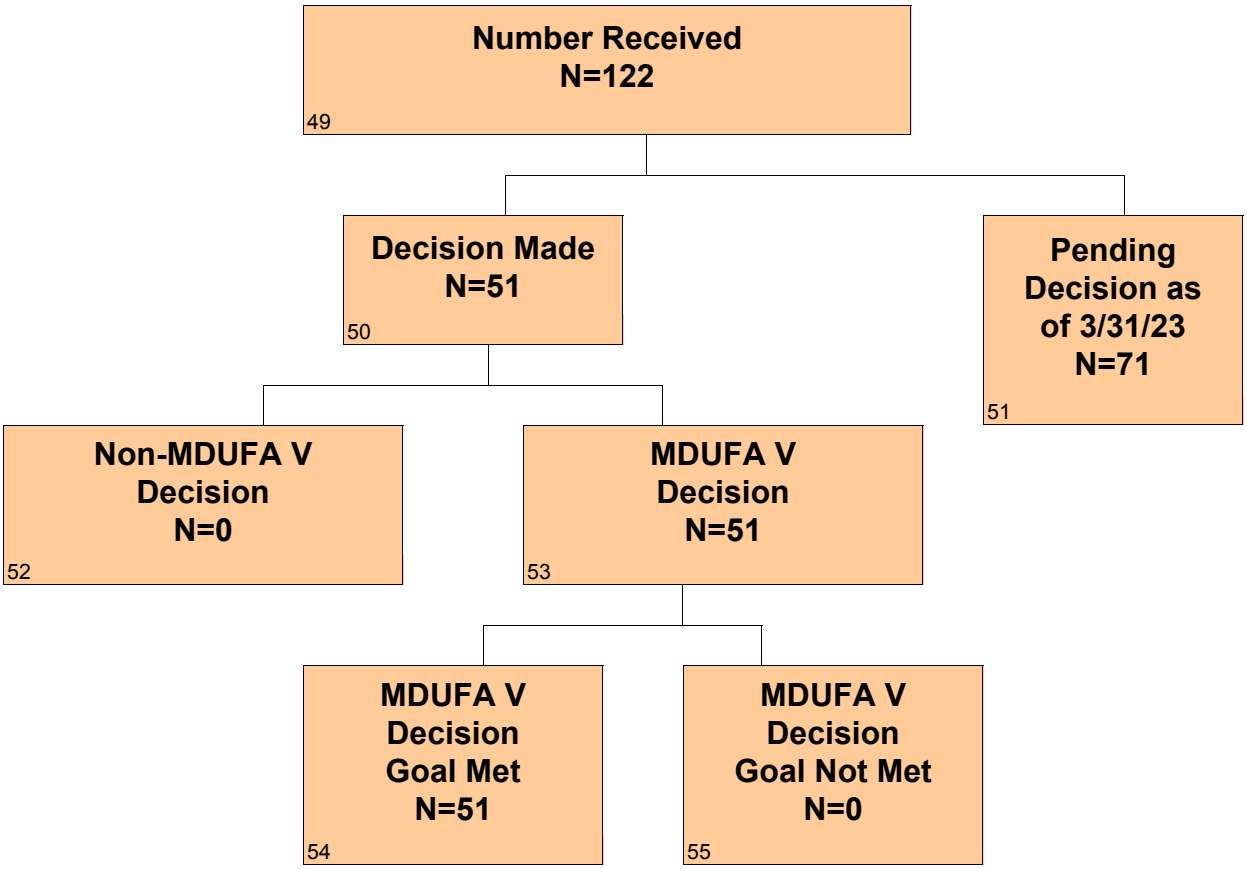
**Table 2.3 OHT8 - Office of Radiological Health**
**PMA 180-Day Supplements MDUFA V Performance Metric - Rate of Not Approvable**

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

# CDRH PMA Real Time Supplements - FY 2023 as of 3/31/23



## 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 | 122 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 51 | | | | |
| MDUFA Decision Goal Met | 51 | | | | |
| Supplements Pending MDUFA Decision | 71 | | | | |
| 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 | 122 | | | | |
| Number With MDUFA Decision | 51 | | | | |
| Number of Not Approvable | 1 | | | | |
| Rate of Not Approvable | 1.96% | | | | |

### 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 | 10 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 3 | | | | |
| MDUFA Decision Goal Met | 3 | | | | |
| Supplements Pending MDUFA Decision | 7 | | | | |
| 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 | 10 | | | | |
| Number With MDUFA Decision | 3 | | | | |
| 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 | 84 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 35 | | | | |
| MDUFA Decision Goal Met | 35 | | | | |
| Supplements Pending MDUFA Decision | 49 | | | | |
| 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 | 84 | | | | |
| Number With MDUFA Decision | 35 | | | | |
| Number of Not Approvable | 0 | | | | |
| Rate of Not Approvable | 0.00% | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Submissions that Missed the Goal | 0 | | | | |
| 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 | 7 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 3 | | | | |
| MDUFA Decision Goal Met | 3 | | | | |
| 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 | 7 | | | | |
| Number With MDUFA Decision | 3 | | | | |
| 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 | 3 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 1 | | | | |
| MDUFA Decision Goal Met | 1 | | | | |
| Supplements Pending MDUFA Decision | 2 | | | | |
| 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 | 3 | | | | |
| Number With MDUFA Decision | 1 | | | | |
| Number of Not Approvable | 1 | | | | |
| Rate of Not Approvable | 100.00% | | | | |

**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 | 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 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 | 2 | | | | |
| Number With MDUFA Decision | 1 | | | | |
| 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 | 1 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Goal Met | 0 | | | | |
| Supplements Pending MDUFA Decision | 1 | | | | |
| Supplements Pending MDUFA Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

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

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Submissions that Missed the Goal | 0 | | | | |
| 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 | 14 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 7 | | | | |
| MDUFA Decision Goal Met | 7 | | | | |
| Supplements Pending MDUFA Decision | 7 | | | | |
| 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 | 14 | | | | |
| Number With MDUFA Decision | 7 | | | | |
| 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.

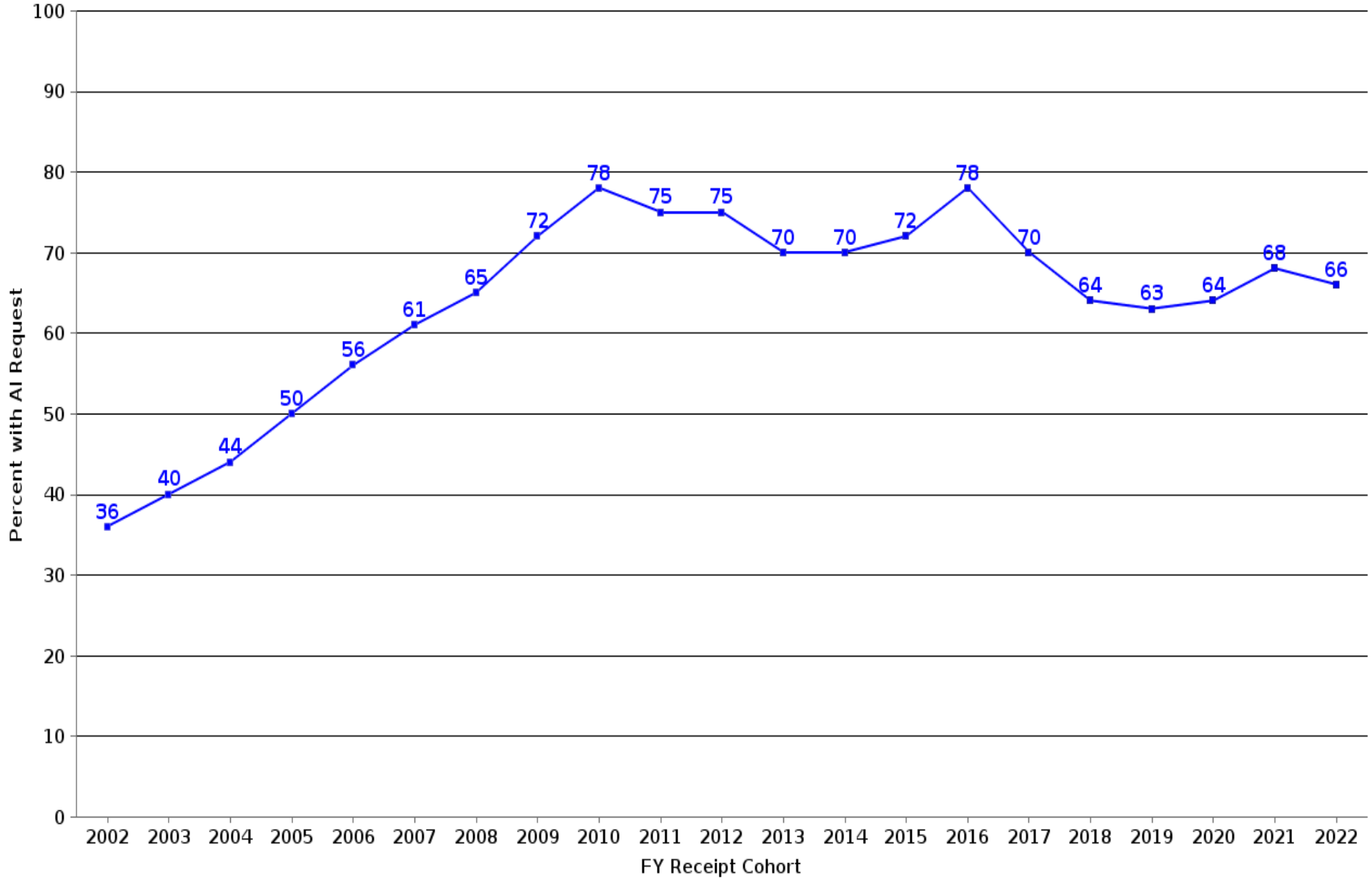
# Section 5 PMA Annual Metrics and Goals

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

# 510(k)s

## Q2FY2023

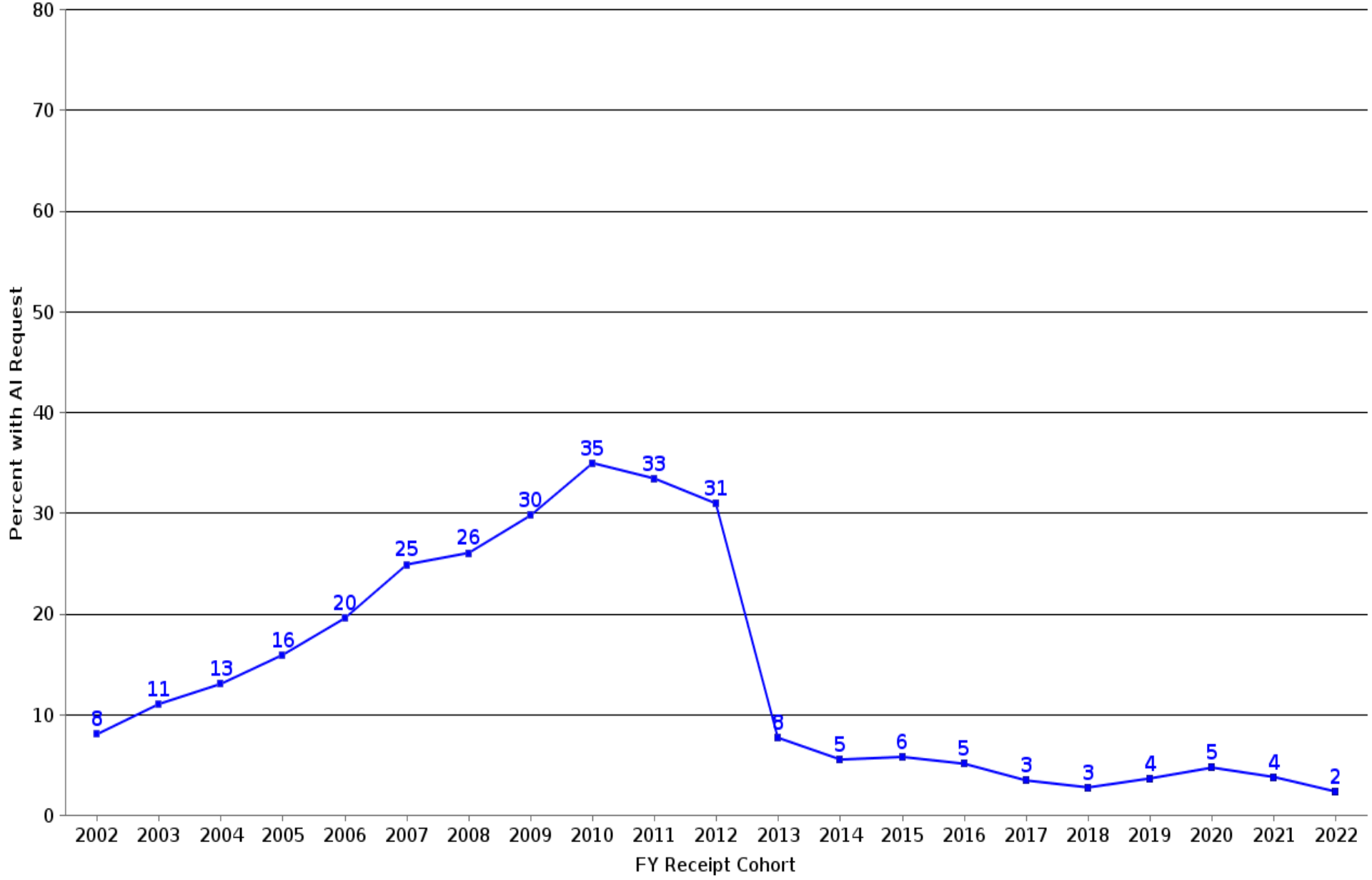
# Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle




AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 1/31/23

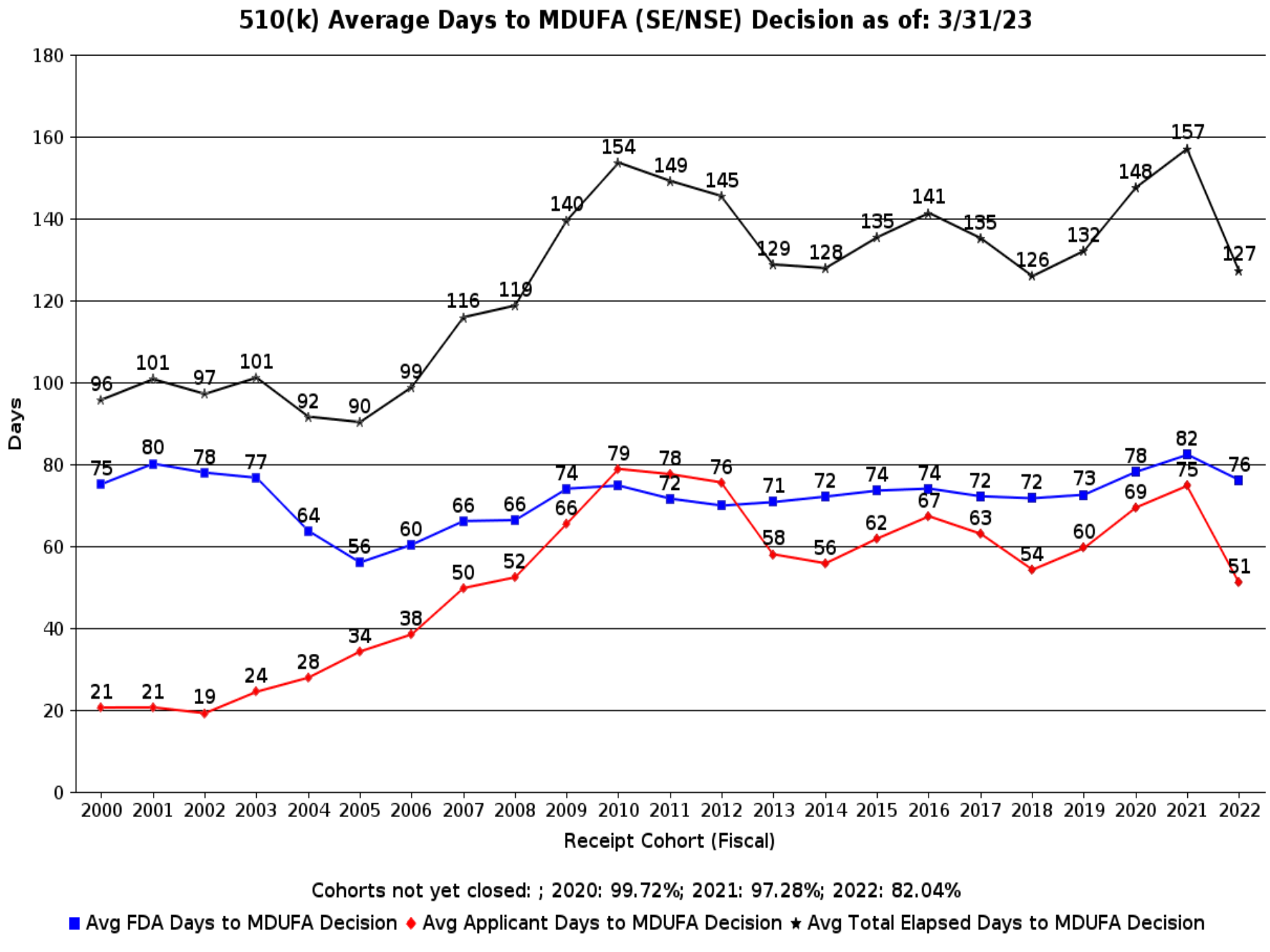
■ % with 1st Cycle AI Request

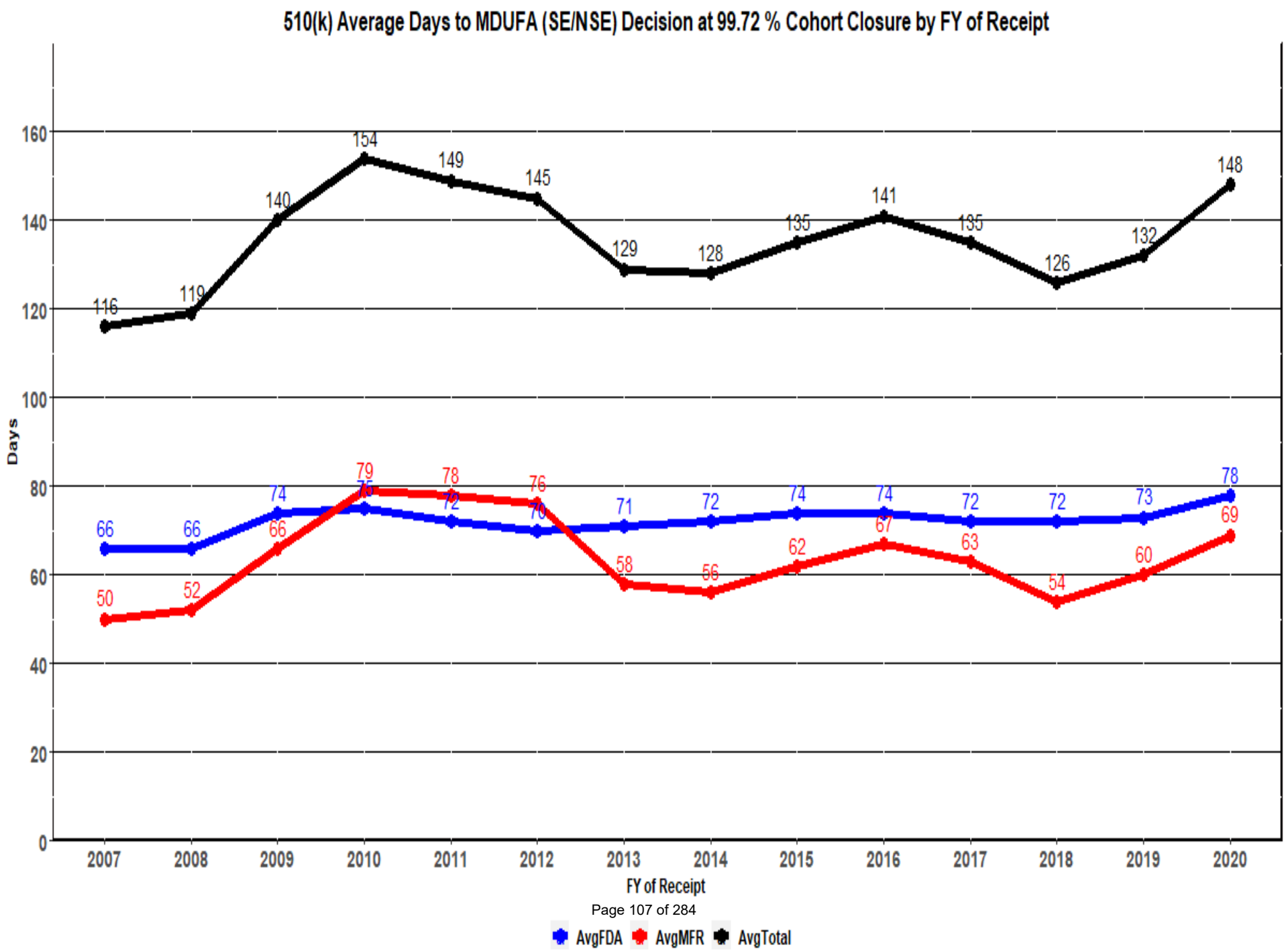
# Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle

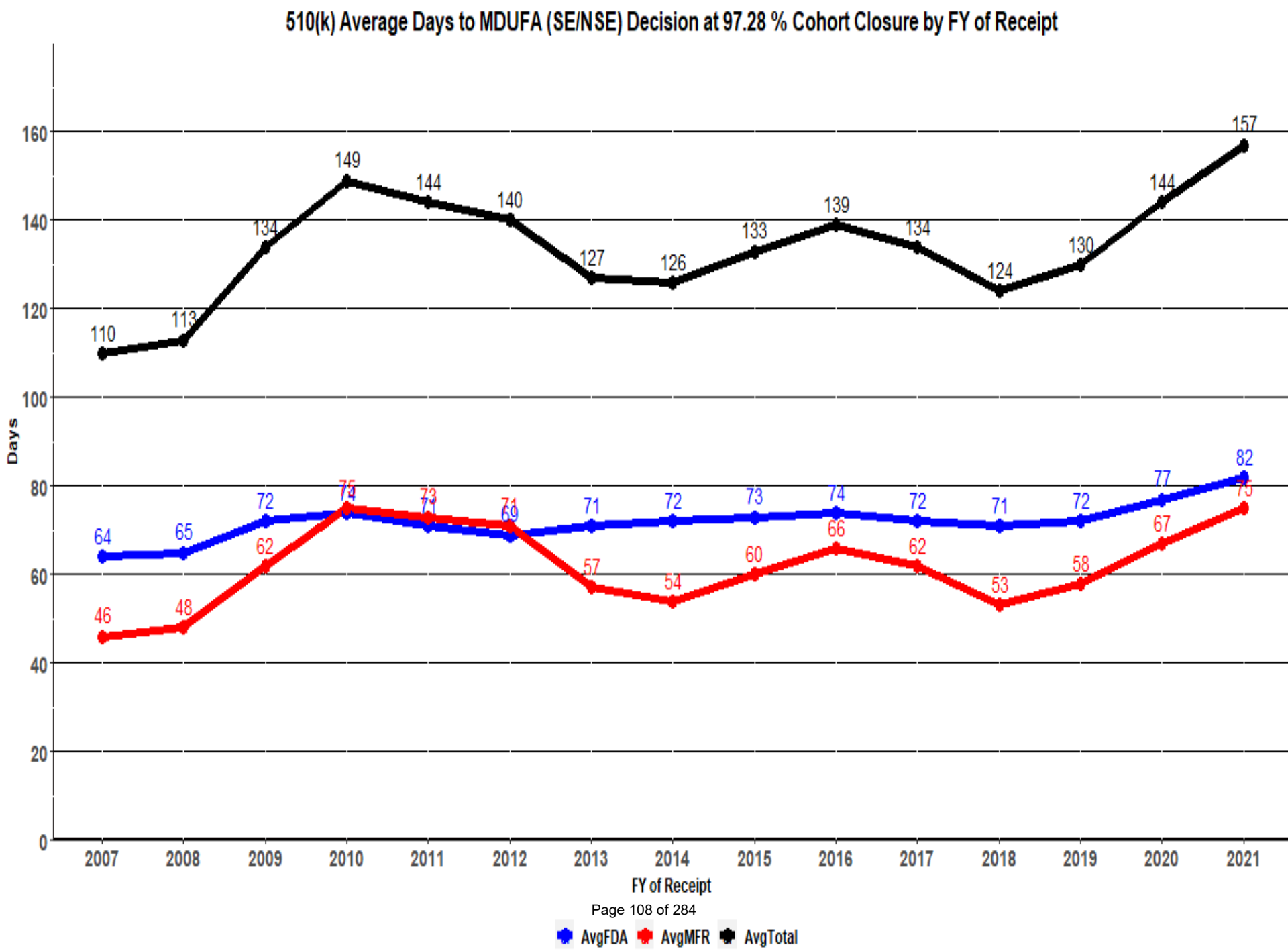


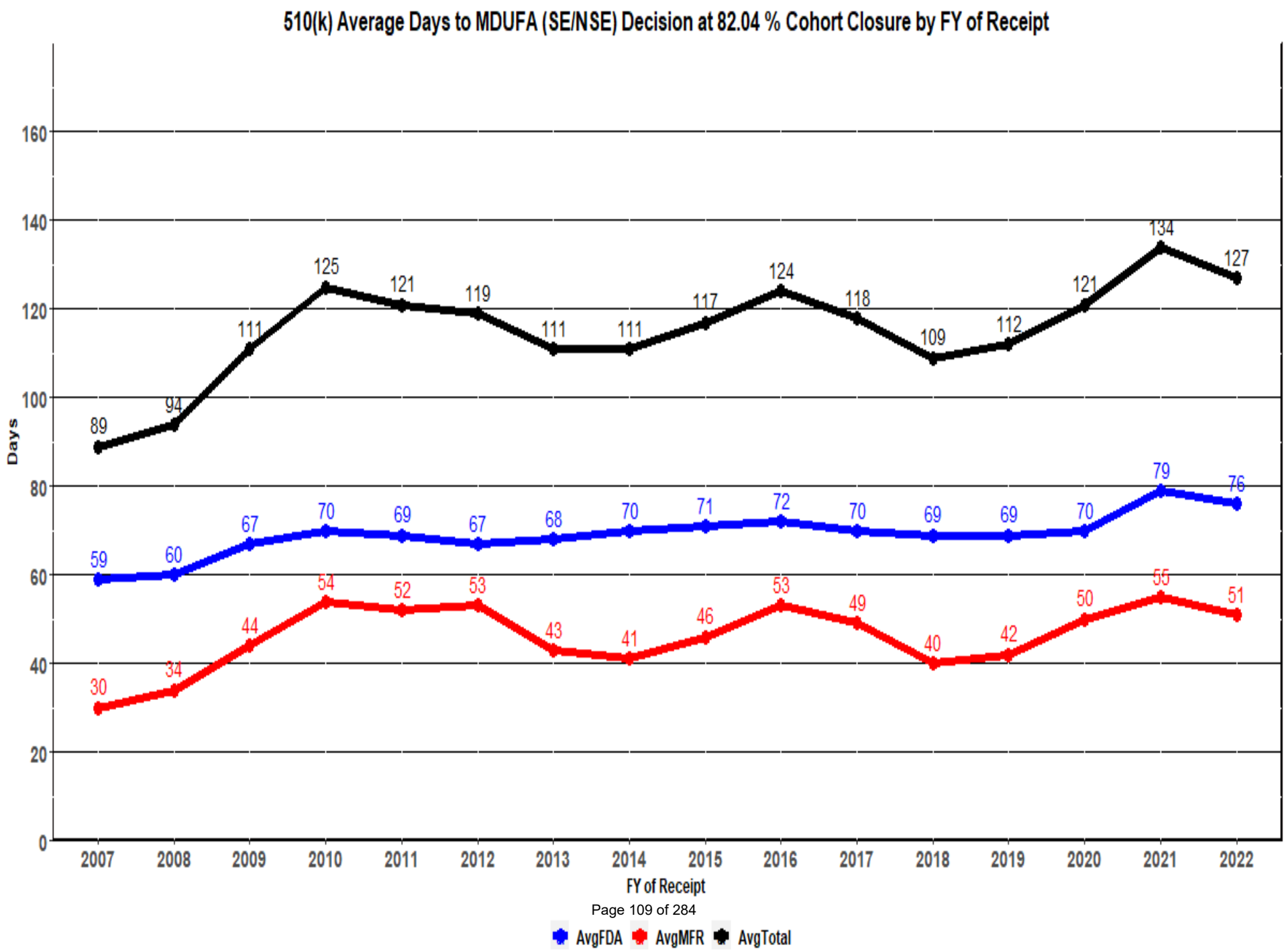

AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 8/31/22

■ % with 2nd Cycle AI Request


510(k) Average Days to MDUFA (SE/NSE) Decision as of: 3/31/23
Days
Receipt Cohort (Fiscal)
Cohorts not yet closed: ; 2020: 99.72%; 2021: 97.28%; 2022: 82.04%
Avg FDA Days to MDUFA Decision
Avg Applicant Days to MDUFA Decision
Avg Total Elapsed Days to MDUFA Decision

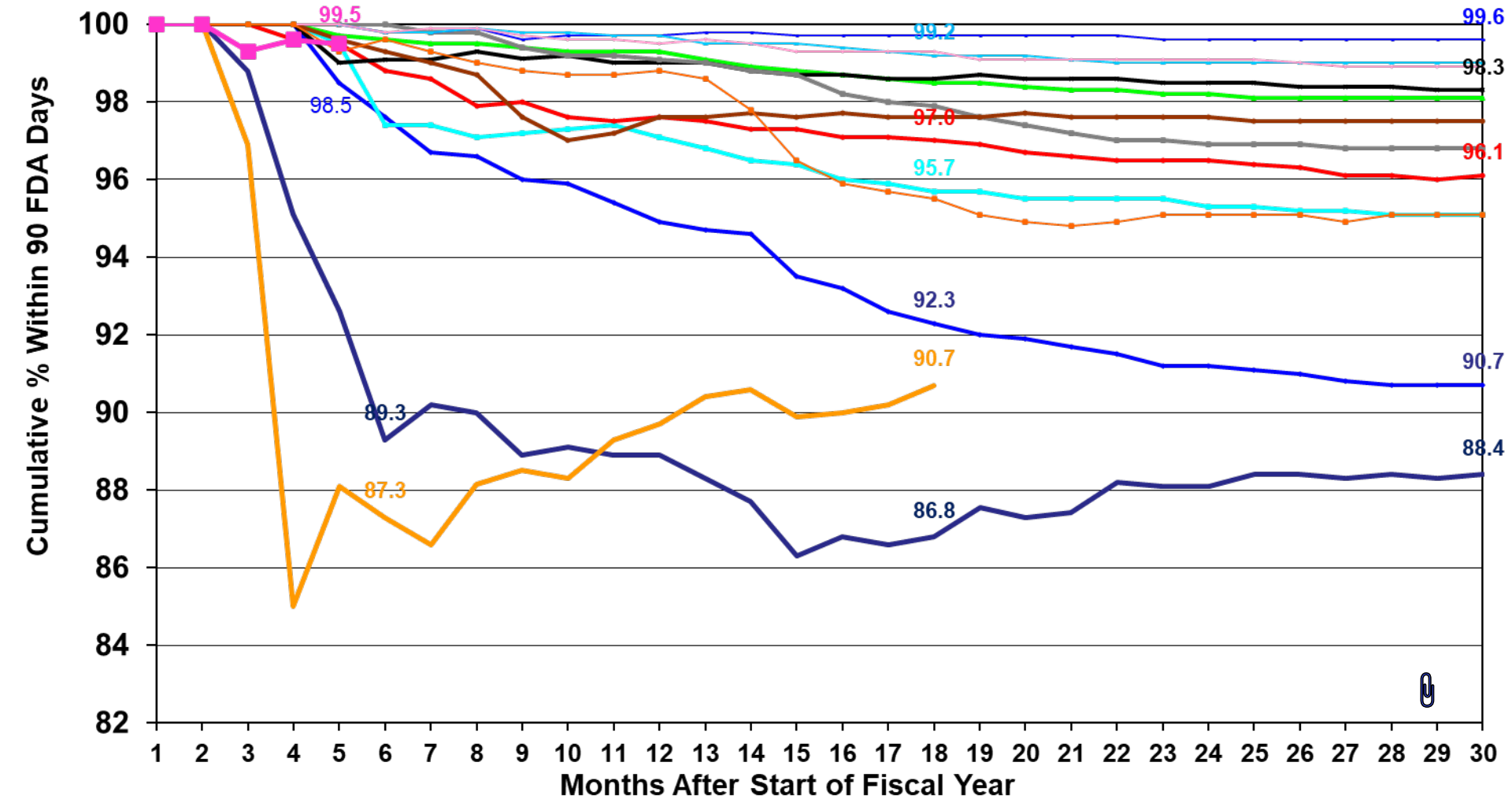

510(k) Average Days to MDUFA (SE/NSE) Decision at 99.72 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
FY of Receipt
116
119
140
154
149
145
129
128
135
141
135
126
132
148
66
66
74
75
72
70
71
72
74
74
72
72
73
78
50
52
66
79
78
76
58
56
62
67
63
54
60
69
AvgFDA
AvgMFR
AvgTotal


