

**Agenda for Quarterly Meeting on
MDUFA IV (FY 2018-2022) Performance**

June 2, 2022, 12:00 – 1:00 pm

Zoom

Welcome –

Guidance Development

FDA MDUFA Performance — Actions through March 31, 2022

- Report on decision goals for 2nd Quarter FY 2022

Registration and Listing

Qualitative Update on Finances – 2nd Quarter FY 2022

- User fee receipts through the 2nd Quarter FY 2022

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Medical Devices

Guidance Documents

Pursuant to the MDUFA IV 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 IV 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 2022

| # | 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 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 | 10/5/2021 | Yes | No | N/A | No |
| 2 | Q1 | ⁴ De Novo Classification Process (Evaluation of Automatic Class III Designation) www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation | 10/5/2021 | 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 | 10/5/2021 | Yes | No | N/A | No |
| 4 | Q1 | ⁴ Acceptance Review for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests | 10/5/2021 | Yes | No | N/A | No |
| 5 | Q1 | Surgical Staplers and Staples for Internal Use - Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance- | 10/8/2021 | Yes | No | N/A | A-List |

¹ www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.

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-2022-fy2022.

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 |
|----|----------------|--|-------------|--|--|---|----------|
| | | documents/surgical-staplers-and-staples-internal-use-labeling-recommendations | | | | | |
| 6 | Q1 | Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-unique-device-identification-policy-regarding-global-unique-device-identification | 10/14/21 | No | No | N/A | A-List |
| 7 | Q1 | Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products | 10/20/21 | No | Yes | Section 709(c) of the FDA Reauthorization Act | No |
| 8 | Q1 | Content of Premarket Submissions for Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions | 11/4/21 | Yes | Yes | MDUFA IV Commitment Letter Section IV.I.3.c. | A-List |
| 9 | Q1 | ⁵ Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised | 11/15/21 | No | No | N/A | No |
| 10 | Q1 | ⁵ Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health | 11/15/21 | Yes | No | N/A | No |
| 11 | 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 | 12/16/21 | No | No | N/A | No |
| 12 | Q1 | Digital Health Technologies for Remote Data Acquisition in Clinical Investigations | 12/23/21 | Yes | No | N/A | No |

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

| # | Quarter Issued | Title & Website Link | Date Issued | Related to the Process for the Review of Devices | Required by Statute or Commitment Letter | Statutory or Commitment Letter Citation (if applicable) | A/B List |
|----|----------------|---|-------------|--|--|---|----------|
| | | www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations | | | | | |
| 13 | Q1 | 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 | 12/23/21 | Yes | No | N/A | A-List |
| 14 | Q1 | Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-during-coronavirus-disease | 12/23/21 | Yes | No | N/A | A-List |
| 15 | Q1 | Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-medical-devices-physiologic-closed-loop-control-technology | 12/23/21 | Yes | No | N/A | No |
| 16 | Q1 | Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions | 12/23/21 | Yes | No | N/A | No |
| 17 | Q1 | Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/arthroscopy-pump-tubing-sets-intended-multiple-patient-use-premarket-notification-510k-submissions | 12/23/21 | Yes | No | N/A | No |
| 18 | Q1 | Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/pathology-peer-review-nonclinical-toxicology-studies-questions-and-answers | 12/27/21 | 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 | Q1 | Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-and-clinical-investigation-devices-used-treatment-benign-prostatic-hyperplasia-bph | 12/27/21 | Yes | No | N/A | No |
| 20 | Q2 | Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc | 1/11/22 | No | No | N/A | A-List |
| 21 | Q2 | Patient Engagement in the Design and Conduct of Medical Device Clinical Studies www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies | 1/26/22 | Yes | No | N/A | B-List |
| 22 | Q2 | Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-selecting-developing-modifying-and-adapting-patient-reported-outcome-instruments-use | 1/26/22 | Yes | Yes | MDUFA Commitment Letter IV.F.3.a | No |
| 23 | Q2 | Principles of Premarket Pathways for Combination Products www.fda.gov/regulatory-information/search-fda-guidance-documents/principles-premarket-pathways-combination-products | 1/31/22 | Yes | No | N/A | No |
| 24 | Q2 | Appeal Options Available to Mammography Facilities Concerning Adverse Accreditation Decisions, Suspension/Revocation of Certificates, or Patient and Physician Notification Orders www.fda.gov/regulatory-information/search-fda-guidance-documents/appeal-options-available-mammography-facilities-concerning-adverse-accreditation-decisions | 3/2/22 | No | No | N/A | No |
| 25 | Q2 | ⁴ Center for Devices and Radiological Health (CDRH) Appeals Processes www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes | 3/2/22 | 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 | Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C www.fda.gov/regulatory-information/search-fda-guidance-documents/initiation-voluntary-recalls-under-21-cfr-part-7-subpart-c | 3/4/22 | No | No | N/A | No |
| 27 | Q2 | Certain Ophthalmic Products: Policy Regarding Compliance With 21 CFR Part 4 Guidance for Industry www.fda.gov/regulatory-information/search-fda-guidance-documents/certain-ophthalmic-products-policy-regarding-compliance-21-cfr-part-4-guidance-industry | 3/23/22 | No | No | N/A | No |

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**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CDRH Performance Data ----
Actions through 31 March 2022**

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Acronyms and Abbreviations

| | |
|--------|--|
| 510(k) | Premarket Notification |
| CDRH | Center for Devices and Radiologic Health |
| CLIA | Clinical Laboratory Improvement Amendments |
| IDE | Investigational Device Exemption |
| IVD | In Vitro Diagnostic |
| LDT | Laboratory Developed Test |
| 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 and Radiological Health

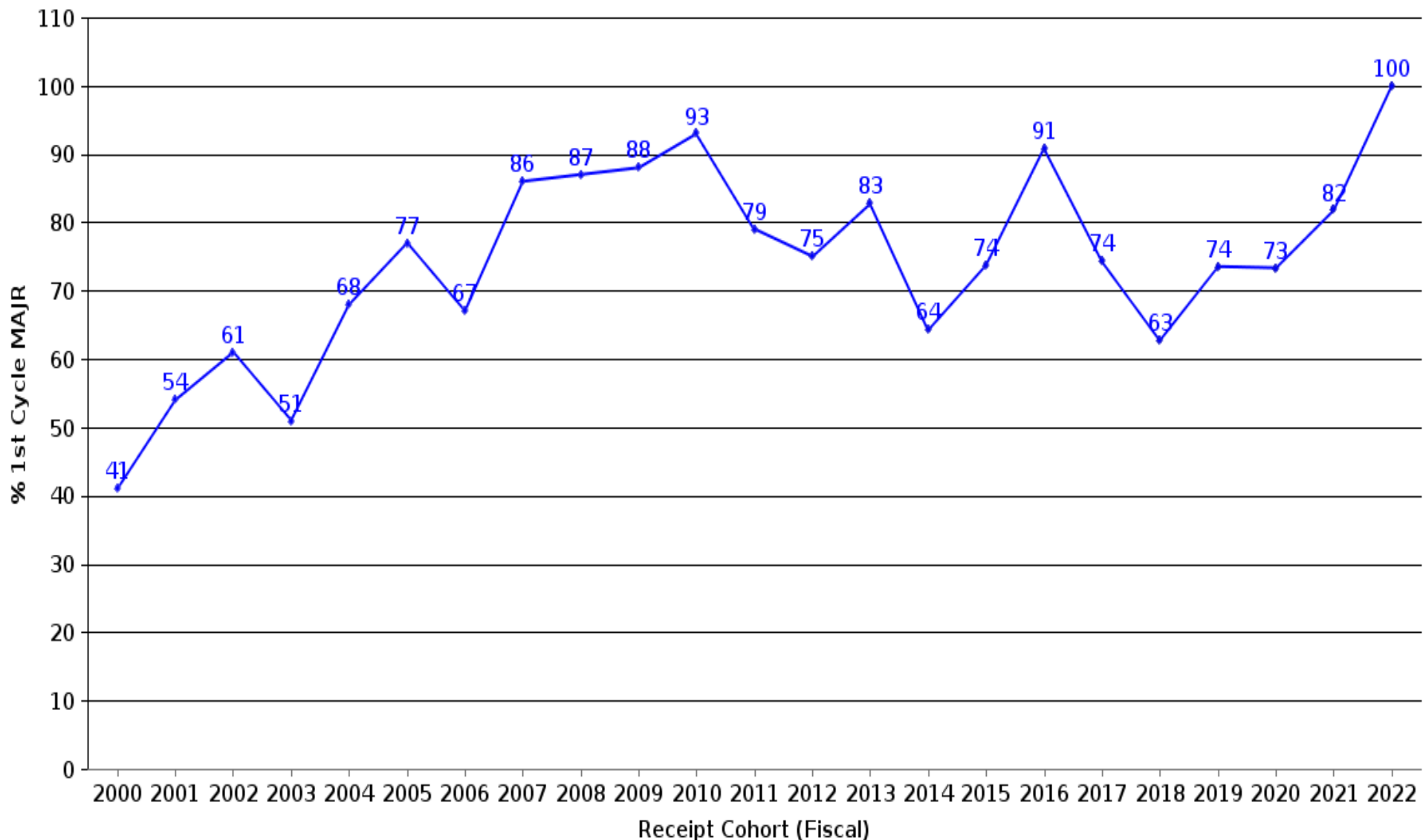
Note: Data may change in subsequent quarterly and annual reports.

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PMA's

Q2FY2022

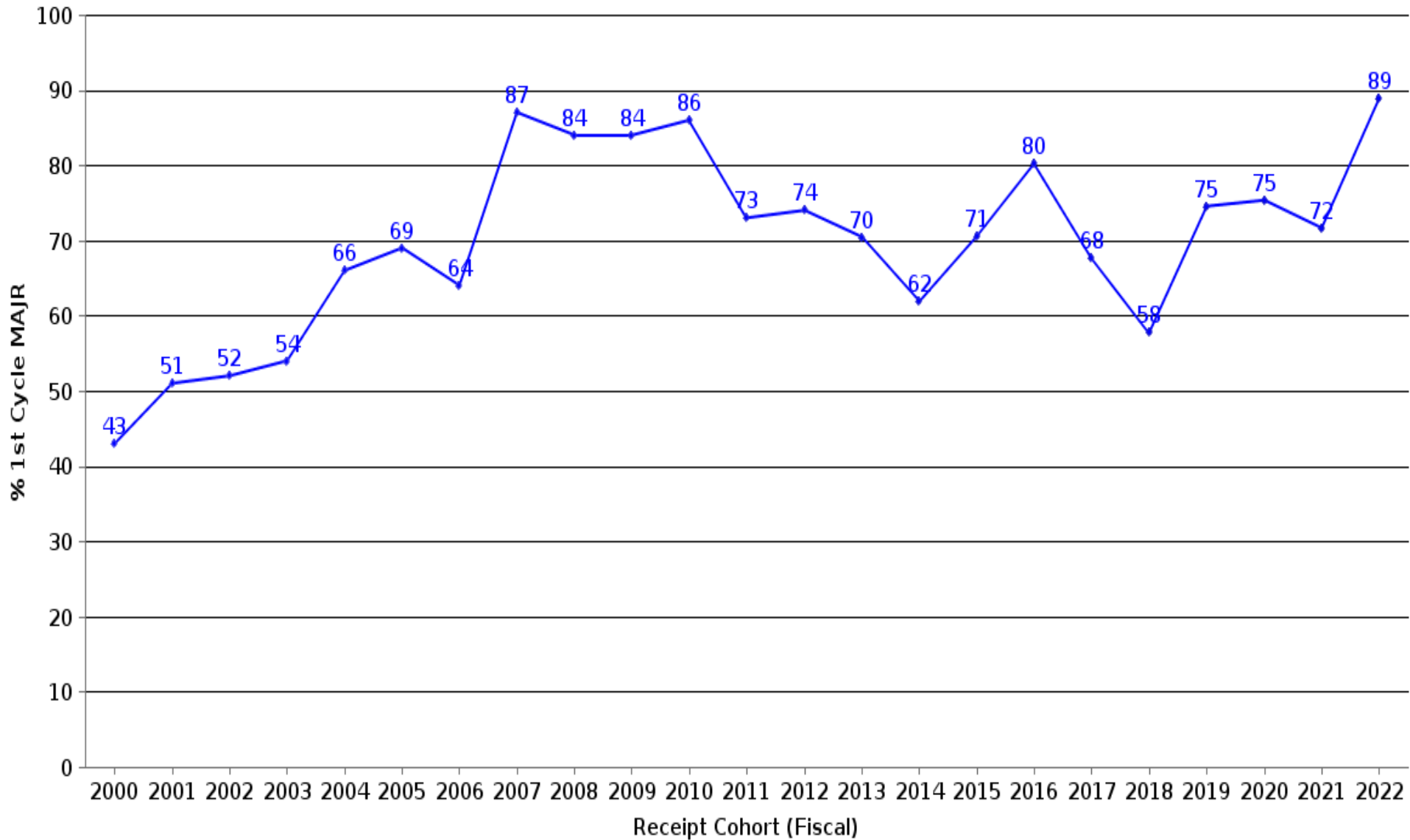
PMA Originals Filed As Of 12/31/21: 1st Cycle Major Deficiency Rate as of 3/31/22



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 12/31/21.

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

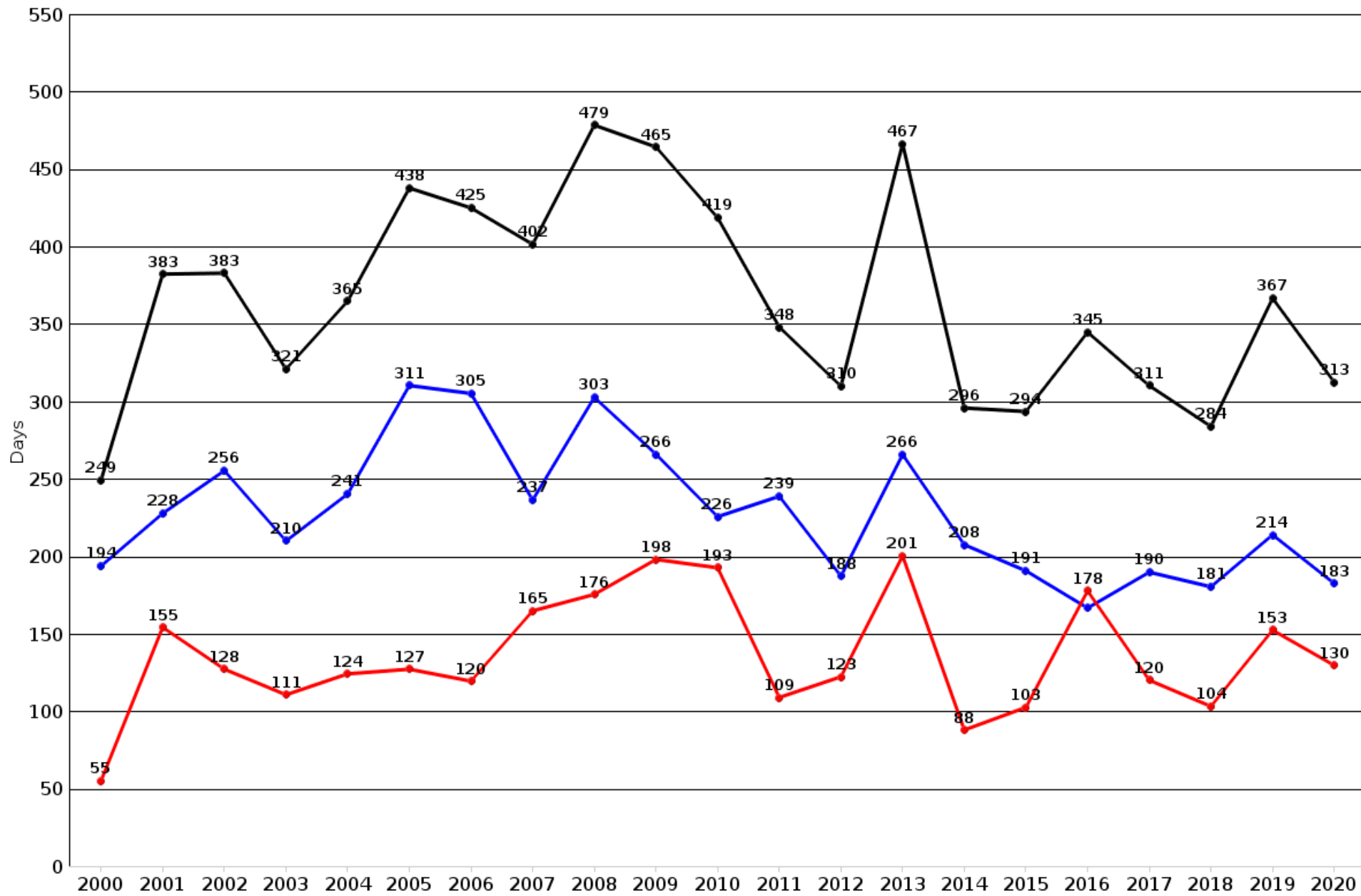
PMA Originals and Panel Track Supplements Filed As Of 12/31/21: 1st Cycle Major Deficiency Rate as of 3/31/22



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 12/31/21. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

◆ % 1st Cycle MAJR PMAO/PTS

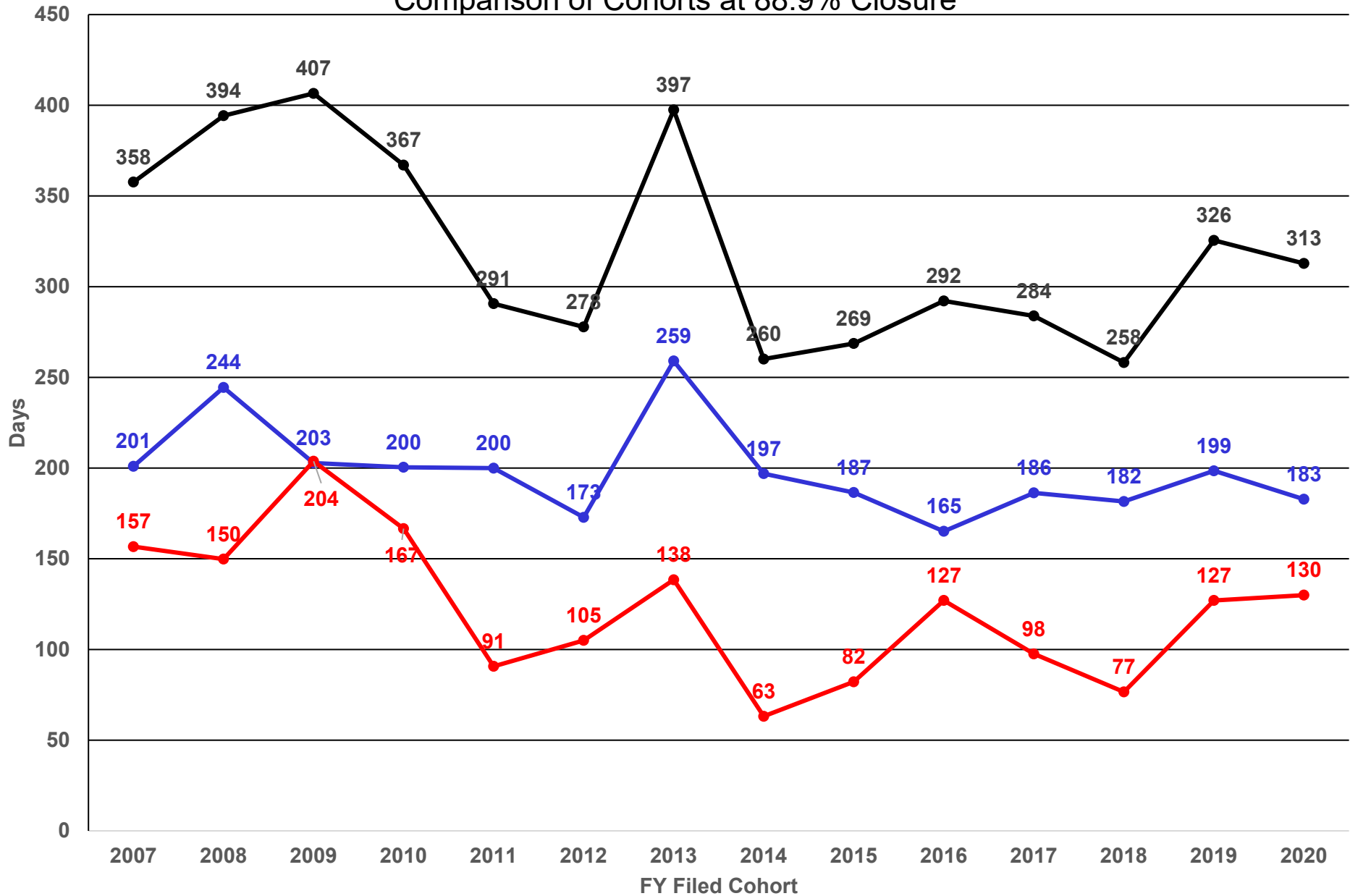
PMA Originals Filed As Of 03/31/2022: Average Time to MDUFA Decision



Cohorts not yet closed: 2020: 88.89%

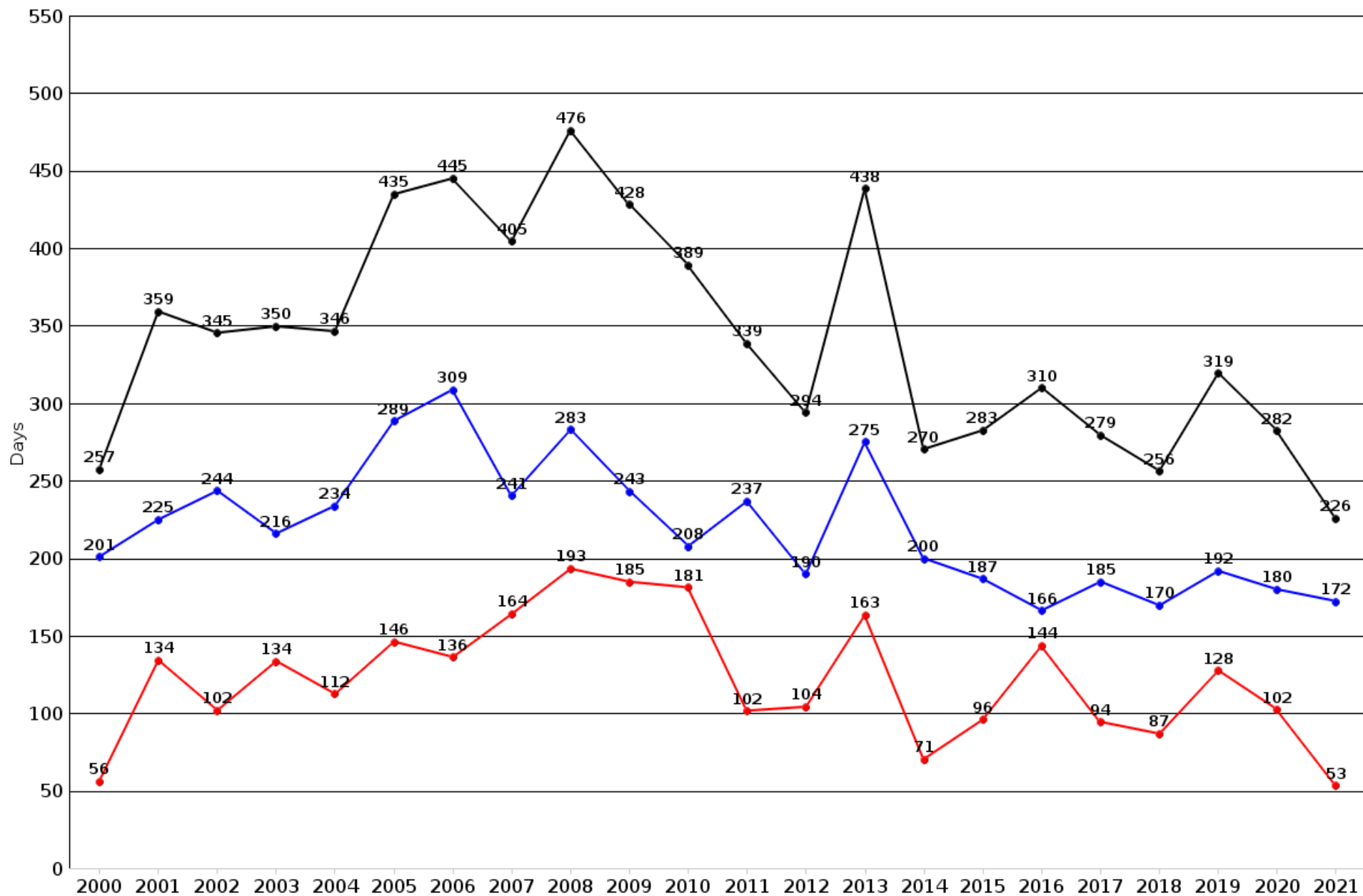
● Avg FDA Days to MDUFA PMAO ● Avg MFR Days to MDUFA PMAO ● Avg Total Days to MDUFA PMAO

PMA Originals Filed as of 3/31/2022: Average Time to MDUFA Decision Comparison of Cohorts at 88.9% Closure



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

PMA Originals and Panel Track Supplements Filed As Of 03/31/2022: Average Time to MDUFA Decision

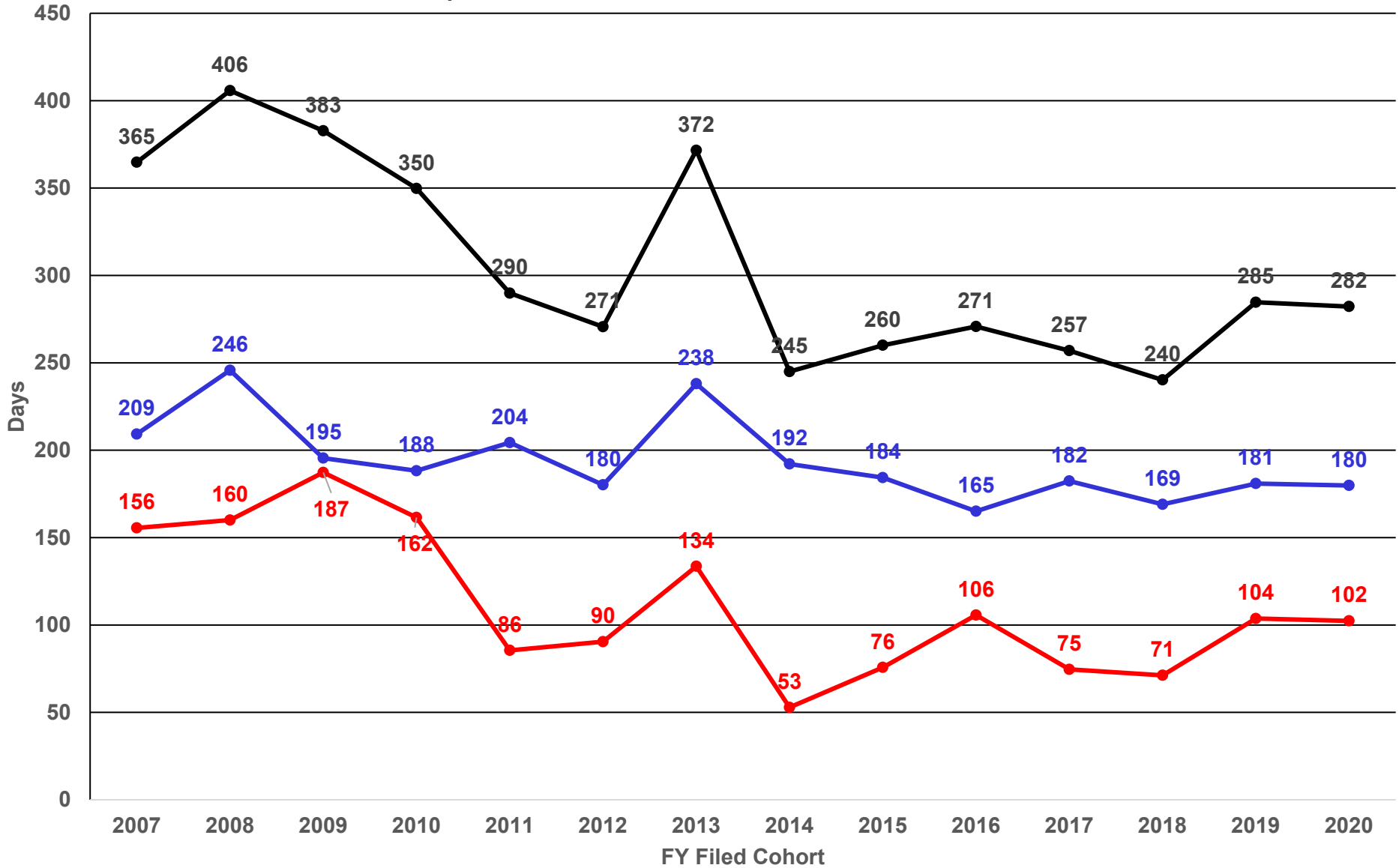


Cohorts not yet closed: 2018: 98.59%; 2020: 91.78%; 2021: 59.15%

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

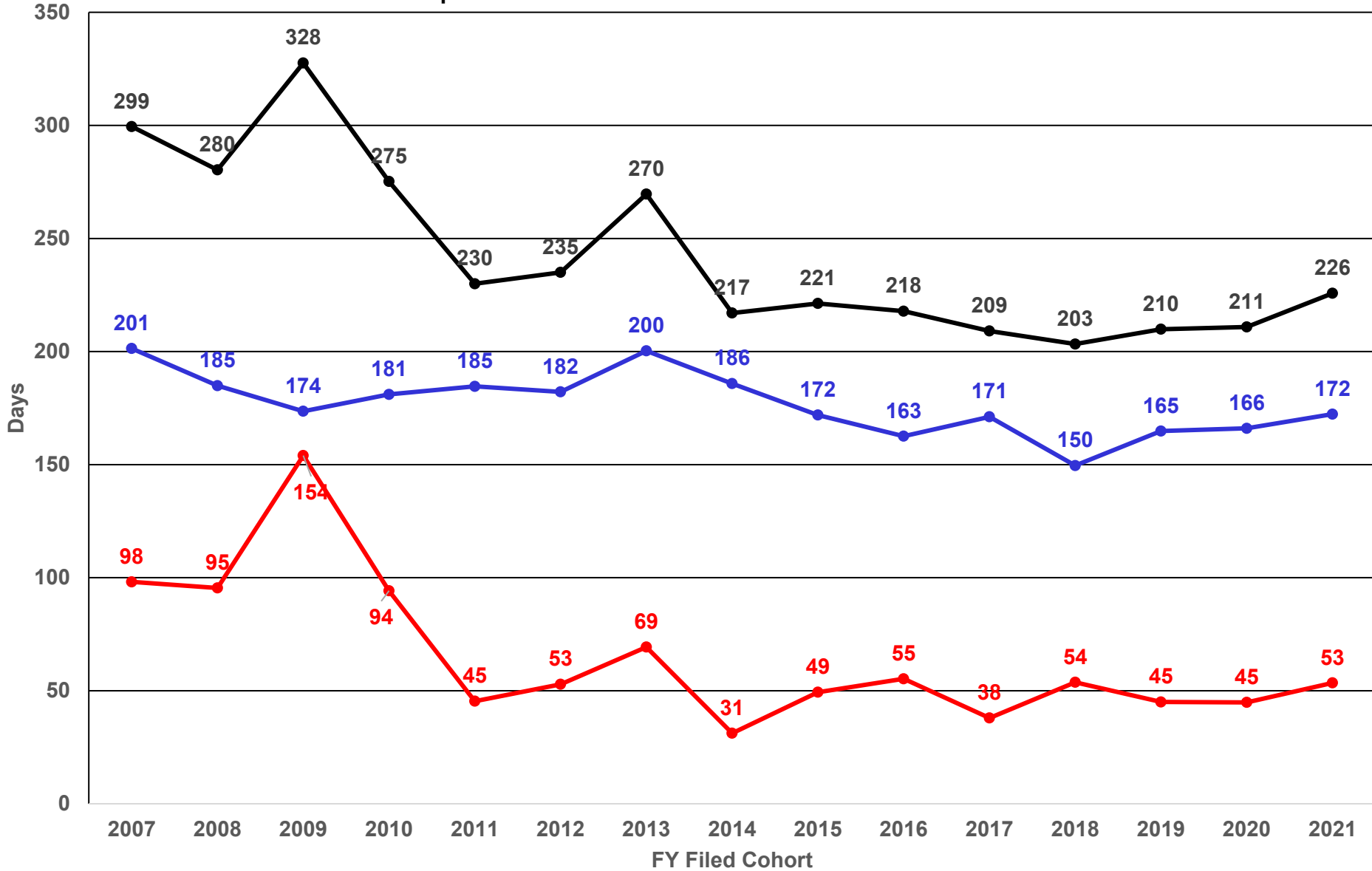
PMA Originals and Panel Track Supplements Filed as of 3/31/2022: Average Time to MDUFA Decision