510(k) Average Days to MDUFA (SE/NSE) Decision at 97.28 % 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

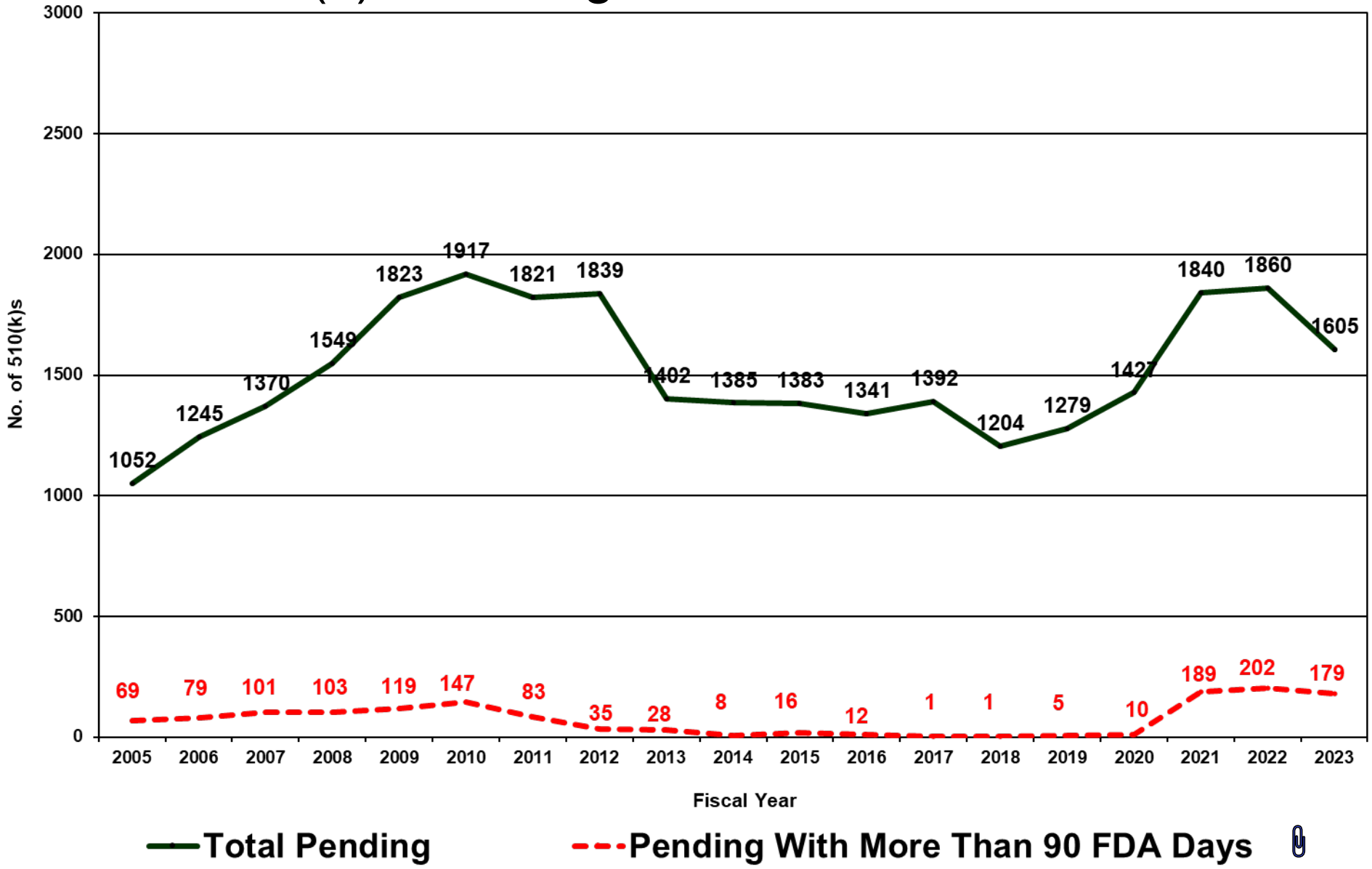

510(k) Average Days to MDUFA (SE/NSE) Decision at 82.04 % Cohort Closure by FY of Receipt
Days
0
20
40
60
80
100
120
140
160
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
FY of Receipt
89
94
111
125
121
119
111
111
117
124
118
109
112
121
134
127
59
60
67
70
69
67
68
70
71
72
70
69
69
70
79
76
30
34
44
54
52
53
43
41
46
53
49
40
42
50
55
51
AvgFDA
AvgMFR
AvgTotal

# Trend in 510(k) MDUFA Decision Goal Performance

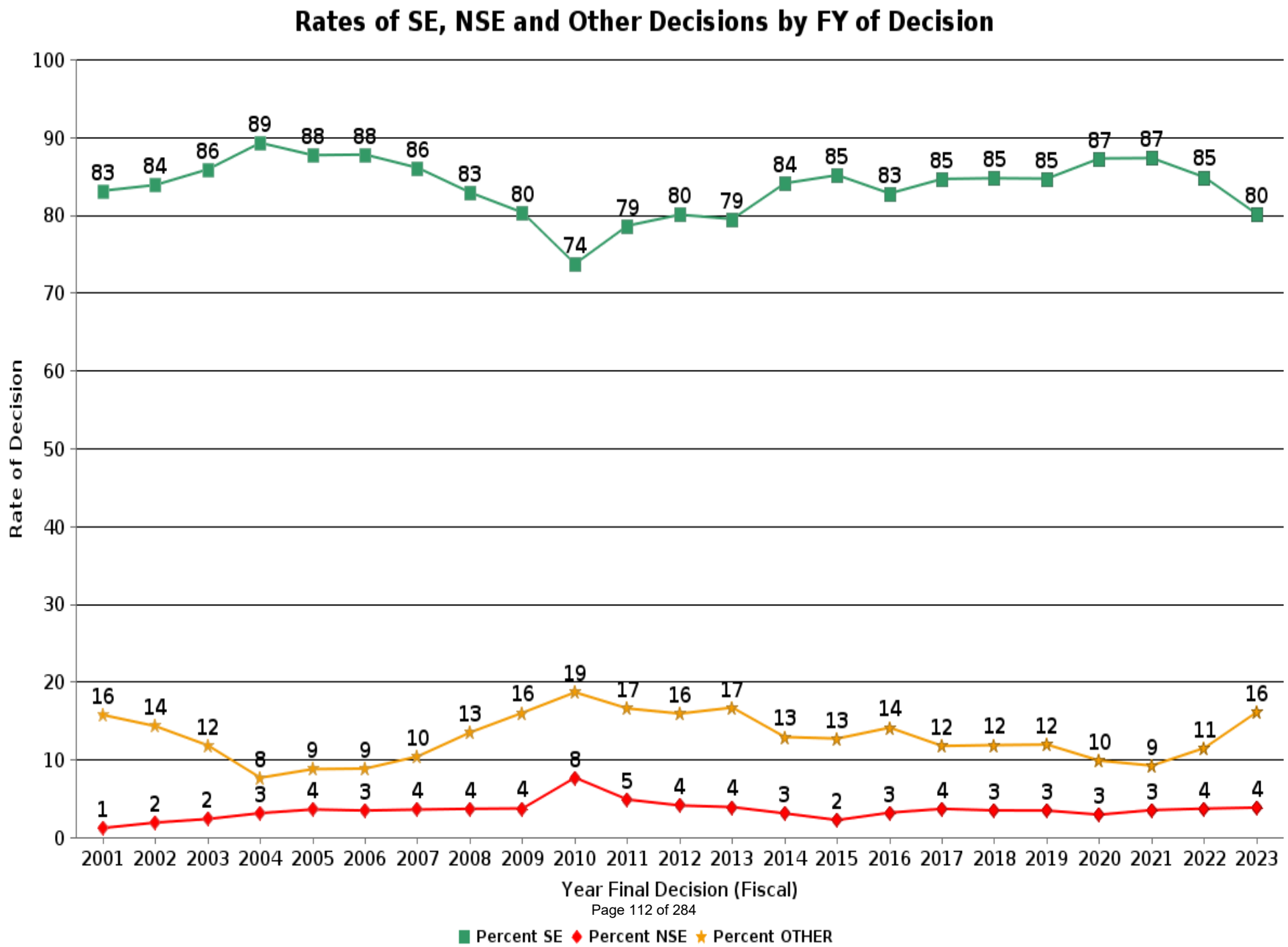
## Comparison of FY10 – FY23 Receipt Cohorts



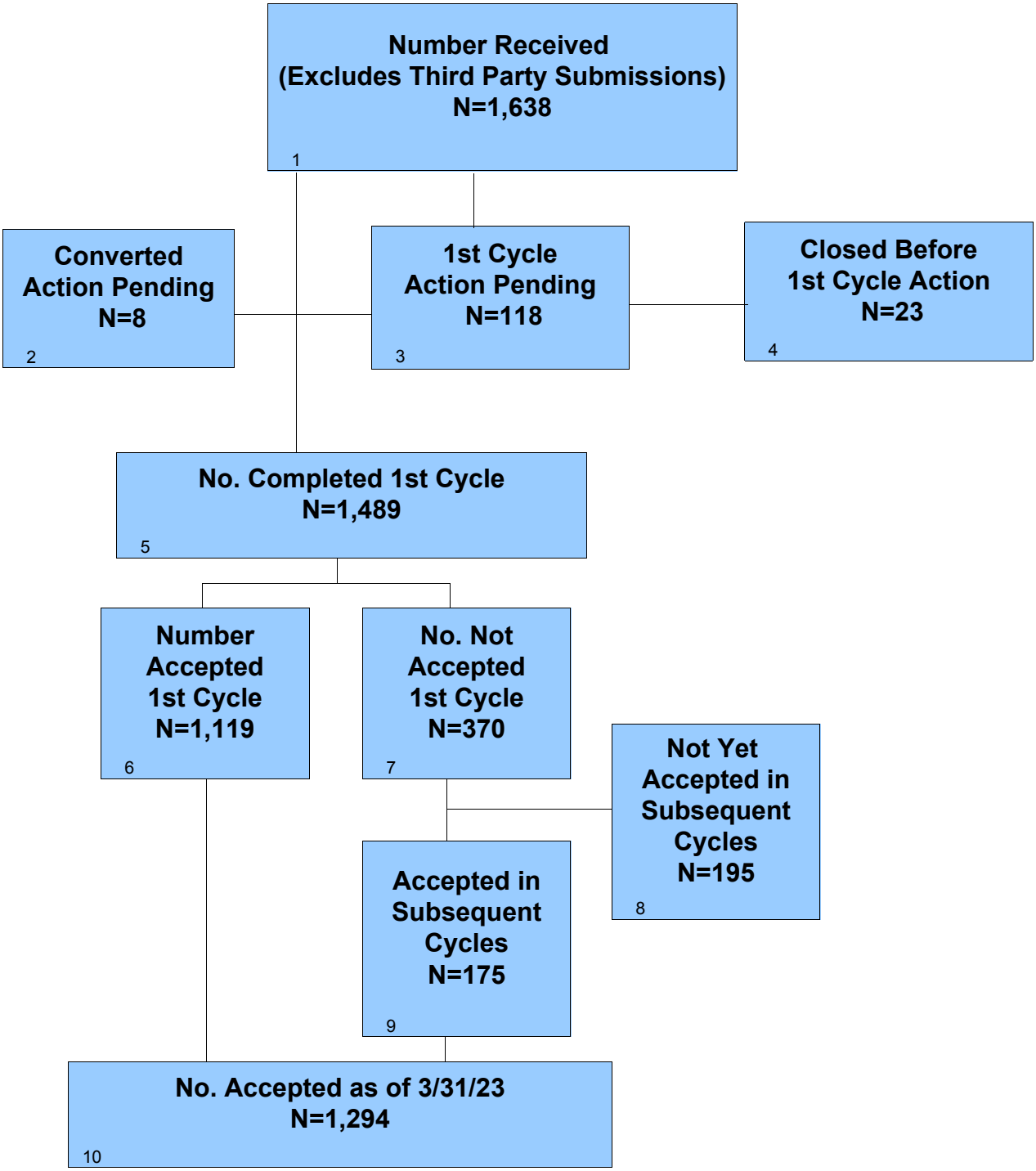
# 510(k)s Pending at End of Quarter/Year



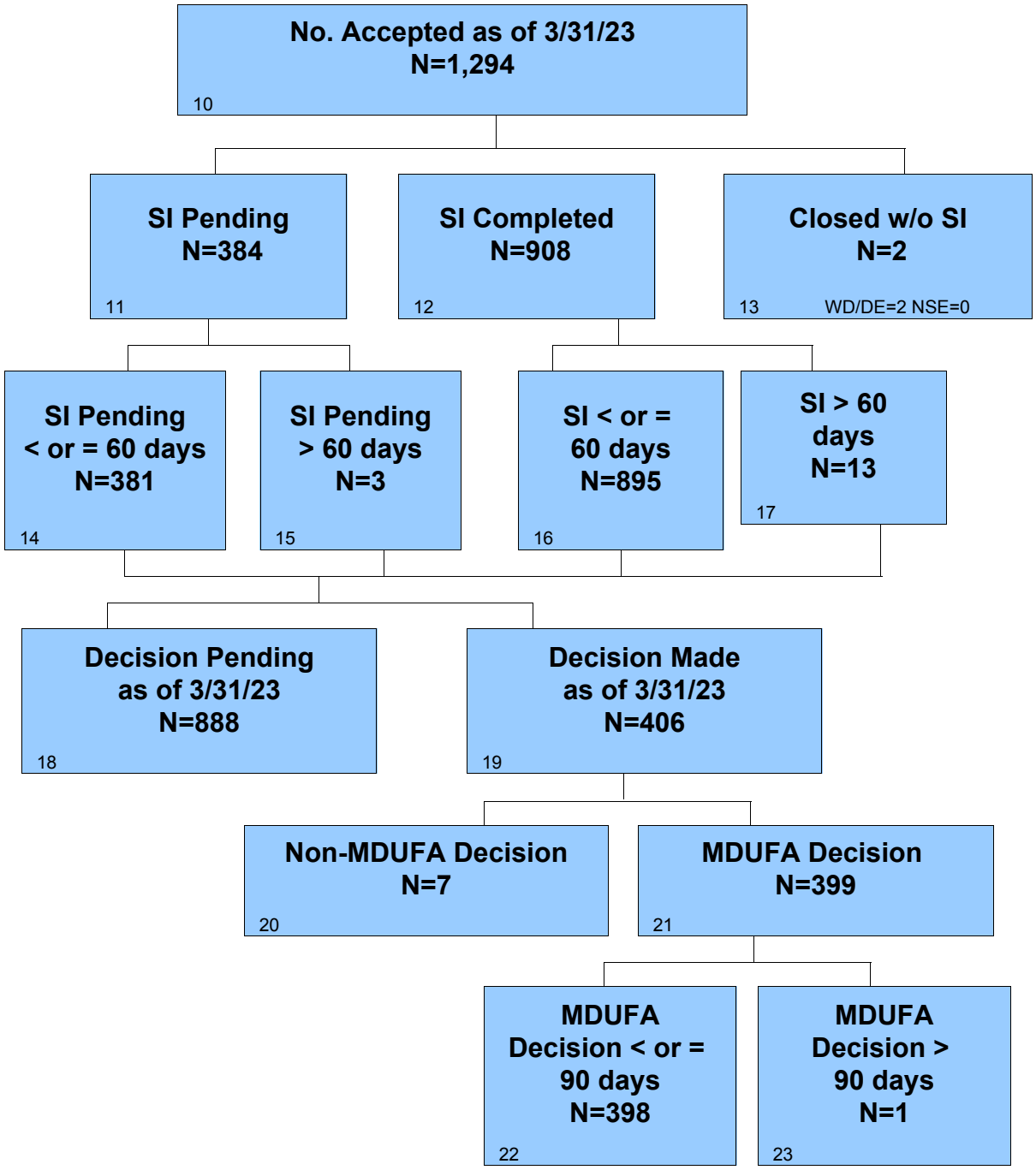

"Pending" means 510ks under review or on hold following a positive RTA decision (FY13 and later).


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 3/31/23



# CDRH 510(k)s - FY 2023
# as of 3/31/23 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 | 1,638 | | | | |
| Closed Before First RTA or TS Action [1] | 23 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 1,109 | | | | |
| Number Without a RTA or TS Review and > 15 Days Since Date Received [3] | 10 | | | | |
| Number Without a RTA or TS Review and <= 15 Days Since Date Received [1] | 126 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 370 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 24.85% | | | | |

**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 | 1,294 | | | | |
| Deleted or Withdrawn Prior to SI | 2 | | | | |
| SI Within 60 FDA Days | 895 | | | | |
| SI Over 60 FDA Days | 13 | | | | |
| SI Pending Within 60 FDA Days | 381 | | | | |
| SI Pending Over 60 FDA Days | 3 | | | | |
| 510(k)s NSE Without SI | 0 | | | | |
| Current SI Performance Percent Within 60 FDA Days | 98.24% | | | | |

**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 | 908 | | | | |
| Average Number of FDA Days to Substantive Interaction | 50.68 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 35 | | | | |
| 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 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 | 1,294 | | | | |
| Non-MDUFA V Decision | 7 | | | | |
| MDUFA V Decision (SE/NSE) | 399 | | | | |
| MDUFA V Decision Within 90 FDA Days | 398 | | | | |
| 510(k)s Pending MDUFA V Decision | 888 | | | | |
| 510(k)s Pending MDUFA V Decision Over 90 FDA Days | 1 | | | | |
| Current Performance Percent Within 90 FDA Days | 99.50% | | | | |

**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 | 1.30 | | | | |
| Number With MDUFA V Decision | 399 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 57.38 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 53 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 62 | | | | |
| 80th Percentile FDA Days to MDUFA V Decision | 87 | | | | |
| Maximum FDA Days to MDUFA V Decision | 91 | | | | |
| **Average Number of Industry Days to MDUFA V Decision** | 8.21 | | | | |
| 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 | 14 | | | | |
| Maximum Industry Days to MDUFA V Decision | 84 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 65.58 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 55 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 70 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 94 | | | | |
| Maximum Total Days to MDUFA V Decision | 168 | | | | |

### 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 | 1,294 | | | | |
| Number With MDUFA V Decision | 399 | | | | |
| Number of SE Decision | 397 | | | | |
| Number of NSE Decision | 2 | | | | |
| Number of Withdrawal | 5 | | | | |
| Number of Deleted | 0 | | | | |
| Rate of SE Decision | 99.50% | | | | |
| Rate of NSE Decision | 0.50% | | | | |
| Rate of Withdrawal | 0.39% | | | | |
| Rate of Deleted | 0.00% | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Submissions that Missed the Goal | 1 | | | | |
| Mean FDA Days for Submissions that Missed the Goal | 91.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

### 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 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 | 82 | | | | |
| Non-MDUFA V Decision | 2 | | | | |
| MDUFA V Decision (SE/NSE) | 27 | | | | |
| MDUFA V Decision Within 90 FDA Days | 27 | | | | |
| 510(k)s Pending MDUFA V Decision | 53 | | | | |
| 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 | 234 | | | | |
| Closed Before First RTA or TS Action [1] | 2 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 99 | | | | |
| 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] | 16 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 113 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 52.31% | | | | |

**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 | 151 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 88 | | | | |
| SI Over 60 FDA Days | 9 | | | | |
| SI Pending Within 60 FDA Days | 52 | | | | |
| SI Pending Over 60 FDA Days | 2 | | | | |
| 510(k)s NSE Without SI | 0 | | | | |
| Current SI Performance Percent Within 60 FDA Days | 88.89% | | | | |

**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 | 97 | | | | |
| Average Number of FDA Days to Substantive Interaction | 54.23 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 50 | | | | |
| 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 | 66 | | | | |

**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 | 151 | | | | |
| Non-MDUFA V Decision | 0 | | | | |
| MDUFA V Decision (SE/NSE) | 29 | | | | |
| MDUFA V Decision Within 90 FDA Days | 29 | | | | |
| 510(k)s Pending MDUFA V Decision | 122 | | | | |
| 510(k)s Pending MDUFA V Decision Over 90 FDA Days | 1 | | | | |
| Current Performance Percent Within 90 FDA Days | 96.67% | | | | |

**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 | 1.31 | | | | |
| Number With MDUFA V Decision | 29 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 65.41 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 43 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 59 | | | | |
| 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 | 90 | | | | |
| **Average Number of Industry Days to MDUFA V Decision** | 9.07 | | | | |
| 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 | 13 | | | | |
| Maximum Industry Days to MDUFA V Decision | 72 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 74.48 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 43 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 60 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 87 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 98 | | | | |
| Maximum Total Days to MDUFA V Decision | 161 | | | | |

**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 | 151 | | | | |
| Number With MDUFA V Decision | 29 | | | | |
| Number of SE Decision | 28 | | | | |
| Number of NSE Decision | 1 | | | | |
| Number of Withdrawal | 0 | | | | |
| Number of Deleted | 0 | | | | |
| Rate of SE Decision | 96.55% | | | | |
| Rate of NSE Decision | 3.45% | | | | |
| Rate of Withdrawal | 0.00% | | | | |
| Rate of Deleted | 0.00% | | | | |

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

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

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

| Performance Metric | FY 2023 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 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 | 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 | 171 | | | | |
| Closed Before First RTA or TS Action [1] | 4 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 134 | | | | |
| 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] | 11 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 21 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 13.46% | | | | |

**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 | 149 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 101 | | | | |
| SI Over 60 FDA Days | 1 | | | | |
| SI Pending Within 60 FDA Days | 46 | | | | |
| SI Pending Over 60 FDA Days | 1 | | | | |
| 510(k)s NSE Without SI | 0 | | | | |
| Current SI Performance Percent Within 60 FDA Days | 98.06% | | | | |

**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 | 102 | | | | |
| Average Number of FDA Days to Substantive Interaction | 50.16 | | | | |
| 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 | 60 | | | | |
| Maximum FDA Days to Substantive Interaction | 66 | | | | |

**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 | 149 | | | | |
| Non-MDUFA V Decision | 0 | | | | |
| MDUFA V Decision (SE/NSE) | 35 | | | | |
| MDUFA V Decision Within 90 FDA Days | 34 | | | | |
| 510(k)s Pending MDUFA V Decision | 114 | | | | |
| 510(k)s Pending MDUFA V Decision Over 90 FDA Days | 0 | | | | |
| Current Performance Percent Within 90 FDA Days | 97.14% | | | | |

**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 | 1.34 | | | | |
| Number With MDUFA V Decision | 35 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 55.43 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 28 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 51 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 59 | | | | |
| 80th Percentile FDA Days to MDUFA V Decision | 87 | | | | |
| Maximum FDA Days to MDUFA V Decision | 91 | | | | |
| **Average Number of Industry Days to MDUFA V Decision** | 10.34 | | | | |
| 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 | 16 | | | | |
| Maximum Industry Days to MDUFA V Decision | 78 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 65.77 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 28 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 51 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 63 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 101 | | | | |
| Maximum Total Days to MDUFA V Decision | 139 | | | | |

**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 | 149 | | | | |
| Number With MDUFA V Decision | 35 | | | | |
| Number of SE Decision | 34 | | | | |
| Number of NSE Decision | 1 | | | | |
| Number of Withdrawal | 0 | | | | |
| Number of Deleted | 0 | | | | |
| Rate of SE Decision | 97.14% | | | | |
| Rate of NSE Decision | 2.86% | | | | |
| Rate of Withdrawal | 0.00% | | | | |
| 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 | 1 | | | | |
| Mean FDA Days for Submissions that Missed the Goal | 91.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 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 | 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 | 189 | | | | |
| Closed Before First RTA or TS Action [1] | 3 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 130 | | | | |
| 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] | 12 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 44 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 25.29% | | | | |

**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 | 152 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 94 | | | | |
| SI Over 60 FDA Days | 0 | | | | |
| 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 | 100.00% | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Substantive Interaction | 94 | | | | |
| Average Number of FDA Days to Substantive Interaction | 51.34 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 43 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 56 | | | | |
| 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 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 | 152 | | | | |
| Non-MDUFA V Decision | 0 | | | | |
| MDUFA V Decision (SE/NSE) | 30 | | | | |
| MDUFA V Decision Within 90 FDA Days | 30 | | | | |
| 510(k)s Pending MDUFA V Decision | 122 | | | | |
| 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 | 1.23 | | | | |
| Number With MDUFA V Decision | 30 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 52.17 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 28 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 30 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 58 | | | | |
| 80th Percentile FDA Days to MDUFA V Decision | 86 | | | | |
| Maximum FDA Days to MDUFA V Decision | 90 | | | | |
| **Average Number of Industry Days to MDUFA V Decision** | 5.20 | | | | |
| 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 | 1 | | | | |
| Maximum Industry Days to MDUFA V Decision | 62 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 57.37 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 28 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 30 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 60 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 87 | | | | |
| Maximum Total Days to MDUFA V Decision | 150 | | | | |

**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 | 152 | | | | |
| Number With MDUFA V Decision | 30 | | | | |
| Number of SE Decision | 30 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 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 | 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 | 299 | | | | |
| Closed Before First RTA or TS Action [1] | 4 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 216 | | | | |
| 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] | 19 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 60 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 21.74% | | | | |

**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 | 247 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 160 | | | | |
| SI Over 60 FDA Days | 2 | | | | |
| SI Pending Within 60 FDA Days | 85 | | | | |
| SI Pending Over 60 FDA Days | 0 | | | | |
| 510(k)s NSE Without SI | 0 | | | | |
| Current SI Performance Percent Within 60 FDA Days | 98.77% | | | | |

**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 | 162 | | | | |
| Average Number of FDA Days to Substantive Interaction | 49.75 | | | | |
| 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 | 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 | 247 | | | | |
| Non-MDUFA V Decision | 0 | | | | |
| MDUFA V Decision (SE/NSE) | 86 | | | | |
| MDUFA V Decision Within 90 FDA Days | 86 | | | | |
| 510(k)s Pending MDUFA V Decision | 161 | | | | |
| 510(k)s Pending MDUFA V Decision Over 90 FDA Days | 0 | | | | |
| Current Performance Percent Within 90 FDA Days | 100.00% | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 1.36 | | | | |
| Number With MDUFA V Decision | 86 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 60.51 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 31 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 56 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 70 | | | | |
| 80th Percentile FDA Days to MDUFA V Decision | 85 | | | | |
| Maximum FDA Days to MDUFA V Decision | 90 | | | | |
| **Average Number of Industry Days to MDUFA V Decision** | 9.02 | | | | |
| 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 | 15 | | | | |
| Maximum Industry Days to MDUFA V Decision | 83 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 69.53 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 39 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 57 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 78 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 93 | | | | |
| Maximum Total Days to MDUFA V Decision | 164 | | | | |

**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 | 247 | | | | |
| Number With MDUFA V Decision | 86 | | | | |
| Number of SE Decision | 86 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 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 | 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 | 130 | | | | |
| Closed Before First RTA or TS Action [1] | 1 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 84 | | | | |
| 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] | 10 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 34 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 28.57% | | | | |

**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 | 98 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 70 | | | | |
| SI Over 60 FDA Days | 1 | | | | |
| SI Pending Within 60 FDA Days | 27 | | | | |
| SI Pending Over 60 FDA Days | 0 | | | | |
| 510(k)s NSE Without SI | 0 | | | | |
| Current SI Performance Percent Within 60 FDA Days | 98.59% | | | | |

**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 | 71 | | | | |
| Average Number of FDA Days to Substantive Interaction | 53.35 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 46 | | | | |
| 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 | 64 | | | | |

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

| Performance Metric | FY 2023 95% Within 90 FDA Days | FY 2024 95% Within 90 FDA Days | FY 2025 95% Within 90 FDA Days | FY 2026 95% Within 90 FDA Days | FY 2027 95% Within 90 FDA Days |
|---|---|---|---|---|---|
| 510(k)s Accepted | 98 | | | | |
| Non-MDUFA V Decision | 2 | | | | |
| MDUFA V Decision (SE/NSE) | 24 | | | | |
| MDUFA V Decision Within 90 FDA Days | 24 | | | | |
| 510(k)s Pending MDUFA V Decision | 72 | | | | |
| 510(k)s Pending MDUFA V Decision Over 90 FDA Days | 0 | | | | |
| Current Performance Percent Within 90 FDA Days | 100.00% | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 1.25 | | | | |
| Number With MDUFA V Decision | 24 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 59.38 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 47 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 81 | | | | |
| 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** | 11.79 | | | | |
| 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 | 33 | | | | |
| Maximum Industry Days to MDUFA V Decision | 67 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 71.17 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 48 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 88 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 103 | | | | |
| Maximum Total Days to MDUFA V Decision | 157 | | | | |

**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 | 98 | | | | |
| Number With MDUFA V Decision | 24 | | | | |
| Number of SE Decision | 24 | | | | |
| Number of NSE Decision | 0 | | | | |
| Number of Withdrawal | 1 | | | | |
| Number of Deleted | 0 | | | | |
| Rate of SE Decision | 100.00% | | | | |
| Rate of NSE Decision | 0.00% | | | | |
| Rate of Withdrawal | 1.02% | | | | |
| Rate of Deleted | 0.00% | | | | |

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

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

**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 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 | 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 | 299 | | | | |
| Closed Before First RTA or TS Action [1] | 4 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 206 | | | | |
| 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] | 29 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 60 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 22.56% | | | | |

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

### Table 6.2 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 | 236 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 176 | | | | |
| SI Over 60 FDA Days | 0 | | | | |
| SI Pending Within 60 FDA Days | 60 | | | | |
| 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 | 176 | | | | |
| Average Number of FDA Days to Substantive Interaction | 49.22 | | | | |
| 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 | 236 | | | | |
| Non-MDUFA V Decision | 2 | | | | |
| MDUFA V Decision (SE/NSE) | 104 | | | | |
| MDUFA V Decision Within 90 FDA Days | 104 | | | | |
| 510(k)s Pending MDUFA V Decision | 130 | | | | |
| 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 | 1.28 | | | | |
| Number With MDUFA V Decision | 104 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 56.60 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 53 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 60 | | | | |
| 80th Percentile FDA Days to MDUFA V Decision | 85 | | | | |
| Maximum FDA Days to MDUFA V Decision | 90 | | | | |
| **Average Number of Industry Days to MDUFA V Decision** | 6.38 | | | | |
| 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 | 8 | | | | |
| Maximum Industry Days to MDUFA V Decision | 84 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 62.97 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 55 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 60 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 92 | | | | |
| Maximum Total Days to MDUFA V Decision | 168 | | | | |

**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 | 236 | | | | |
| Number With MDUFA V Decision | 104 | | | | |
| Number of SE Decision | 104 | | | | |
| Number of NSE Decision | 0 | | | | |
| Number of Withdrawal | 2 | | | | |
| Number of Deleted | 0 | | | | |
| Rate of SE Decision | 100.00% | | | | |
| Rate of NSE Decision | 0.00% | | | | |
| Rate of Withdrawal | 0.85% | | | | |
| 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 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 | 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 | 112 | | | | |
| Closed Before First RTA or TS Action [1] | 4 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 78 | | | | |
| 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] | 13 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 15 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 15.79% | | | | |

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

### Table 6.2 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 | 83 | | | | |
| Deleted or Withdrawn Prior to SI | 2 | | | | |
| SI Within 60 FDA Days | 62 | | | | |
| SI Over 60 FDA Days | 0 | | | | |
| SI Pending Within 60 FDA Days | 19 | | | | |
| 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 | 62 | | | | |
| Average Number of FDA Days to Substantive Interaction | 52.29 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 46 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 57 | | | | |
| 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 | 83 | | | | |
| Non-MDUFA V Decision | 2 | | | | |
| MDUFA V Decision (SE/NSE) | 28 | | | | |
| MDUFA V Decision Within 90 FDA Days | 28 | | | | |
| 510(k)s Pending MDUFA V Decision | 53 | | | | |
| 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 | 1.04 | | | | |
| Number With MDUFA V Decision | 28 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 56.07 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 48 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 61 | | | | |
| 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** | 2.61 | | | | |
| 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 | 73 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 58.68 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 29 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 48 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 61 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 89 | | | | |
| Maximum Total Days to MDUFA V Decision | 161 | | | | |