Comparison of Cohorts at 91.8% Closure

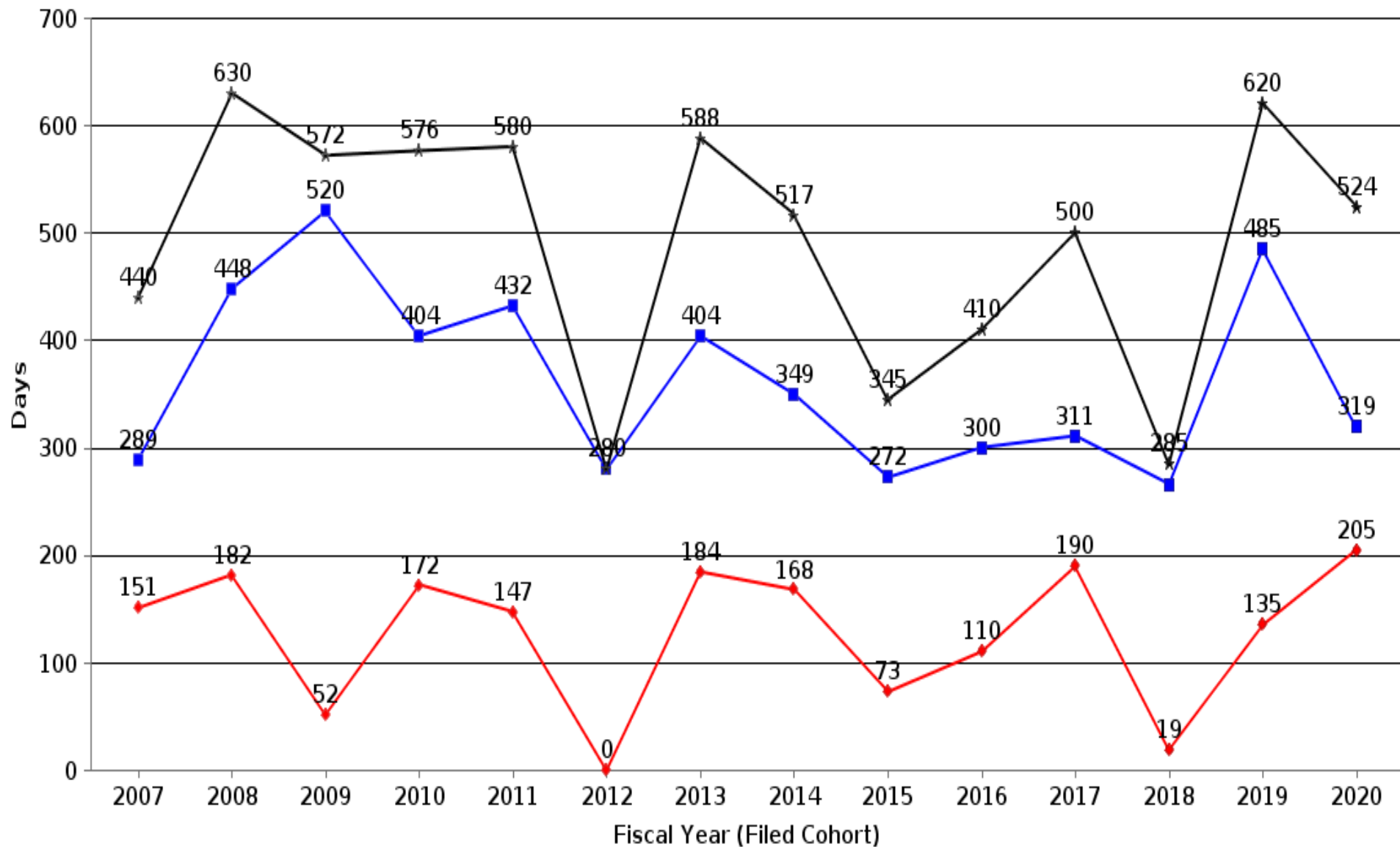


PMA Originals and Panel Track Supplements Filed as of 3/31/2022: Average Time to MDUFA Decision

Comparison of Cohorts at 59.2% Closure



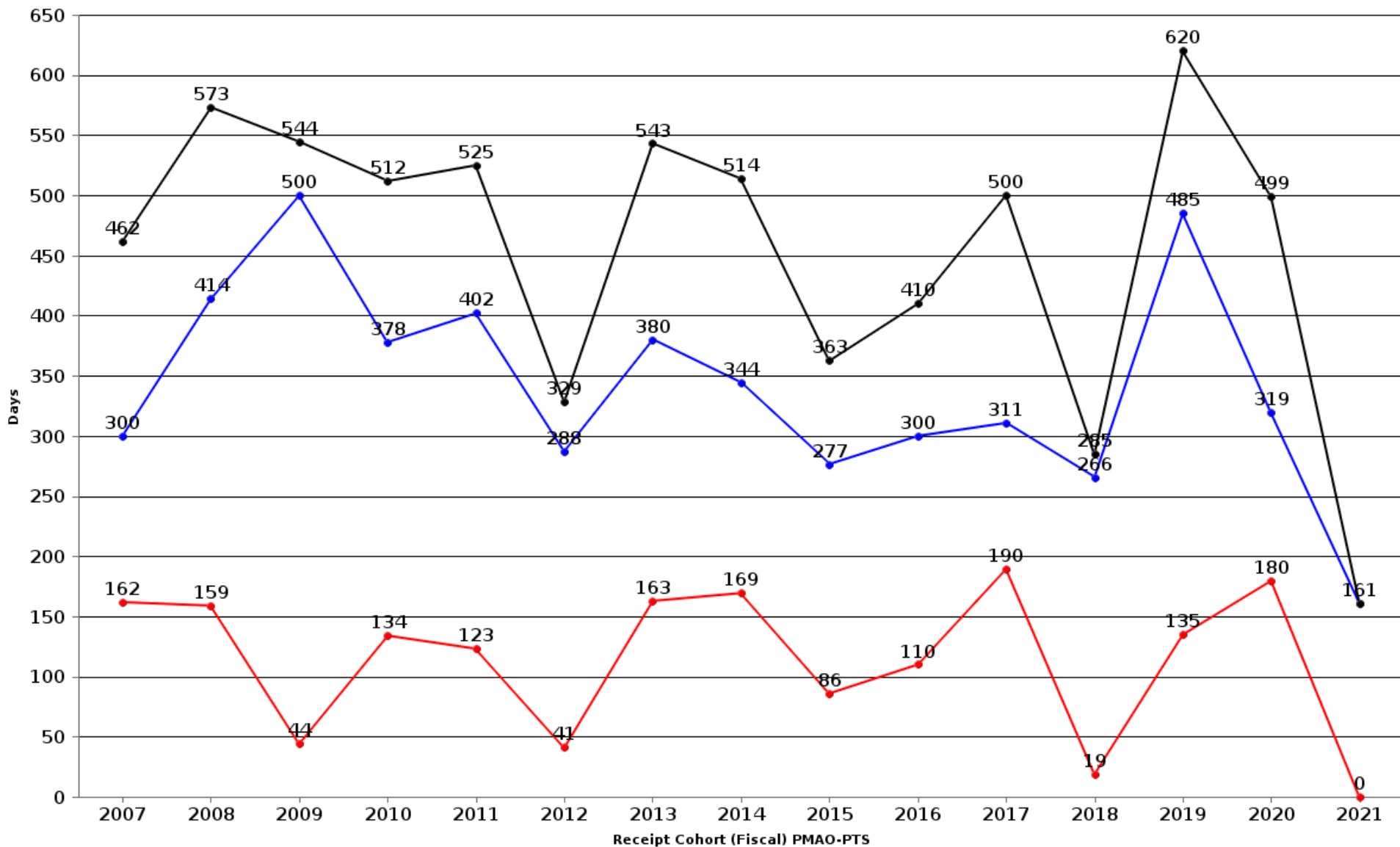
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2022/03/31



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

PMA Originals and Panel Track Supplements With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2022/03/31

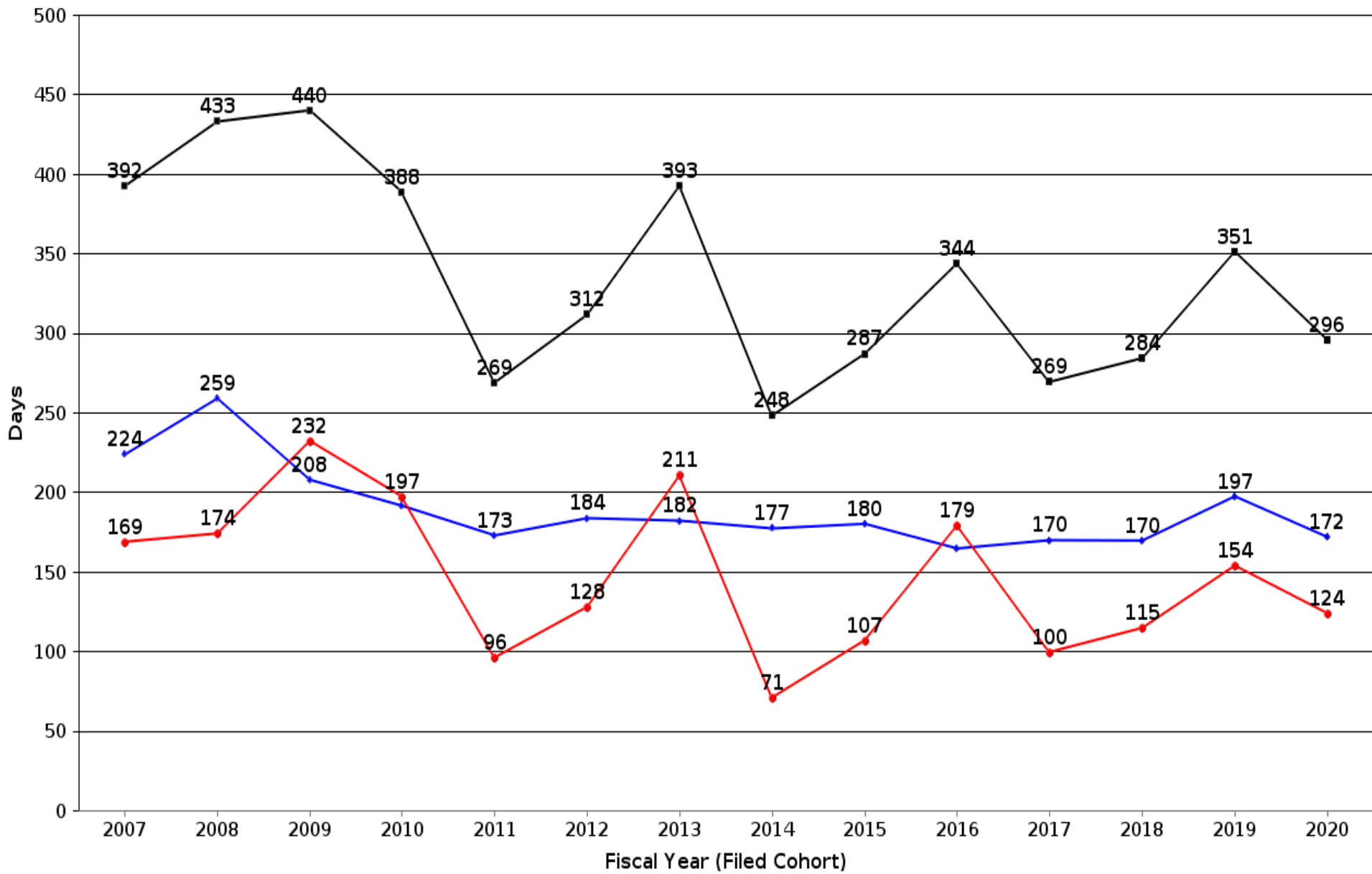


Numbers Filed/Closed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; +2012 = 2/2; 2013 = 17/17; + 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/1

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

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

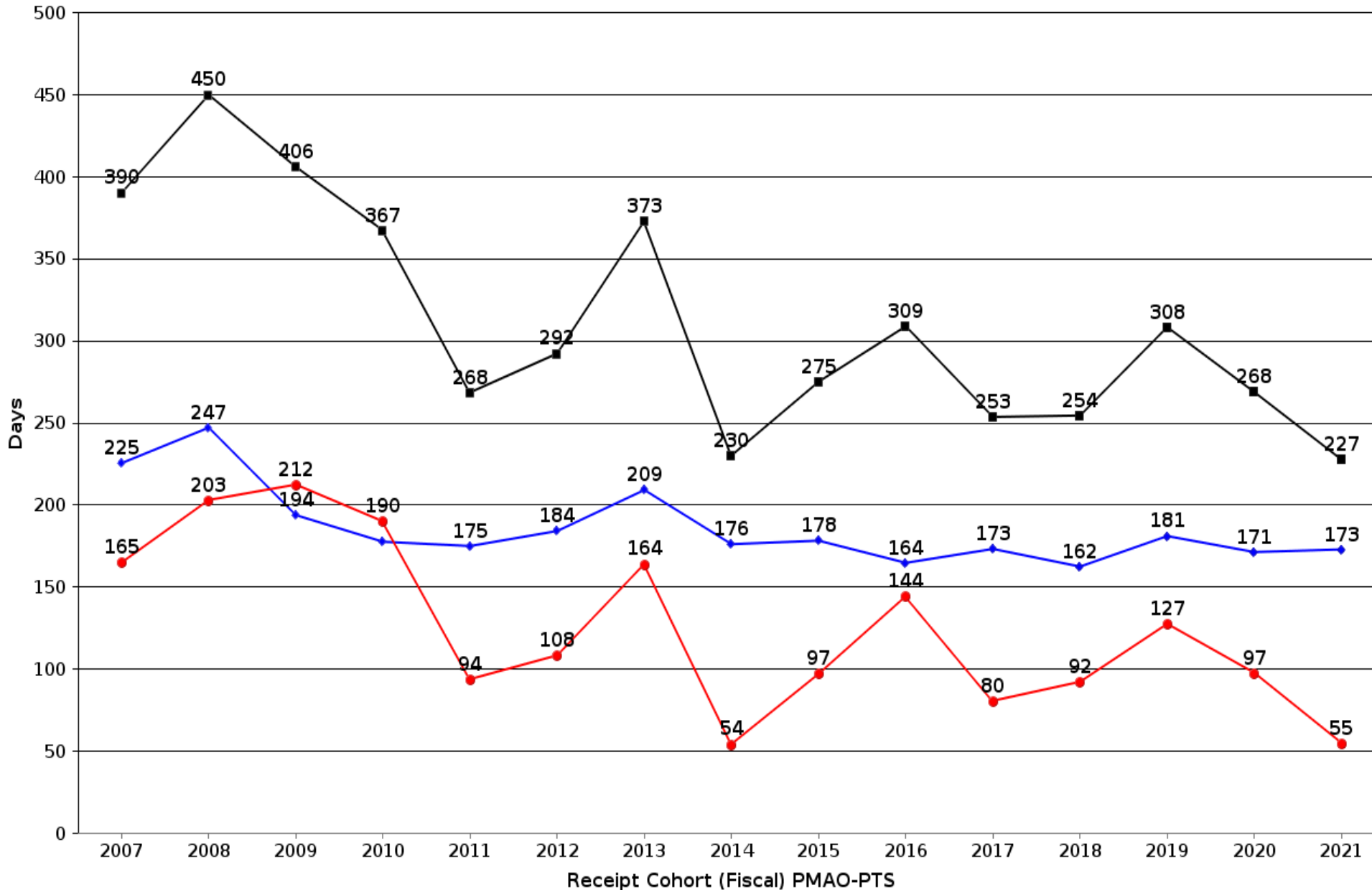
PMA Originals: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2022/03/31



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 = 42/37

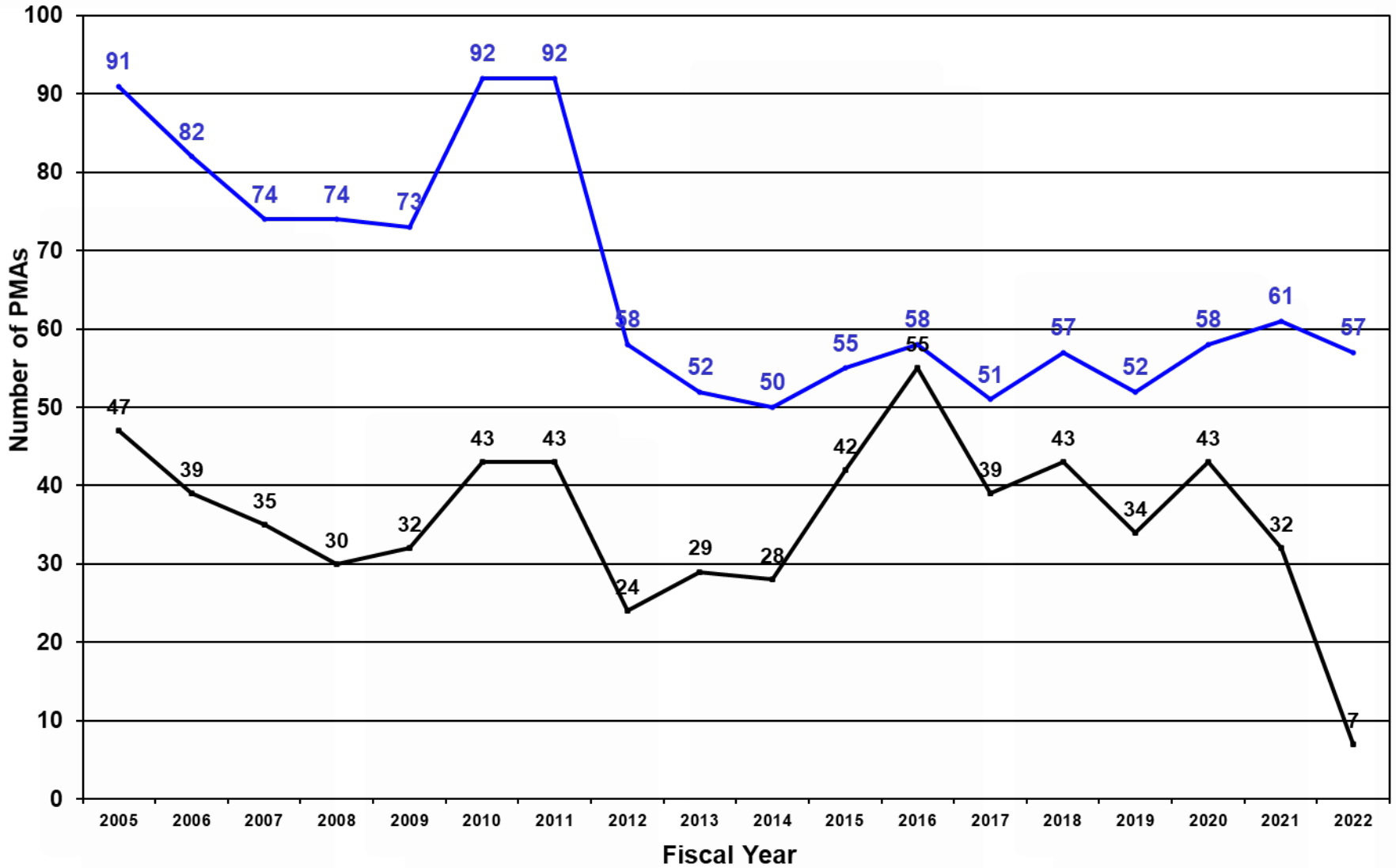
◆ Avg FDA Days to MDUFA Decision PMAO ● Avg MFR Days to MDUFA Decision PMAO ■ Avg Total Days to MDUFA Decision PMAO

PMA Originals and Panel Track Supplements: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2022/03/31



Numbers Filed/Closed: 2007 = 31/31; 2008 = 29/29; 2009 = 36/36; 2010 = 50/50; 2011 = 37/37; 2012 = 32/32; 2013 = 27/27; 2014 = 36/36; 2015 = 62/62; 2016 = 70/70; 2017 = 60/60; 2018 = 66/65; 2019 = 53/53; 2020 = 69/63; 2021 = 70/41

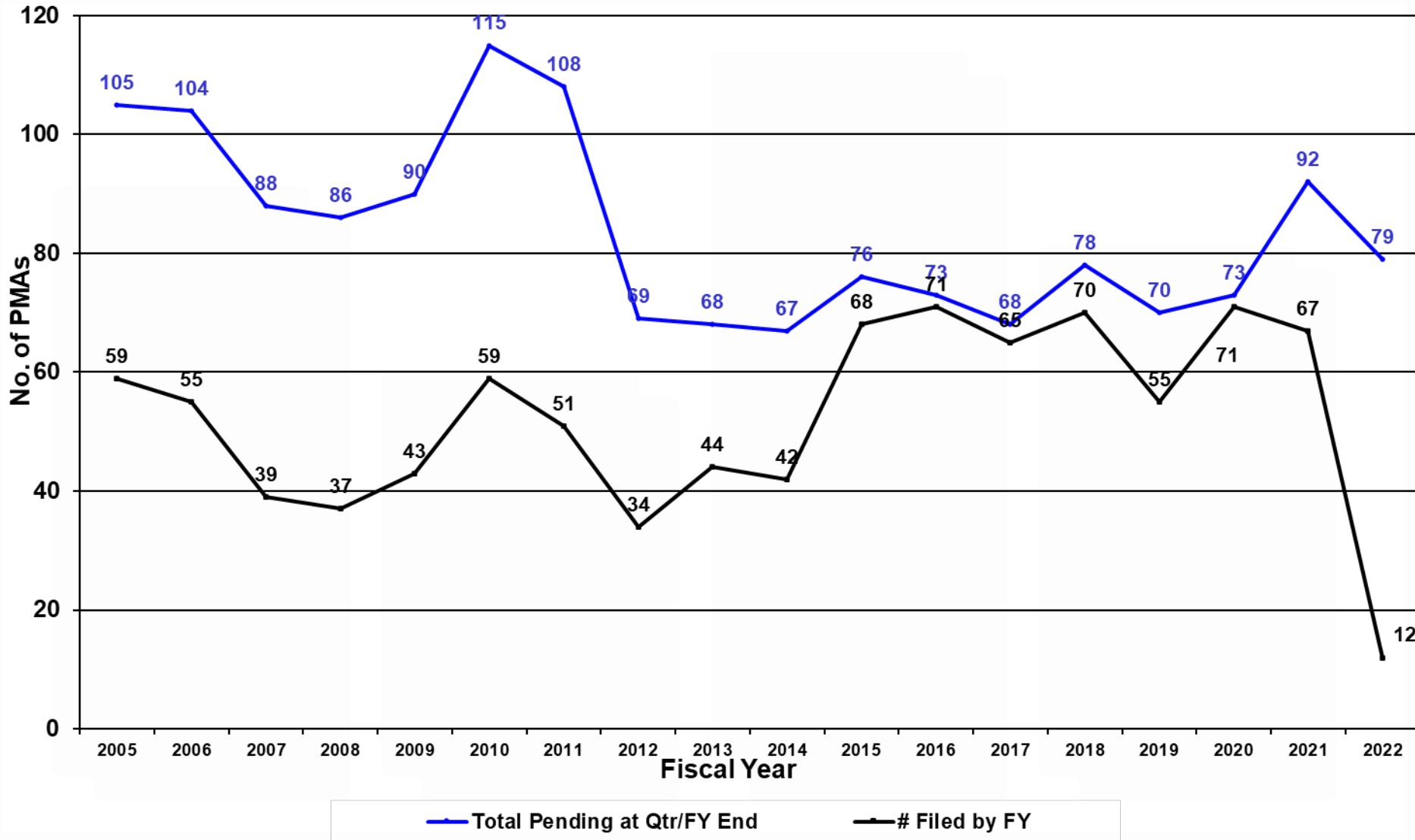
PMA Originals Pending* at End of Quarter/Year



—●— Total Pending at Qtr/FY End
 —●— # Filed by FY

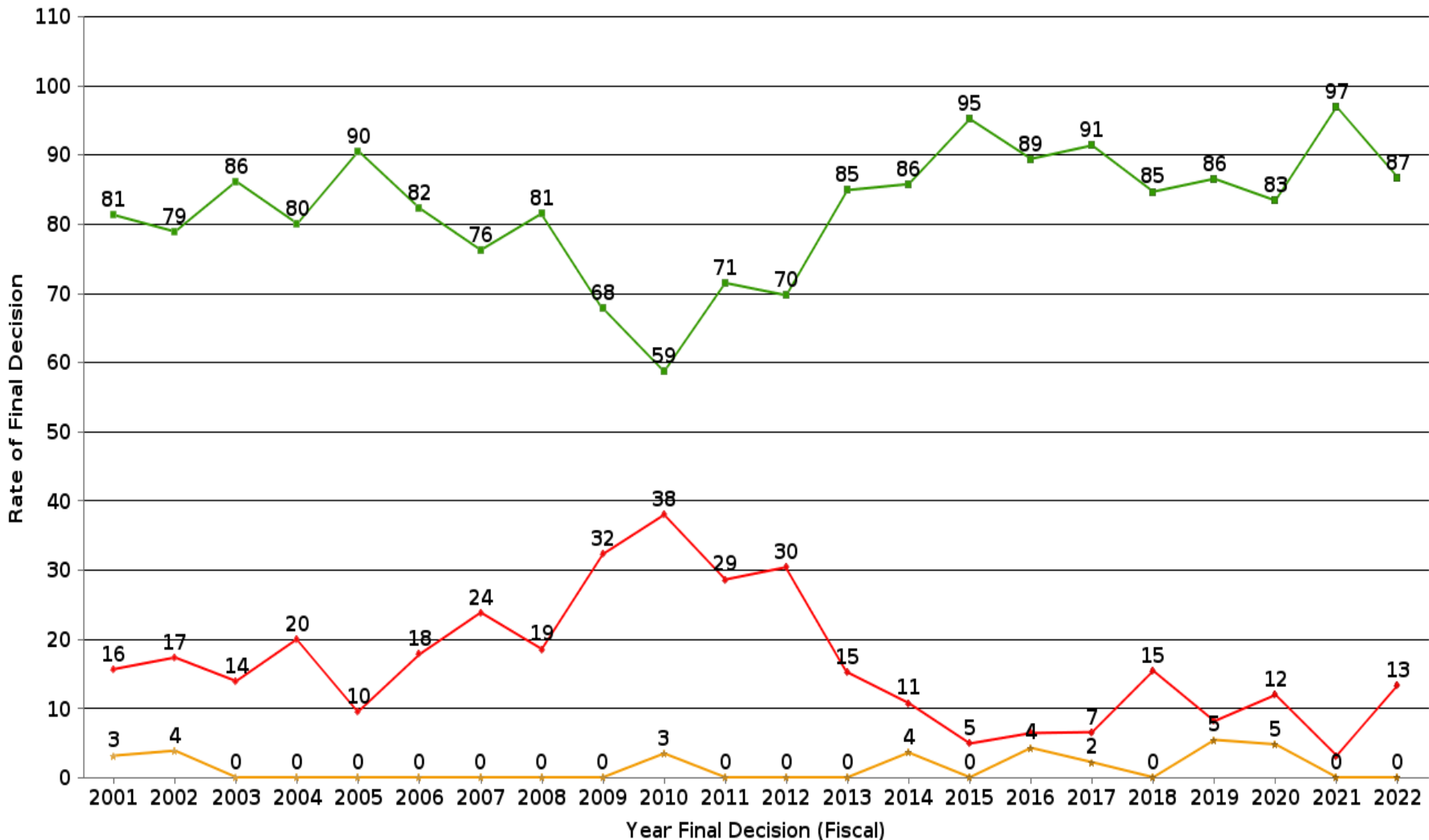
* Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year. For the current FY, numbers filed are updated starting in Q2.

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. For the current FY, numbers filed are updated starting in Q2.

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

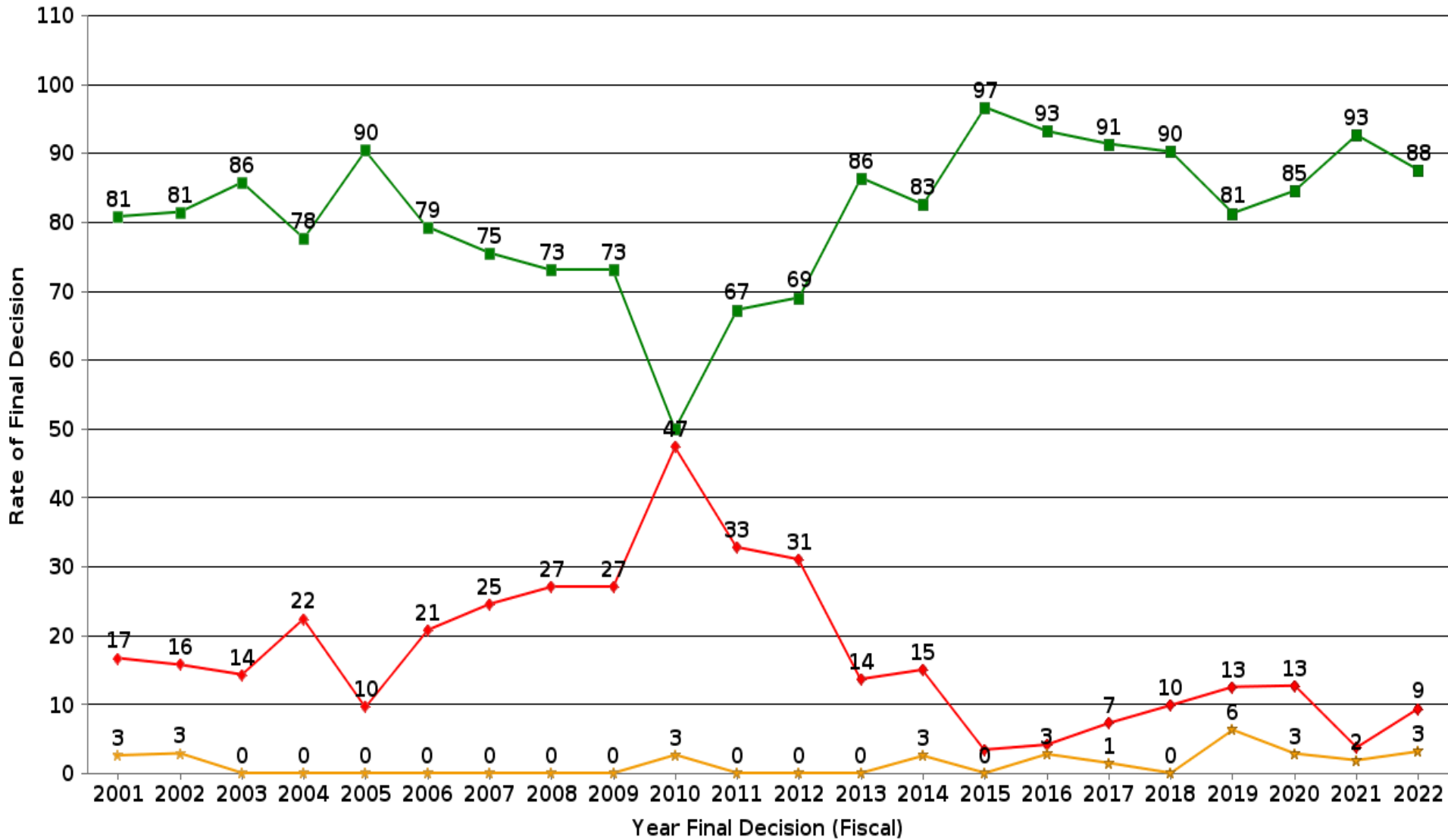


Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

■ % Approved PMAO ◆ % WTDR PMAO ★ % Other PMAO

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

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

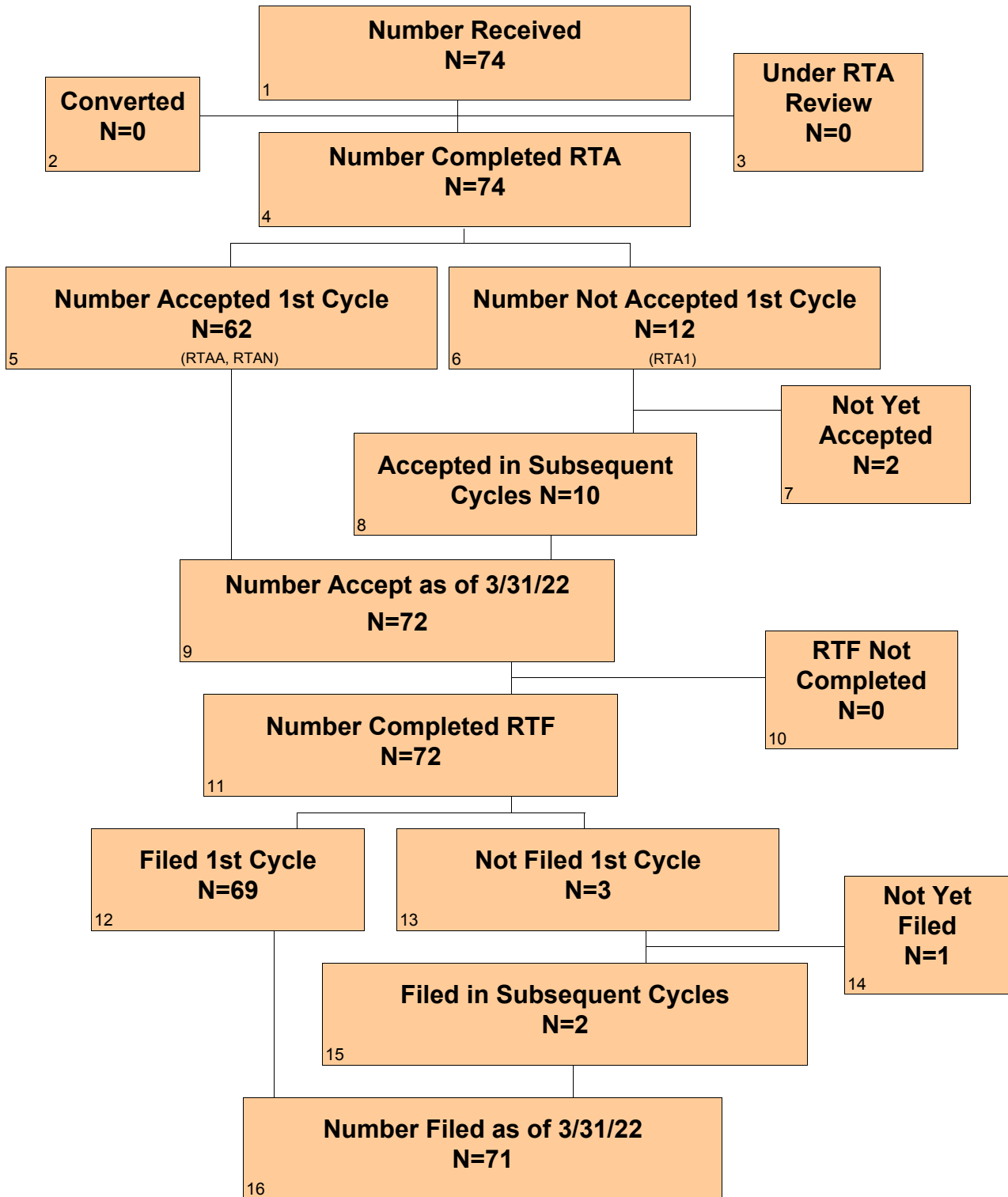


Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

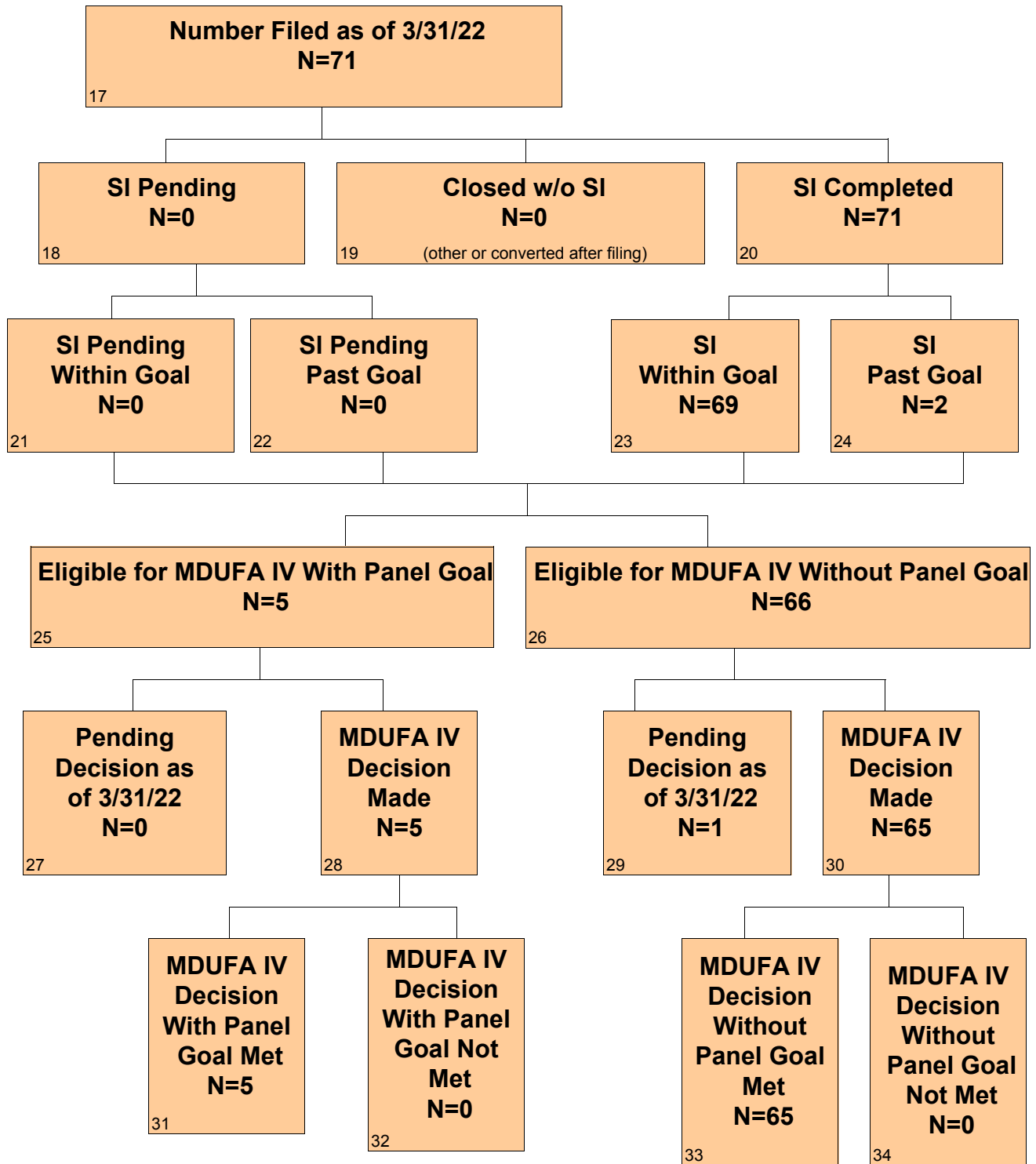
■ % Approved PMAO-PTS ♦ % WTDR PMAO-PTS ★ % All Other PMAO-PTS