**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 | 83 | | | | |
| Number With MDUFA V Decision | 28 | | | | |
| Number of SE Decision | 28 | | | | |
| Number of NSE Decision | 0 | | | | |
| Number of Withdrawal | 2 | | | | |
| Number of Deleted | 0 | | | | |
| Rate of SE Decision | 100.00% | | | | |
| Rate of NSE Decision | 0.00% | | | | |
| Rate of Withdrawal | 2.41% | | | | |
| Rate of Deleted | 0.00% | | | | |

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

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

**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 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 | 82 | | | | |
| Non-MDUFA V Decision | 2 | | | | |
| MDUFA V Decision (SE/NSE) | 27 | | | | |
| MDUFA V Decision Within 90 FDA Days | 27 | | | | |
| 510(k)s Pending MDUFA V Decision | 53 | | | | |
| 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 | 204 | | | | |
| Closed Before First RTA or TS Action [1] | 1 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 162 | | | | |
| 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] | 16 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 23 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 12.30% | | | | |

**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 | 178 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 144 | | | | |
| SI Over 60 FDA Days | 0 | | | | |
| 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 | 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 | 144 | | | | |
| Average Number of FDA Days to Substantive Interaction | 49.04 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 32 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 53 | | | | |
| 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 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 | 178 | | | | |
| Non-MDUFA V Decision | 1 | | | | |
| MDUFA V Decision (SE/NSE) | 63 | | | | |
| MDUFA V Decision Within 90 FDA Days | 63 | | | | |
| 510(k)s Pending MDUFA V Decision | 114 | | | | |
| 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 | 1.40 | | | | |
| Number With MDUFA V Decision | 63 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 54.08 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 27 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 48 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 58 | | | | |
| 80th Percentile FDA Days to MDUFA V Decision | 85 | | | | |
| Maximum FDA Days to MDUFA V Decision | 89 | | | | |
| **Average Number of Industry Days to MDUFA V Decision** | 11.08 | | | | |
| 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 | 29 | | | | |
| Maximum Industry Days to MDUFA V Decision | 59 | | | | |
| **Average Number of Total Days to MDUFA V Decision** | 65.16 | | | | |
| 20th Percentile Total Days to MDUFA V Decision | 27 | | | | |
| 40th Percentile Total Days to MDUFA V Decision | 49 | | | | |
| 60th Percentile Total Days to MDUFA V Decision | 63 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 107 | | | | |
| Maximum Total Days to MDUFA V Decision | 141 | | | | |

**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 | 178 | | | | |
| Number With MDUFA V Decision | 63 | | | | |
| Number of SE Decision | 63 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 IVD (Non-LDT) 510(k) MDUFA V Decision Metric**

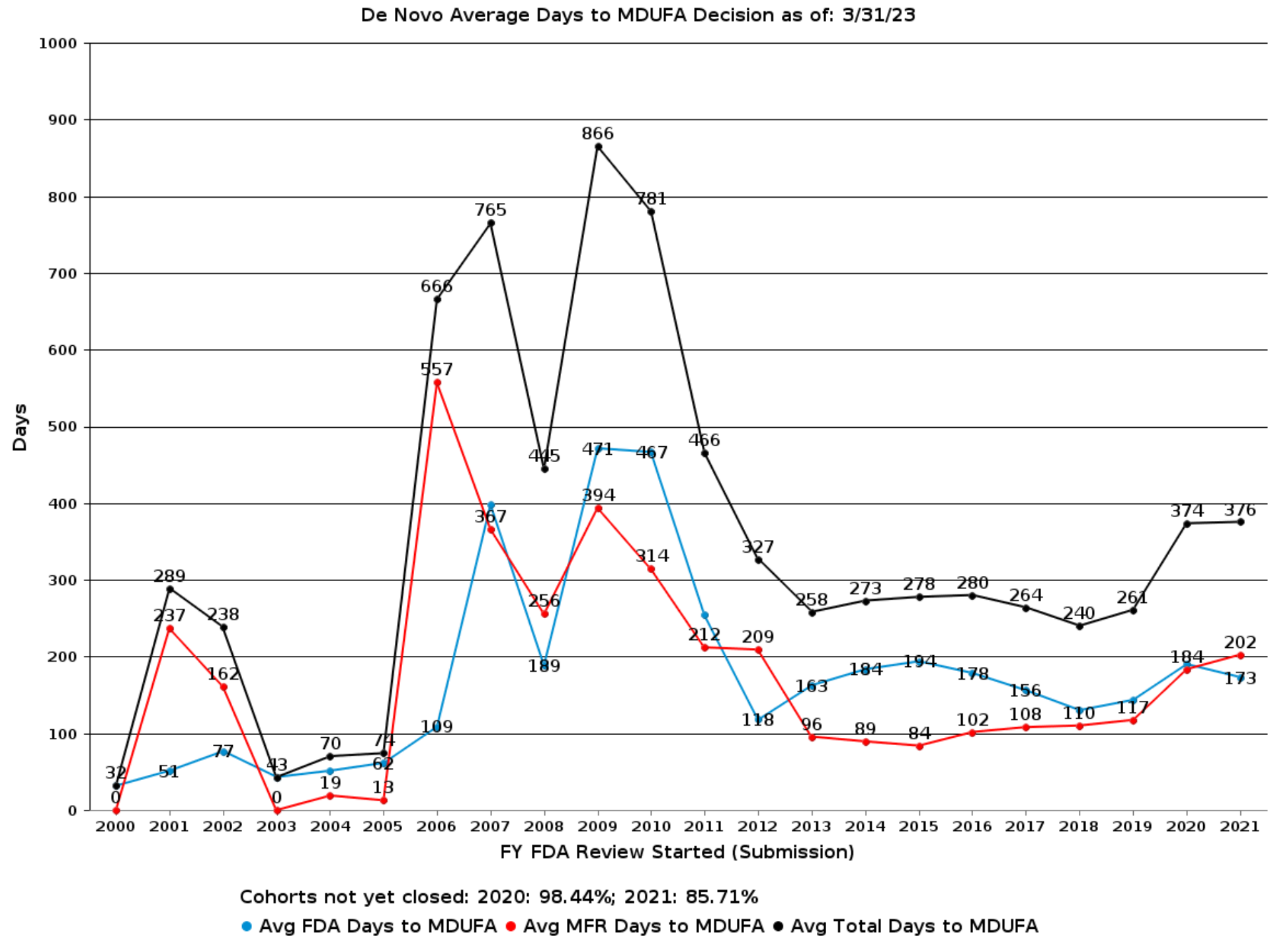
| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| 510(k)s Accepted | N/A | | | | |
| Non-MDUFA V Decision | N/A | | | | |
| MDUFA V Decision (SE/NSE) | N/A | | | | |
| MDUFA V Decision Within 90 FDA Days | N/A | | | | |
| 510(k)s Pending MDUFA V Decision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

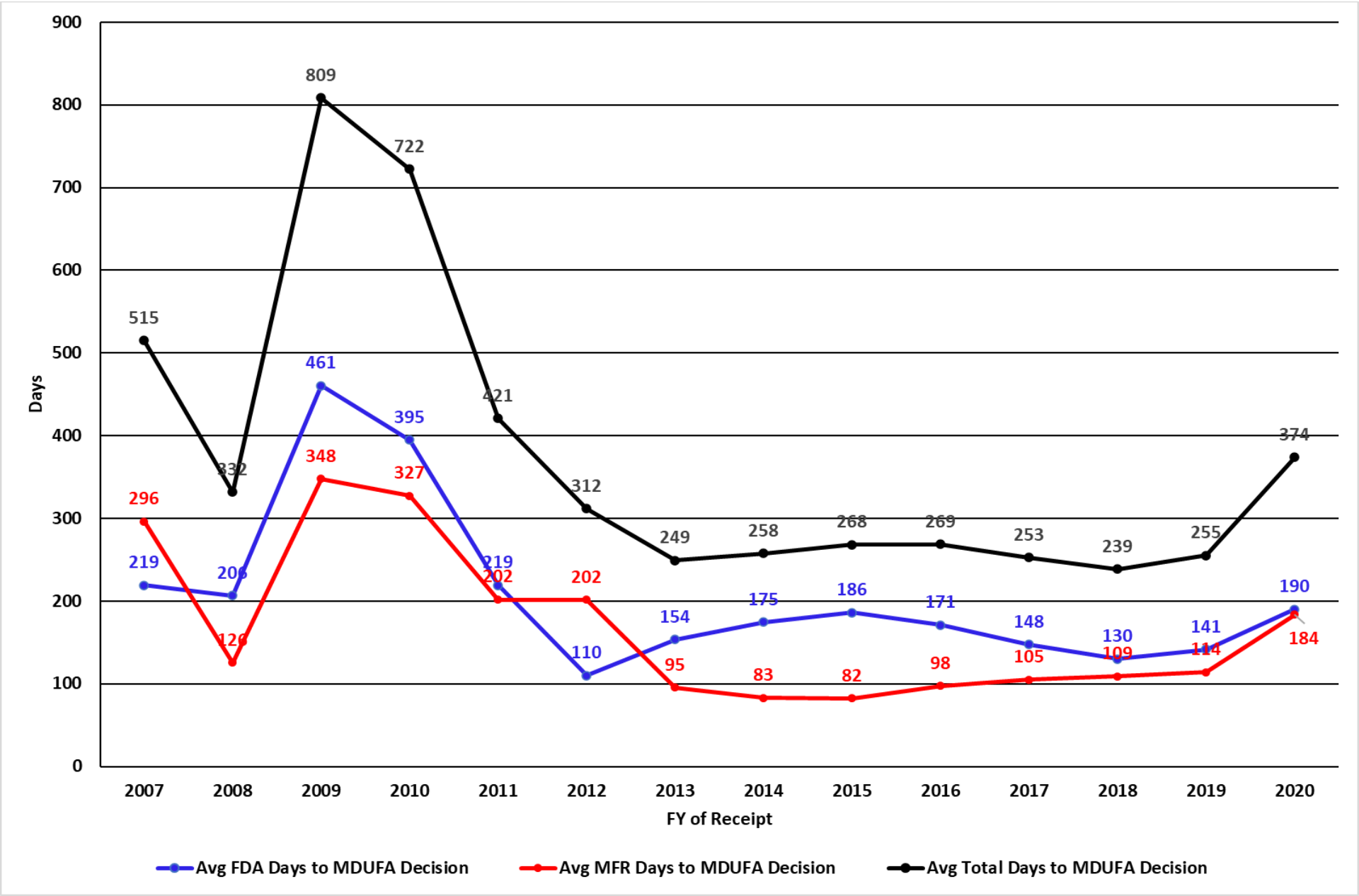
# De Novos

## Q2FY2023


De Novo Average Days to MDUFA Decision as of: 3/31/23
Days
FY FDA Review Started (Submission)
Cohorts not yet closed: 2020: 98.44%; 2021: 85.71%
Avg FDA Days to MDUFA
Avg MFR Days to MDUFA
Avg Total Days to MDUFA

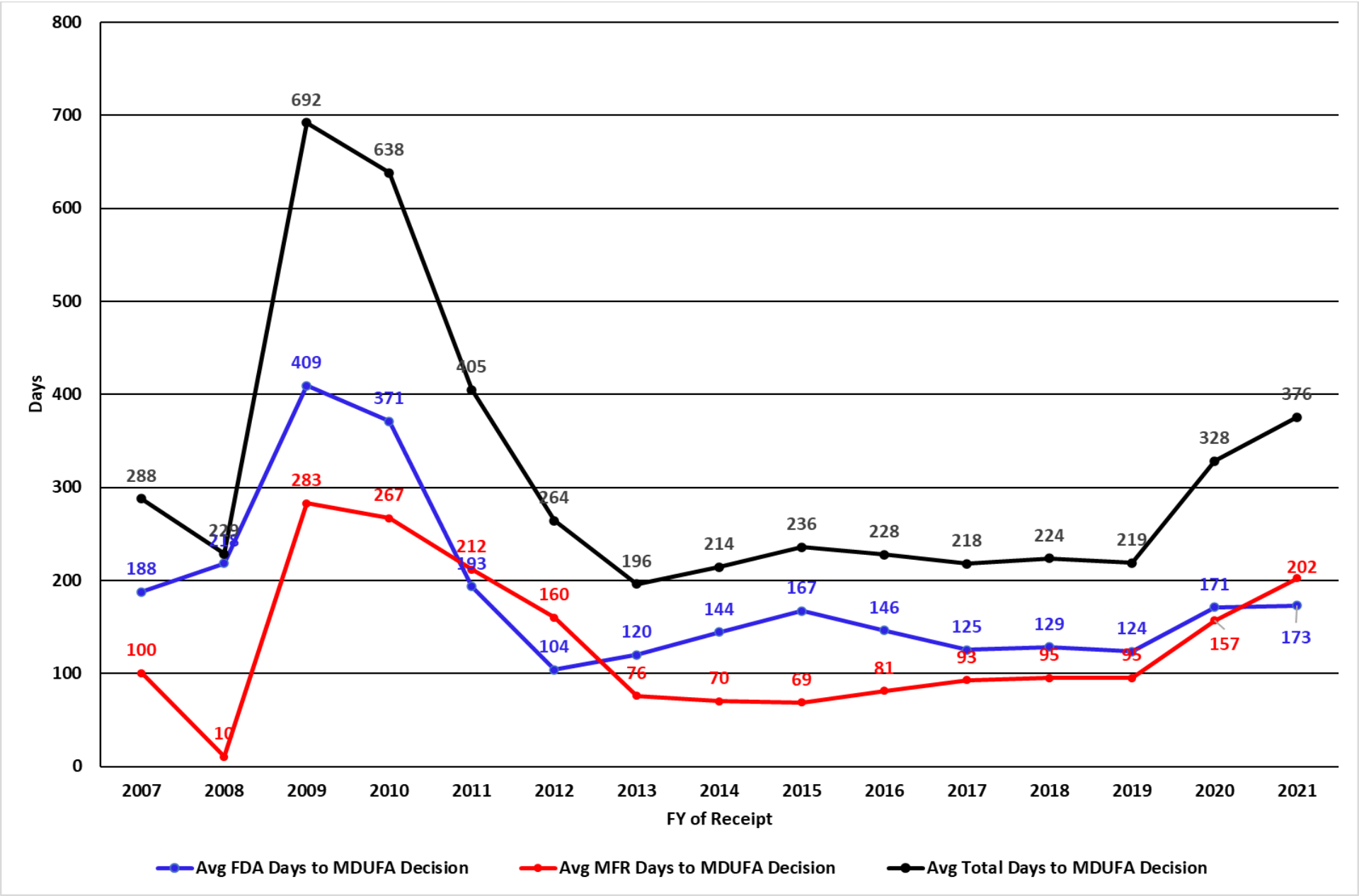
# Average Time to MDUFA Decision: De Novos

(98.4% closure comparison)

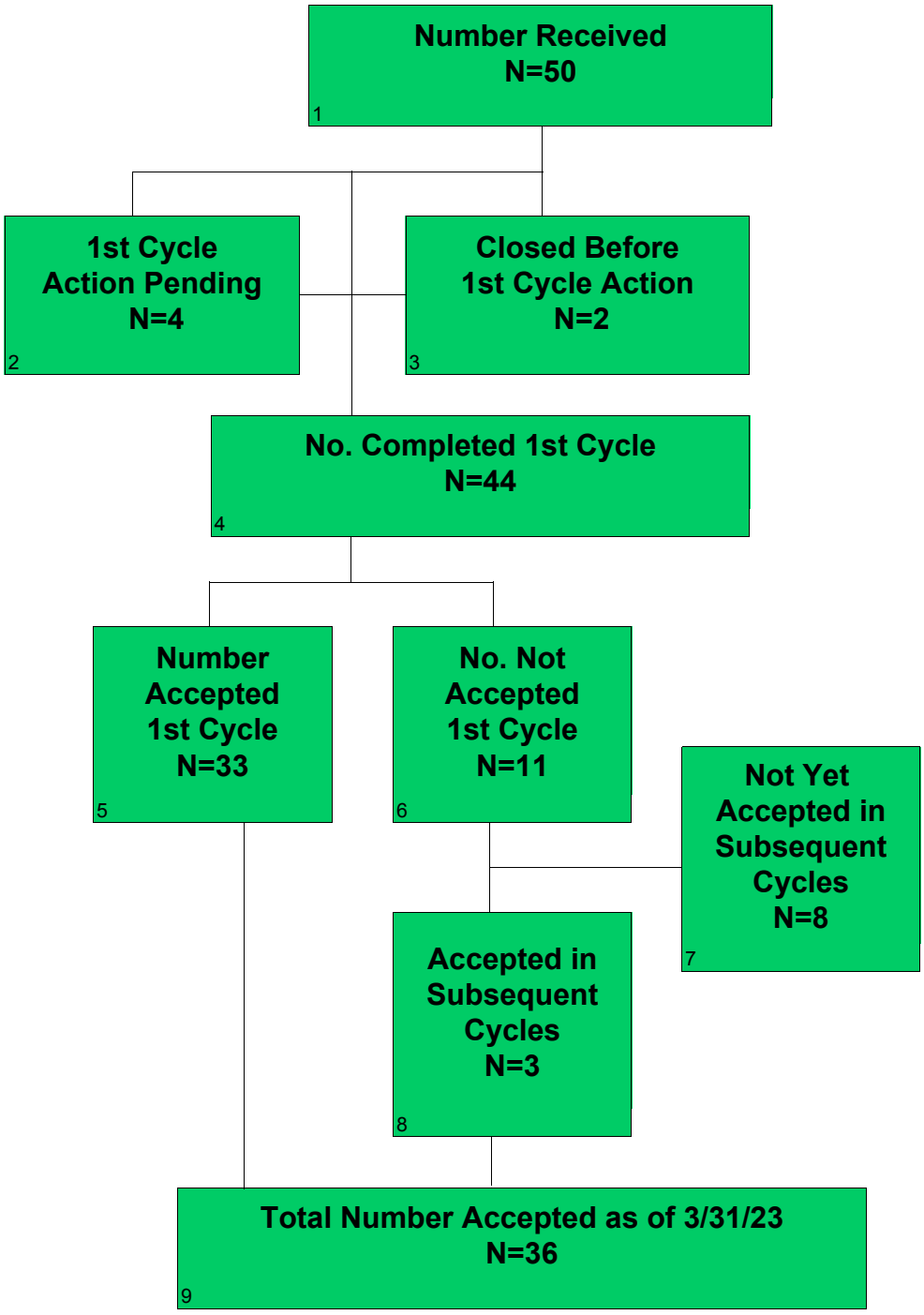


# Average Time to MDUFA Decision: De Novos

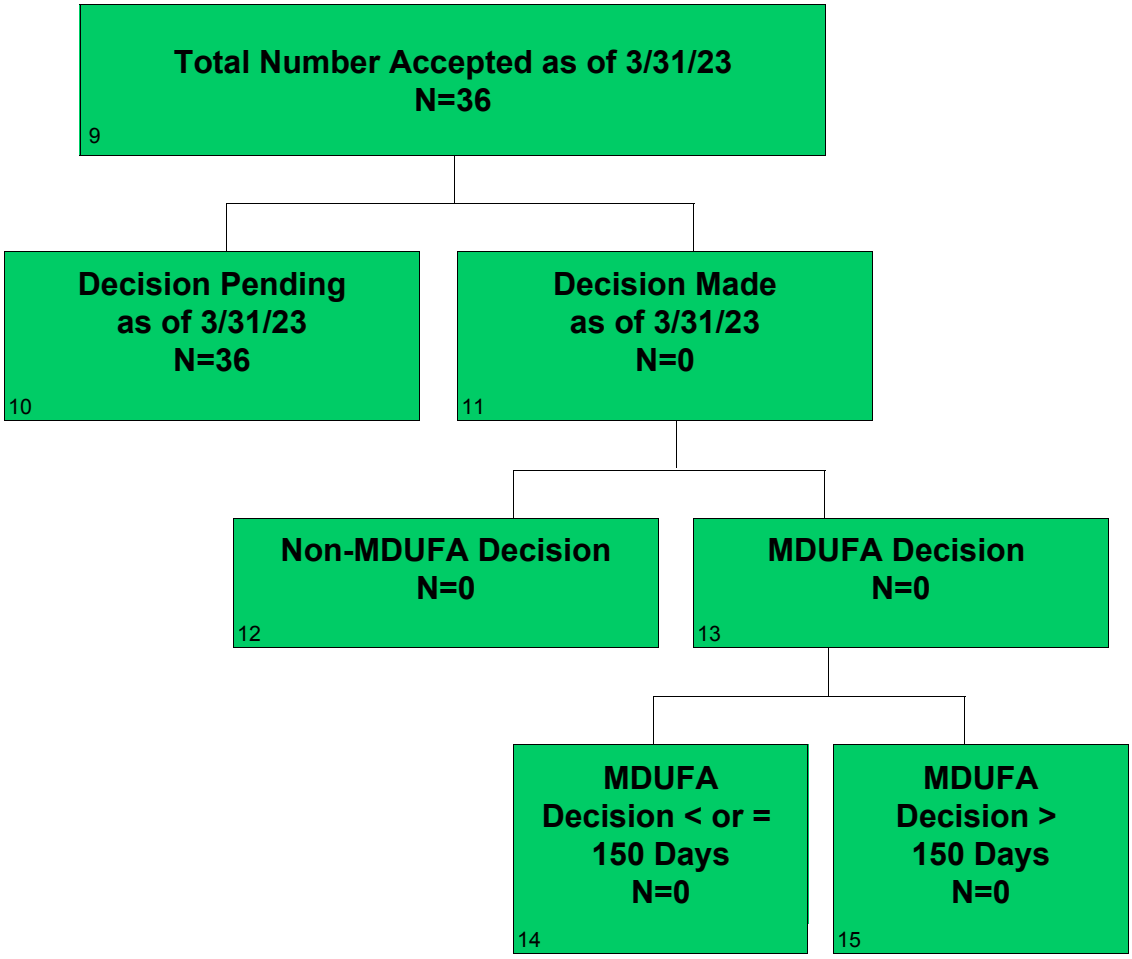
(85.7% closure comparison)



# CDRH De Novo - FY 2023
# as of 3/31/23



# CDRH De Novo - FY 2023
# as of 3/31/23 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 | 50 | | | | |
| Closed Before First RTA or TS Action | 2 | | | | |
| Number Accepted or Passed TS on First Cycle | 33 | | | | |
| 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 | 4 | | | | |
| Number Not Accepted or Failed TS on First Cycle | 11 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle | 25.00% | | | | |

**1.The data contained in this row should be combined with the data in the row above, "Number Accepted or Passed TS on First Cycle", to determine the total number of submissions accepted or passed on the first RTA or TS cycle (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 | 36 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 36 | | | | |
| De Novos Pending MDUFA Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

**Table 8.3 CDRH - De Novo Time to MDUFA V Decision**

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 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 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 | 36 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | | | | |

**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 | 8 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 8 | | | | |
| De Novos Pending MDUFA Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

## Section 8 - De Novo Office Level Metrics

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 6 | | | | |
| 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 | 3 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle | 50.00% | | | | |

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

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

| Performance Metric | FY 2023 70% Within 150 FDA Days | FY 2024 70% Within 150 FDA Days | FY 2025 70% Within 150 FDA Days | FY 2026 70% Within 150 FDA Days | FY 2027 70% Within 150 FDA Days |
|---|---|---|---|---|---|
| De Novos Accepted | 5 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 5 | | | | |
| 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 | 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 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 | 5 | | | | |
| 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

**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 | 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 | 1 | | | | |
| 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 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 | 7 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 7 | | | | |
| De Novos Pending MDUFA Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 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 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 | 7 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

**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 | 5 | | | | |
| Closed Before First RTA or TS Action | 0 | | | | |
| Number Accepted or Passed TS on First Cycle | 4 | | | | |
| 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 | 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 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 | 4 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 4 | | | | |
| De Novos Pending MDUFA Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 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 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 | 4 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

**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 | 10 | | | | |
| Closed Before First RTA or TS Action | 1 | | | | |
| 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 | 4 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle | 44.44% | | | | |

**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 | 6 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 6 | | | | |
| De Novos Pending MDUFA Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 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 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 | 6 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

**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 | 6 | | | | |
| 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 | 0 | | | | |
| 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 | 3 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 3 | | | | |
| De Novos Pending MDUFA Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 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 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 | 3 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

**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 | 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

**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 | 11 | | | | |
| Closed Before First RTA or TS Action | 0 | | | | |
| Number Accepted or Passed TS on First Cycle | 9 | | | | |
| 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 | 2 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle | 18.18% | | | | |

**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 | 9 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA Decision | 9 | | | | |
| De Novos Pending MDUFA Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Average Review Cycles | 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 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 | 9 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

**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 | 8 | | | | |
| Non-MDUFA Decision | 0 | | | | |
| MDUFA Decision | 0 | | | | |
| MDUFA Decision Within 150 FDA Days | 0 | | | | |
| De Novos Pending MDUFA IV Decision | 8 | | | | |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | | | | |
| Current Performance Percent Within 150 FDA Days | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 2 | | | | |
| 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 | 2 | | | | |
| Number Not Accepted or Failed TS on First Cycle | 0 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle | N/A | | | | |

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

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

| Performance Metric | FY 2023 70% Within 150 FDA Days | FY 2024 70% Within 150 FDA Days | FY 2025 70% Within 150 FDA Days | FY 2026 70% Within 150 FDA Days | FY 2027 70% Within 150 FDA Days |
|---|---|---|---|---|---|
| De Novos Accepted | 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 8.3 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 | 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 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 | 0 | | | | |
| 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 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 | 0.00 | | | | |
| Mean Industry Days for Submissions That Missed the Goal | 0.00 | | | | |

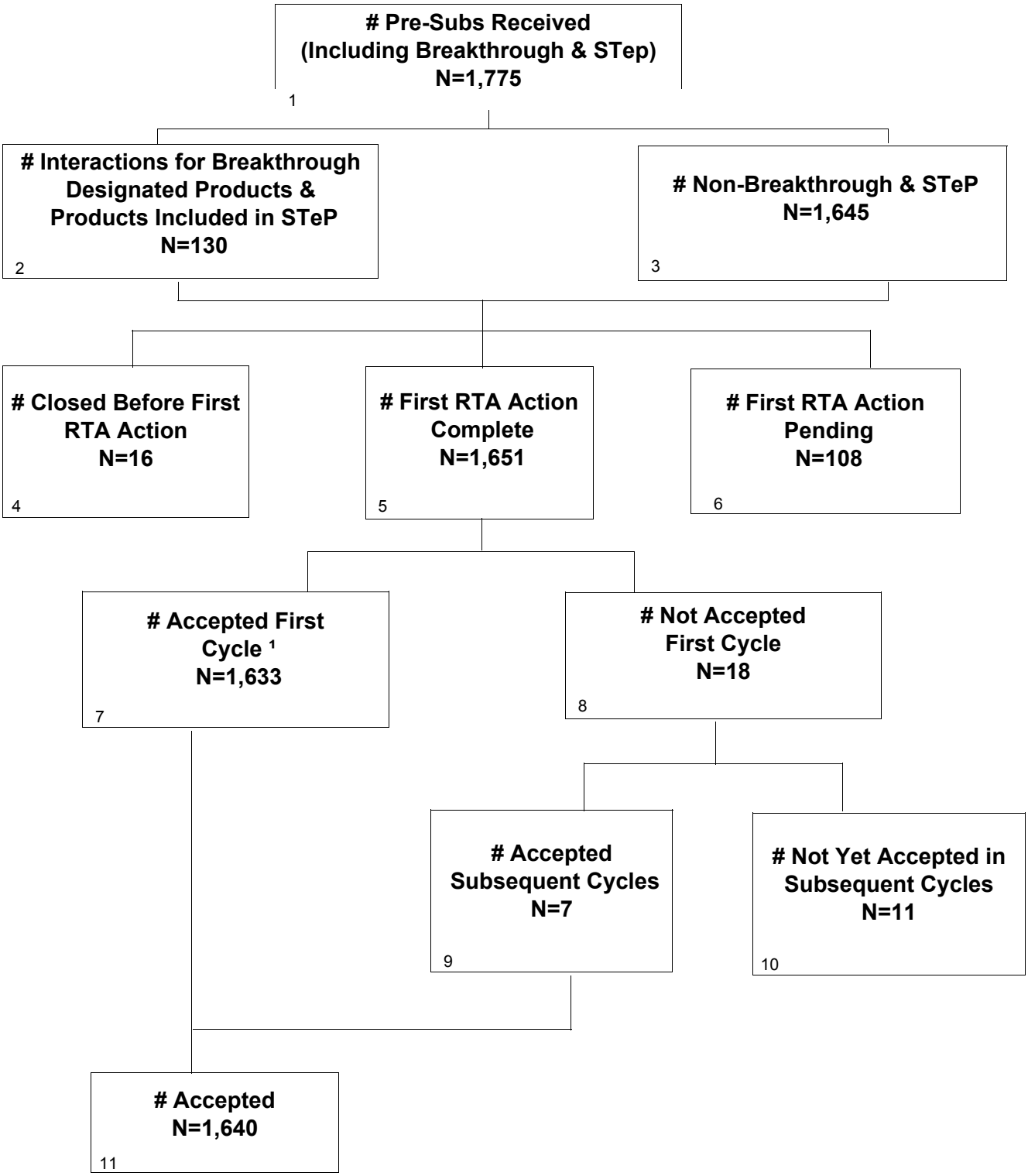
**Table 8.6 OHT8 - Office of Radiological Health**
**LDT De Novo MDUFA V Metrics**

| 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**

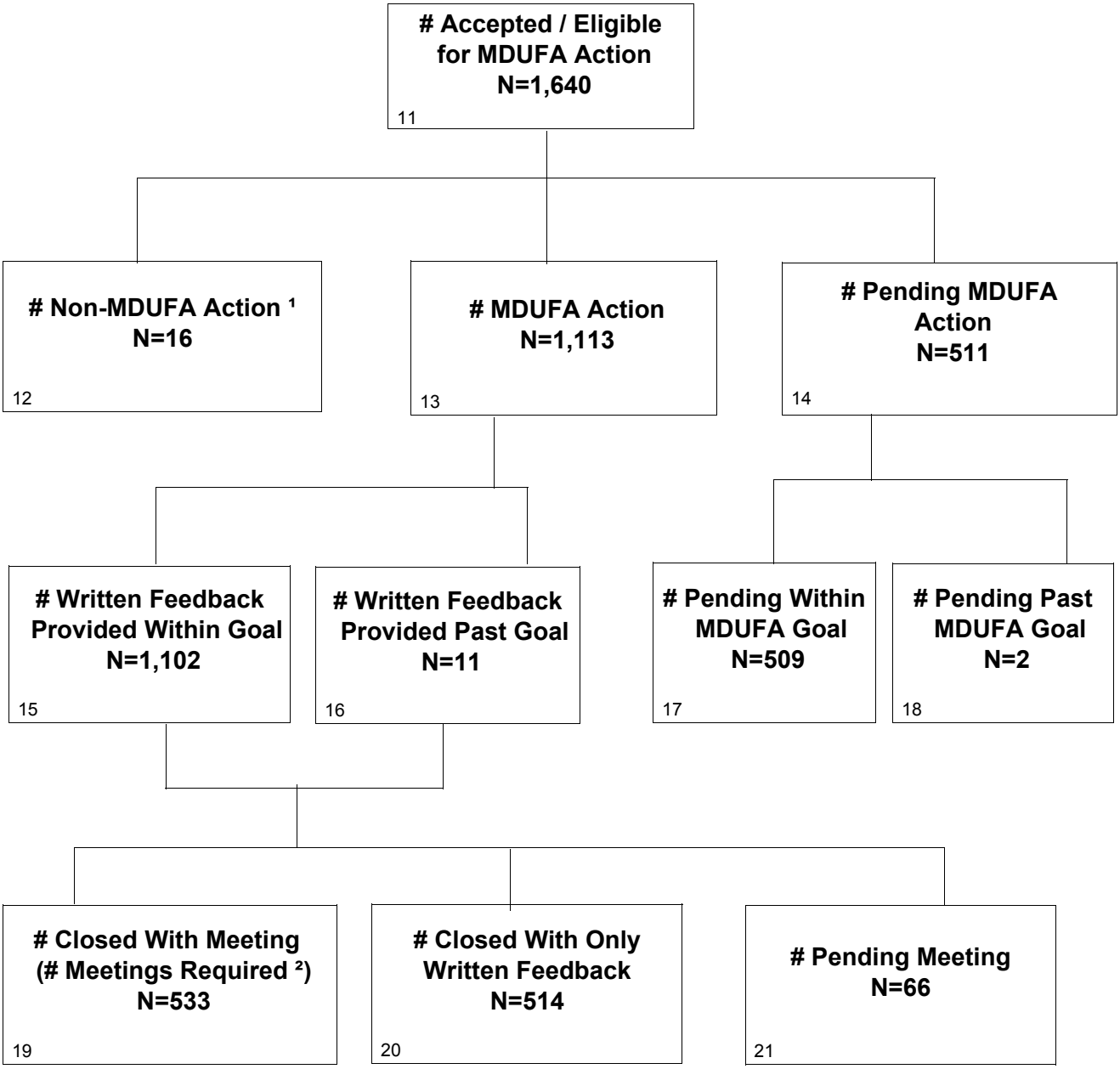
| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| De Novos Accepted | N/A | | | | |
| Non-MDUFA Decision | N/A | | | | |
| MDUFA Decision | N/A | | | | |
| MDUFA Decision Within 150 FDA Days | N/A | | | | |
| De Novos Pending MDUFA IV Decision | N/A | | | | |
| 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 3/31/23