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

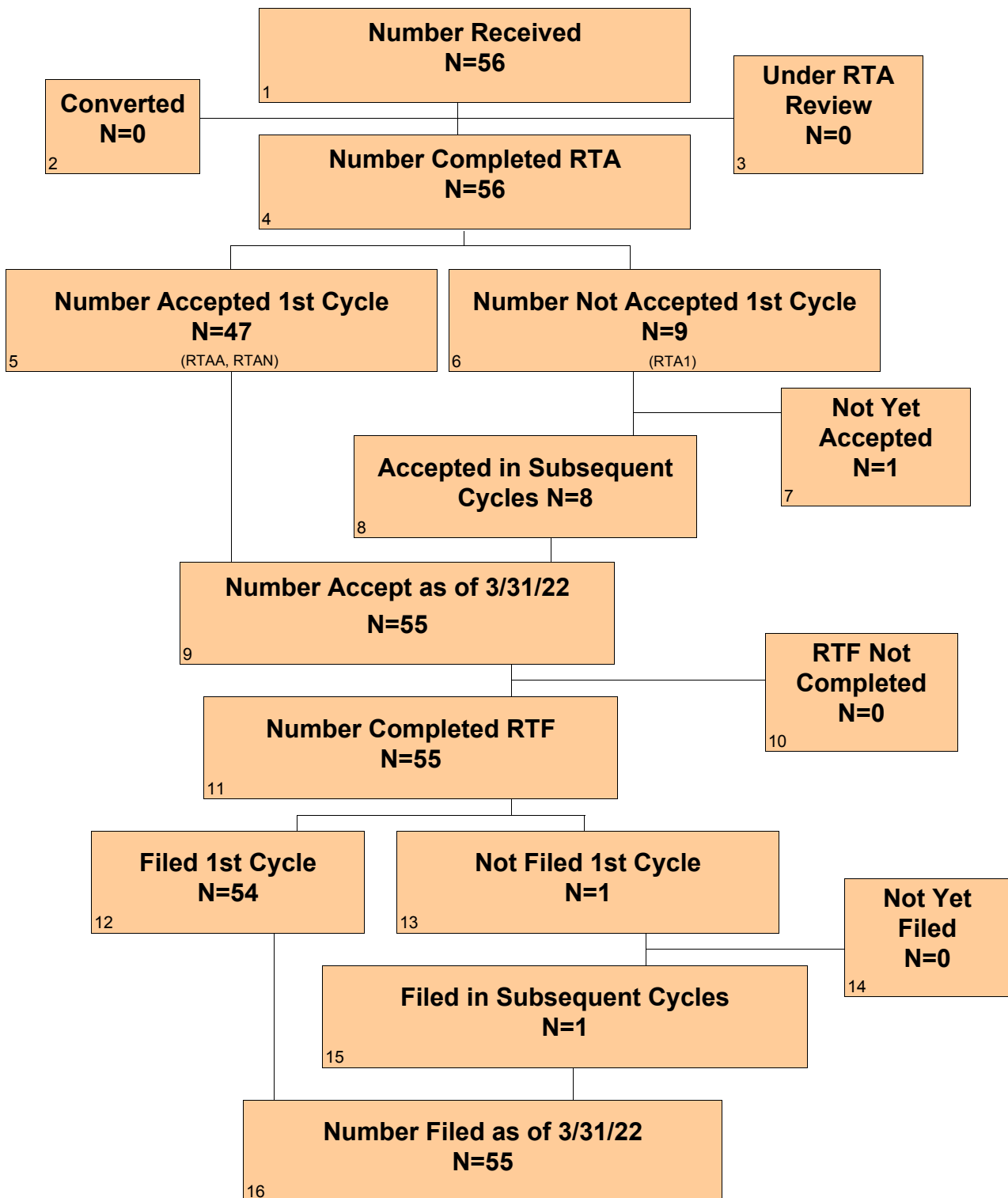
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/22



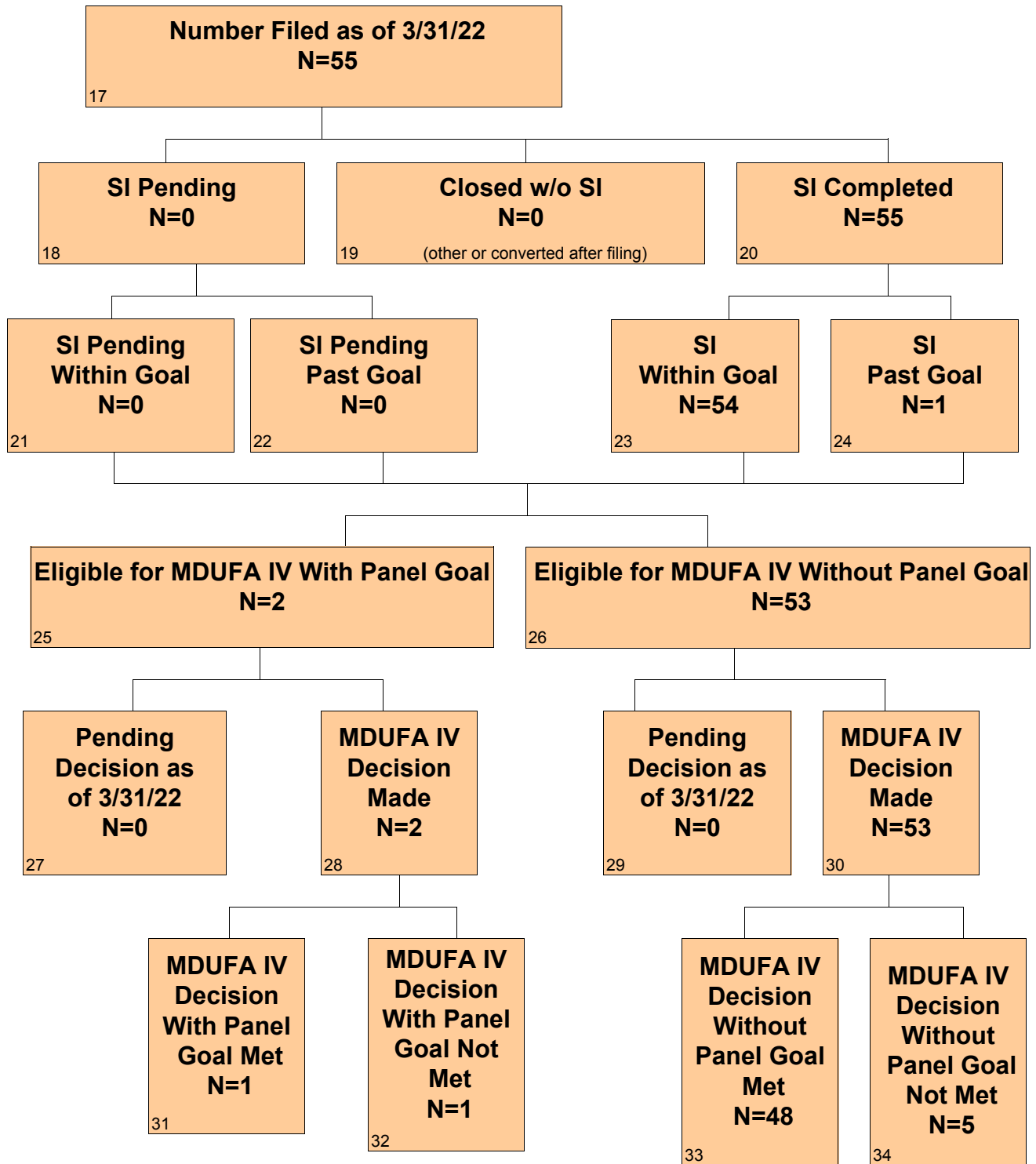
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/22 Continued



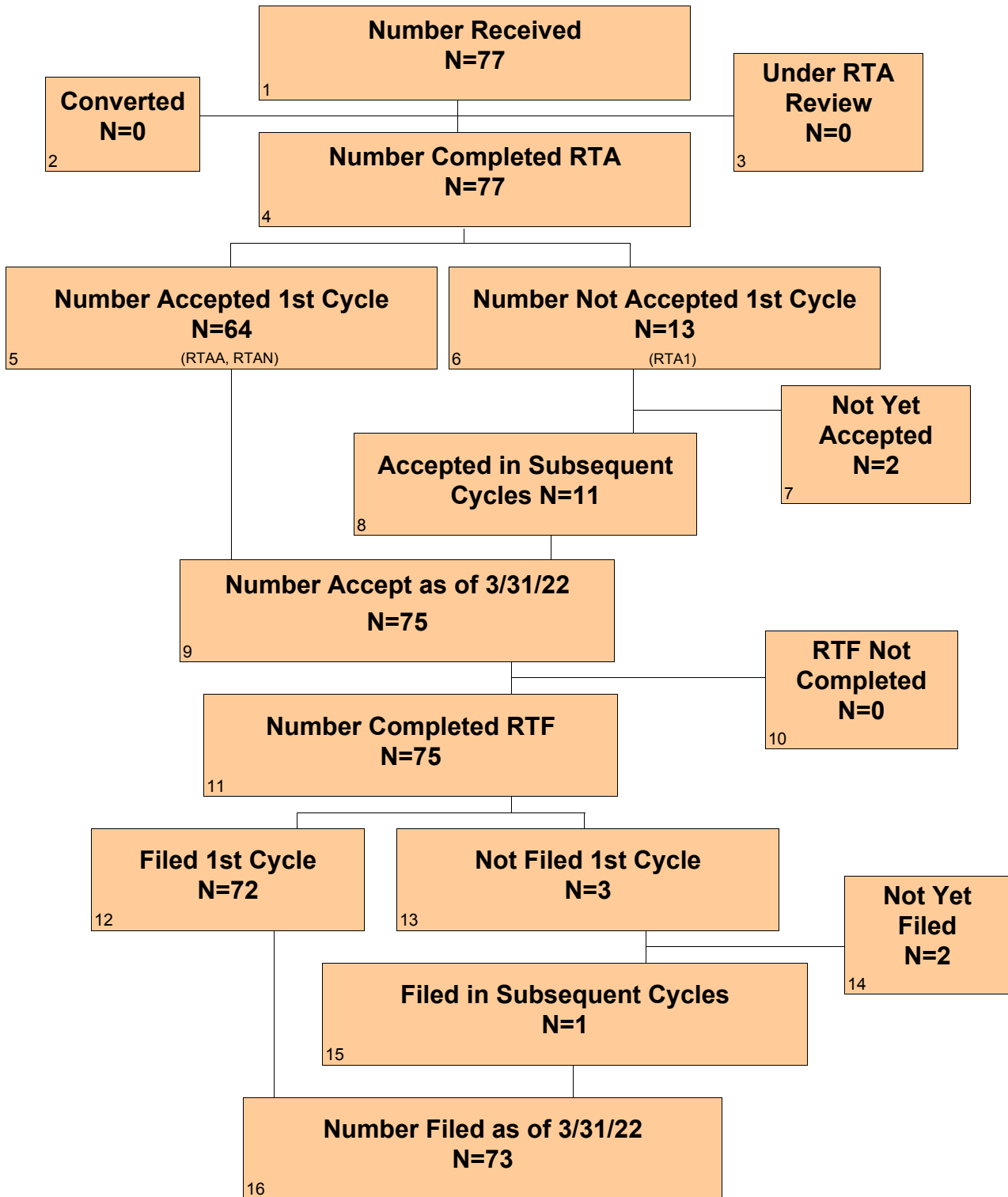
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/22



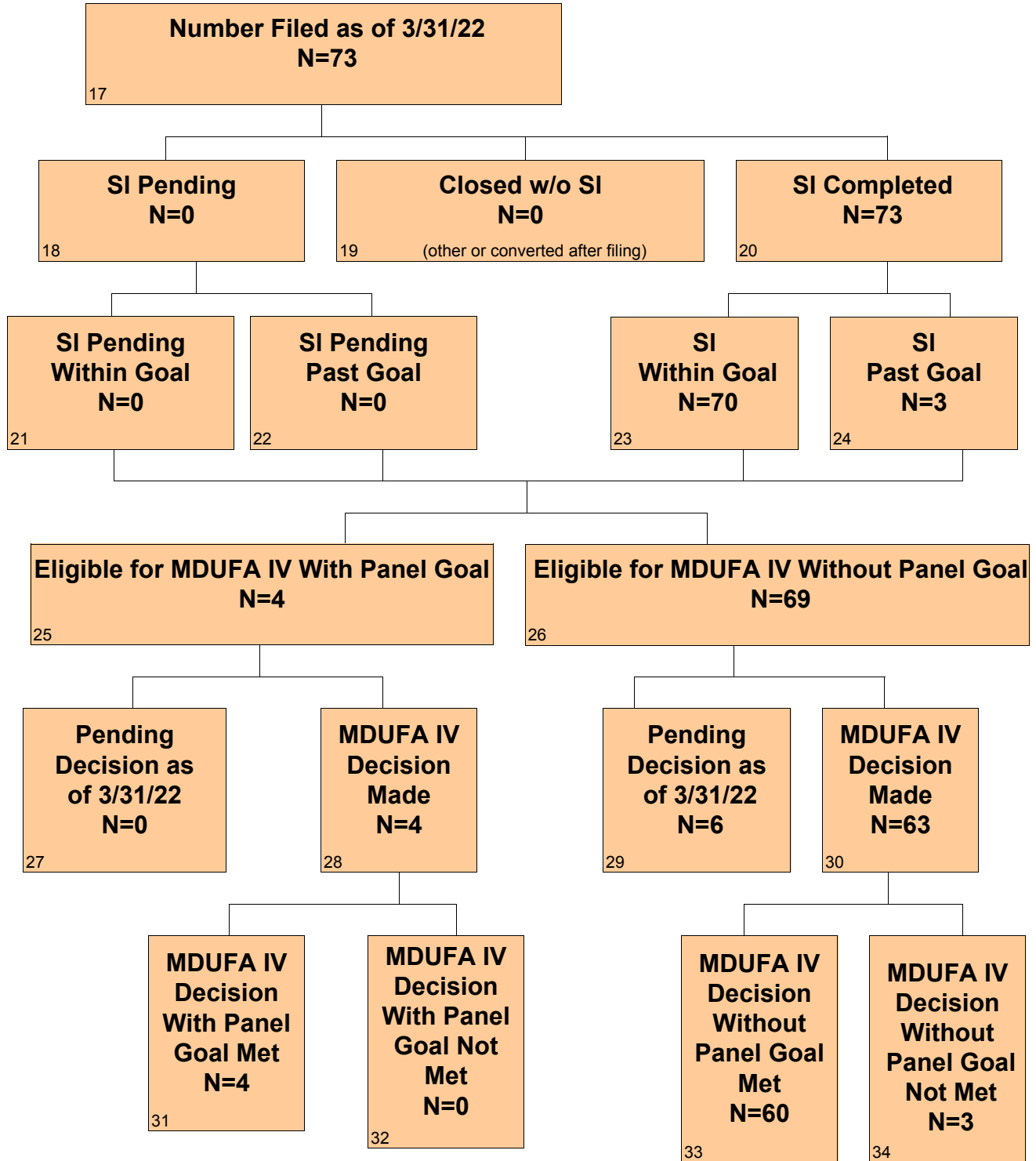
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/22 Continued



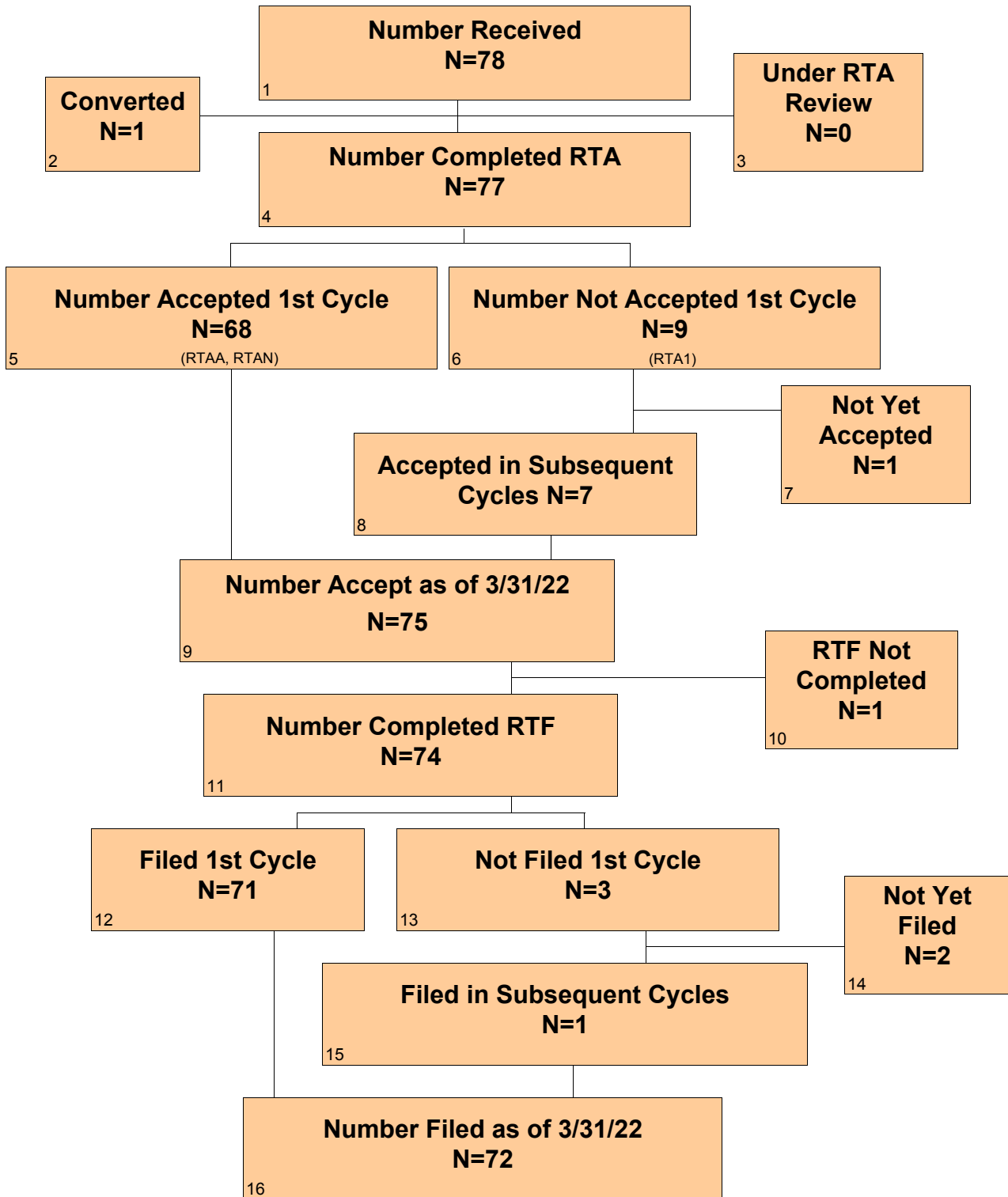
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 3/31/22



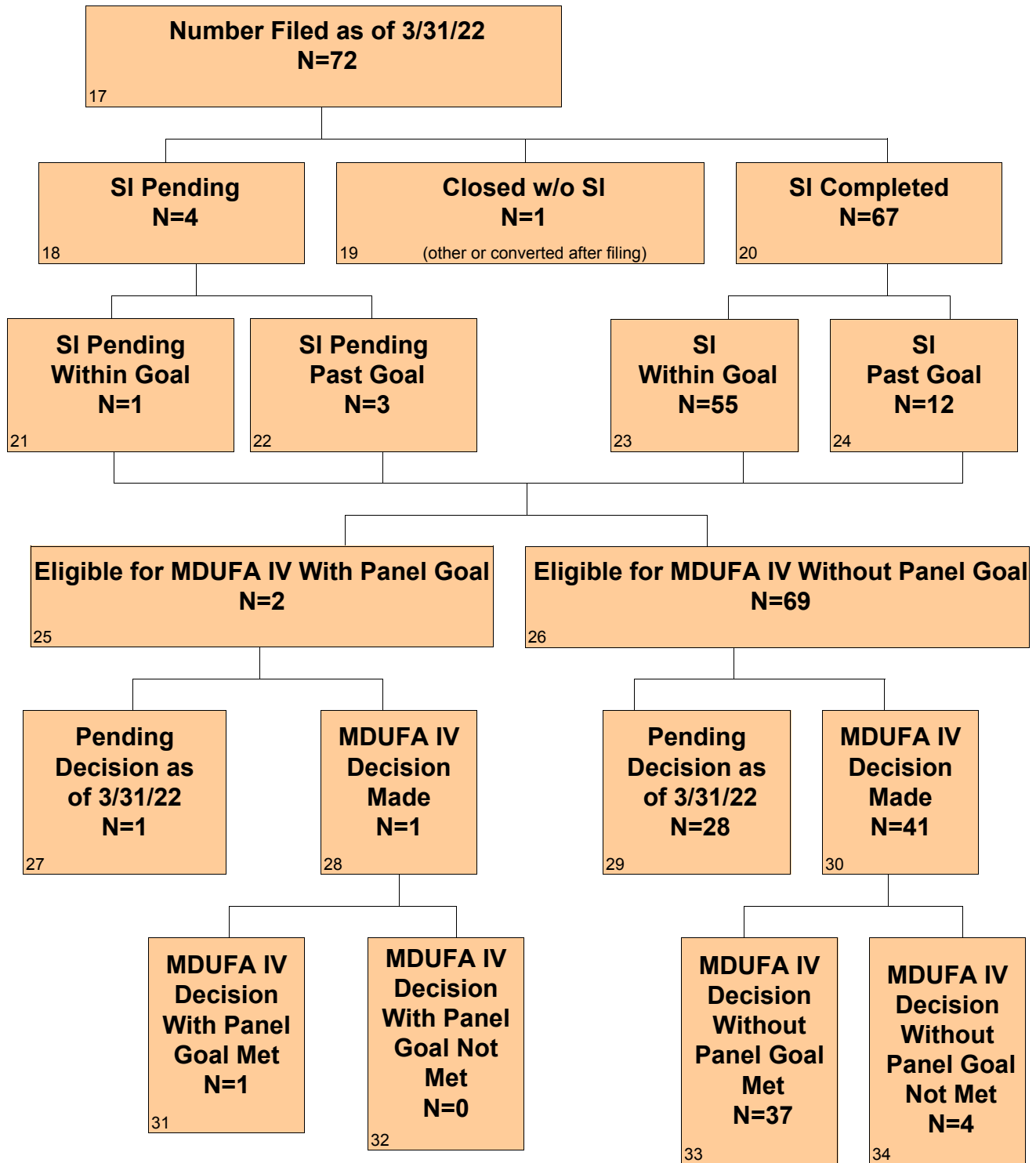
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 3/31/22 Continued



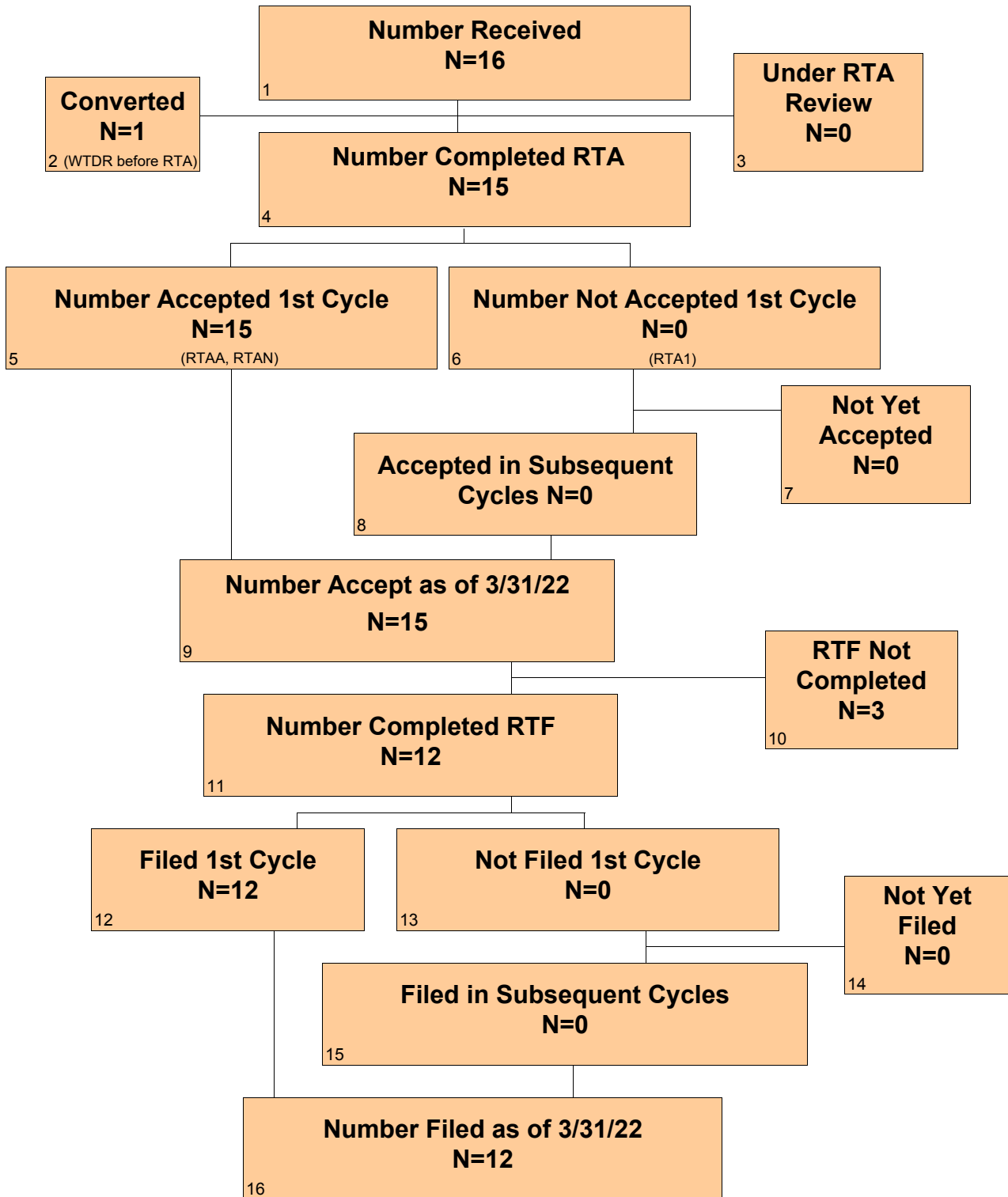
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 3/31/22



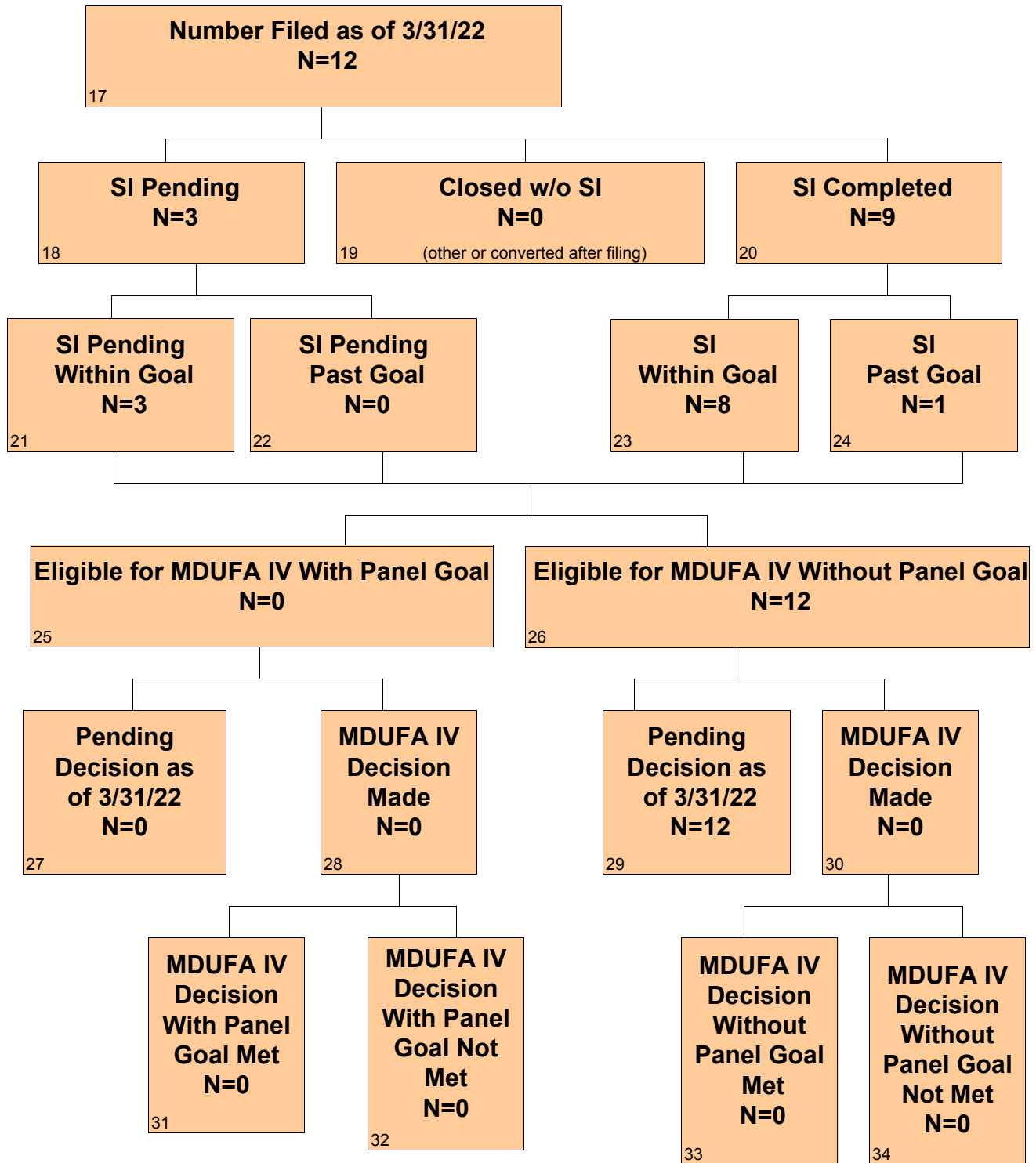
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 3/31/22 Continued