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

# CDRH Pre-Sub - FY 2023
# as of 3/31/23 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 | 1,775 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 130 | | | | |
| Number Closed Before First RTA Action | 16 | | | | |
| Number Accepted First RTA Cycle [1] | 1,578 | | | | |
| Number Without First Cycle RTA Review and > 15 Days Since Date Received [2] | 55 | | | | |
| Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending) | 108 | | | | |
| Number Not Accepted First RTA Cycle | 18 | | | | |
| 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 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 | 1,640 | | | | |
| Number with Non-MDUFA Action [3] | 16 | | | | |
| Number with MDUFA Action | 1,113 | | | | |
| Written Feedback Provided Within Goal | 1,102 | | | | |
| Number Pending MDUFA Action | 511 | | | | |
| Pending MDUFA Action Past Goal | 2 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 1,624 | | | | |
| Current Performance Percent Within Goal | 98.83% | | | | |

**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 | 1,113 | | | | |
| Average FDA Days to Written Feedback | 60.70 | | | | |
| 20th Percentile FDA Days to Written Feedback | 53 | | | | |
| 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 | 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 | 48 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 39.81 | | | | |

**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] | 532 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 358 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 39 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 113 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 22 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 72.62% | | | | |

**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 | 204 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 8 | | | | |
| Number Closed Before First RTA Action | 2 | | | | |
| Number Accepted First RTA Cycle [1] | 182 | | | | |
| Number Without First Cycle RTA Review and > 15 Days Since Date Received [2] | 6 | | | | |
| Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending) | 12 | | | | |
| Number Not Accepted First RTA Cycle | 2 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 1.05% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 189 | | | | |
| Number with Non-MDUFA Action [3] | 3 | | | | |
| Number with MDUFA Action | 128 | | | | |
| Written Feedback Provided Within Goal | 123 | | | | |
| Number Pending MDUFA Action | 58 | | | | |
| Pending MDUFA Action Past Goal | 1 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 186 | | | | |
| Current Performance Percent Within Goal | 95.35% | | | | |

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

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

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

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

**Table 9.3 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 | 128 | | | | |
| Average FDA Days to Written Feedback | 64.79 | | | | |
| 20th Percentile FDA Days to Written Feedback | 59 | | | | |
| 40th Percentile FDA Days to Written Feedback | 65 | | | | |
| 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 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 | 12 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 41.50 | | | | |

**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] | 68 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 43 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 2 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 17 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 6 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 65.15% | | | | |

**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 | 340 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 36 | | | | |
| Number Closed Before First RTA Action | 2 | | | | |
| Number Accepted First RTA Cycle [1] | 308 | | | | |
| Number Without First Cycle RTA Review and > 15 Days Since Date Received [2] | 6 | | | | |
| Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending) | 22 | | | | |
| Number Not Accepted First RTA Cycle | 2 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 0.63% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 315 | | | | |
| Number with Non-MDUFA Action [3] | 1 | | | | |
| Number with MDUFA Action | 230 | | | | |
| Written Feedback Provided Within Goal | 225 | | | | |
| Number Pending MDUFA Action | 84 | | | | |
| Pending MDUFA Action Past Goal | 0 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 314 | | | | |
| Current Performance Percent Within Goal | 97.83% | | | | |

**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 | 230 | | | | |
| Average FDA Days to Written Feedback | 57.04 | | | | |
| 20th Percentile FDA Days to Written Feedback | 46 | | | | |
| 40th Percentile FDA Days to Written Feedback | 57 | | | | |
| 60th Percentile FDA Days to Written Feedback | 64 | | | | |
| 80th Percentile FDA Days to Written Feedback | 68 | | | | |
| Maximum FDA Days to Written Feedback | 81 | | | | |

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

**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] | 121 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 85 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 9 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 21 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 6 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 75.89% | | | | |

**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 | 205 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 17 | | | | |
| Number Closed Before First RTA Action | 1 | | | | |
| Number Accepted First RTA Cycle [1] | 183 | | | | |
| 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) | 15 | | | | |
| Number Not Accepted First RTA Cycle | 3 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 1.59% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 189 | | | | |
| Number with Non-MDUFA Action [3] | 5 | | | | |
| Number with MDUFA Action | 118 | | | | |
| Written Feedback Provided Within Goal | 117 | | | | |
| Number Pending MDUFA Action | 66 | | | | |
| Pending MDUFA Action Past Goal | 0 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 184 | | | | |
| Current Performance Percent Within Goal | 99.15% | | | | |

**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 | 118 | | | | |
| Average FDA Days to Written Feedback | 60.85 | | | | |
| 20th Percentile FDA Days to Written Feedback | 53 | | | | |
| 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 | 2 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 60.00 | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Required [1] | 61 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 42 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 3 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 15 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 1 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 72.41% | | | | |

**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 | 159 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 7 | | | | |
| Number Closed Before First RTA Action | 1 | | | | |
| Number Accepted First RTA Cycle [1] | 142 | | | | |
| Number Without First Cycle RTA Review and > 15 Days Since Date Received [2] | 2 | | | | |
| Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending) | 11 | | | | |
| Number Not Accepted First RTA Cycle | 3 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 2.04% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 144 | | | | |
| Number with Non-MDUFA Action [3] | 2 | | | | |
| Number with MDUFA Action | 93 | | | | |
| Written Feedback Provided Within Goal | 93 | | | | |
| Number Pending MDUFA Action | 49 | | | | |
| Pending MDUFA Action Past Goal | 0 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 142 | | | | |
| 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 | 93 | | | | |
| Average FDA Days to Written Feedback | 57.27 | | | | |
| 20th Percentile FDA Days to Written Feedback | 48 | | | | |
| 40th Percentile FDA Days to Written Feedback | 59 | | | | |
| 60th Percentile FDA Days to Written Feedback | 64 | | | | |
| 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 | 6 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 32.00 | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Required [1] | 45 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 33 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 3 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 8 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 1 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 78.57% | | | | |

**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 | 181 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 19 | | | | |
| Number Closed Before First RTA Action | 3 | | | | |
| Number Accepted First RTA Cycle [1] | 155 | | | | |
| Number Without First Cycle RTA Review and > 15 Days Since Date Received [2] | 7 | | | | |
| Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending) | 13 | | | | |
| Number Not Accepted First RTA Cycle | 3 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 1.82% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 164 | | | | |
| Number with Non-MDUFA Action [3] | 0 | | | | |
| Number with MDUFA Action | 102 | | | | |
| Written Feedback Provided Within Goal | 102 | | | | |
| Number Pending MDUFA Action | 62 | | | | |
| Pending MDUFA Action Past Goal | 1 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 164 | | | | |
| Current Performance Percent Within Goal | 99.03% | | | | |

**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 | 102 | | | | |
| Average FDA Days to Written Feedback | 65.89 | | | | |
| 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 | 70 | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Not Scheduled By Day 30 | 9 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 37.33 | | | | |

**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] | 62 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 39 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 5 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 17 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 1 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 68.42% | | | | |

**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 | 145 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 21 | | | | |
| Number Closed Before First RTA Action | 2 | | | | |
| Number Accepted First RTA Cycle [1] | 124 | | | | |
| Number Without First Cycle RTA Review and > 15 Days Since Date Received [2] | 6 | | | | |
| Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending) | 12 | | | | |
| Number Not Accepted First RTA Cycle | 1 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 0.76% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 130 | | | | |
| Number with Non-MDUFA Action [3] | 2 | | | | |
| Number with MDUFA Action | 90 | | | | |
| Written Feedback Provided Within Goal | 90 | | | | |
| Number Pending MDUFA Action | 38 | | | | |
| Pending MDUFA Action Past Goal | 0 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 128 | | | | |
| 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 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 | 90 | | | | |
| Average FDA Days to Written Feedback | 57.22 | | | | |
| 20th Percentile FDA Days to Written Feedback | 45 | | | | |
| 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 | 70 | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Not Scheduled By Day 30 | 1 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 41.00 | | | | |

**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] | 36 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 25 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 2 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 6 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 3 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 73.53% | | | | |

**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 | 411 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 20 | | | | |
| Number Closed Before First RTA Action | 4 | | | | |
| Number Accepted First RTA Cycle [1] | 366 | | | | |
| Number Without First Cycle RTA Review and > 15 Days Since Date Received [2] | 22 | | | | |
| Number Without a First Cycle RTA Review and <= 15 Days Since Date Received (First RTA Action Pending) | 18 | | | | |
| Number Not Accepted First RTA Cycle | 1 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 0.26% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 388 | | | | |
| Number with Non-MDUFA Action [3] | 1 | | | | |
| Number with MDUFA Action | 272 | | | | |
| Written Feedback Provided Within Goal | 272 | | | | |
| Number Pending MDUFA Action | 115 | | | | |
| Pending MDUFA Action Past Goal | 0 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 387 | | | | |
| 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 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 | 272 | | | | |
| Average FDA Days to Written Feedback | 62.39 | | | | |
| 20th Percentile FDA Days to Written Feedback | 60 | | | | |
| 40th Percentile FDA Days to Written Feedback | 64 | | | | |
| 60th Percentile FDA Days to Written Feedback | 69 | | | | |
| 80th Percentile FDA Days to Written Feedback | 70 | | | | |
| Maximum FDA Days to Written Feedback | 70 | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Not Scheduled By Day 30 | 5 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 39.00 | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Required [1] | 76 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 47 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 13 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 16 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 0 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 74.60% | | | | |

**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 | 130 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 2 | | | | |
| Number Closed Before First RTA Action | 1 | | | | |
| Number Accepted First RTA Cycle [1] | 118 | | | | |
| 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) | 5 | | | | |
| Number Not Accepted First RTA Cycle | 3 | | | | |
| Rate of Submissions Not Accepted for Review on First RTA Cycle | 2.42% | | | | |

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

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

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

| Performance Metric | MDUFA V Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|---|---|---|---|---|---|
| | FY 2023 90% / 75% Within MDUFA Goal [1] | FY 2024 90% / 80% Within MDUFA Goal [2] | FY 2025 90% Within MDUFA Goal | FY 2026 90% Within MDUFA Goal | FY 2027 90% Within MDUFA Goal |
| Number Accepted / Eligible for MDUFA Action | 121 | | | | |
| Number with Non-MDUFA Action [3] | 2 | | | | |
| Number with MDUFA Action | 80 | | | | |
| Written Feedback Provided Within Goal | 80 | | | | |
| Number Pending MDUFA Action | 39 | | | | |
| Pending MDUFA Action Past Goal | 0 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 119 | | | | |
| 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 | 80 | | | | |
| Average FDA Days to Written Feedback | 59.96 | | | | |
| 20th Percentile FDA Days to Written Feedback | 54 | | | | |
| 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)**

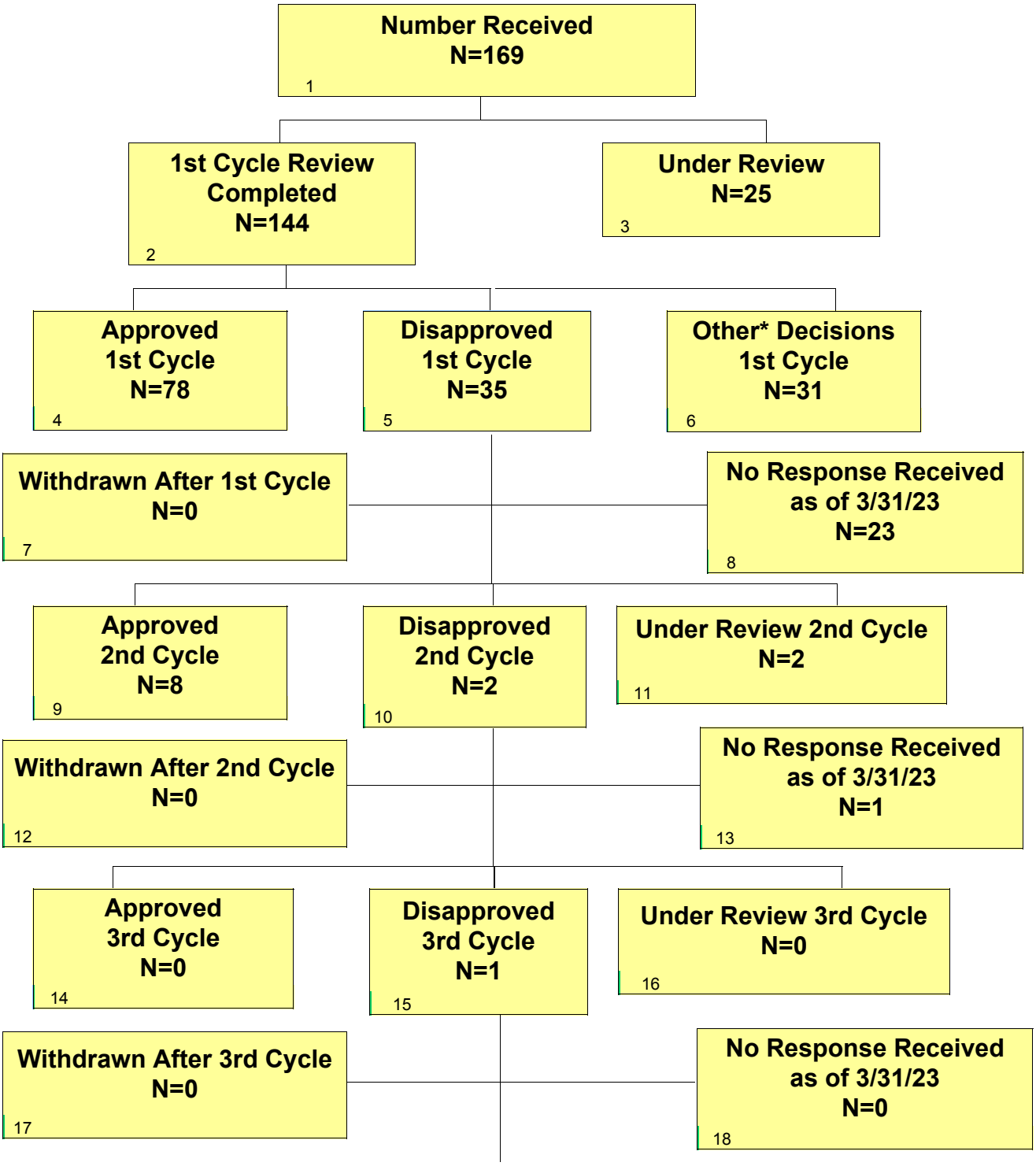
| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Not Scheduled By Day 30 | 2 | | | | |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 44.50 | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Meetings Required [1] | 63 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 44 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 2 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 13 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 4 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 72.13% | | | | |

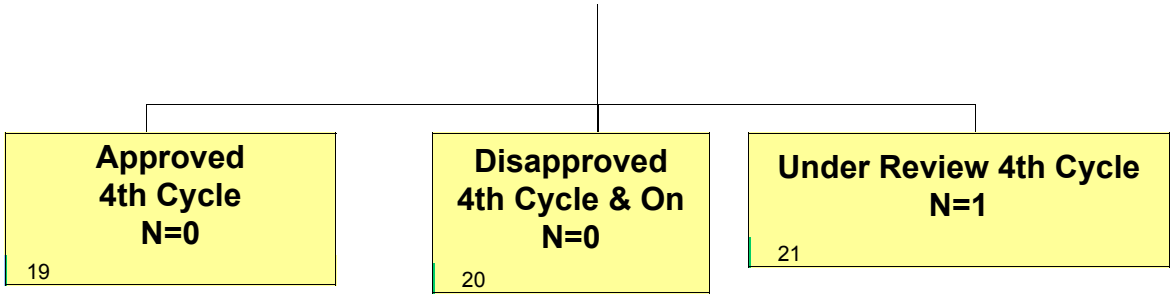
**1. Number of meetings requested and then held after written feedback is provided.**

# CDRH IDEs - FY 2023
# as of 3/31/23




*** Other decisions include withdrawn (N=6), withdrawn and converted (N=22), RTA (N=0), nonsignificant risk device (N=3), exempt (N=0), product jurisdiction pending (N=0), or product jurisdiction transferred (N=0), Basic Physiological Research (N=0).**

# CDRH IDEs - FY 2023
# as of 3/31/23



## 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 | 169 | | | | |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.09 | | | | |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.09 | | | | |

## 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 | 19 | | | | |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.20 | | | | |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.20 | | | | |

### 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 | 38 | | | | |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.28 | | | | |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.28 | | | | |

### 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 | 16 | | | | |
| 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 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 | 21 | | | | |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.08 | | | | |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.08 | | | | |

### 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 | 38 | | | | |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.05 | | | | |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.05 | | | | |

**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 | 10 | | | | |
| 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 | 23 | | | | |
| 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 | 4 | | | | |
| 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 | | | | |

# 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 | 90$^{th}$ Percentile FDA Days to MDUFA Decision | The 90$^{th}$ percentile of FDA days to MDUFA decision on 3$^{rd}$ Party 510(k) submissions received in this fiscal year |

## Section 8 De Novo MDUFA V Performance

### Table 8.1 and Tables 8.1.x De Novo Acceptance Review Decision - Definitions

| # | Measure | Description |
|---|---|---|
| 1 | Number Received | Number of De Novo submissions received in this fiscal year. |
| 2 | Closed Before First RTA or TS Action | Number Received (line 1) that were closed with a final decision before RTA or Technical Screening action. |
| 3 | Number Accepted or Passed TS on First Cycle | Number Received (line 1) that received an "RTA Accepted" (RTAA) decision or passed Technical Screening (TSOK) in the first RTA/TS review cycle. |
| 4 | Number Without a RTA or TS Review and > 15 Days Since Date Received | Number Received (line 1) that did not receive an RTA or TS decision in the 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).<br><br>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.<br><br>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.<br><br>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 31 March 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 | 0 | | | | |
| MDUFA V Decision Goal Met | 0 | | | | |
| PMAs Pending MDUFA V Decision | 2 | | | | |
| PMAs Pending MDUFA V Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 90% Within 320 FDA Days | FY 2024 90% Within 320 FDA Days | FY 2025 90% Within 320 FDA Days | FY 2026 90% Within 320 FDA Days | FY 2027 90% Within 320 FDA Days |
|---|---|---|---|---|---|
| Number of PMAs Filed | 0 | | | | |
| 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 | 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 1.8 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 | 0.00 | | | | |
| Maximum Industry Days to MDUFA V Decision | 0 | | | | |
| **Average Total Days to MDUFA V Decision** | 0 | | | | |
| 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 | 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 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 | 2 | | | | |
| SI Goal Met | 0 | | | | |
| SI Goal Not Met | 2 | | | | |
| SI Pending Within Goal | 0 | | | | |
| 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 | 2 | | | | |
| Non-MDUFA V Decision | 0 | | | | |
| MDUFA V Decision | 0 | | | | |
| MDUFA V Decision Goal Met | 0 | | | | |
| Supplements Pending MDUFA V Decision | 2 | | | | |
| Supplements Pending MDUFA V Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number Received | 2 | | | | |
| Number with MDUFA V Decision | 0 | | | | |
| Number of Not Approvable | 0 | | | | |
| Rate of Not Approvable | N/A | | | | |

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Submissions that Missed the Goal | 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 | 1 | | | | |
| Non-MDUFA V Decision | 0 | | | | |
| MDUFA V Decision | 1 | | | | |
| MDUFA V Decision Goal Met | 1 | | | | |
| Supplements Pending MDUFA V Decision | 0 | | | | |
| Supplements Pending MDUFA V Decision Past Goal | 0 | | | | |
| Current Performance Percent Goal Met | 100% | | | | |

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

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

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

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of Submissions that Missed the Goal | 0 | | | | |
| 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 | 18 | | | | |
| Closed Before First RTA or TS Action [1] | 0 | | | | |
| Number Accepted or Passed TS on First Cycle [2] | 10 | | | | |
| 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] | 5 | | | | |
| Number Not Accepted or Failed TS on First Cycle [2] | 3 | | | | |
| Rate of Submissions Not Accepted for Review or Failed TS on First Cycle [2] | 23.08% | | | | |

**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 | 12 | | | | |
| Deleted or Withdrawn Prior to SI | 0 | | | | |
| SI Within 60 FDA Days | 9 | | | | |
| SI Over 60 FDA Days | 0 | | | | |
| SI Pending Within 60 FDA Days | 3 | | | | |
| 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 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 | 9 | | | | |
| Average Number of FDA Days to Substantive Interaction | 49.44 | | | | |
| 20th Percentile FDA Days to Substantive Interaction | 39 | | | | |
| 40th Percentile FDA Days to Substantive Interaction | 52 | | | | |
| 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 | 12 | | | | |
| Non-MDUFA V Decision | 0 | | | | |
| MDUFA V Decision (SE/NSE) | 5 | | | | |
| MDUFA V Decision Within 90 FDA Days | 5 | | | | |
| 510(k)s Pending MDUFA V Decision | 7 | | | | |
| 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 | 1.00 | | | | |
| Number With MDUFA V Decision | 5 | | | | |
| **Average Number of FDA Days to MDUFA V Decision** | 62.60 | | | | |
| 20th Percentile FDA Days to MDUFA V Decision | 30 | | | | |
| 40th Percentile FDA Days to MDUFA V Decision | 60 | | | | |
| 60th Percentile FDA Days to MDUFA V Decision | 82 | | | | |
| 80th Percentile FDA Days to MDUFA V Decision | 86 | | | | |
| Maximum FDA Days to MDUFA V Decision | 90 | | | | |
| **Average Number of 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 Number of Total Days to MDUFA V Decision** | 62.60 | | | | |
| 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 | 82 | | | | |
| 80th Percentile Total Days to MDUFA V Decision | 86 | | | | |
| Maximum Total Days to MDUFA V Decision | 90 | | | | |

**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 | 12 | | | | |
| Number With MDUFA V Decision | 5 | | | | |
| Number of SE Decision | 5 | | | | |
| 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 | 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 | | | | |

## 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 | 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 8.3 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 | 0 | | | | |
| 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 | 40 | | | | |
| Interactions for Breakthrough Designated Products & Products Included in STeP | 1 | | | | |
| Number Closed Before First RTA Action | 7 | | | | |
| Number Accepted First RTA Cycle [1] | 27 | | | | |
| 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) | 3 | | | | |
| 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 | 27 | | | | |
| Number with Non-MDUFA Action [3] | 7 | | | | |
| Number with MDUFA Action | 19 | | | | |
| Written Feedback Provided Within Goal | 18 | | | | |
| Number Pending MDUFA Action | 7 | | | | |
| Pending MDUFA Action Past Goal | 0 | | | | |
| Number in MDUFA Cohort (up to max 4300)[4] | 26 | | | | |
| Current Performance Percent Within Goal | 94.74% | | | | |

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

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

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

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

**Table 9.3 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 | 20 | | | | |
| Average FDA Days to Written Feedback | 57.00 | | | | |
| 20th Percentile FDA Days to Written Feedback | 50 | | | | |
| 40th Percentile FDA Days to Written Feedback | 57 | | | | |
| 60th Percentile FDA Days to Written Feedback | 62 | | | | |
| 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] | 10 | | | | |
| Meeting Minutes Submitted Within 15 Days of Meeting | 9 | | | | |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | | | | |
| Meeting Minutes Past 15 Days of Meeting | 1 | | | | |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 0 | | | | |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 90.00% | | | | |

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

## Section 10 IDE- Center Level Metric

### Table 10.1 CBER - IDE MDUFA V Decision Performance Goal

| Performance Metric | FY 2023 | FY 2024 | FY 2025 | FY 2026 | FY 2027 |
|---|---|---|---|---|---|
| Number of IDEs Received | 14 | | | | |
| 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****

# Medical Devices

## 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 |

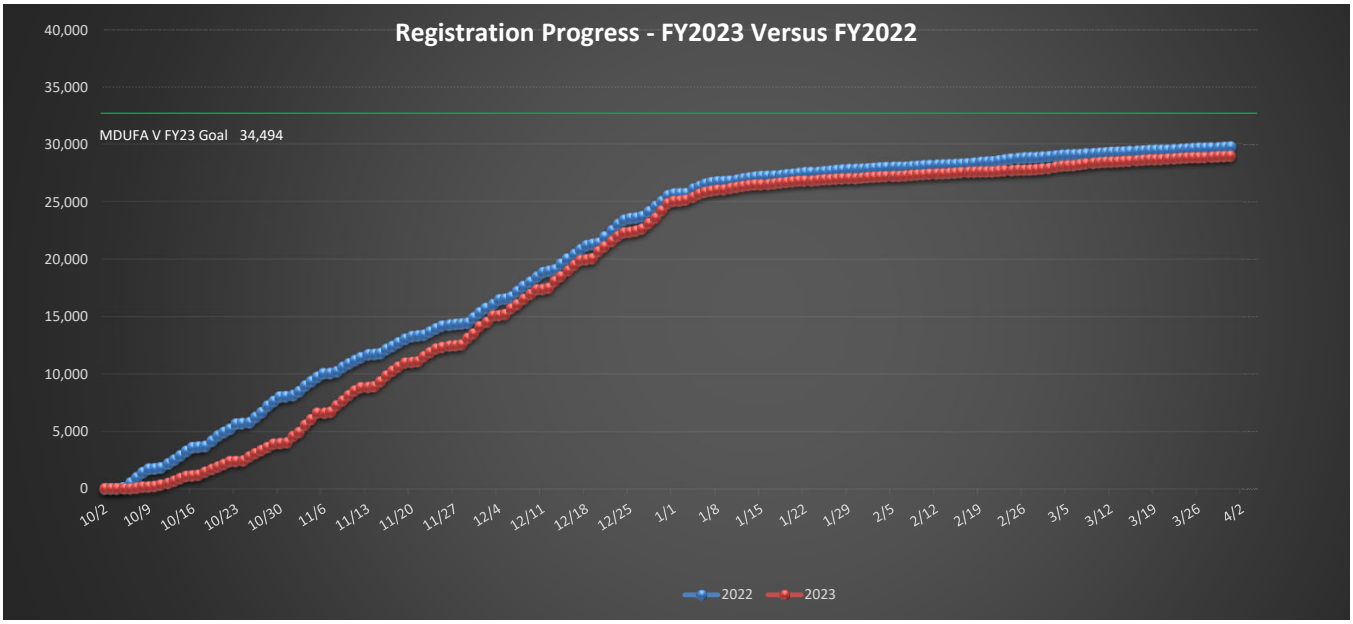
| # | Quarter Issued | Title & Website Link | Date Issued | Related to the Process for the Review of Devices | Required by Statute or Commitment Letter | Statutory or Commitment Letter Citation (if applicable) | A/B List |
|---|---|---|---|---|---|---|---|
| 32 | Q2 | General Considerations for Animal 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 |

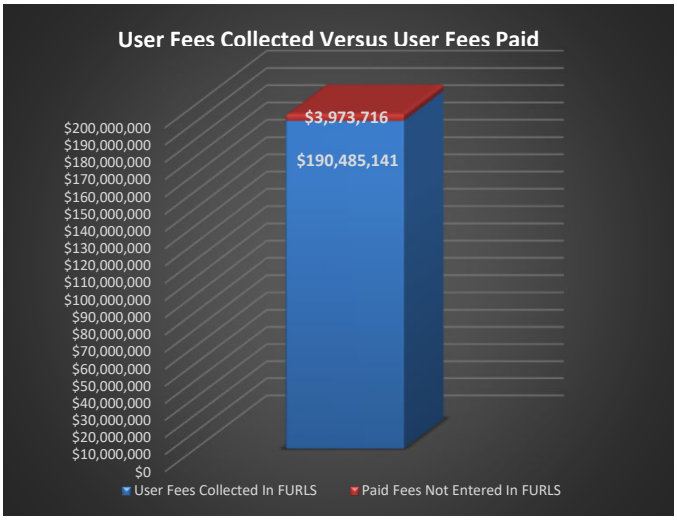
[5] This is a Level 1 guidance document that is immediately in effect as defined in section 701(h)(1)(C) of the FD&C Act and 21 CFR 10.115(g)(2).

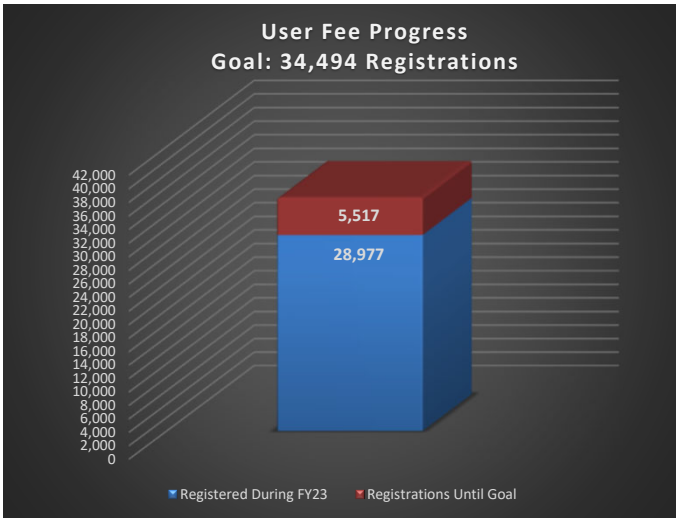
# MDUFA V Registrations - 2nd Quarter Summary FY2023*

| Current Active Registrations by Type | FY23 Q2 | | | FY22 Year End Active Totals | | | FY23 vs End FY22 |
|---|---|---|---|---|---|---|---|
| | Domestic | Foreign | Total | Domestic | Foreign | Total | |
| Manufacturer/ Complaint File Handler | 6,483 | 11,694 | 18,177 | 6,848 | 12,892 | 19,738 | 92.09% |
| Contract Manufacturer | 1,193 | 1,782 | 2,975 | 1,234 | 1,798 | 3,032 | 98.12% |
| Contract Sterilizer | 68 | 168 | 236 | 68 | 166 | 234 | 100.85% |
| Specification Developer | 1,592 | 532 | 2,124 | 1,768 | 573 | 2,341 | 90.73% |
| Reprocessor of Single Use Devices | 28 | 4 | 32 | 25 | 5 | 30 | 106.67% |
| U.S. Manufacturer of Export Only Devices | 121 | 0 | 121 | 138 | 0 | 138 | 87.68% |
| Repackager/Relabeler | 1,056 | 201 | 1,257 | 1,178 | 209 | 1,387 | 90.63% |
| Remanufacturer | 14 | 8 | 22 | 22 | 10 | 32 | 68.75% |
| Foreign Exporter/Private Label Distributor | | 1,047 | 1,047 | | 1,156 | 1,156 | 90.57% |
| Initial Importer | 3,140 | | 3,140 | 3,640 | | 3,640 | 86.26% |
| Unknown | 5 | 15 | 20 | 6 | 12 | 18 | 111.11% |
| **Total:** | **13,700** | **15,451** | **29,151** | **14,927** | **16,821** | **31,748** | **91.82%** |

*Note: This data is current as of 3/31/2023



| FY 2023 Medical Device User Fee Collections as of March 31st, 2023 Excludes Unearned Fees | | | | | |
|---|---|---|---|---|---|
| | **Receipts** | **Refunds** | **Net** | **Authorized** | **% of Authorized** |
| Registration Fees | $190,672,571 | -$58,437 | $190,614,134 | | |
| Application Fees | $44,439,935 | -$290,331 | $44,149,604 | | |
| **Total** | **$235,112,506** | **-$348,768** | **$234,763,738** | **$324,777,000** | **72%** |

| 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 | $193,896,877 | $208,670,231 | $214,600,996 | $274,998,679 | $266,397,753 |
| | | | | | |
| | **FY 2023** | **FY 2024** | **FY 2025** | **FY 2026** | **FY 2027** |
| MD V | $234,763,738 | | | | |

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

| CDRH Data 2nd Quarter FY 2023 by Submission type | # Waived | # Reduced |
|---|---|---|
| **Full Fee applications[2/]** | 2 | 0 |
| PMA | 2 | 0 |
| PDP | 0 | 0 |
| PMR | 0 | 0 |
| BLA | | |
| BLA efficacy supplement | | |
| **Panel Track Supplements** | 0 | 0 |
| **De Novo Classification** | 2 | 38 |
| **180-Day Supplements** | 3 | 2 |
| **Real-Time Supplements** | 0 | 11 |
| **510(k)s** | 26 | 757 |
| **30-day Notices /135 day supplements*** | 8 | 13 |
| **513(g)s** | 0 | 34 |
| **PMA Annual Report** | 0 | 14 |
| **Total** | **41** | **869** |

[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 4 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**