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 3/31/22



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 3/31/22 Continued



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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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 74 | 56 | 77 | 78 | 16 |
| Closed Before RTA Action | 0 | 0 | 0 | 1 | 1 |
| Number with Accepted RTA Review | 62 | 46 | 63 | 59 | 15 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 1 | 1 | 9 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 12 | 9 | 13 | 9 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 16.22% | 16.07% | 16.88% | 11.69% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 74 | 56 | 77 | 78 | 16 |
| Number Accepted | 62 | 47 | 64 | 68 | 15 |
| Completed RTF | 72 | 55 | 75 | 74 | 12 |
| Number Not Filed | 3 | 1 | 3 | 3 | 0 |
| Rate of Submissions Not Filed | 4.17% | 1.82% | 4.00% | 4.05% | 0.00% |

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

Performance Goal

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 71 | 55 | 73 | 72 | 12 |
| SI Goal Met | 69 | 54 | 70 | 55 | 8 |
| SI Goal Not Met | 2 | 1 | 3 | 12 | 1 |
| SI Pending Within Goal | 0 | 0 | 0 | 1 | 3 |
| SI Pending Past Goal | 0 | 0 | 0 | 3 | 0 |
| Closed Without SI | 0 | 0 | 0 | 1 | 0 |
| Current SI Performance Percent Goal Met | 97.18% | 98.18% | 95.89% | 78.57% | 88.89% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 71 | 55 | 73 | 67 | 9 |
| Average Number of FDA Days to Substantive Interaction | 87.03 | 89.95 | 91.74 | 110.16 | 93.00 |
| 20th Percentile FDA Days to Substantive Interaction | 84 | 87 | 88 | 87 | 87 |
| 40th Percentile FDA Days to Substantive Interaction | 88 | 88 | 88 | 89 | 89 |
| 60th Percentile FDA Days to Substantive Interaction | 90 | 89 | 90 | 90 | 90 |
| 80th Percentile FDA Days to Substantive Interaction | 90 | 90 | 90 | 90 | 90 |
| Maximum FDA Days to Substantive Interaction | 178 | 246 | 325 | 490 | 129 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 66 | 53 | 69 | 70 | 12 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| MDUFA IV Decision | 65 | 53 | 63 | 41 | 0 |
| MDUFA IV Decision Goal Met | 65 | 48 | 60 | 37 | 0 |
| PMAs Pending MDUFA IV Decision | 1 | 0 | 6 | 28 | 12 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 2 | 8 | 0 |
| Current Performance Percent Goal Met | 100.00% | 90.57% | 92.31% | 75.51% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 5 | 2 | 4 | 2 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 5 | 2 | 4 | 1 | 0 |
| MDUFA IV Decision Goal Met | 5 | 1 | 4 | 1 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 50.00% | 100.00% | 100.00% | N/A |

| Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review) | | | | | |
|---|----------------|----------------|----------------|----------------|----------------|
| Performance Metric - Time to MDUFA IV Decision | | | | | |
| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
| Number with MDUFA IV Decision | 65 | 53 | 63 | 41 | 0 |
| Average FDA Days to MDUFA IV Decision | 162.15 | 180.74 | 171.00 | 172.59 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 144 | 147 | 175 | 134 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 177 | 178 | 179 | 177 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 178 | 180 | 180 | 179 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 180 | 180 | 180 | 180 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 279 | 338 | 406 | 490 | 0 |
| Average Industry Days to MDUFA IV Decision | 93.18 | 127.28 | 97.44 | 54.76 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 18 | 31 | 32 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 88 | 130 | 69 | 37 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 162 | 192 | 168 | 85 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 360 | 540 | 521 | 355 | 0 |
| Average Total Days to MDUFA IV Decision | 255.34 | 308.02 | 268.44 | 227.34 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 167 | 175 | 177 | 176 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 180 | 204 | 207 | 182 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 257 | 310 | 260 | 225 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 342 | 440 | 353 | 268 | 0 |
| Maximum Total Days to MDUFA IV Decision | 540 | 718 | 609 | 490 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 5 | 2 | 4 | 1 | 0 |
| Average FDA Days to MDUFA IV Decision | 265.80 | 485.00 | 319.25 | 161.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 193 | 299 | 319 | 161 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 267 | 423 | 319 | 161 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 316 | 547 | 320 | 161 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 320 | 671 | 320 | 161 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 322 | 795 | 320 | 161 | 0 |
| Average Industry Days to MDUFA IV Decision | 19.00 | 135.00 | 179.75 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 104 | 88 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 125 | 110 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 145 | 130 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 19 | 166 | 248 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 95 | 187 | 416 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 284.80 | 620.00 | 499.00 | 161.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 256 | 403 | 407 | 161 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 297 | 548 | 430 | 161 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 316 | 692 | 449 | 161 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 320 | 837 | 567 | 161 | 0 |
| Maximum Total Days to MDUFA IV Decision | 322 | 982 | 736 | 161 | 0 |

Table 1.9 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)

Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 66 | 53 | 69 | 70 | 12 |
| Number with MDUFA IV Decision | 65 | 53 | 63 | 41 | 0 |
| Number of Withdrawal | 6 | 3 | 4 | 2 | 0 |
| Number of Not Approvable | 8 | 7 | 5 | 1 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 9.23% | 5.66% | 6.35% | 4.88% | N/A |
| Rate of Not Approvable | 12.31% | 13.21% | 7.94% | 2.44% | N/A |

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

Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 5 | 2 | 4 | 2 | 0 |
| Number With MDUFA IV Decision | 5 | 2 | 4 | 1 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 4 | 1 | 2 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | 0.00% | 0.00% | 0.00% | N/A |
| Rate of Not Approvable | 80.00% | 50.00% | 50.00% | 0.00% | N/A |

Table 1.11 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)

Performance Metric - Submissions Missing Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 5 | 5 | 12 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 266.60 | 247.00 | 304.50 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 235.00 | 133.00 | 44.75 | 0.00 |

Table 1.12 CDRH - PMA Original and Panel-Track Supplements (with Panel Review)

Performance Metric - Submissions Missing Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 1 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 795.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 187.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 1 | 4 | 11 | 5 | 1 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 1 | 4 | 11 | 3 | 0 |
| MDUFA IV Decision Goal Met | 1 | 4 | 11 | 3 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 1 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 1 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 75.00% | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 15 | 17 | 15 | 20 | 2 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| MDUFA IV Decision | 15 | 17 | 13 | 9 | 0 |
| MDUFA IV Decision Goal Met | 15 | 13 | 12 | 7 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 2 | 10 | 2 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 1 | 7 | 0 |
| Current Performance Percent Goal Met | 100.00% | 76.47% | 85.71% | 43.75% | N/A |

*Includes submission that went to panel

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

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 16 | 7 | 6 | 8 | 1 |
| Closed Before RTA Action | 0 | 0 | 0 | 0 | 1 |
| Number with Accepted RTA Review | 11 | 6 | 4 | 6 | 0 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 5 | 1 | 2 | 2 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 31.25% | 14.29% | 33.33% | 25.00% | N/A |

**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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 16 | 7 | 6 | 8 | 1 |
| Number Accepted | 11 | 6 | 4 | 6 | 0 |
| Completed RTF | 16 | 7 | 6 | 7 | 0 |
| Number Not Filed | 1 | 1 | 0 | 0 | 0 |
| Rate of Submissions Not Filed | 6.25% | 14.29% | 0.00% | 0.00% | N/A |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 16 | 7 | 6 | 7 | 0 |
| SI Goal Met | 16 | 7 | 6 | 6 | 0 |
| SI Goal Not Met | 0 | 0 | 0 | 1 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 0 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 85.71% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 16 | 7 | 6 | 7 | 0 |
| Average Number of FDA Days to Substantive Interaction | 87.13 | 88.86 | 88.00 | 98.71 | 0.00 |
| 20th Percentile FDA Days to Substantive Interaction | 86 | 88 | 87 | 89 | 0 |
| 40th Percentile FDA Days to Substantive Interaction | 87 | 89 | 88 | 90 | 0 |
| 60th Percentile FDA Days to Substantive Interaction | 90 | 90 | 88 | 90 | 0 |
| 80th Percentile FDA Days to Substantive Interaction | 90 | 90 | 88 | 90 | 0 |
| Maximum FDA Days to Substantive Interaction | 90 | 90 | 90 | 154 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 15 | 7 | 6 | 7 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 15 | 7 | 6 | 5 | 0 |
| MDUFA IV Decision Goal Met | 15 | 7 | 6 | 5 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 1 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 1 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Goal Met | 1 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | N/A | N/A | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 15 | 7 | 6 | 5 | 0 |
| Average FDA Days to MDUFA IV Decision | 177.33 | 179.14 | 180.00 | 161.60 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 176 | 179 | 180 | 160 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 178 | 180 | 180 | 179 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 179 | 180 | 180 | 180 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 180 | 180 | 180 | 180 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 180 | 180 | 180 | 180 | 0 |
| Average Industry Days to MDUFA IV Decision | 130.93 | 65.43 | 160.17 | 131.60 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 4 | 68 | 43 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 52 | 20 | 81 | 73 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 141 | 50 | 108 | 109 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 278 | 148 | 277 | 181 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 360 | 180 | 400 | 355 | 0 |
| Average Total Days to MDUFA IV Decision | 308.27 | 244.57 | 340.17 | 293.20 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 178 | 184 | 248 | 223 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 232 | 200 | 261 | 252 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 321 | 230 | 288 | 288 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 450 | 328 | 457 | 343 | 0 |
| Maximum Total Days to MDUFA IV Decision | 528 | 359 | 580 | 445 | 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 IV Decision**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 1 | 0 | 0 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 176.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 176 | 0 | 0 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 176 | 0 | 0 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 176 | 0 | 0 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 176 | 0 | 0 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 176 | 0 | 0 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 95.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 95 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 95 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 95 | 0 | 0 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 95 | 0 | 0 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 95 | 0 | 0 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 271.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 271 | 0 | 0 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 271 | 0 | 0 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 271 | 0 | 0 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 271 | 0 | 0 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 271 | 0 | 0 | 0 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 15 | 7 | 6 | 7 | 0 |
| Number with MDUFA IV Decision | 15 | 7 | 6 | 5 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 1 | 0 |
| Number of Not Approvable | 4 | 1 | 2 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | 0.00% | 0.00% | 20.00% | N/A |
| Rate of Not Approvable | 26.67% | 14.29% | 33.33% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 0 | 0 | 0 | 0 |
| Number With MDUFA IV Decision | 1 | 0 | 0 | 0 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 1 | 0 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | N/A | N/A | N/A | N/A |
| Rate of Not Approvable | 100.00% | N/A | N/A | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 23 | 14 | 23 | 19 | 5 |
| Closed Before RTA Action | 0 | 0 | 0 | 0 | 0 |
| Number with Accepted RTA Review | 20 | 11 | 21 | 18 | 5 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 3 | 3 | 2 | 1 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 13.04% | 21.43% | 8.70% | 5.26% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 23 | 14 | 23 | 19 | 5 |
| Number Accepted | 20 | 11 | 21 | 18 | 5 |
| Completed RTF | 22 | 14 | 23 | 19 | 3 |
| Number Not Filed | 1 | 0 | 0 | 0 | 0 |
| Rate of Submissions Not Filed | 4.55% | 0.00% | 0.00% | 0.00% | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 22 | 14 | 23 | 19 | 3 |
| SI Goal Met | 22 | 14 | 23 | 19 | 3 |
| SI Goal Not Met | 0 | 0 | 0 | 0 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 0 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 22 | 14 | 23 | 19 | 3 |
| Average Number of FDA Days to Substantive Interaction | 83.36 | 85.21 | 88.26 | 88.74 | 87.33 |
| 20th Percentile FDA Days to Substantive Interaction | 84 | 85 | 87 | 88 | 86 |
| 40th Percentile FDA Days to Substantive Interaction | 87 | 88 | 88 | 89 | 87 |
| 60th Percentile FDA Days to Substantive Interaction | 89 | 89 | 90 | 90 | 88 |
| 80th Percentile FDA Days to Substantive Interaction | 90 | 90 | 90 | 90 | 89 |
| Maximum FDA Days to Substantive Interaction | 90 | 90 | 90 | 90 | 90 |

Table 1.5 OHT2 -Office of Cardiovascular Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 21 | 12 | 22 | 19 | 3 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 21 | 12 | 19 | 13 | 0 |
| MDUFA IV Decision Goal Met | 21 | 12 | 19 | 13 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 3 | 6 | 3 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

Table 1.6 OHT2 - Office of Cardiovascular Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 1 | 2 | 1 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 1 | 2 | 1 | 0 | 0 |
| MDUFA IV Decision Goal Met | 1 | 1 | 1 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 50.00% | 100.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 21 | 12 | 19 | 13 | 0 |
| Average FDA Days to MDUFA IV Decision | 174.00 | 178.92 | 178.05 | 174.31 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 161 | 159 | 176 | 176 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 178 | 178 | 179 | 178 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 179 | 180 | 180 | 178 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 180 | 180 | 180 | 180 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 279 | 295 | 180 | 180 | 0 |
| Average Industry Days to MDUFA IV Decision | 51.48 | 107.00 | 82.16 | 32.38 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 10 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 67 | 15 | 22 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 45 | 122 | 59 | 47 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 91 | 171 | 113 | 54 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 162 | 322 | 424 | 78 | 0 |
| Average Total Days to MDUFA IV Decision | 225.48 | 285.92 | 260.21 | 206.69 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 168 | 170 | 177 | 177 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 180 | 245 | 194 | 199 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 229 | 302 | 236 | 225 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 324 | 363 | 293 | 232 | 0 |
| Maximum Total Days to MDUFA IV Decision | 340 | 501 | 604 | 258 | 0 |

Table 1.8 OHT2 - Office of Cardiovascular Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 1 | 2 | 1 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 197.00 | 485.00 | 318.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 197 | 299 | 318 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 197 | 423 | 318 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 197 | 547 | 318 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 197 | 671 | 318 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 197 | 795 | 318 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 135.00 | 63.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 104 | 63 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 125 | 63 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 145 | 63 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 166 | 63 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 187 | 63 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 197.00 | 620.00 | 381.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 197 | 403 | 381 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 197 | 548 | 381 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 197 | 692 | 381 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 197 | 837 | 381 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 197 | 982 | 381 | 0 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 21 | 12 | 22 | 19 | 3 |
| Number with MDUFA IV Decision | 21 | 12 | 19 | 13 | 0 |
| Number of Withdrawal | 0 | 0 | 1 | 0 | 0 |
| Number of Not Approvable | 1 | 1 | 1 | 1 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | 0.00% | 5.26% | 0.00% | N/A |
| Rate of Not Approvable | 4.76% | 8.33% | 5.26% | 7.69% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 1 | 2 | 1 | 0 | 0 |
| Number With MDUFA IV Decision | 1 | 2 | 1 | 0 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 0 | 1 | 1 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | 0.00% | 0.00% | N/A | N/A |
| Rate of Not Approvable | 0.00% | 50.00% | 100.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 1 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 795.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 187.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 9 | 3 | 7 | 4 | 0 |
| Closed Before RTA Action | 0 | 0 | 0 | 0 | 0 |
| Number with Accepted RTA Review | 8 | 3 | 6 | 4 | 0 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 0 | 1 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 1 | 0 | 0 | 0 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 11.11% | 0.00% | 0.00% | 0.00% | N/A |

**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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 9 | 3 | 7 | 4 | 0 |
| Number Accepted | 8 | 3 | 7 | 4 | 0 |
| Completed RTF | 9 | 3 | 7 | 4 | 0 |
| Number Not Filed | 1 | 0 | 1 | 0 | 0 |
| Rate of Submissions Not Filed | 11.11% | 0.00% | 14.29% | 0.00% | N/A |

**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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 8 | 3 | 6 | 4 | 0 |
| SI Goal Met | 8 | 3 | 6 | 4 | 0 |
| SI Goal Not Met | 0 | 0 | 0 | 0 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 0 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 8 | 3 | 6 | 4 | 0 |
| Average Number of FDA Days to Substantive Interaction | 99.50 | 139.67 | 89.17 | 88.25 | 0.00 |
| 20th Percentile FDA Days to Substantive Interaction | 87 | 86 | 88 | 88 | 0 |
| 40th Percentile FDA Days to Substantive Interaction | 88 | 87 | 89 | 88 | 0 |
| 60th Percentile FDA Days to Substantive Interaction | 90 | 119 | 90 | 88 | 0 |
| 80th Percentile FDA Days to Substantive Interaction | 91 | 182 | 90 | 89 | 0 |
| Maximum FDA Days to Substantive Interaction | 178 | 246 | 90 | 90 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 5 | 3 | 5 | 4 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 5 | 3 | 4 | 2 | 0 |
| MDUFA IV Decision Goal Met | 5 | 3 | 4 | 2 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 1 | 2 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 1 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 80.00% | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 3 | 0 | 1 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 3 | 0 | 1 | 0 | 0 |
| MDUFA IV Decision Goal Met | 3 | 0 | 1 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | N/A | 100.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 5 | 3 | 4 | 2 | 0 |
| Average FDA Days to MDUFA IV Decision | 178.00 | 228.33 | 156.75 | 180.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 159 | 172 | 143 | 180 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 177 | 177 | 179 | 180 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 179 | 212 | 180 | 180 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 197 | 275 | 180 | 180 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 266 | 338 | 180 | 180 | 0 |
| Average Industry Days to MDUFA IV Decision | 102.20 | 121.00 | 342.00 | 134.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 77 | 2 | 269 | 69 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 97 | 5 | 332 | 112 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 108 | 76 | 338 | 156 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 122 | 217 | 412 | 199 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 163 | 357 | 521 | 242 | 0 |
| Average Total Days to MDUFA IV Decision | 280.20 | 349.33 | 498.75 | 314.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 248 | 247 | 449 | 249 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 270 | 308 | 512 | 292 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 285 | 375 | 517 | 336 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 302 | 450 | 555 | 379 | 0 |
| Maximum Total Days to MDUFA IV Decision | 350 | 524 | 609 | 422 | 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 IV Decision**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 3 | 0 | 1 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 318.67 | 0.00 | 319.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 316 | 0 | 319 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 319 | 0 | 319 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 320 | 0 | 319 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 321 | 0 | 319 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 322 | 0 | 319 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 0.00 | 136.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 136 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 136 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 136 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 136 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 0 | 136 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 318.67 | 0.00 | 455.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 316 | 0 | 455 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 319 | 0 | 455 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 320 | 0 | 455 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 321 | 0 | 455 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 322 | 0 | 455 | 0 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 5 | 3 | 5 | 4 | 0 |
| Number with MDUFA IV Decision | 5 | 3 | 4 | 2 | 0 |
| Number of Withdrawal | 1 | 0 | 1 | 0 | 0 |
| Number of Not Approvable | 0 | 1 | 1 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 20.00% | 0.00% | 25.00% | 0.00% | N/A |
| Rate of Not Approvable | 0.00% | 33.33% | 25.00% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 3 | 0 | 1 | 0 | 0 |
| Number With MDUFA IV Decision | 3 | 0 | 1 | 0 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 3 | 0 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | N/A | 0.00% | N/A | N/A |
| Rate of Not Approvable | 100.00% | N/A | 0.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 1 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 311.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 335.00 | 0.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 3 | 2 | 5 | 6 | 2 |
| Closed Before RTA Action | 0 | 0 | 0 | 0 | 0 |
| Number with Accepted RTA Review | 1 | 1 | 3 | 3 | 2 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 2 | 1 | 2 | 3 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 66.67% | 50.00% | 40.00% | 50.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 3 | 2 | 5 | 6 | 2 |
| Number Accepted | 1 | 1 | 3 | 3 | 2 |
| Completed RTF | 2 | 2 | 4 | 6 | 2 |
| Number Not Filed | 0 | 0 | 0 | 1 | 0 |
| Rate of Submissions Not Filed | 0.00% | 0.00% | 0.00% | 16.67% | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 2 | 2 | 4 | 5 | 2 |
| SI Goal Met | 1 | 2 | 4 | 4 | 0 |
| SI Goal Not Met | 1 | 0 | 0 | 1 | 1 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 1 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 50.00% | 100.00% | 100.00% | 80.00% | 0.00% |

**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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2 | 2 | 4 | 5 | 1 |
| Average Number of FDA Days to Substantive Interaction | 93.50 | 90.00 | 89.25 | 108.20 | 129.00 |
| 20th Percentile FDA Days to Substantive Interaction | 90 | 90 | 89 | 86 | 129 |
| 40th Percentile FDA Days to Substantive Interaction | 92 | 90 | 89 | 88 | 129 |
| 60th Percentile FDA Days to Substantive Interaction | 95 | 90 | 90 | 90 | 129 |
| 80th Percentile FDA Days to Substantive Interaction | 97 | 90 | 90 | 110 | 129 |
| Maximum FDA Days to Substantive Interaction | 99 | 90 | 90 | 189 | 129 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 2 | 2 | 3 | 4 | 2 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 1 | 2 | 3 | 2 | 0 |
| MDUFA IV Decision Goal Met | 1 | 1 | 1 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 1 | 0 | 0 | 2 | 2 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 50.00% | 33.33% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 0 | 0 | 1 | 1 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 0 | 0 | 1 | 0 | 0 |
| MDUFA IV Decision Goal Met | 0 | 0 | 1 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | N/A | N/A | 100.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 1 | 2 | 3 | 2 | 0 |
| Average FDA Days to MDUFA IV Decision | 159.00 | 181.00 | 198.67 | 204.50 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 159 | 179 | 189 | 192 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 159 | 180 | 198 | 200 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 159 | 182 | 204 | 209 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 159 | 183 | 209 | 217 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 159 | 184 | 214 | 226 | 0 |
| Average Industry Days to MDUFA IV Decision | 6.00 | 90.00 | 41.67 | 85.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 6 | 49 | 27 | 50 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 6 | 76 | 31 | 73 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 6 | 104 | 40 | 97 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 6 | 131 | 55 | 120 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 6 | 159 | 69 | 144 | 0 |
| Average Total Days to MDUFA IV Decision | 165.00 | 271.00 | 240.33 | 289.50 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 165 | 231 | 218 | 267 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 165 | 258 | 223 | 282 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 165 | 284 | 237 | 297 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 165 | 311 | 260 | 312 | 0 |
| Maximum Total Days to MDUFA IV Decision | 165 | 337 | 283 | 327 | 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 IV Decision**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 0 | 0 | 1 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 0.00 | 0.00 | 320.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 0.00 | 104.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 104 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 104 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 104 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 104 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 0 | 104 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 0.00 | 0.00 | 424.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 424 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 424 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 424 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 424 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 0 | 0 | 424 | 0 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 2 | 2 | 3 | 4 | 2 |
| Number with MDUFA IV Decision | 1 | 2 | 3 | 2 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 1 | 0 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | 0.00% | 0.00% | 0.00% | N/A |
| Rate of Not Approvable | 100.00% | 0.00% | 0.00% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 0 | 0 | 1 | 1 | 0 |
| Number With MDUFA IV Decision | 0 | 0 | 1 | 0 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 0 | 0 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | N/A | N/A | 0.00% | N/A | N/A |
| Rate of Not Approvable | N/A | N/A | 0.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 1 | 2 | 2 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 184.00 | 208.00 | 204.50 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 21.00 | 46.00 | 85.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 4 | 5 | 4 | 9 | 1 |
| Closed Before RTA Action | 0 | 0 | 0 | 0 | 0 |
| Number with Accepted RTA Review | 3 | 4 | 1 | 8 | 1 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 1 | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 1 | 0 | 3 | 1 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 25.00% | 0.00% | 75.00% | 11.11% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 4 | 5 | 4 | 9 | 1 |
| Number Accepted | 3 | 5 | 1 | 8 | 1 |
| Completed RTF | 4 | 5 | 3 | 8 | 1 |
| Number Not Filed | 0 | 0 | 0 | 0 | 0 |
| Rate of Submissions Not Filed | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 4 | 5 | 3 | 8 | 1 |
| SI Goal Met | 3 | 5 | 3 | 8 | 1 |
| SI Goal Not Met | 1 | 0 | 0 | 0 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 0 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 75.00% | 100.00% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 4 | 5 | 3 | 8 | 1 |
| Average Number of FDA Days to Substantive Interaction | 90.50 | 84.80 | 90.00 | 87.50 | 90.00 |
| 20th Percentile FDA Days to Substantive Interaction | 90 | 84 | 90 | 85 | 90 |
| 40th Percentile FDA Days to Substantive Interaction | 90 | 90 | 90 | 87 | 90 |
| 60th Percentile FDA Days to Substantive Interaction | 90 | 90 | 90 | 89 | 90 |
| 80th Percentile FDA Days to Substantive Interaction | 91 | 90 | 90 | 90 | 90 |
| Maximum FDA Days to Substantive Interaction | 92 | 90 | 90 | 90 | 90 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 4 | 5 | 2 | 8 | 1 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 4 | 5 | 2 | 6 | 0 |
| MDUFA IV Decision Goal Met | 4 | 5 | 2 | 6 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 1 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------------------|------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 0 | 0 | 1 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 0 | 0 | 1 | 0 | 0 |
| MDUFA IV Decision Goal Met | 0 | 0 | 1 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | N/A | N/A | 100.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 4 | 5 | 2 | 6 | 0 |
| Average FDA Days to MDUFA IV Decision | 180.00 | 188.00 | 132.50 | 174.67 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 180 | 162 | 107 | 167 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 180 | 180 | 124 | 178 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 180 | 180 | 141 | 179 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 180 | 206 | 158 | 180 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 180 | 310 | 175 | 180 | 0 |
| Average Industry Days to MDUFA IV Decision | 186.75 | 172.00 | 32.00 | 9.17 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 56 | 96 | 13 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 134 | 151 | 26 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 253 | 184 | 38 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 320 | 224 | 51 | 22 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 360 | 343 | 64 | 33 | 0 |
| Average Total Days to MDUFA IV Decision | 366.75 | 360.00 | 164.50 | 183.83 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 236 | 256 | 158 | 178 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 314 | 282 | 162 | 179 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 433 | 325 | 167 | 180 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 500 | 430 | 171 | 200 | 0 |
| Maximum Total Days to MDUFA IV Decision | 540 | 653 | 175 | 202 | 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 IV Decision**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 0 | 0 | 1 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 0.00 | 0.00 | 320.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 0 | 0 | 320 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 0.00 | 416.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 416 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 416 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 416 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 416 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 0 | 416 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 0.00 | 0.00 | 736.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 736 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 736 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 736 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 736 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 0 | 0 | 736 | 0 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 4 | 5 | 2 | 8 | 1 |
| Number with MDUFA IV Decision | 4 | 5 | 2 | 6 | 0 |
| Number of Withdrawal | 0 | 1 | 1 | 0 | 0 |
| Number of Not Approvable | 0 | 2 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | 20.00% | 50.00% | 0.00% | N/A |
| Rate of Not Approvable | 0.00% | 40.00% | 0.00% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 0 | 0 | 1 | 0 | 0 |
| Number With MDUFA IV Decision | 0 | 0 | 1 | 0 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 0 | 0 | 1 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | N/A | N/A | 0.00% | N/A | N/A |
| Rate of Not Approvable | N/A | N/A | 100.00% | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 2 | 4 | 2 | 4 | 2 |
| Closed Before RTA Action | 0 | 0 | 0 | 0 | 0 |
| Number with Accepted RTA Review | 2 | 2 | 2 | 3 | 2 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 0 | 2 | 0 | 1 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 0.00% | 50.00% | 0.00% | 25.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 2 | 4 | 2 | 4 | 2 |
| Number Accepted | 2 | 2 | 2 | 3 | 2 |
| Completed RTF | 2 | 3 | 2 | 4 | 2 |
| Number Not Filed | 0 | 0 | 0 | 0 | 0 |
| Rate of Submissions Not Filed | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 2 | 3 | 2 | 4 | 2 |
| SI Goal Met | 2 | 3 | 2 | 3 | 1 |
| SI Goal Not Met | 0 | 0 | 0 | 0 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 1 | 1 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

Table 1.4 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 2 | 3 | 2 | 3 | 1 |
| Average Number of FDA Days to Substantive Interaction | 86.50 | 88.67 | 88.50 | 84.00 | 89.00 |
| 20th Percentile FDA Days to Substantive Interaction | 84 | 88 | 88 | 81 | 89 |
| 40th Percentile FDA Days to Substantive Interaction | 86 | 89 | 88 | 82 | 89 |
| 60th Percentile FDA Days to Substantive Interaction | 87 | 89 | 89 | 84 | 89 |
| 80th Percentile FDA Days to Substantive Interaction | 89 | 90 | 89 | 87 | 89 |
| Maximum FDA Days to Substantive Interaction | 90 | 90 | 89 | 90 | 89 |

Table 1.5 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 2 | 3 | 2 | 4 | 2 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 2 | 3 | 2 | 2 | 0 |
| MDUFA IV Decision Goal Met | 2 | 3 | 2 | 2 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 2 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

Table 1.6 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Goal Met | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

Table 1.7 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 2 | 3 | 2 | 2 | 0 |
| Average FDA Days to MDUFA IV Decision | 180.00 | 146.33 | 178.50 | 168.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 180 | 121 | 178 | 161 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 180 | 156 | 178 | 166 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 180 | 174 | 179 | 170 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 180 | 177 | 179 | 175 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 180 | 179 | 180 | 180 | 0 |
| Average Industry Days to MDUFA IV Decision | 141.50 | 203.67 | 103.50 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 57 | 67 | 41 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 113 | 122 | 83 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 170 | 209 | 124 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 226 | 330 | 166 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 283 | 450 | 207 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 321.50 | 350.00 | 282.00 | 168.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 237 | 191 | 219 | 161 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 293 | 282 | 261 | 166 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 350 | 387 | 303 | 170 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 406 | 505 | 345 | 175 | 0 |
| Maximum Total Days to MDUFA IV Decision | 463 | 623 | 387 | 180 | 0 |

Table 1.8 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |

Table 1.9 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 2 | 3 | 2 | 4 | 2 |
| Number with MDUFA IV Decision | 2 | 3 | 2 | 2 | 0 |
| Number of Withdrawal | 0 | 1 | 0 | 0 | 0 |
| Number of Not Approvable | 0 | 1 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 0.00% | 33.33% | 0.00% | 0.00% | N/A |
| Rate of Not Approvable | 0.00% | 33.33% | 0.00% | 0.00% | N/A |

Table 1.10 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 0 | 0 | 0 | 0 | 0 |
| Number With MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 0 | 0 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | N/A | N/A | N/A | N/A | N/A |
| Rate of Not Approvable | N/A | N/A | N/A | N/A | N/A |

Table 1.11 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | N/A | N/A | N/A | N/A | N/A |
| Non-MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| MDUFA IV Decision Goal Met | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision | N/A | N/A | N/A | N/A | N/A |
| PMAs Pending MDUFA IV Decision Past Goal | N/A | N/A | N/A | N/A | N/A |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 17 | 21 | 30 | 28 | 5 |
| Closed Before RTA Action | 0 | 0 | 0 | 1 | 0 |
| Number with Accepted RTA Review | 17 | 19 | 26 | 17 | 5 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 0 | 0 | 9 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 0 | 2 | 4 | 1 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 0.00% | 9.52% | 13.33% | 3.70% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Received | 17 | 21 | 30 | 28 | 5 |
| Number Accepted | 17 | 19 | 26 | 26 | 5 |
| Completed RTF | 17 | 21 | 30 | 26 | 4 |
| Number Not Filed | 0 | 0 | 2 | 2 | 0 |
| Rate of Submissions Not Filed | 0.00% | 0.00% | 6.67% | 7.69% | 0.00% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 17 | 21 | 29 | 25 | 4 |
| SI Goal Met | 17 | 20 | 26 | 11 | 3 |
| SI Goal Not Met | 0 | 1 | 3 | 10 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 1 |
| SI Pending Past Goal | 0 | 0 | 0 | 3 | 0 |
| Closed Without SI | 0 | 0 | 0 | 1 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 95.24% | 89.66% | 45.83% | 100.00% |

**Table 1.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interactions | 17 | 21 | 29 | 21 | 3 |
| Average Number of FDA Days to Substantive Interaction | 84.29 | 87.76 | 96.55 | 150.38 | 89.00 |
| 20th Percentile FDA Days to Substantive Interaction | 84 | 87 | 87 | 88 | 88 |
| 40th Percentile FDA Days to Substantive Interaction | 87 | 88 | 88 | 90 | 89 |
| 60th Percentile FDA Days to Substantive Interaction | 89 | 89 | 90 | 93 | 90 |
| 80th Percentile FDA Days to Substantive Interaction | 90 | 90 | 90 | 197 | 90 |
| Maximum FDA Days to Substantive Interaction | 90 | 91 | 325 | 490 | 90 |

**Table 1.5 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 17 | 21 | 29 | 24 | 4 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| MDUFA IV Decision | 17 | 21 | 27 | 11 | 0 |
| MDUFA IV Decision Goal Met | 17 | 17 | 26 | 9 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 2 | 12 | 4 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 1 | 8 | 0 |
| Current Performance Percent Goal Met | 100.00% | 80.95% | 92.86% | 47.37% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|--------------------------------|--------------------------------|--------------------------------|--------------------------------|--------------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 0 | 0 | 0 | 1 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| MDUFA IV Decision Goal Met | 0 | 0 | 0 | 1 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | N/A | N/A | N/A | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 17 | 21 | 27 | 11 | 0 |
| Average FDA Days to MDUFA IV Decision | 123.35 | 178.67 | 165.37 | 168.09 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 90 | 134 | 135 | 97 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 99 | 173 | 179 | 107 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 141 | 177 | 180 | 134 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 174 | 180 | 180 | 178 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 180 | 299 | 406 | 490 | 0 |
| Average Industry Days to MDUFA IV Decision | 86.18 | 142.38 | 68.63 | 61.18 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 16 | 24 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 75 | 81 | 63 | 33 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 149 | 325 | 138 | 110 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 336 | 540 | 257 | 318 | 0 |
| Average Total Days to MDUFA IV Decision | 209.53 | 321.05 | 234.00 | 229.27 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 90 | 155 | 159 | 123 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 139 | 179 | 191 | 176 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 213 | 257 | 253 | 207 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 266 | 619 | 318 | 305 | 0 |
| Maximum Total Days to MDUFA IV Decision | 511 | 718 | 458 | 490 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| Average FDA Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 161.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 161.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |
| Maximum Total Days to MDUFA IV Decision | 0 | 0 | 0 | 161 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 17 | 21 | 29 | 24 | 4 |
| Number with MDUFA IV Decision | 17 | 21 | 27 | 11 | 0 |
| Number of Withdrawal | 5 | 1 | 1 | 1 | 0 |
| Number of Not Approvable | 2 | 1 | 1 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | 29.41% | 4.76% | 3.70% | 9.09% | N/A |
| Rate of Not Approvable | 11.76% | 4.76% | 3.70% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| Number Filed | 0 | 0 | 0 | 1 | 0 |
| Number With MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 0 | 0 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | N/A | N/A | N/A | 0.00% | N/A |
| Rate of Not Approvable | N/A | N/A | N/A | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Submissions that Missed the Goal | 0 | 4 | 2 | 10 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 287.25 | 254.00 | 324.50 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 288.50 | 119.00 | 36.70 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 1 | 4 | 11 | 5 | 1 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 1 | 4 | 11 | 3 | 0 |
| MDUFA IV Decision Goal Met | 1 | 4 | 11 | 3 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 1 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 1 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 75.00% | N/A |

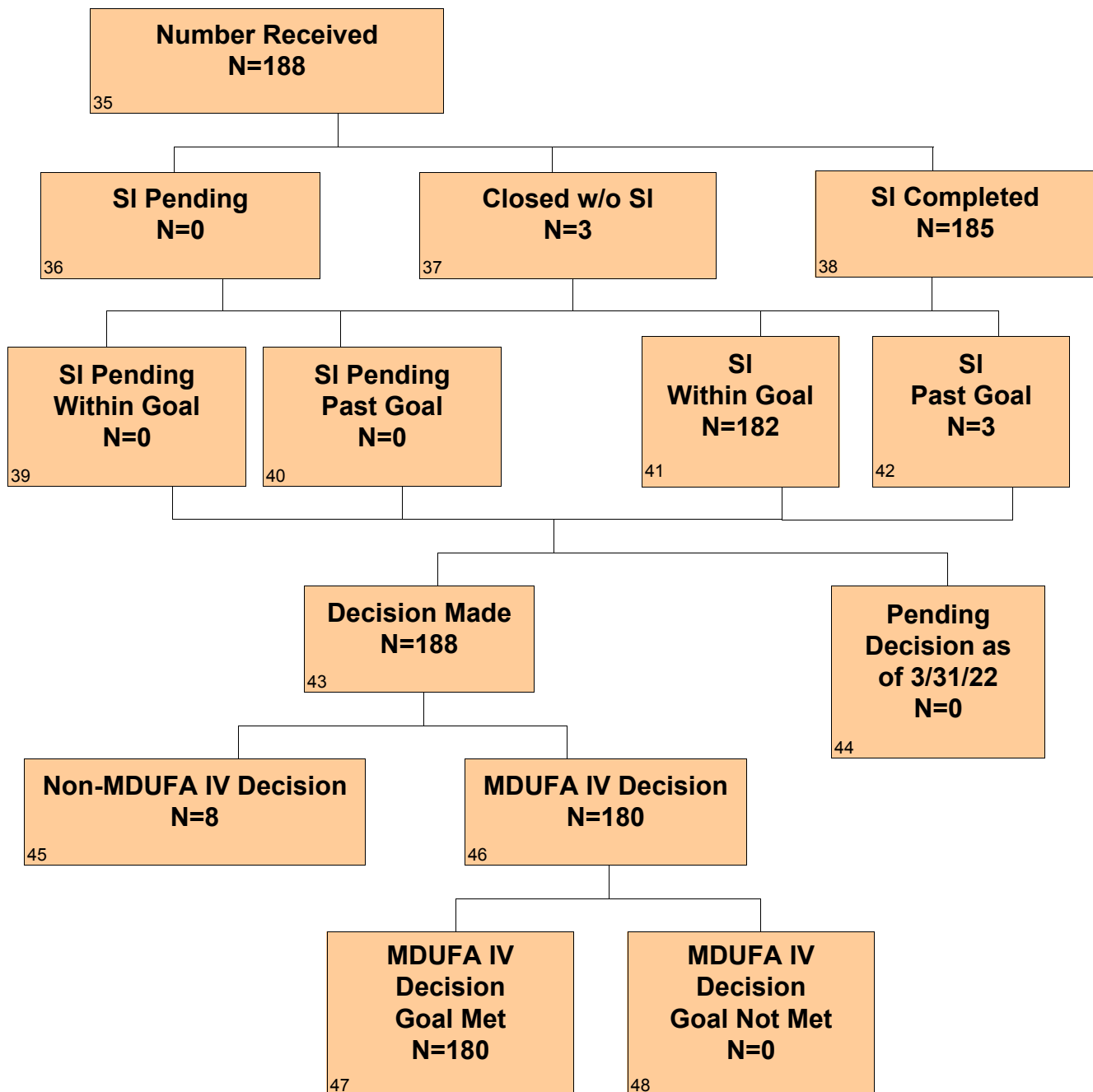
*Includes submission that went to panel

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

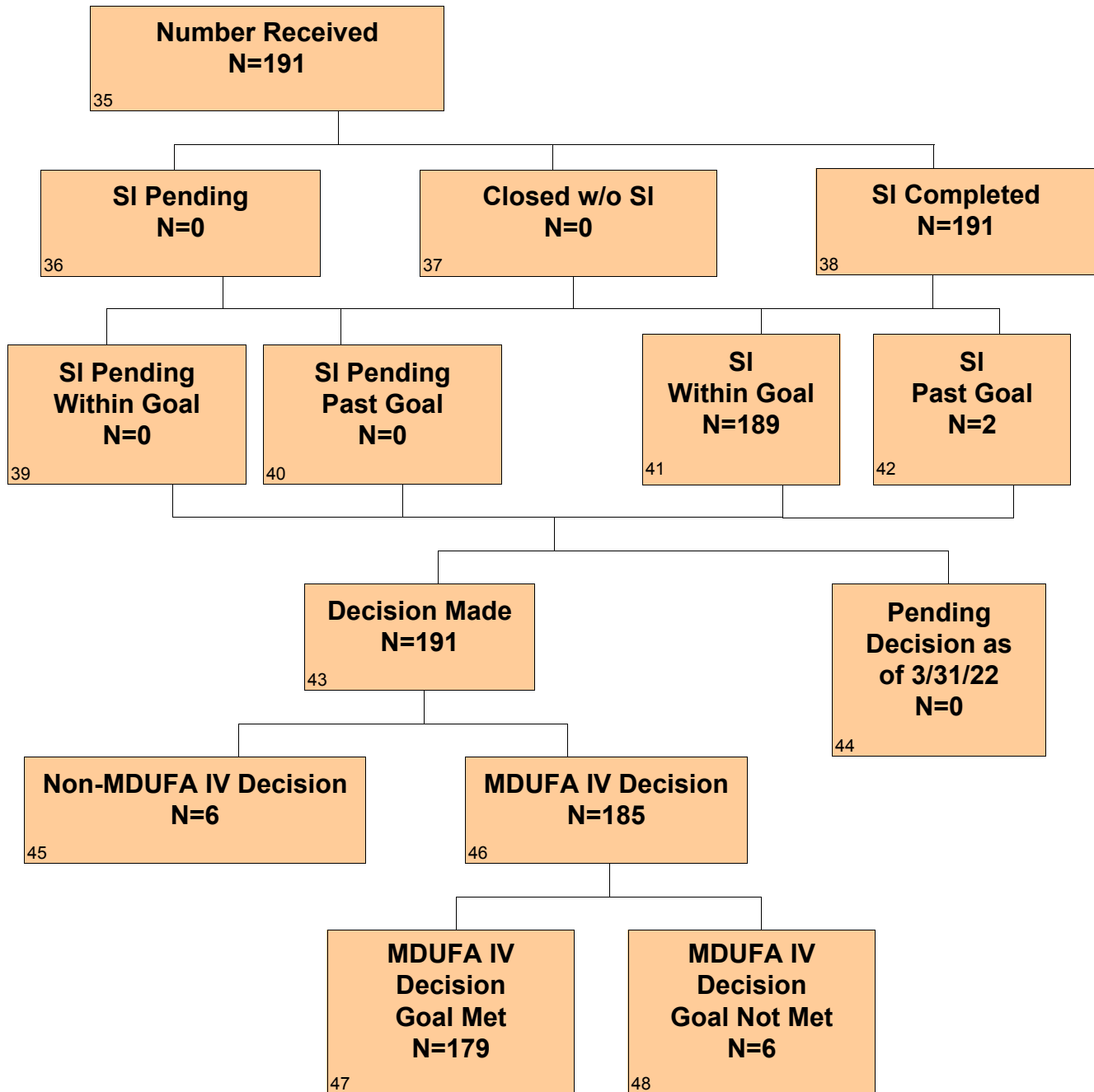
| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 15 | 17 | 15 | 20 | 2 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| MDUFA IV Decision | 15 | 17 | 13 | 9 | 0 |
| MDUFA IV Decision Goal Met | 15 | 13 | 12 | 7 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 2 | 10 | 2 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 1 | 7 | 0 |
| Current Performance Percent Goal Met | 100.00% | 76.47% | 85.71% | 43.75% | N/A |

*Includes submission that went to panel

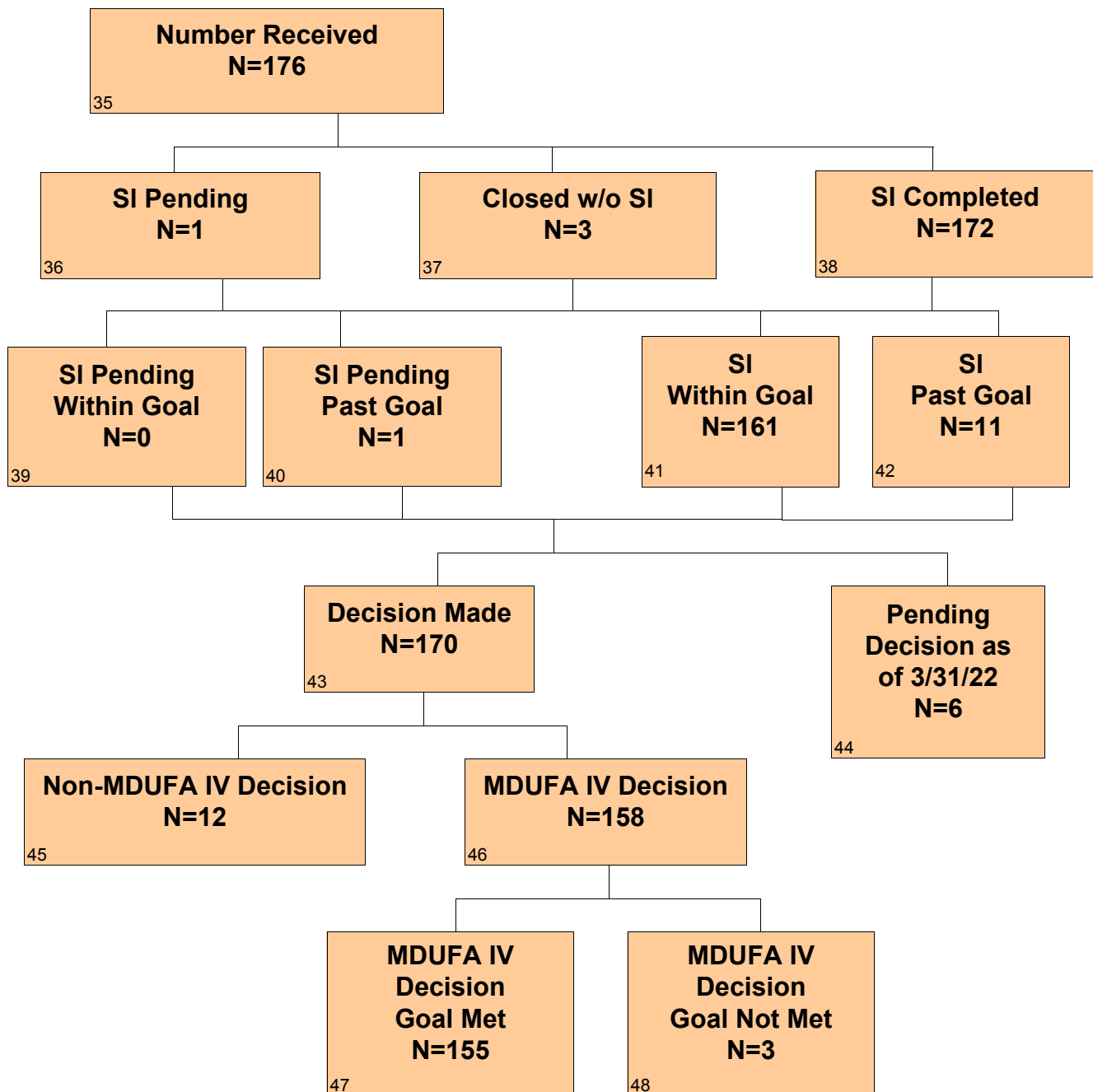
CDRH PMA 180 Day Supplements - FY 2018 as of 3/31/22



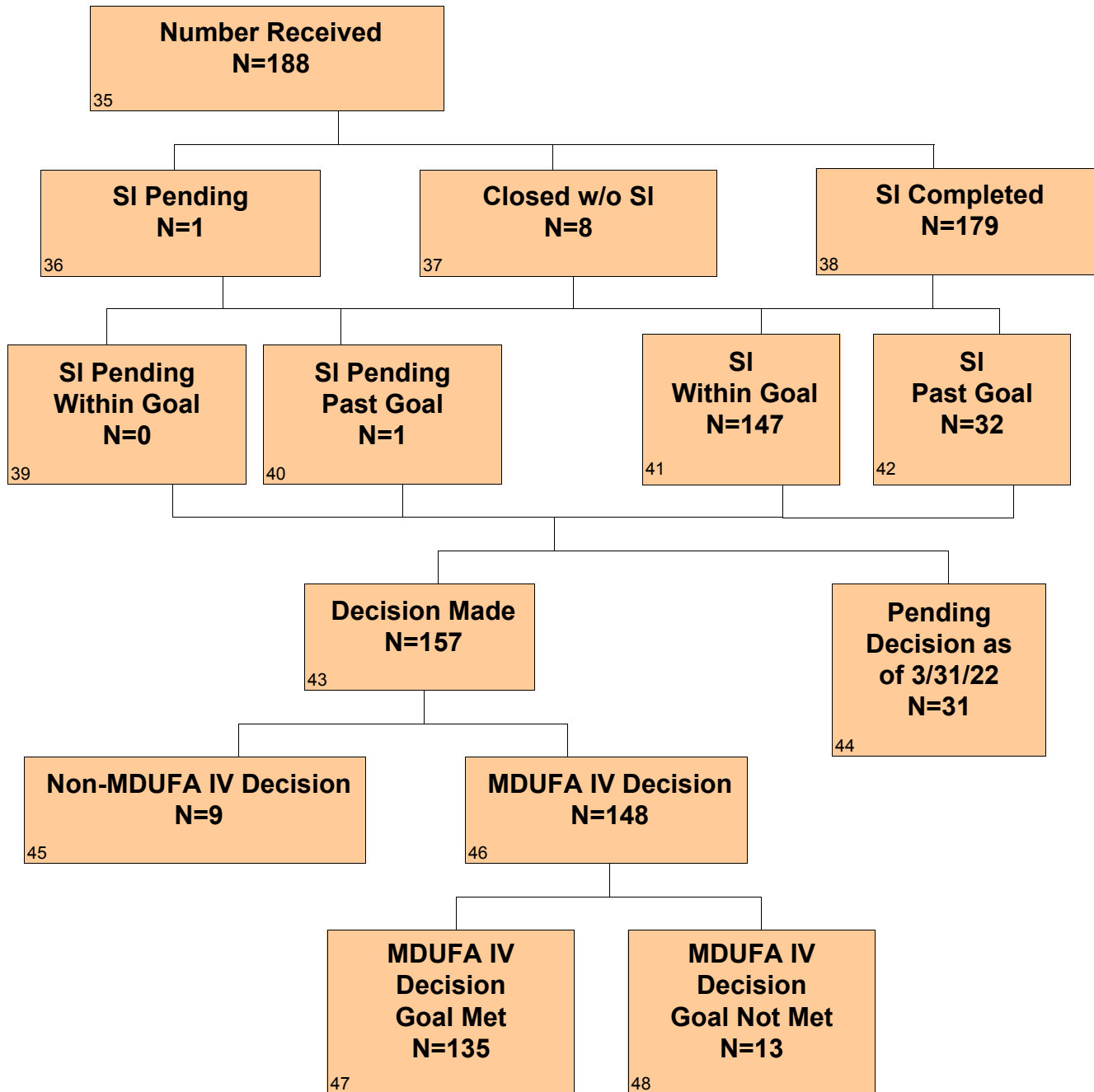
CDRH PMA 180 Day Supplements - FY 2019 as of 3/31/22



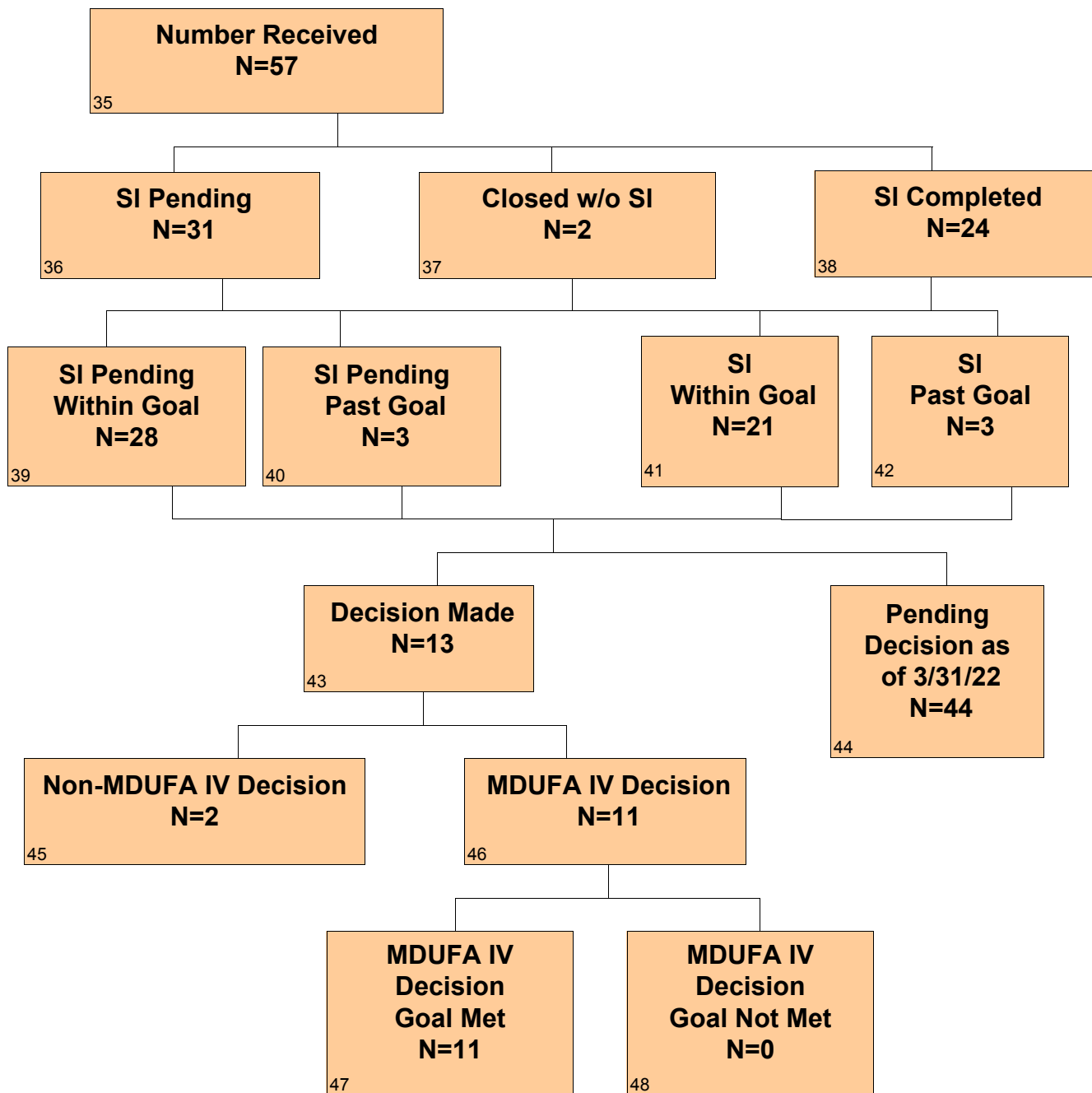
CDRH PMA 180 Day Supplements - FY 2020 as of 3/31/22



CDRH PMA 180 Day Supplements - FY 2021 as of 3/31/22



CDRH PMA 180 Day Supplements - FY 2022 as of 3/31/22



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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 188 | 191 | 176 | 188 | 57 |
| SI Goal Met | 182 | 189 | 161 | 147 | 21 |
| SI Goal Not Met | 3 | 2 | 11 | 32 | 3 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 28 |
| SI Pending Past Goal | 0 | 0 | 1 | 1 | 3 |
| Closed Without SI | 3 | 0 | 3 | 8 | 2 |
| Current SI Performance Percent Goal Met | 98.38% | 98.95% | 93.06% | 81.67% | 77.78% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 188 | 191 | 176 | 188 | 57 |
| Non-MDUFA IV Decision | 8 | 6 | 12 | 9 | 2 |
| MDUFA IV Decision | 180 | 185 | 158 | 148 | 11 |
| MDUFA IV Decision Goal Met | 180 | 179 | 155 | 135 | 11 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 6 | 31 | 44 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 2 | 6 | 0 |
| Current Performance Percent Goal Met | 100.00% | 96.76% | 96.88% | 87.66% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 188 | 191 | 176 | 188 | 57 |
| Number with MDUFA IV Decision | 180 | 185 | 158 | 148 | 11 |
| Number of Not Approvable | 13 | 10 | 8 | 4 | 0 |
| Rate of Not Approvable | 7.22% | 5.41% | 5.06% | 2.70% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 6 | 5 | 19 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 263.33 | 374.80 | 225.68 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 69.67 | 69.60 | 29.42 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 20 | 36 | 28 | 15 | 7 |
| SI Goal Met | 20 | 36 | 28 | 14 | 5 |
| SI Goal Not Met | 0 | 0 | 0 | 1 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 2 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 93.33% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 20 | 36 | 28 | 15 | 7 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 20 | 36 | 28 | 12 | 2 |
| MDUFA IV Decision Goal Met | 20 | 35 | 28 | 12 | 2 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 3 | 5 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 97.22% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 20 | 36 | 28 | 15 | 7 |
| Number with MDUFA IV Decision | 20 | 36 | 28 | 12 | 2 |
| Number of Not Approvable | 1 | 1 | 1 | 2 | 0 |
| Rate of Not Approvable | 5.00% | 2.78% | 3.57% | 16.67% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 1 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 302.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 41.00 | 0.00 | 0.00 | 0.00 |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 94 | 81 | 70 | 94 | 19 |
| SI Goal Met | 91 | 81 | 66 | 79 | 7 |
| SI Goal Not Met | 1 | 0 | 4 | 7 | 1 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 10 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 1 |
| Closed Without SI | 2 | 0 | 0 | 8 | 0 |
| Current SI Performance Percent Goal Met | 98.91% | 100.00% | 94.29% | 91.86% | 77.78% |

**Table 2.2 OHT2 - Office of Cardiovascular Devices
PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 94 | 81 | 70 | 94 | 19 |
| Non-MDUFA IV Decision | 2 | 3 | 2 | 8 | 0 |
| MDUFA IV Decision | 92 | 78 | 65 | 72 | 5 |
| MDUFA IV Decision Goal Met | 92 | 78 | 65 | 72 | 5 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 3 | 14 | 14 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 94 | 81 | 70 | 94 | 19 |
| Number with MDUFA IV Decision | 92 | 78 | 65 | 72 | 5 |
| Number of Not Approvable | 6 | 6 | 4 | 2 | 0 |
| Rate of Not Approvable | 6.52% | 7.69% | 6.15% | 2.78% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 15 | 16 | 19 | 19 | 7 |
| SI Goal Met | 14 | 15 | 16 | 18 | 0 |
| SI Goal Not Met | 1 | 1 | 0 | 1 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 5 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 3 | 0 | 2 |
| Current SI Performance Percent Goal Met | 93.33% | 93.75% | 100.00% | 94.74% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 15 | 16 | 19 | 19 | 7 |
| Non-MDUFA IV Decision | 0 | 2 | 7 | 1 | 2 |
| MDUFA IV Decision | 15 | 14 | 11 | 17 | 0 |
| MDUFA IV Decision Goal Met | 15 | 14 | 11 | 16 | 0 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 1 | 1 | 5 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 94.12% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 15 | 16 | 19 | 19 | 7 |
| Number with MDUFA IV Decision | 15 | 14 | 11 | 17 | 0 |
| Number of Not Approvable | 0 | 2 | 2 | 0 | 0 |
| Rate of Not Approvable | 0.00% | 14.29% | 18.18% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 233.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 49.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 9 | 10 | 7 | 15 | 4 |
| SI Goal Met | 9 | 9 | 6 | 5 | 2 |
| SI Goal Not Met | 0 | 1 | 1 | 9 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 2 |
| SI Pending Past Goal | 0 | 0 | 0 | 1 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 90.00% | 85.71% | 33.33% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 9 | 10 | 7 | 15 | 4 |
| Non-MDUFA IV Decision | 1 | 1 | 0 | 0 | 0 |
| MDUFA IV Decision | 8 | 9 | 6 | 13 | 0 |
| MDUFA IV Decision Goal Met | 8 | 5 | 6 | 8 | 0 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 1 | 2 | 4 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 1 | 1 | 0 |
| Current Performance Percent Goal Met | 100.00% | 55.56% | 85.71% | 57.14% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 9 | 10 | 7 | 15 | 4 |
| Number with MDUFA IV Decision | 8 | 9 | 6 | 13 | 0 |
| Number of Not Approvable | 0 | 0 | 0 | 0 | 0 |
| Rate of Not Approvable | 0.00% | 0.00% | 0.00% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 4 | 1 | 6 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 258.50 | 326.00 | 224.50 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 91.00 | 223.00 | 12.00 | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 13 | 16 | 23 | 20 | 7 |
| SI Goal Met | 12 | 16 | 23 | 19 | 2 |
| SI Goal Not Met | 0 | 0 | 0 | 1 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 5 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 1 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 95.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 13 | 16 | 23 | 20 | 7 |
| Non-MDUFA IV Decision | 2 | 0 | 2 | 0 | 0 |
| MDUFA IV Decision | 11 | 16 | 21 | 15 | 2 |
| MDUFA IV Decision Goal Met | 11 | 15 | 21 | 15 | 2 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 5 | 5 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 93.75% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 13 | 16 | 23 | 20 | 7 |
| Number with MDUFA IV Decision | 11 | 16 | 21 | 15 | 2 |
| Number of Not Approvable | 2 | 0 | 1 | 0 | 0 |
| Rate of Not Approvable | 18.18% | 0.00% | 4.76% | 0.00% | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 1 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 244.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 13.00 | 0.00 | 0.00 | 0.00 |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 0 | 6 | 2 | 4 | 0 |
| SI Goal Met | 0 | 6 | 2 | 4 | 0 |
| SI Goal Not Met | 0 | 0 | 0 | 0 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 0 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | N/A | 100.00% | 100.00% | 100.00% | N/A |

**Table 2.2 OHT6 - Office of Orthopedic Devices
PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 0 | 6 | 2 | 4 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 1 | 0 | 0 |
| MDUFA IV Decision | 0 | 6 | 1 | 3 | 0 |
| MDUFA IV Decision Goal Met | 0 | 6 | 1 | 3 | 0 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 1 | 0 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | N/A | 100.00% | 100.00% | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 0 | 6 | 2 | 4 | 0 |
| Number with MDUFA IV Decision | 0 | 6 | 1 | 3 | 0 |
| Number of Not Approvable | 0 | 0 | 0 | 0 | 0 |
| Rate of Not Approvable | N/A | 0.00% | 0.00% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 37 | 26 | 27 | 21 | 13 |
| SI Goal Met | 36 | 26 | 20 | 8 | 5 |
| SI Goal Not Met | 1 | 0 | 6 | 13 | 2 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 4 |
| SI Pending Past Goal | 0 | 0 | 1 | 0 | 2 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 97.30% | 100.00% | 74.07% | 38.10% | 55.56% |

**Table 2.2 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 37 | 26 | 27 | 21 | 13 |
| Non-MDUFA IV Decision | 3 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 34 | 26 | 26 | 16 | 2 |
| MDUFA IV Decision Goal Met | 34 | 26 | 23 | 9 | 2 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 1 | 5 | 11 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 1 | 5 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 85.19% | 42.86% | 100.00% |

**Table 2.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

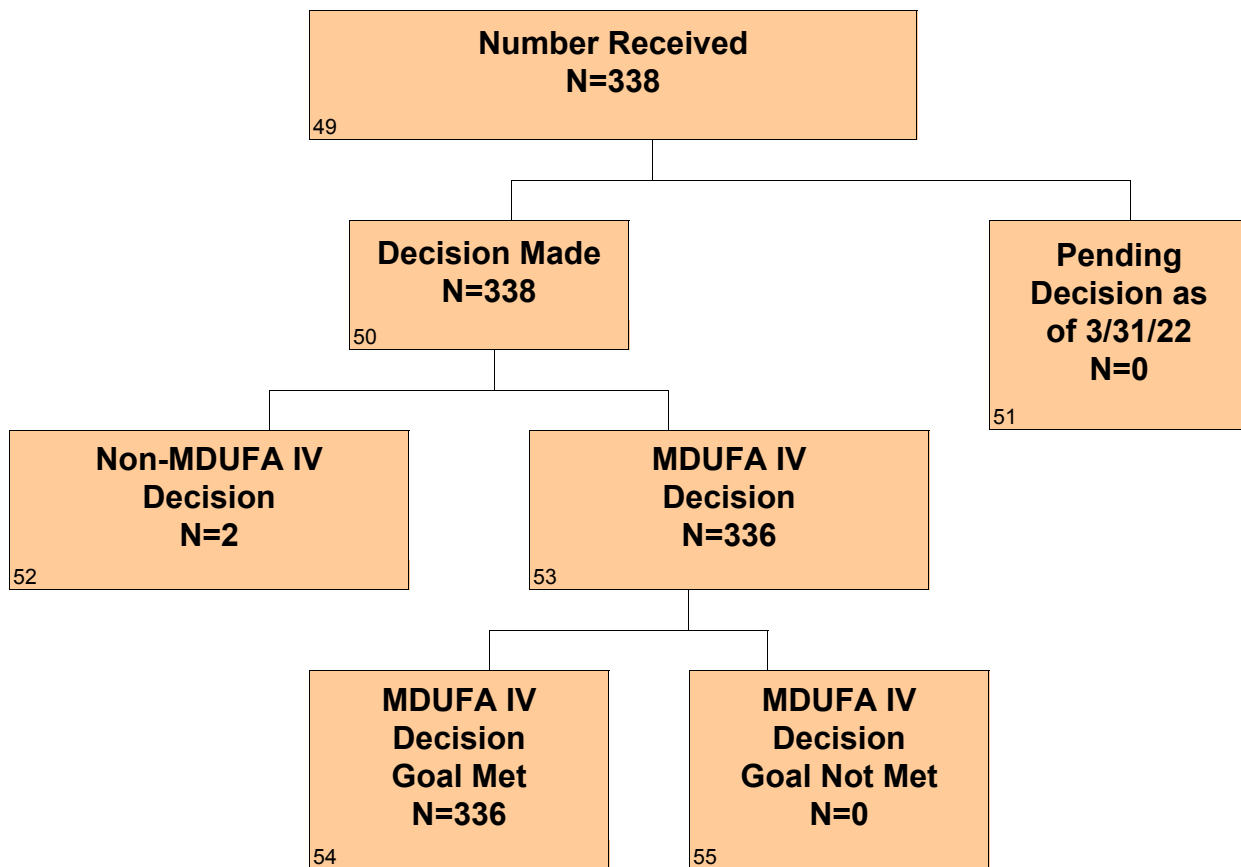
| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 37 | 26 | 27 | 21 | 13 |
| Number with MDUFA IV Decision | 34 | 26 | 26 | 16 | 2 |
| Number of Not Approvable | 4 | 1 | 0 | 0 | 0 |
| Rate of Not Approvable | 11.76% | 3.85% | 0.00% | 0.00% | 0.00% |

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

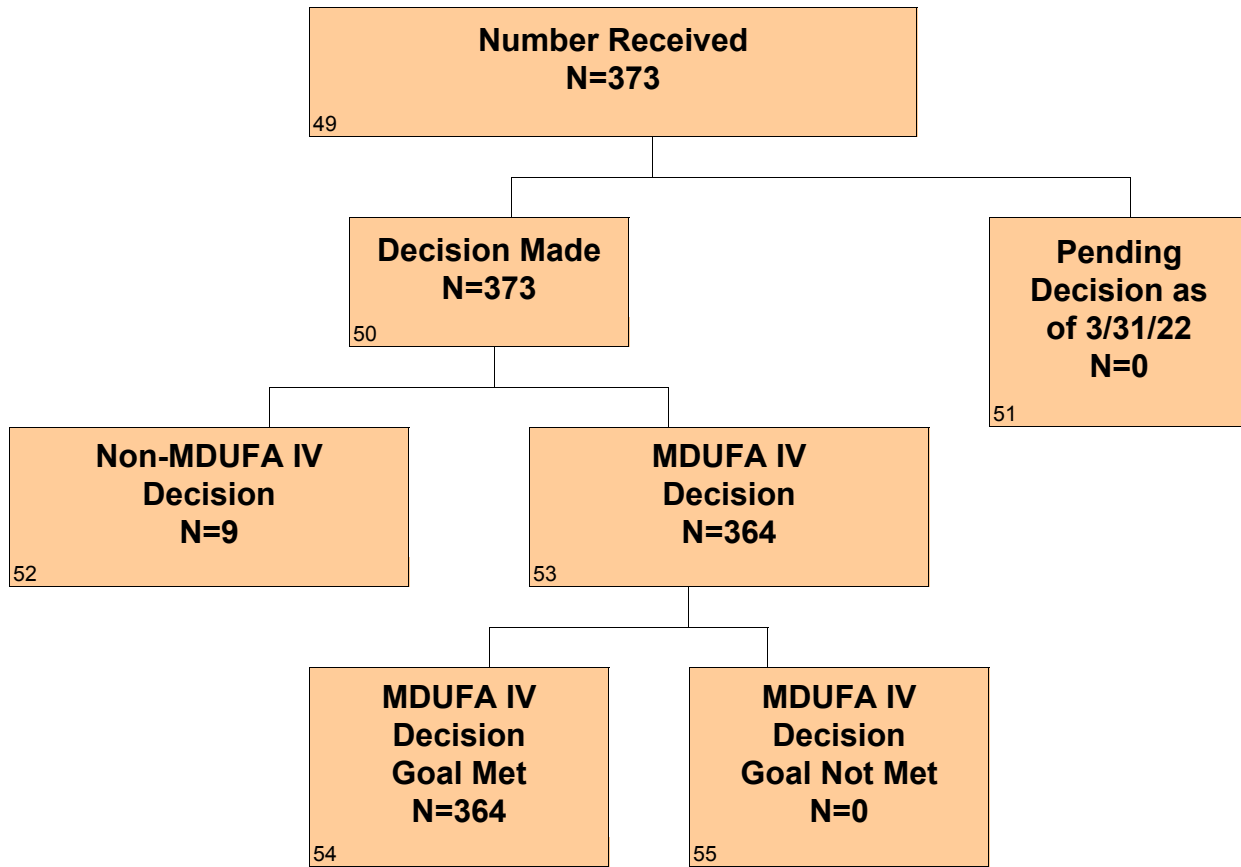
| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 4 | 12 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 387.00 | 225.67 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 31.25 | 36.50 | 0.00 |

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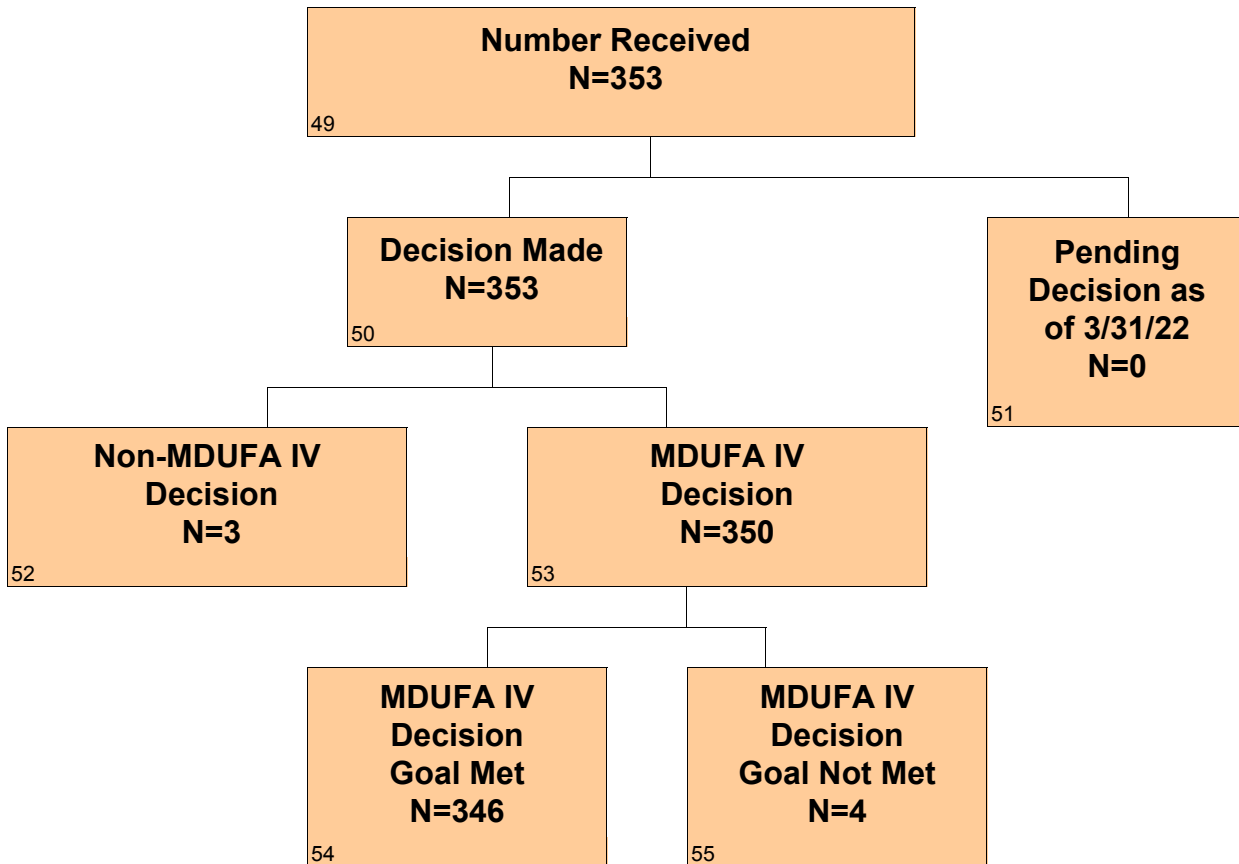
CDRH PMA Real Time Supplements - FY 2018 as of 3/31/22



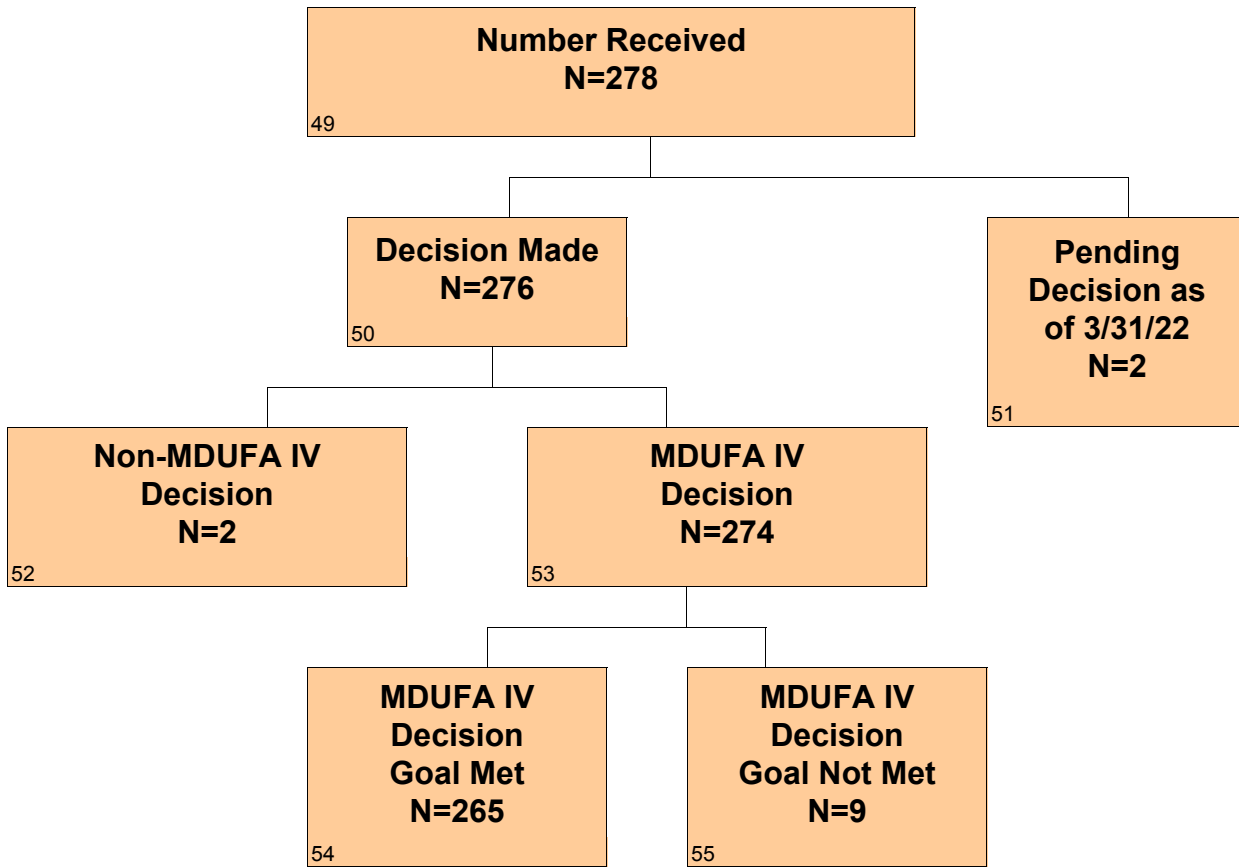
CDRH PMA Real Time Supplements - FY 2019 as of 3/31/22



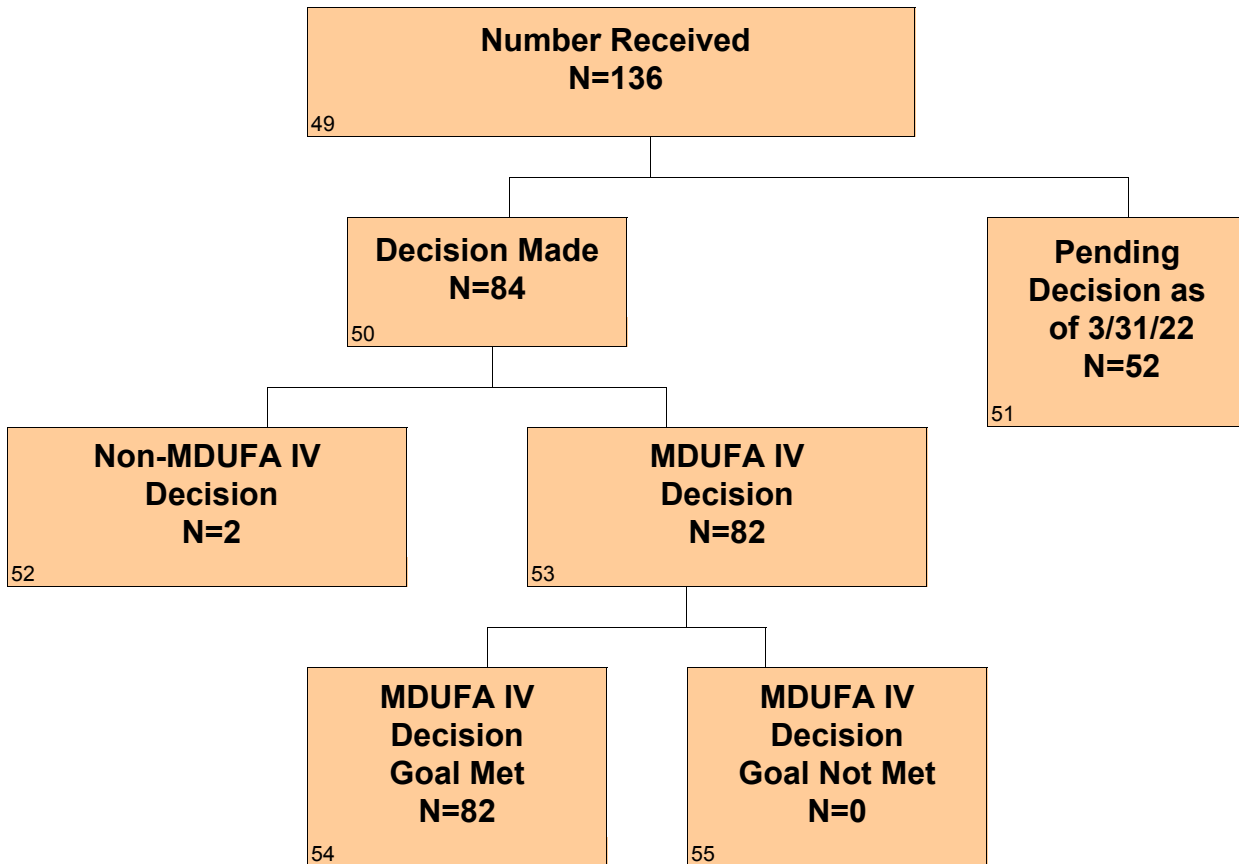
CDRH PMA Real Time Supplements - FY 2020 as of 3/31/22



CDRH PMA Real Time Supplements - FY 2021 as of 3/31/22



CDRH PMA Real Time Supplements - FY 2022 as of 3/31/22



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Section 3 PMA Real-Time Supplements - Center Level Metric

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 338 | 373 | 353 | 278 | 136 |
| Non-MDUFA IV Decision | 2 | 9 | 3 | 2 | 2 |
| MDUFA IV Decision | 336 | 364 | 350 | 274 | 82 |
| MDUFA IV Decision Goal Met | 336 | 364 | 346 | 265 | 82 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 52 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 2 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 98.86% | 96.01% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 338 | 373 | 353 | 278 | 136 |
| Number With MDUFA IV Decision | 336 | 364 | 350 | 274 | 82 |
| Number of Not Approvable | 20 | 29 | 6 | 10 | 1 |
| Rate of Not Approvable | 5.95% | 7.97% | 1.71% | 3.65% | 1.22% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 4 | 11 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 98.25 | 171.82 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

Section 3 PMA Real-Time Supplements - Office Level Metric

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 23 | 40 | 16 | 21 | 10 |
| Non-MDUFA IV Decision | 0 | 2 | 1 | 0 | 0 |
| MDUFA IV Decision | 23 | 38 | 15 | 21 | 3 |
| MDUFA IV Decision Goal Met | 23 | 38 | 15 | 21 | 3 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 7 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 23 | 40 | 16 | 21 | 10 |
| Number With MDUFA IV Decision | 23 | 38 | 15 | 21 | 3 |
| Number of Not Approvable | 1 | 1 | 0 | 0 | 0 |
| Rate of Not Approvable | 4.35% | 2.63% | 0.00% | 0.00% | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 154 | 173 | 193 | 147 | 65 |
| Non-MDUFA IV Decision | 0 | 3 | 2 | 0 | 0 |
| MDUFA IV Decision | 154 | 170 | 191 | 147 | 45 |
| MDUFA IV Decision Goal Met | 154 | 170 | 190 | 146 | 45 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 20 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 99.48% | 99.32% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 154 | 173 | 193 | 147 | 65 |
| Number With MDUFA IV Decision | 154 | 170 | 191 | 147 | 45 |
| Number of Not Approvable | 12 | 15 | 1 | 2 | 1 |
| Rate of Not Approvable | 7.79% | 8.82% | 0.52% | 1.36% | 2.22% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 1 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 99.00 | 134.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 20 | 39 | 36 | 16 | 19 |
| Non-MDUFA IV Decision | 0 | 1 | 0 | 2 | 0 |
| MDUFA IV Decision | 20 | 38 | 36 | 14 | 11 |
| MDUFA IV Decision Goal Met | 20 | 38 | 36 | 14 | 11 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 8 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 20 | 39 | 36 | 16 | 19 |
| Number with MDUFA IV Decision | 20 | 38 | 36 | 14 | 11 |
| Number of Not Approvable | 1 | 8 | 1 | 0 | 0 |
| Rate of Not Approvable | 5.00% | 21.05% | 2.78% | 0.00% | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 13 | 18 | 13 | 13 | 2 |
| Non-MDUFA IV Decision | 1 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 12 | 18 | 13 | 12 | 0 |
| MDUFA IV Decision Goal Met | 12 | 18 | 13 | 10 | 0 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 1 | 2 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 1 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 76.92% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 13 | 18 | 13 | 13 | 2 |
| Number with MDUFA IV Decision | 12 | 18 | 13 | 12 | 0 |
| Number of Not Approvable | 4 | 0 | 0 | 1 | 0 |
| Rate of Not Approvable | 33.33% | 0.00% | 0.00% | 8.33% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 3 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 166.33 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 16 | 32 | 24 | 22 | 14 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 1 |
| MDUFA IV Decision | 16 | 32 | 24 | 22 | 9 |
| MDUFA IV Decision Goal Met | 16 | 32 | 24 | 22 | 9 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 4 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 16 | 32 | 24 | 22 | 14 |
| Number with MDUFA IV Decision | 16 | 32 | 24 | 22 | 9 |
| Number of Not Approvable | 0 | 2 | 3 | 1 | 0 |
| Rate of Not Approvable | 0.00% | 6.25% | 12.50% | 4.55% | 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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 17 | 22 | 9 | 3 | 3 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 17 | 22 | 9 | 3 | 1 |
| MDUFA IV Decision Goal Met | 17 | 22 | 9 | 3 | 1 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 2 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 17 | 22 | 9 | 3 | 3 |
| Number with MDUFA IV Decision | 17 | 22 | 9 | 3 | 1 |
| Number of Not Approvable | 2 | 2 | 1 | 1 | 0 |
| Rate of Not Approvable | 11.76% | 9.09% | 11.11% | 33.33% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

**Table 3.1 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 95 | 49 | 62 | 56 | 23 |
| Non-MDUFA IV Decision | 1 | 3 | 0 | 0 | 1 |
| MDUFA IV Decision | 94 | 46 | 62 | 55 | 13 |
| MDUFA IV Decision Goal Met | 94 | 46 | 59 | 49 | 13 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 1 | 9 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 1 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 95.16% | 87.50% | 100.00% |

**Table 3.2 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 95 | 49 | 62 | 56 | 23 |
| Number with MDUFA IV Decision | 94 | 46 | 62 | 55 | 13 |
| Number of Not Approvable | 0 | 1 | 0 | 5 | 0 |
| Rate of Not Approvable | 0.00% | 2.17% | 0.00% | 9.09% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 3 | 7 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 98.00 | 179.57 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2021 and March 31, 2022.

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Section 5 PMA Annual Metrics and Goals

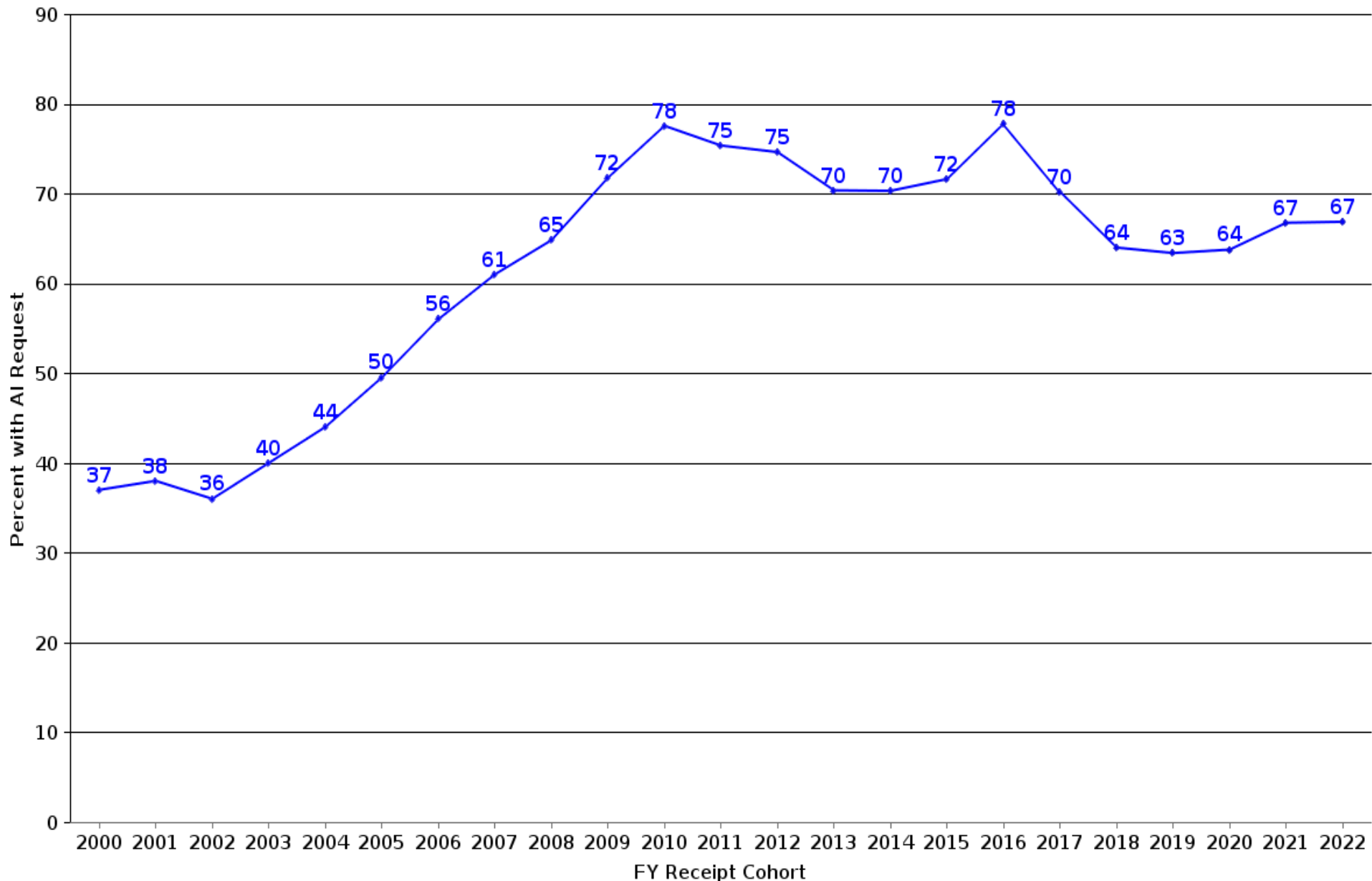
PMA Annual Metrics and Goals will be reported in the Annual Report.

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510(k)s

Q2FY2022

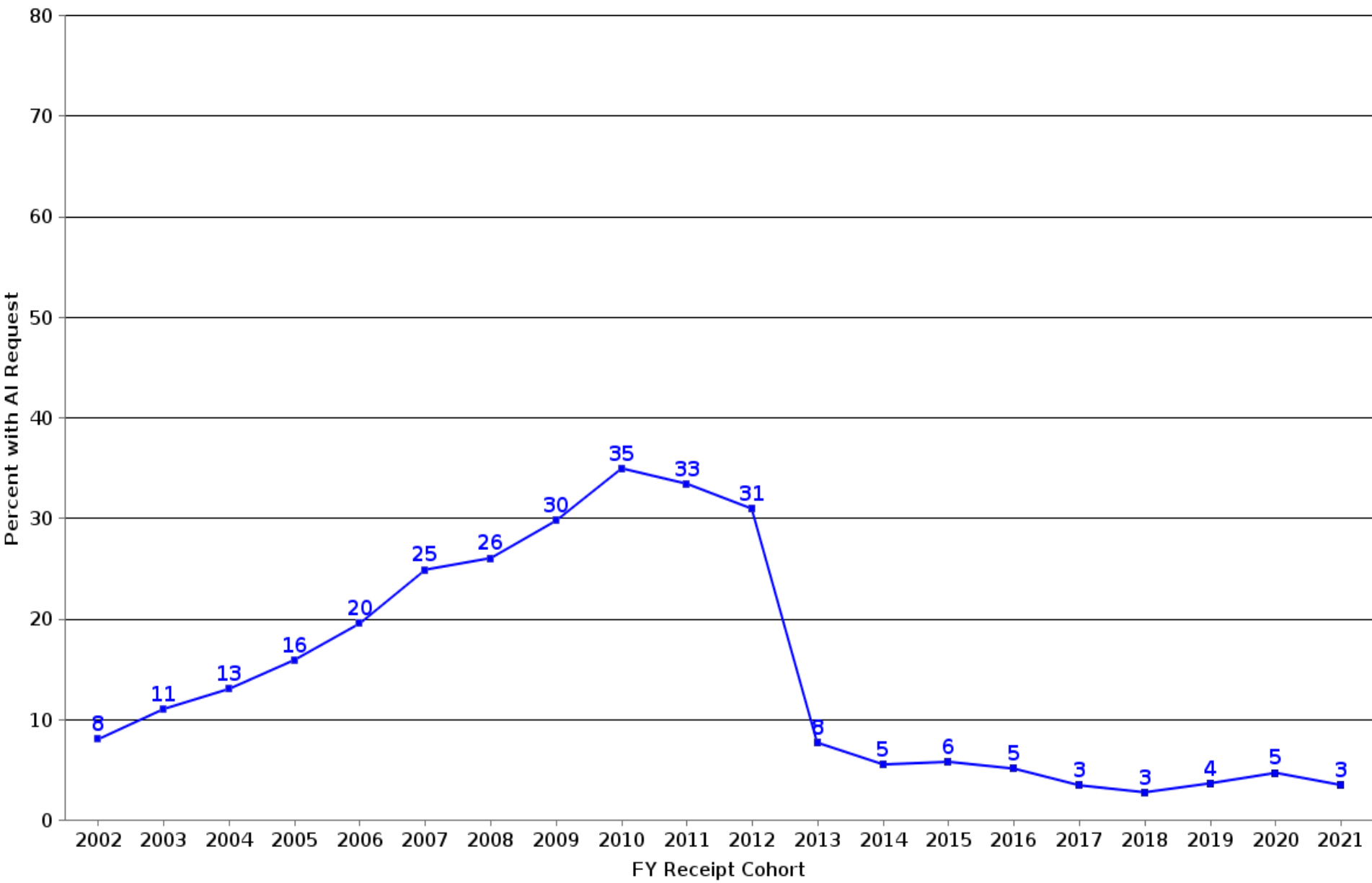
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 1/31/22

◆ % with 1st Cycle AI Request

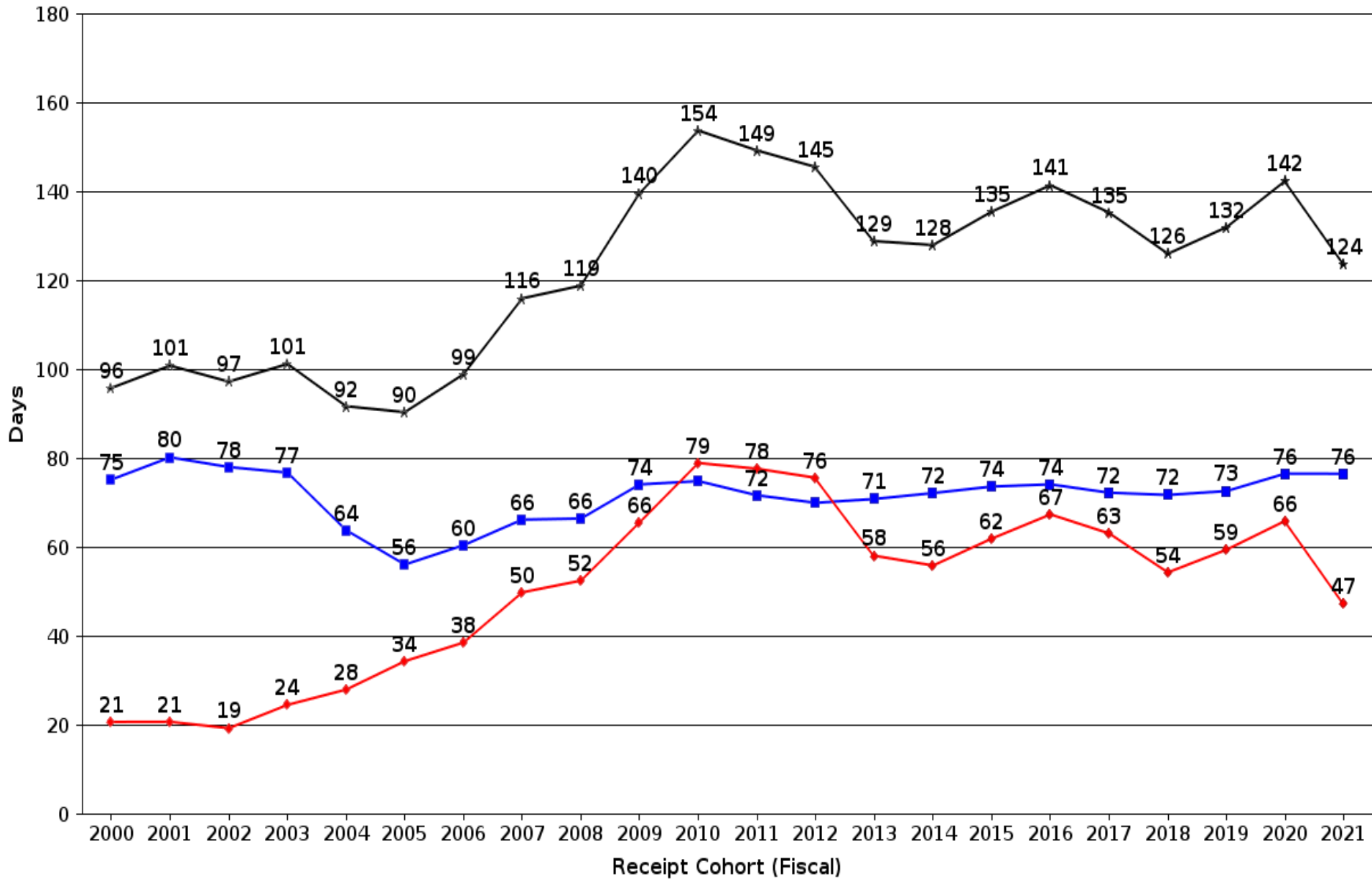
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 8/31/21

■ % with 2nd Cycle AI Request

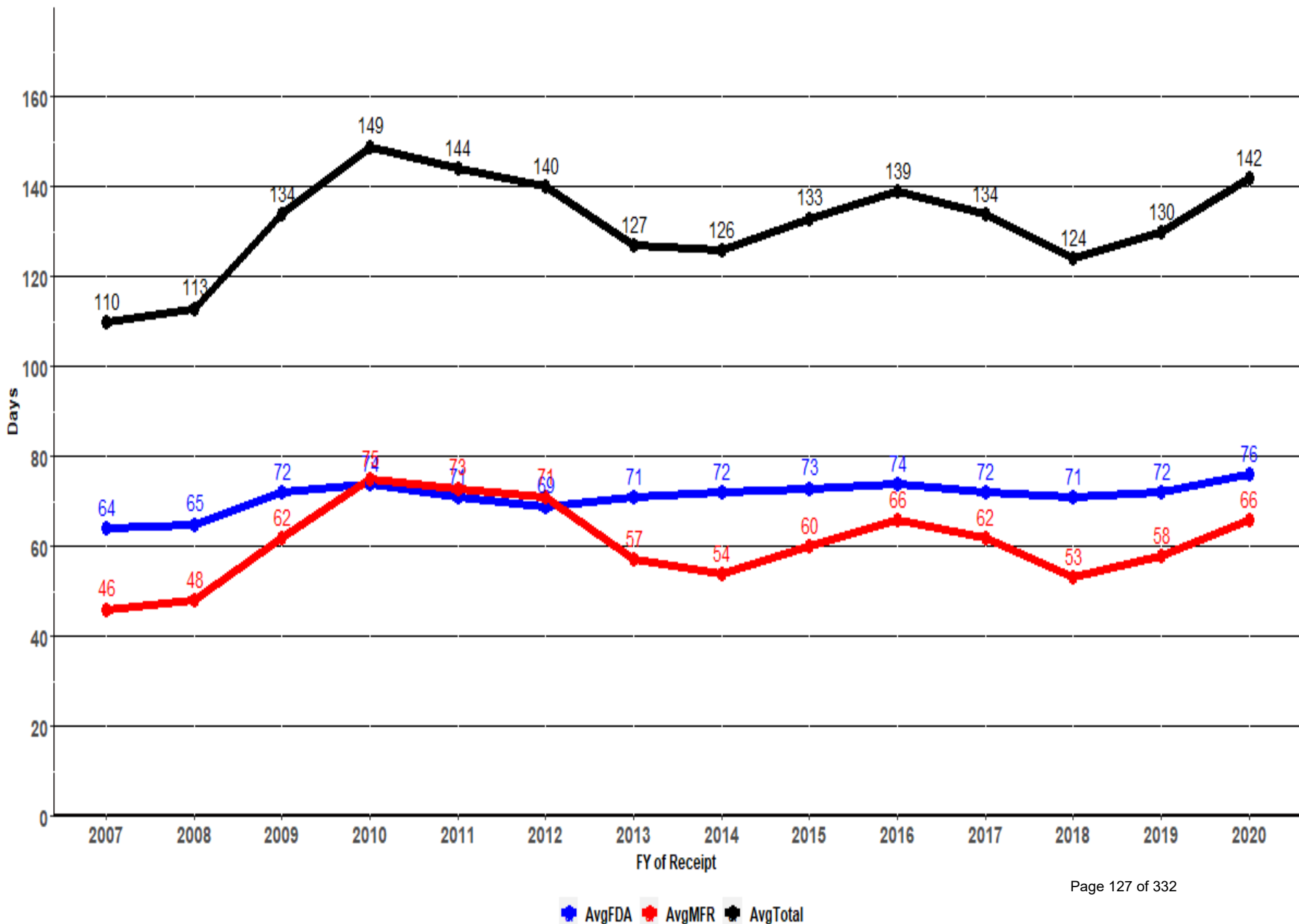
510(k) Average Days to MDUFA (SE/NSE) Decision as of: 3/31/22



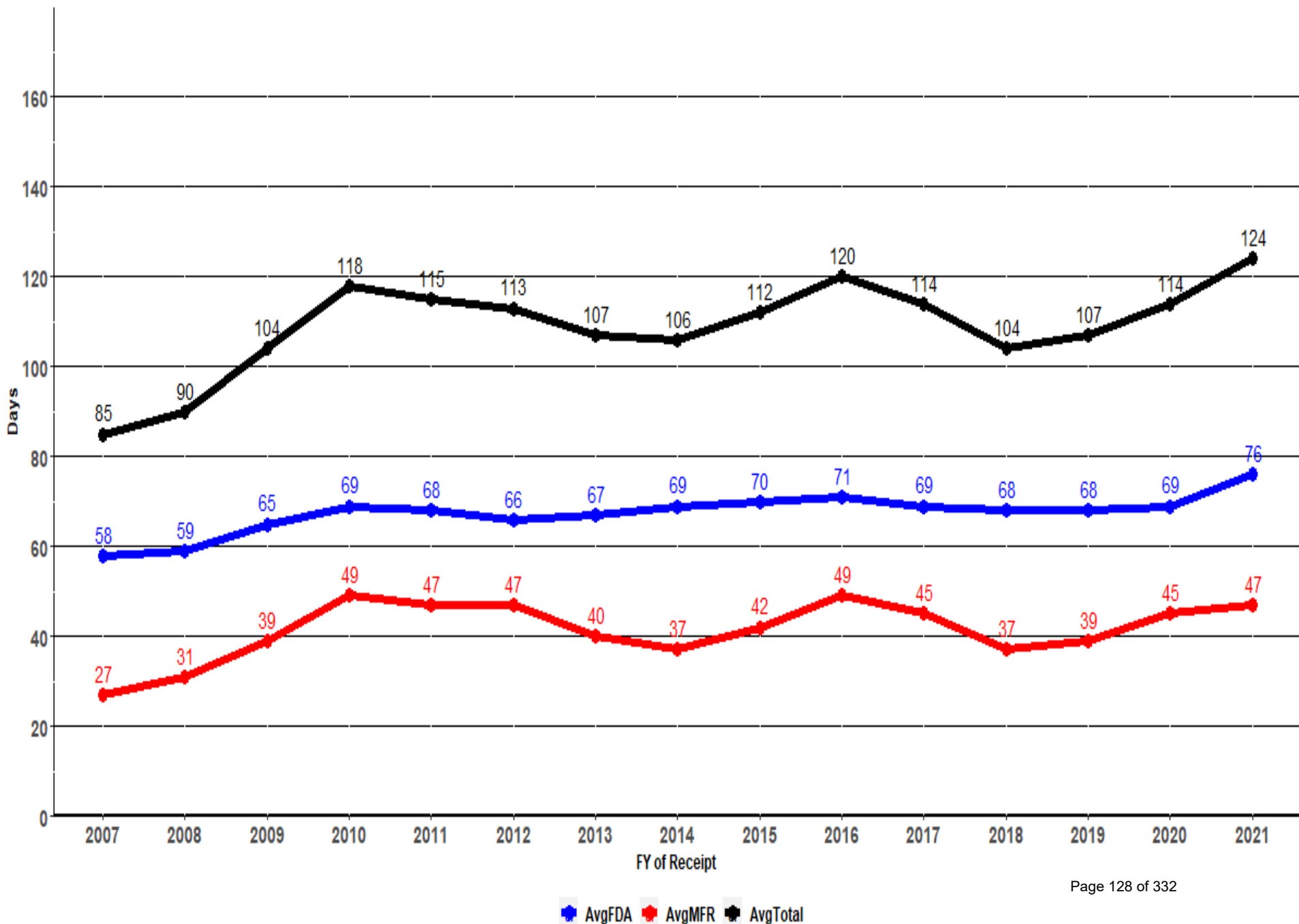
Cohorts not yet closed: 2019: 99.94%; 2020: 97.24%; 2021: 76.79%

■ 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 97.24 % Cohort Closure by FY of Receipt

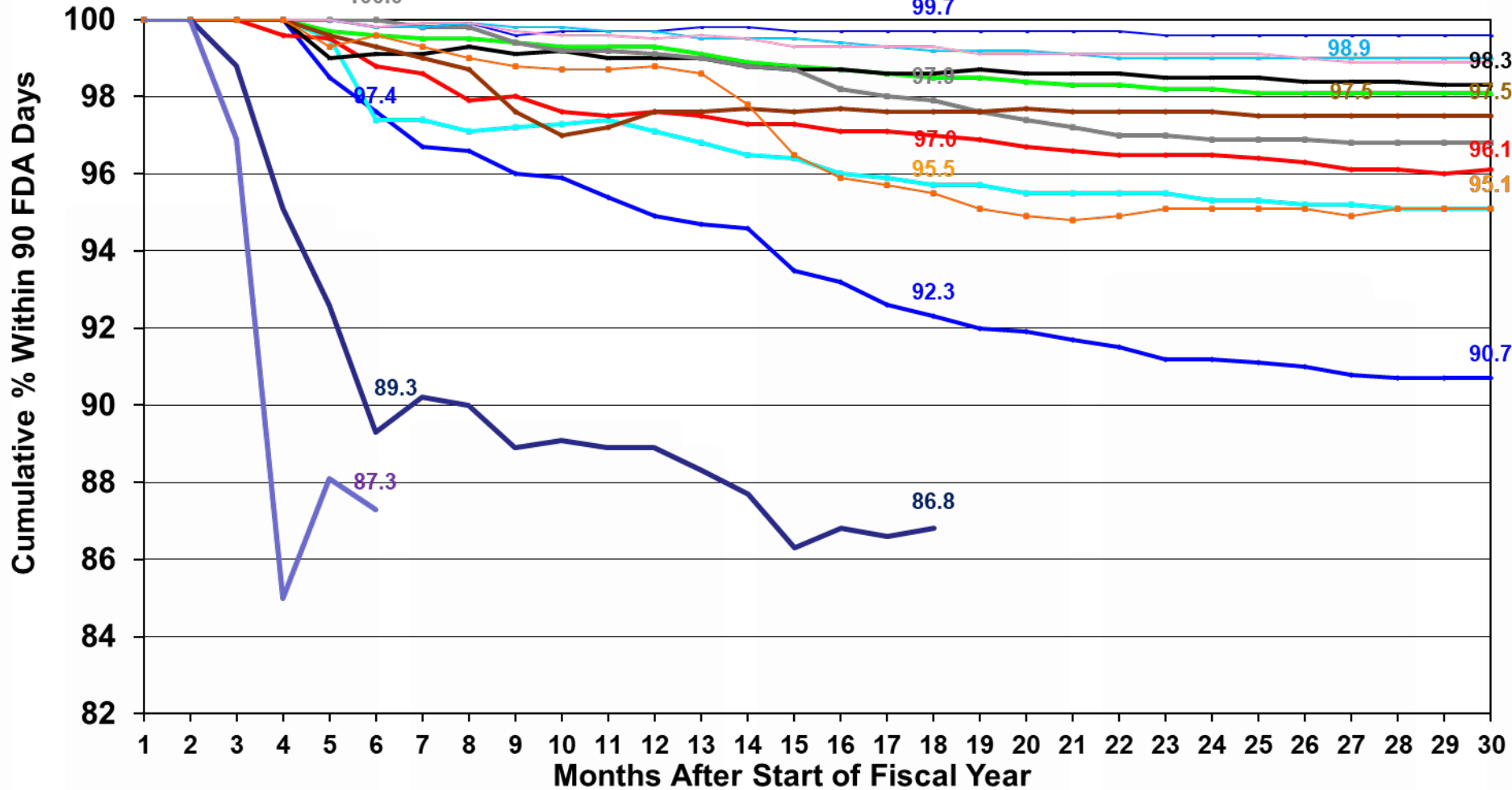


510(k) Average Days to MDUFA (SE/NSE) Decision at 76.79 % Cohort Closure by FY of Receipt



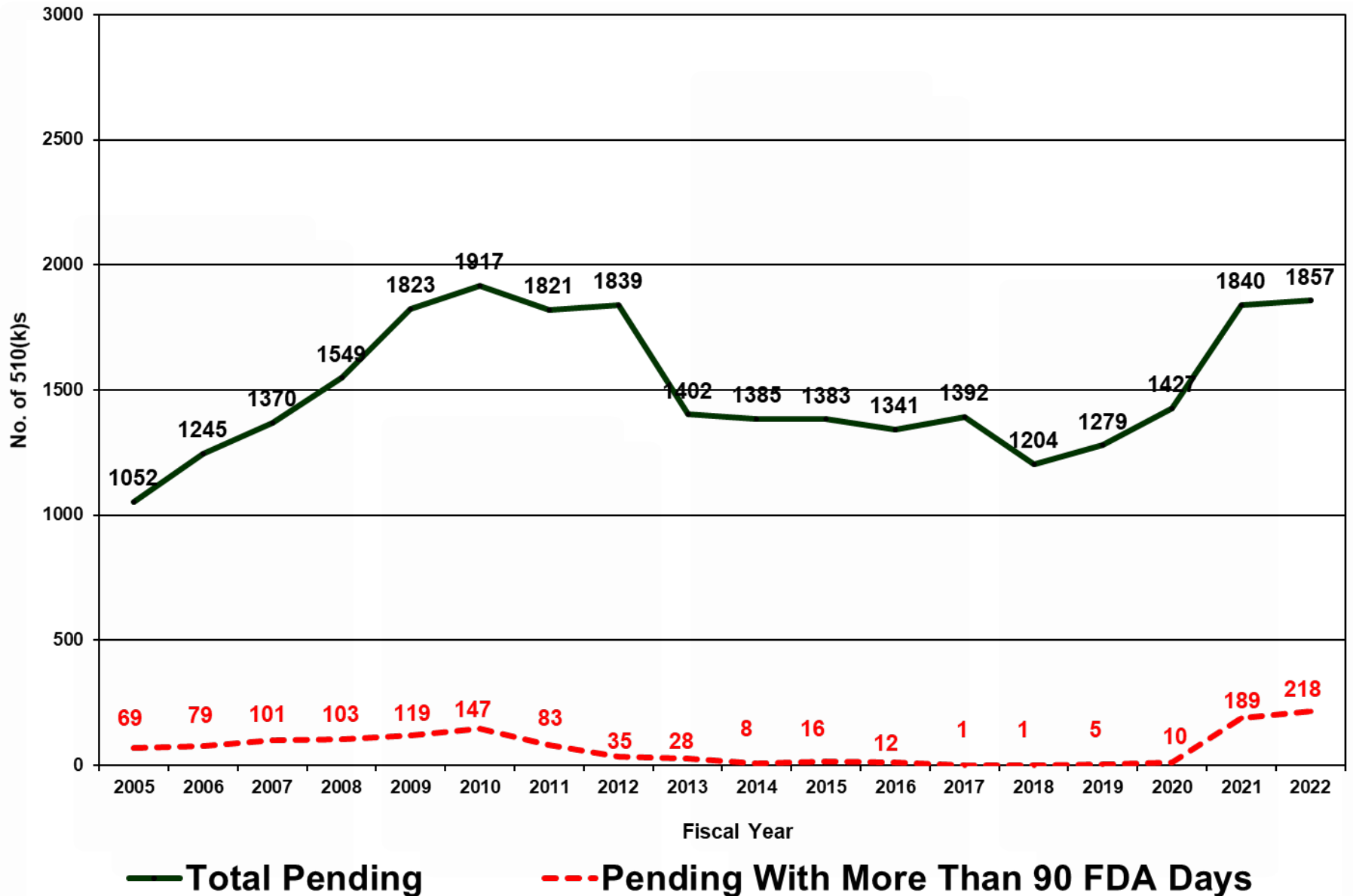
Trend in 510(k) MDUFA Decision Goal Performance

Comparison of FY10 – FY22 Receipt Cohorts



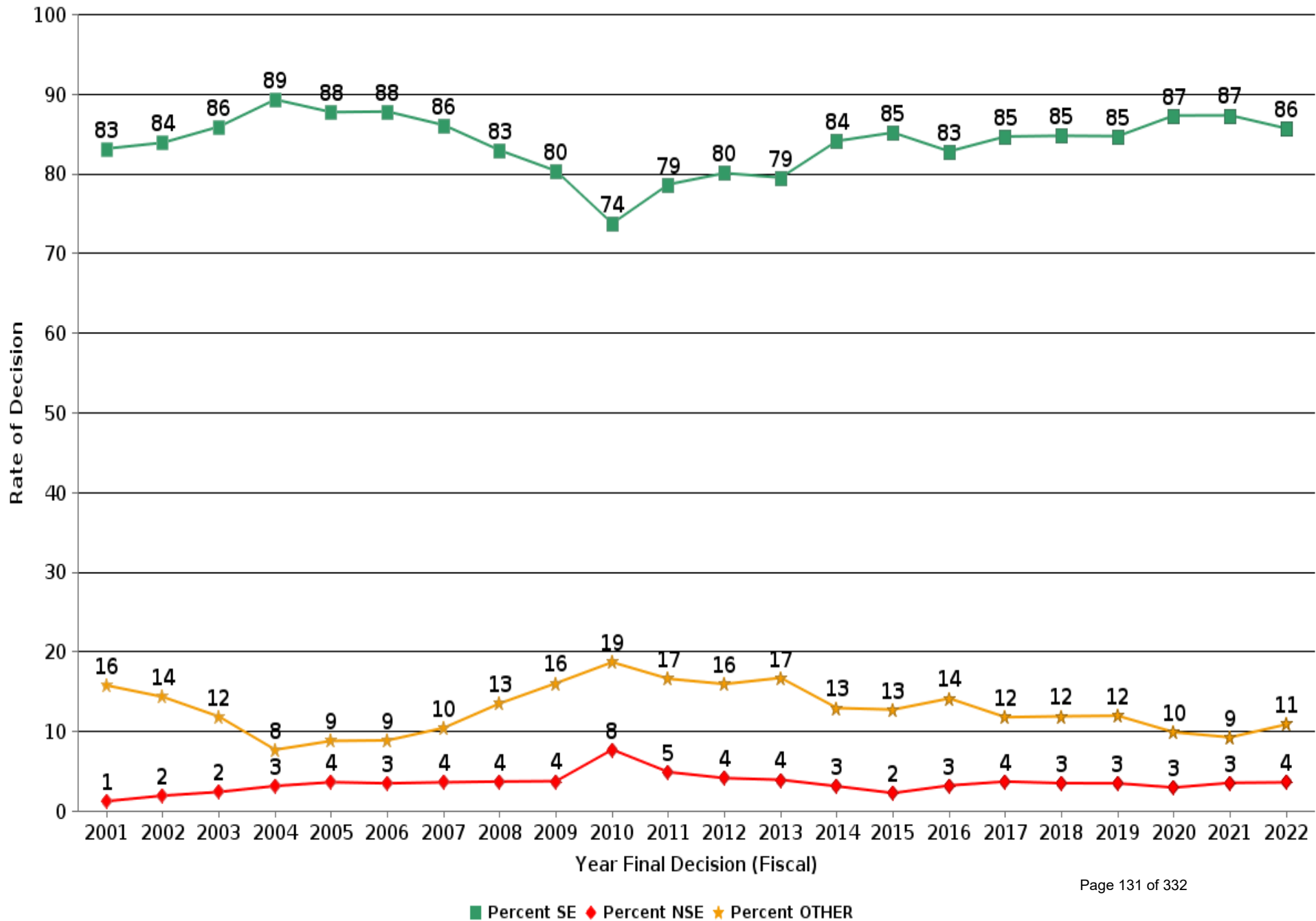
- FY10 Receipt Cohort
- FY11 Receipt Cohort
- FY12 Receipt Cohort
- FY13 Receipt Cohort
- FY14 Receipt Cohort
- FY15 Receipt Cohort
- FY16 Receipt Cohort
- FY17 Receipt Cohort
- FY18 Receipt Cohort
- FY19 Receipt Cohort
- FY20 Receipt Cohort
- FY21 Receipt Cohort
- FY22 Receipt Cohort

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



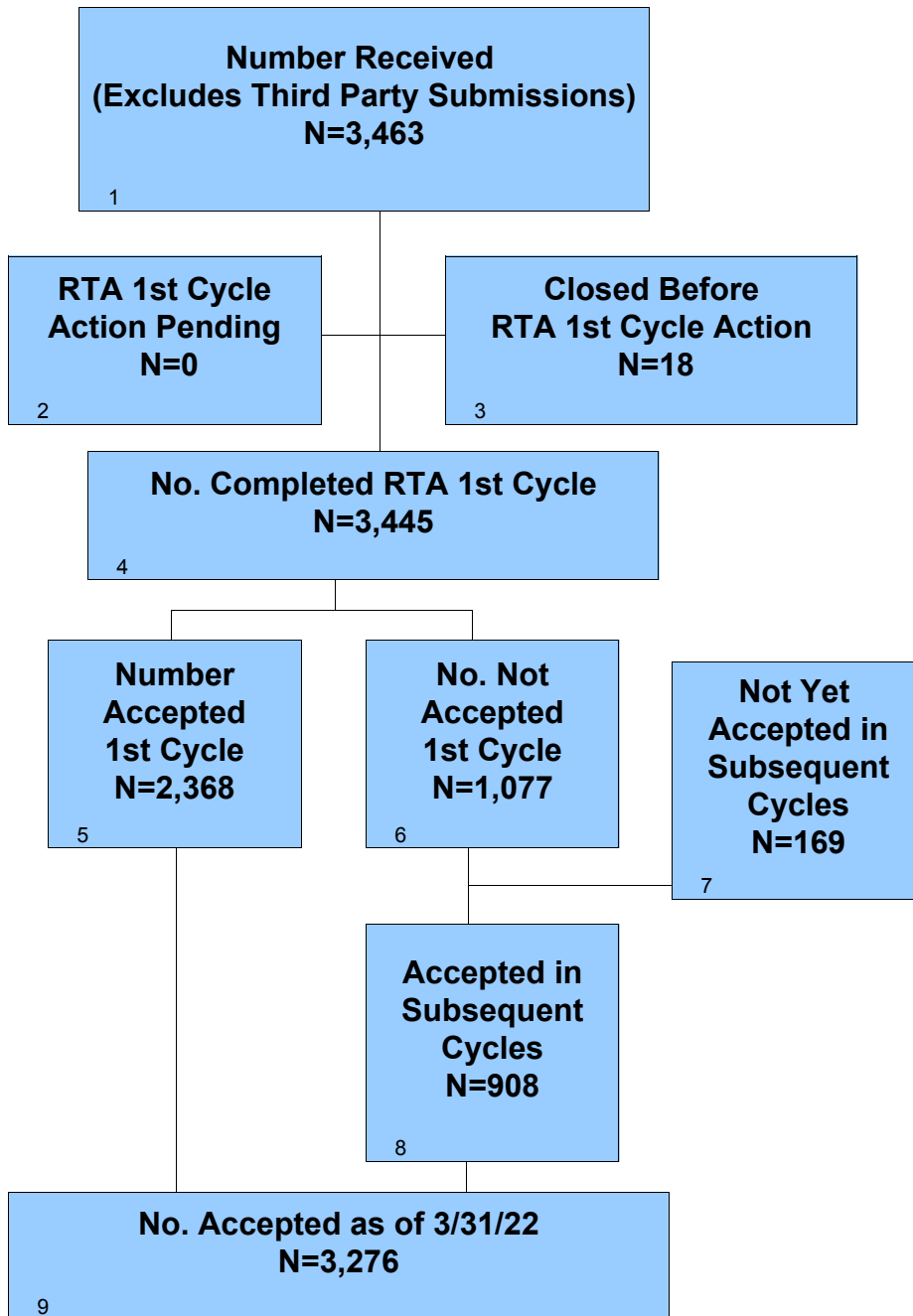
“Pending” means 510ks under review or on hold following a positive RTA decision (FY13 and later).

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

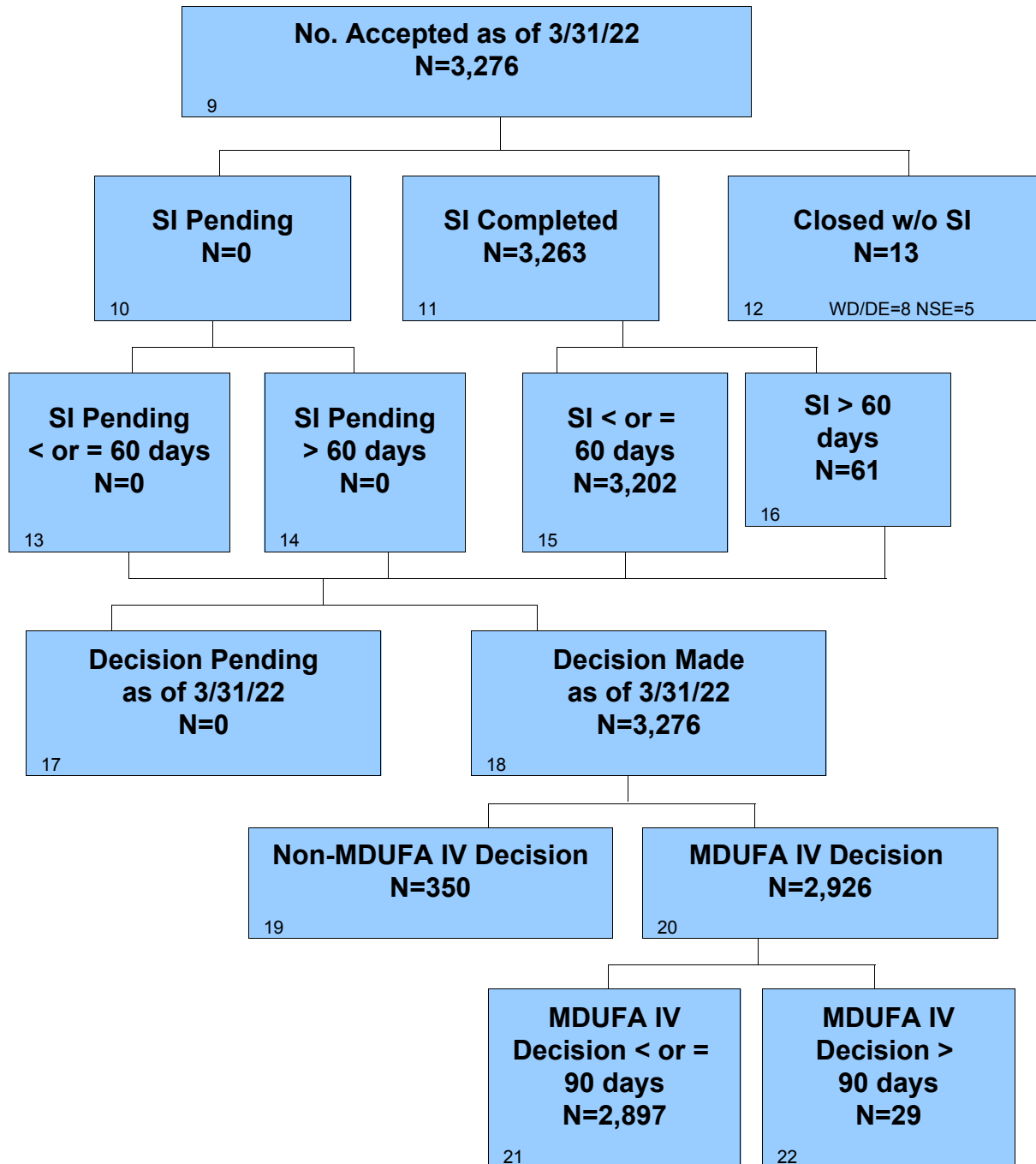


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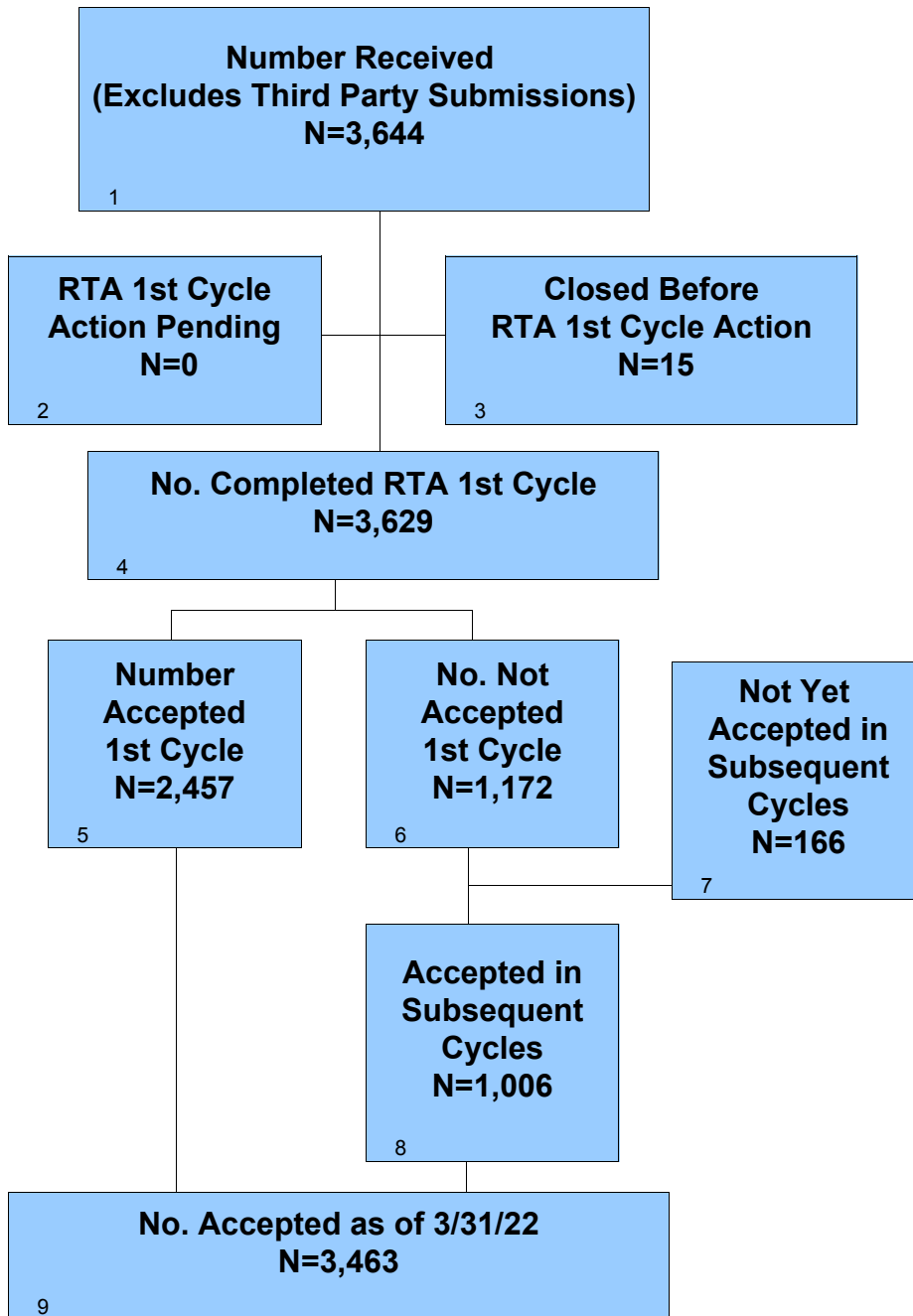
CDRH 510(k)s - FY 2018 as of 3/31/22



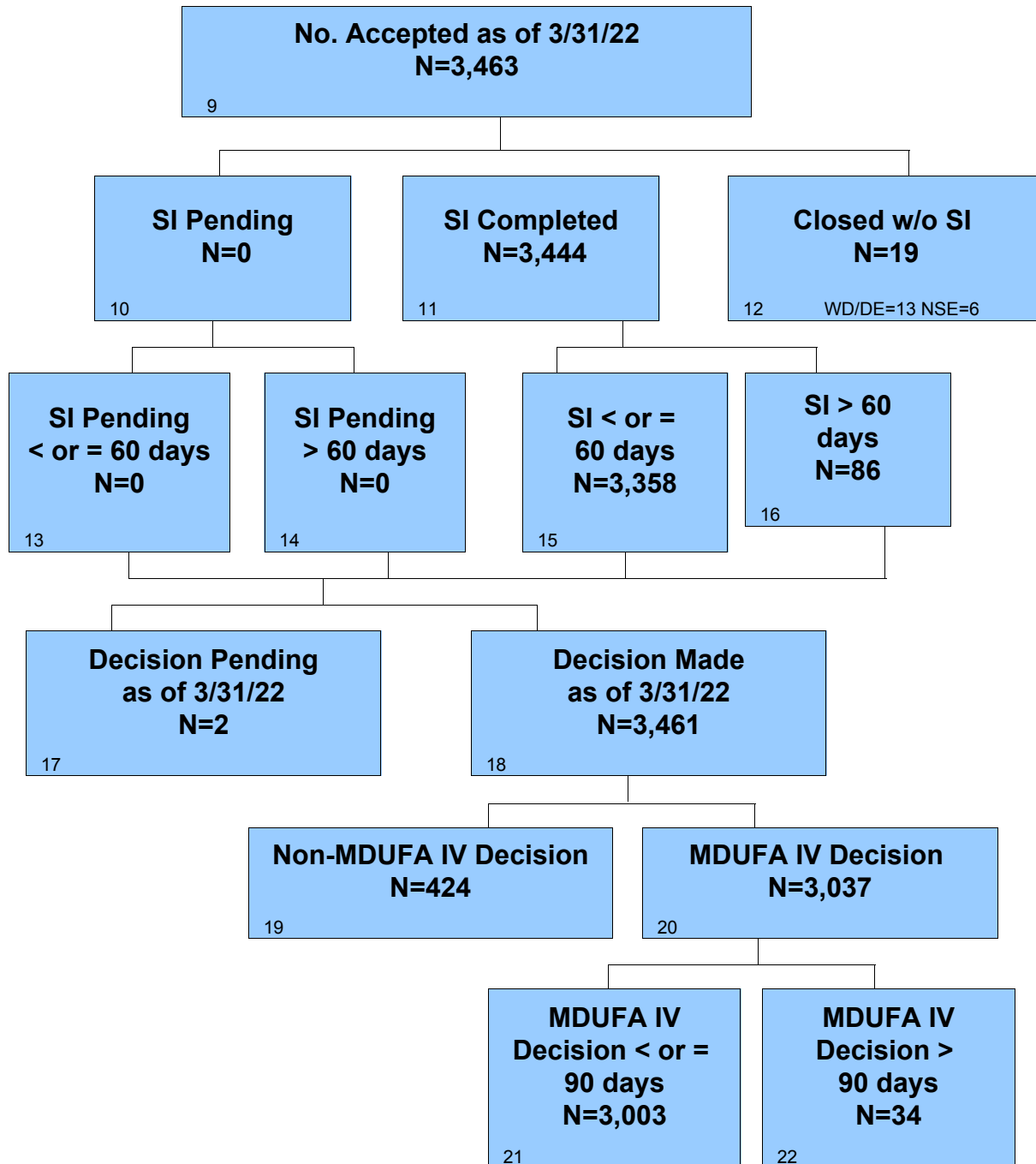
CDRH 510(k)s - FY 2018 as of 3/31/22 Continued



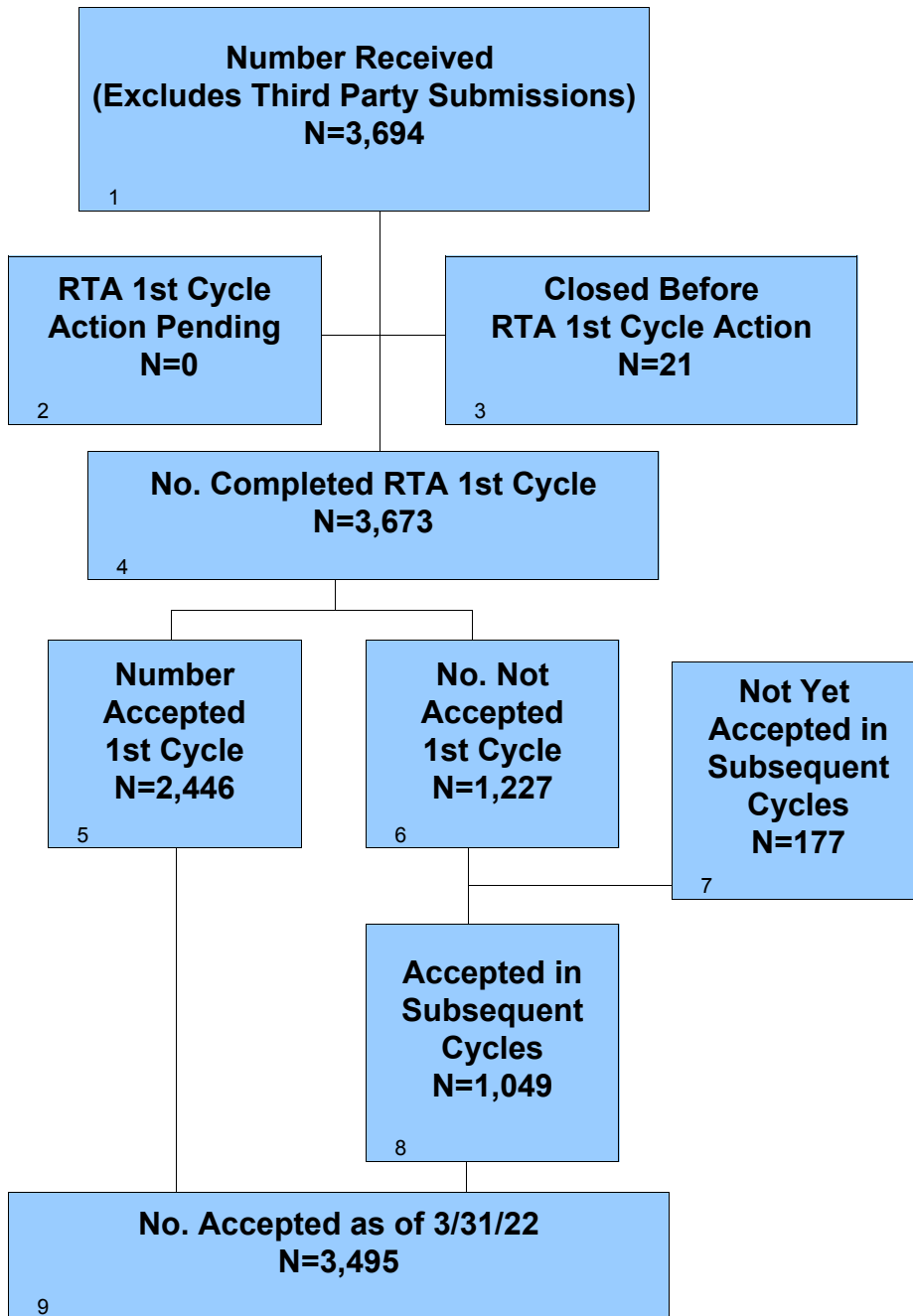
CDRH 510(k)s - FY 2019 as of 3/31/22



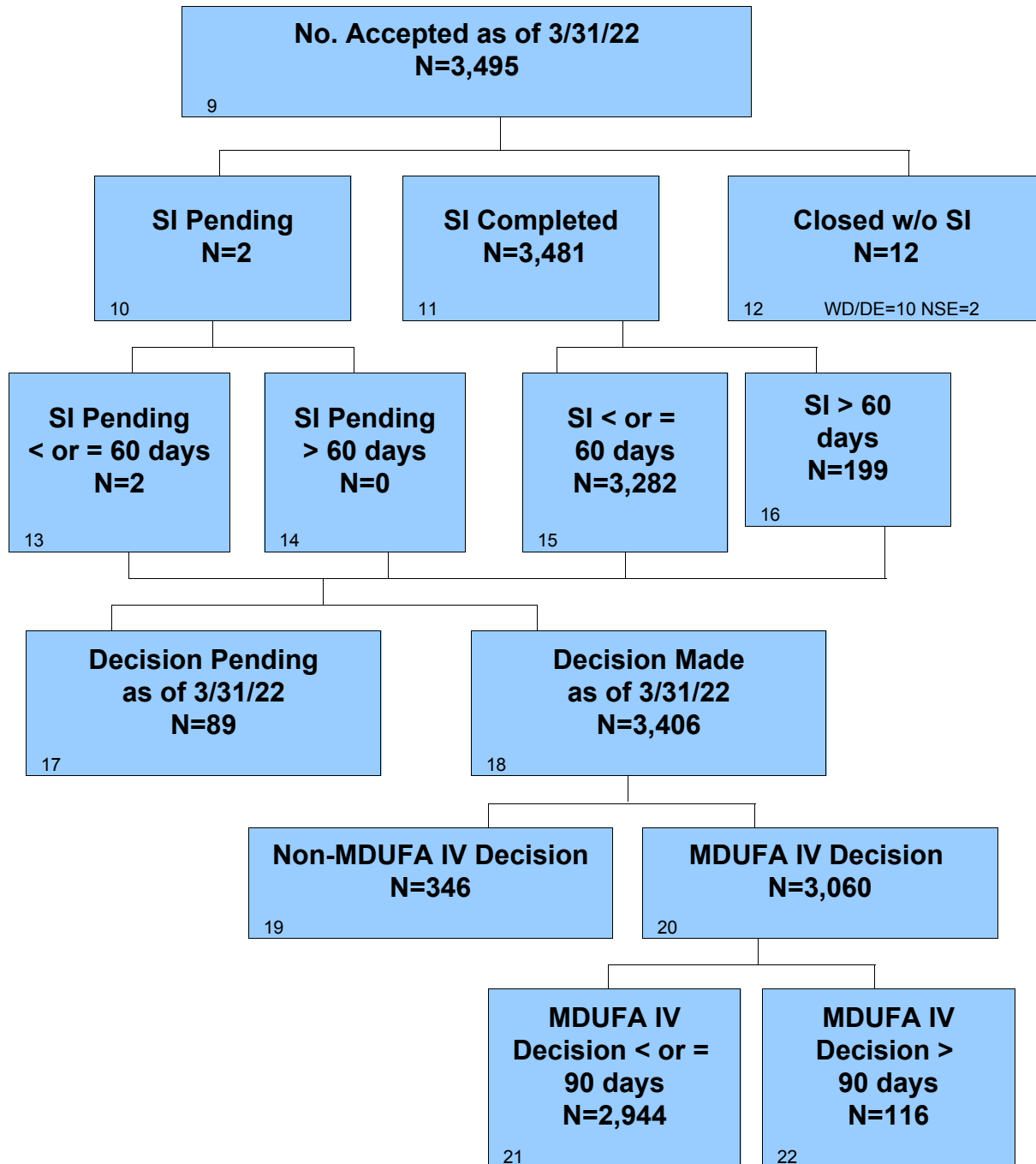
CDRH 510(k)s - FY 2019 as of 3/31/22 Continued



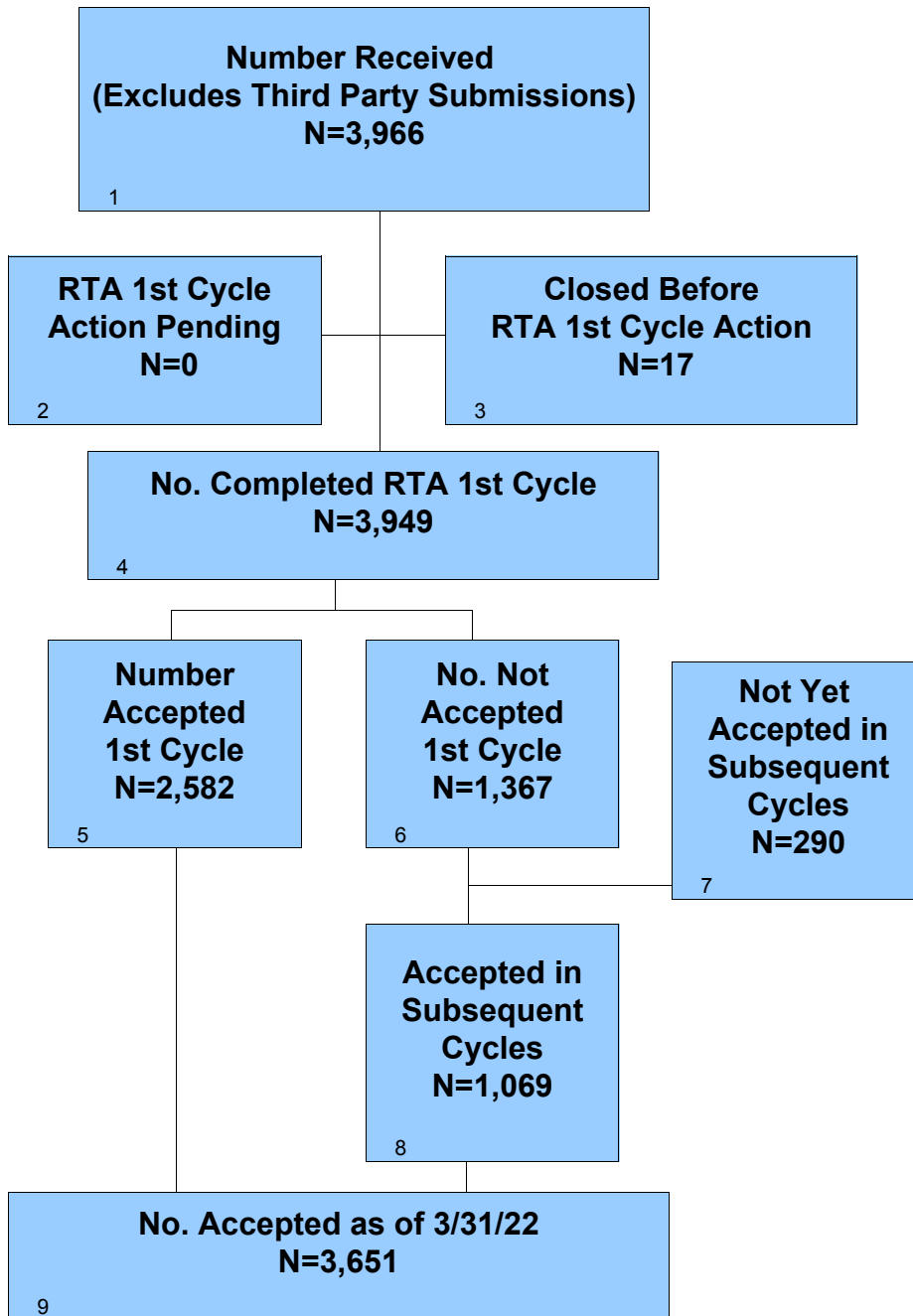
CDRH 510(k)s - FY 2020 as of 3/31/22



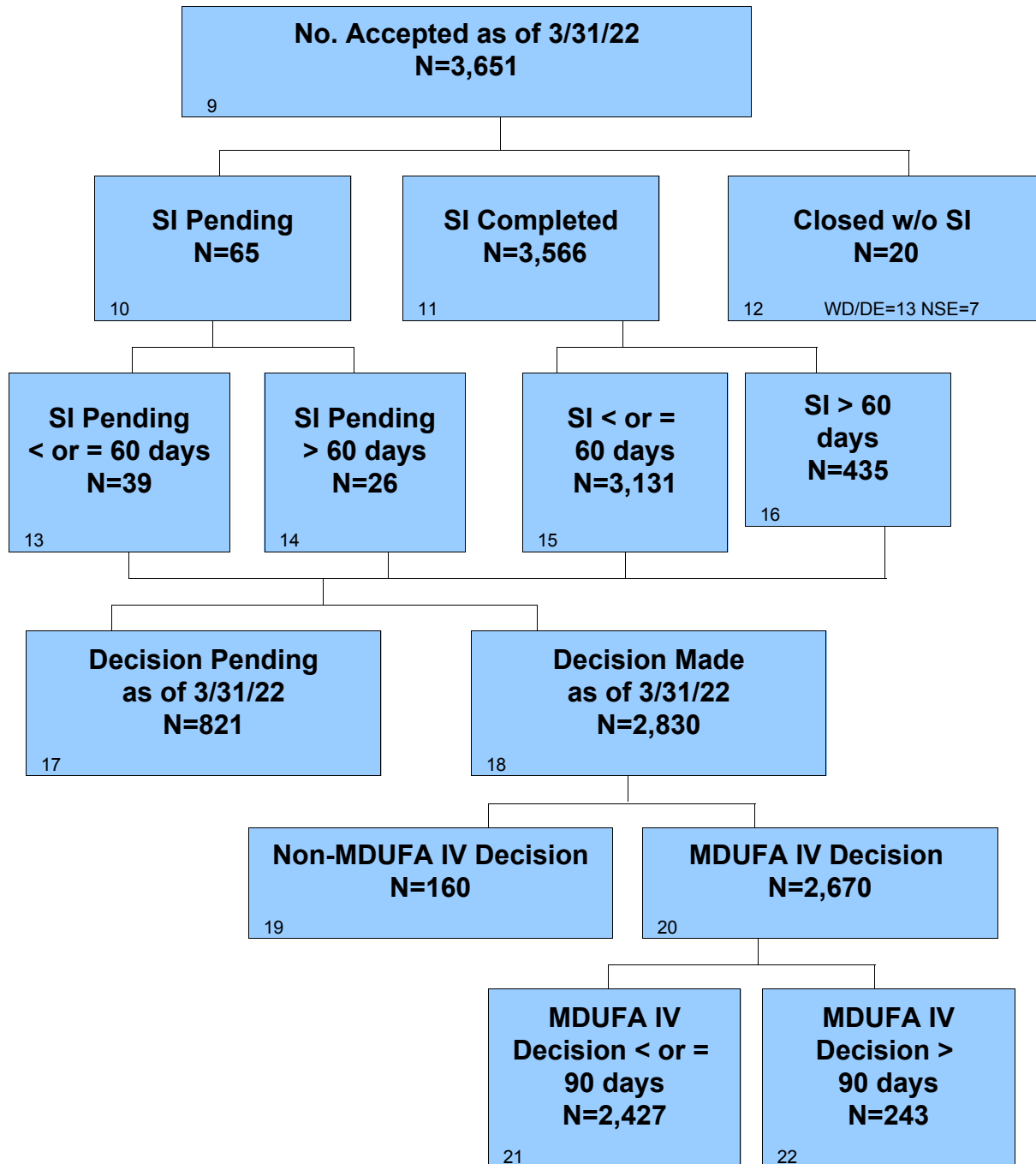
CDRH 510(k)s - FY 2020 as of 3/31/22 Continued



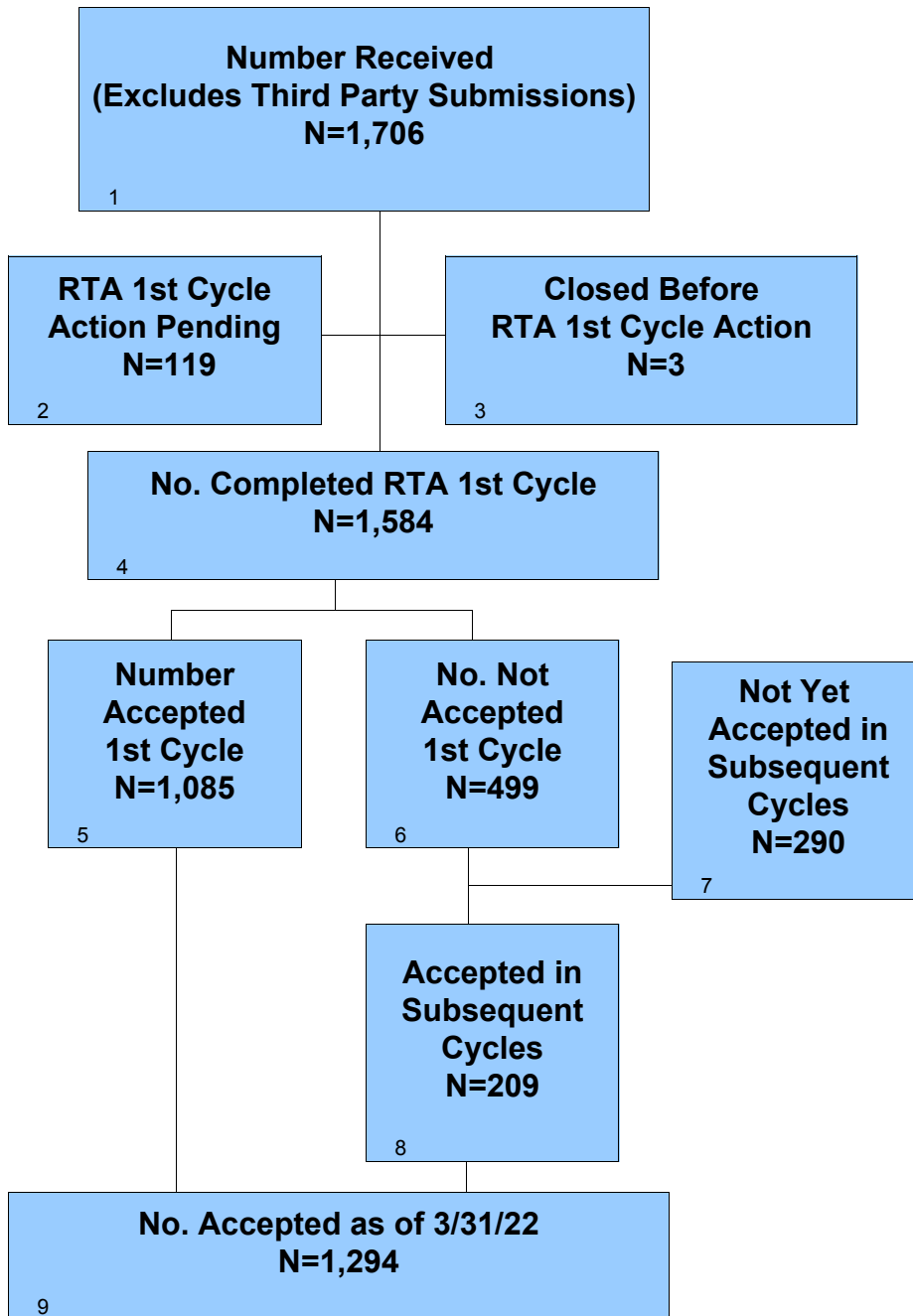
CDRH 510(k)s - FY 2021 as of 3/31/22



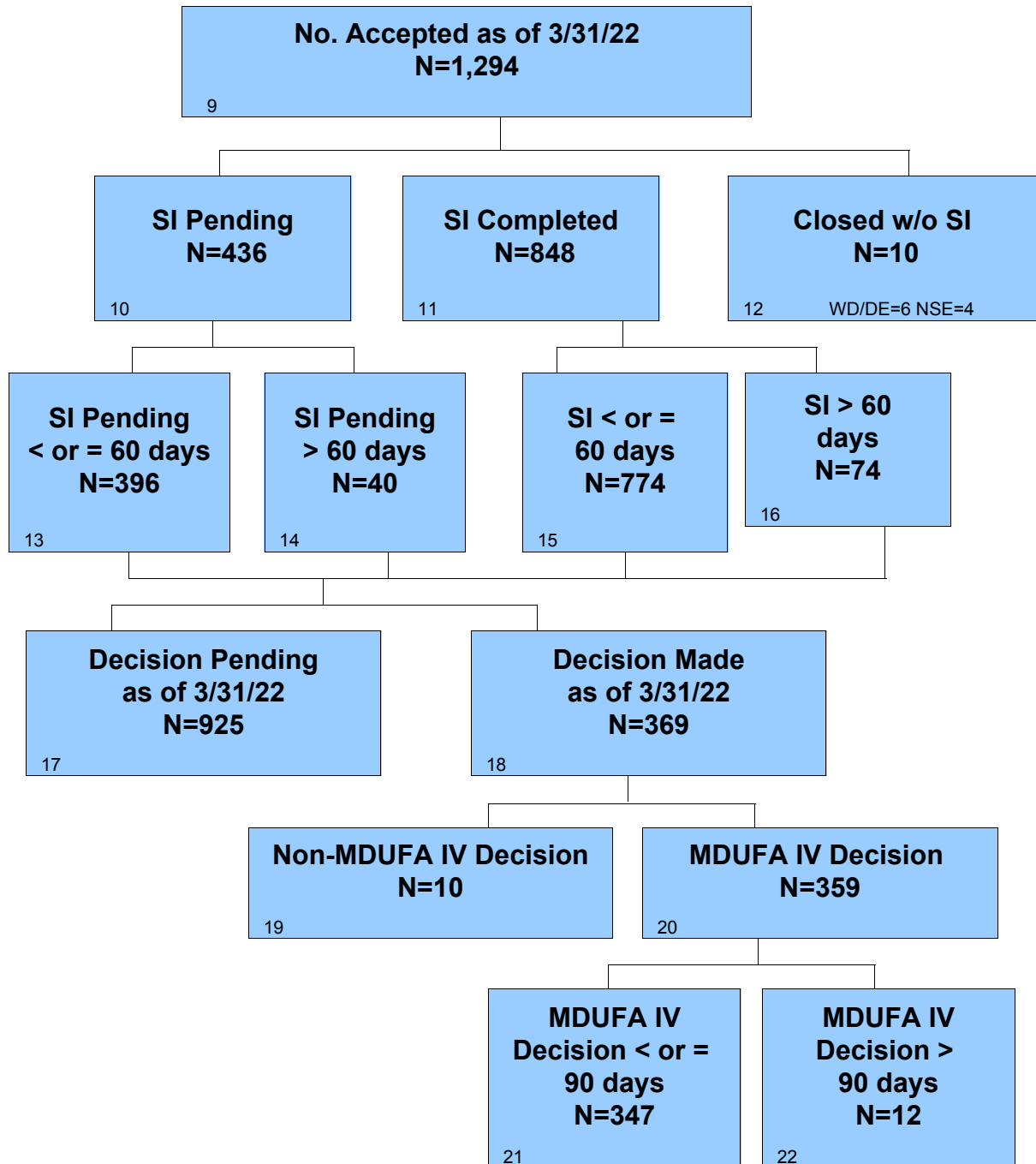
CDRH 510(k)s - FY 2021 as of 3/31/22 Continued



CDRH 510(k)s - FY 2022 as of 3/31/22



CDRH 510(k)s - FY 2022 as of 3/31/22 Continued



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

Table 6.1 CDRH - 510(k) Acceptance Review Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 3,463 | 3,644 | 3,694 | 3,966 | 1,706 |
| Closed Before RTA Action | 18 | 15 | 21 | 17 | 3 |
| Number Accepted | 2,353 | 2,403 | 2,397 | 2,362 | 937 |
| Number Without a RTA Review and > 15 Days Since Date Received | 15 | 54 | 49 | 220 | 148 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 119 |
| Number Not Accepted | 1,077 | 1,172 | 1,227 | 1,367 | 499 |
| Rate of Submissions Not Accepted for Review | 31.26% | 32.30% | 33.41% | 34.62% | 31.50% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 3,276 | 3,463 | 3,495 | 3,651 | 1,294 |
| Deleted or Withdrawn Prior to SI | 8 | 13 | 10 | 13 | 6 |
| SI Within 60 FDA Days | 3,202 | 3,358 | 3,282 | 3,131 | 774 |
| SI Over 60 FDA Days | 61 | 86 | 199 | 435 | 74 |
| SI Pending Within 60 FDA Days | 0 | 0 | 2 | 39 | 396 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 26 | 40 |
| 510(k)s NSE Without SI | 5 | 6 | 2 | 7 | 4 |
| Current SI Performance Percent Within 60 FDA Days | 97.98% | 97.33% | 94.23% | 87.00% | 86.77% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 3,263 | 3,444 | 3,481 | 3,566 | 848 |
| Average Number of FDA Days to Substantive Interaction | 51.04 | 51.42 | 55.02 | 59.09 | 53.86 |
| 20th Percentile FDA Days to Substantive Interaction | 43 | 43 | 46 | 50 | 45 |
| 40th Percentile FDA Days to Substantive Interaction | 55 | 56 | 56 | 57 | 56 |
| 60th Percentile FDA Days to Substantive Interaction | 58 | 58 | 59 | 59 | 58 |
| 80th Percentile FDA Days to Substantive Interaction | 60 | 60 | 60 | 60 | 60 |
| Maximum FDA Days to Substantive Interaction | 86 | 90 | 496 | 381 | 140 |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 3,276 | 3,463 | 3,495 | 3,651 | 1,294 | | | | | |
| Non-MDUFA IV Decision | 350 | 424 | 346 | 160 | 10 | | | | | |
| MDUFA IV Decision (SE/NSE) | 2,926 | 3,037 | 3,060 | 2,670 | 359 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 2,897 | 3,003 | 2,944 | 2,427 | 347 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 2 | 89 | 821 | 925 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 39 | 136 | 43 | | | | | |
| Current Performance Percent Within 90 FDA Days | 99.01% | 98.88% | 95.00% | 86.49% | 86.32% | | | | | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 2 | 2 | 2 | 2 | 1 |
| Number With MDUFA IV Decision | 2,926 | 3,037 | 3,060 | 2,670 | 359 |
| Average Number of FDA Days to MDUFA IV Decision | 72.62 | 73.53 | 77.65 | 77.63 | 59.18 |
| 20th Percentile FDA Days to MDUFA IV Decision | 54 | 55 | 55 | 55 | 29 |
| 40th Percentile FDA Days to MDUFA IV Decision | 79 | 82 | 84 | 83 | 56 |
| 60th Percentile FDA Days to MDUFA IV Decision | 87 | 88 | 88 | 88 | 63 |
| 80th Percentile FDA Days to MDUFA IV Decision | 89 | 90 | 90 | 90 | 88 |
| Maximum FDA Days to MDUFA IV Decision | 220 | 655 | 673 | 381 | 132 |
| Average Number of Industry Days to MDUFA IV Decision | 54.69 | 60.21 | 66.68 | 47.87 | 7.16 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 5 | 0 | 1 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 44 | 49 | 52 | 36 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 127 | 139 | 140 | 96 | 10 |
| Maximum Industry Days to MDUFA IV Decision | 563 | 448 | 571 | 404 | 77 |
| Average Number of Total Days to MDUFA IV Decision | 127.31 | 133.74 | 144.34 | 125.51 | 66.34 |
| 20th Percentile Total Days to MDUFA IV Decision | 57 | 57 | 56 | 57 | 29 |
| 40th Percentile Total Days to MDUFA IV Decision | 89 | 90 | 90 | 89 | 56 |
| 60th Percentile Total Days to MDUFA IV Decision | 128 | 133 | 138 | 127 | 71 |
| 80th Percentile Total Days to MDUFA IV Decision | 212 | 224 | 233 | 189 | 92 |
| Maximum Total Days to MDUFA IV Decision | 783 | 871 | 775 | 493 | 167 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 3,276 | 3,463 | 3,495 | 3,651 | 1,294 |
| Number With MDUFA IV Decision | 2,926 | 3,037 | 3,060 | 2,670 | 359 |
| Number of SE Decision | 2,810 | 2,922 | 2,966 | 2,588 | 352 |
| Number of NSE Decision | 116 | 115 | 94 | 82 | 7 |
| Number of Withdrawal | 185 | 213 | 200 | 125 | 10 |
| Number of Deleted | 156 | 193 | 141 | 32 | 0 |
| Rate of SE Decision | 96.04% | 96.21% | 96.93% | 96.93% | 98.05% |
| Rate of NSE Decision | 3.96% | 3.79% | 3.07% | 3.07% | 1.95% |
| Rate of Withdrawal | 5.65% | 6.15% | 5.72% | 3.42% | 0.77% |
| Rate of Deleted | 4.76% | 5.57% | 4.03% | 0.88% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 29 | 34 | 116 | 243 | 12 |
| Mean FDA Days for Submissions that Missed the Goal | 111.38 | 141.53 | 212.43 | 137.46 | 102.75 |
| Mean Industry Days for Submissions that Missed the Goal | 136.24 | 192.97 | 142.06 | 54.16 | 10.25 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 2 | 1 | 4 | 2 | 2 |
| Non-MDUFA IV Decision | 1 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 1 | 1 | 4 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 1 | 1 | 2 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 2 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 2 | 0 |
| Current Performance Percent Within 90 FDA Days | 100.00% | 100.00% | 50.00% | 0.00% | 0.00% |

Table 6.9 CDRH - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|---------|--------------------|---------|--------------------|---------|--------------------|---------|--------------------|---------|--------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | | 272 | | 278 | | 253 | | 193 | | 88 |
| Non-MDUFA IV Decision | | 41 | | 37 | | 38 | | 11 | | 1 |
| MDUFA IV Decision (SE/NSE) | | 231 | | 241 | | 184 | | 85 | | 4 |
| MDUFA IV Decision Within 90 FDA Days | | 230 | | 237 | | 122 | | 13 | | 2 |
| 510(k)s Pending MDUFA IV Decision | | 0 | | 0 | | 31 | | 97 | | 83 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | | 0 | | 0 | | 31 | | 92 | | 38 |
| Current Performance Percent Within 90 FDA Days | | 99.57% | | 98.34% | | 56.74% | | 7.34% | | 4.76% |

Section 6 510(k) Office Level Metrics (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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 552 | 593 | 536 | 533 | 252 |
| Closed Before RTA Action | 1 | 1 | 0 | 0 | 1 |
| Number Accepted | 208 | 207 | 226 | 207 | 87 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 12 | 8 | 11 | 7 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 24 |
| Number Not Accepted | 343 | 373 | 302 | 315 | 133 |
| Rate of Submissions Not Accepted for Review | 62.25% | 63.01% | 56.34% | 59.10% | 58.59% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 494 | 550 | 503 | 470 | 151 |
| Deleted or Withdrawn Prior to SI | 2 | 6 | 0 | 0 | 0 |
| SI Within 60 FDA Days | 477 | 489 | 413 | 391 | 95 |
| SI Over 60 FDA Days | 14 | 54 | 90 | 64 | 8 |
| SI Pending Within 60 FDA Days | 0 | 0 | 0 | 15 | 48 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s NSE Without SI | 1 | 1 | 0 | 0 | 0 |
| Current SI Performance Percent Within 60 FDA Days | 96.95% | 89.89% | 82.11% | 85.93% | 92.23% |

**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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 491 | 543 | 503 | 455 | 103 |
| Average Number of FDA Days to Substantive Interaction | 55.63 | 56.03 | 55.39 | 55.79 | 52.12 |
| 20th Percentile FDA Days to Substantive Interaction | 54 | 54 | 51 | 53 | 49 |
| 40th Percentile FDA Days to Substantive Interaction | 58 | 58 | 57 | 58 | 56 |
| 60th Percentile FDA Days to Substantive Interaction | 59 | 59 | 60 | 59 | 58 |
| 80th Percentile FDA Days to Substantive Interaction | 60 | 60 | 60 | 60 | 60 |
| Maximum FDA Days to Substantive Interaction | 78 | 87 | 94 | 88 | 82 |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 494 | 550 | 503 | 470 | 151 | | | | | |
| Non-MDUFA IV Decision | 74 | 85 | 56 | 32 | 0 | | | | | |
| MDUFA IV Decision (SE/NSE) | 420 | 465 | 432 | 310 | 37 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 417 | 463 | 428 | 309 | 37 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 15 | 128 | 114 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 1 | 0 | | | | | |
| Current Performance Percent Within 90 FDA Days | 99.29% | 99.57% | 99.07% | 99.36% | 100.00% | | | | | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.67 | 1.69 | 1.69 | 1.64 | 1.22 |
| Number With MDUFA IV Decision | 420 | 465 | 432 | 310 | 37 |
| Average Number of FDA Days to MDUFA IV Decision | 81.05 | 82.39 | 79.87 | 78.10 | 57.03 |
| 20th Percentile FDA Days to MDUFA IV Decision | 77 | 84 | 76 | 60 | 29 |
| 40th Percentile FDA Days to MDUFA IV Decision | 87 | 88 | 87 | 86 | 54 |
| 60th Percentile FDA Days to MDUFA IV Decision | 89 | 89 | 89 | 88 | 60 |
| 80th Percentile FDA Days to MDUFA IV Decision | 90 | 90 | 90 | 90 | 88 |
| Maximum FDA Days to MDUFA IV Decision | 148 | 153 | 115 | 127 | 90 |
| Average Number of Industry Days to MDUFA IV Decision | 65.45 | 68.64 | 70.31 | 56.54 | 3.49 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 18 | 20 | 16 | 10 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 63 | 67 | 63 | 47 | - |
| 80th Percentile Industry Days to MDUFA IV Decision | 152 | 153 | 151 | 115 | 2 |
| Maximum Industry Days to MDUFA IV Decision | 389 | 356 | 449 | 359 | 34 |
| Average Number of Total Days to MDUFA IV Decision | 146.51 | 151.03 | 150.18 | 134.64 | 60.51 |
| 20th Percentile Total Days to MDUFA IV Decision | 79 | 88 | 84 | 60 | 29 |
| 40th Percentile Total Days to MDUFA IV Decision | 103 | 106 | 99 | 90 | 56 |
| 60th Percentile Total Days to MDUFA IV Decision | 148 | 153 | 148 | 134 | 62 |
| 80th Percentile Total Days to MDUFA IV Decision | 241 | 242 | 239 | 203 | 88 |
| Maximum Total Days to MDUFA IV Decision | 479 | 446 | 539 | 486 | 120 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 494 | 550 | 503 | 470 | 151 |
| Number With MDUFA IV Decision | 420 | 465 | 432 | 310 | 37 |
| Number of SE Decision | 402 | 442 | 418 | 300 | 37 |
| Number of NSE Decision | 18 | 23 | 14 | 10 | - |
| Number of Withdrawal | 35 | 48 | 33 | 29 | - |
| Number of Deleted | 39 | 34 | 23 | 1 | - |
| Rate of SE Decision | 95.71% | 95.05% | 96.76% | 96.77% | 100.00% |
| Rate of NSE Decision | 4.29% | 4.95% | 3.24% | 3.23% | 0.00% |
| Rate of Withdrawal | 7.09% | 8.73% | 6.56% | 6.17% | 0.00% |
| Rate of Deleted | 7.89% | 6.18% | 4.57% | 0.21% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 3 | 2 | 4 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 115.33 | 133.50 | 101.25 | 127.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 107.67 | 258.00 | 167.75 | 359.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0% | 0% | 0% | 0% | 0% |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|---|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0% | | 0% | | 0% | | 0% | | 0% | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 357 | 378 | 377 | 386 | 160 |
| Closed Before RTA Action | 4 | 2 | 1 | 2 | 0 |
| Number Accepted | 237 | 266 | 282 | 275 | 110 |
| Number Without a RTA Review and > 15 Days Since Date Received | 2 | 10 | 4 | 17 | 14 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 6 |
| Number Not Accepted | 114 | 100 | 90 | 92 | 30 |
| Rate of Submissions Not Accepted for Review | 32.29% | 26.60% | 23.94% | 23.96% | 19.48% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 341 | 366 | 368 | 374 | 140 |
| Deleted or Withdrawn Prior to SI | 4 | 0 | 1 | 1 | 4 |
| SI Within 60 FDA Days | 324 | 358 | 354 | 345 | 93 |
| SI Over 60 FDA Days | 13 | 8 | 12 | 18 | 3 |
| SI Pending Within 60 FDA Days | 0 | 0 | 0 | 6 | 39 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 2 | 0 |
| 510(k)s NSE Without SI | 0 | 0 | 1 | 2 | 1 |
| Current SI Performance Percent Within 60 FDA Days | 96.14% | 97.81% | 96.46% | 94.01% | 95.88% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 337 | 366 | 366 | 363 | 96 |
| Average Number of FDA Days to Substantive Interaction | 49.74 | 50.76 | 51.63 | 51.19 | 51.22 |
| 20th Percentile FDA Days to Substantive Interaction | 30 | 30 | 36 | 30 | 42 |
| 40th Percentile FDA Days to Substantive Interaction | 53 | 56 | 57 | 57 | 56 |
| 60th Percentile FDA Days to Substantive Interaction | 58 | 59 | 59 | 59 | 58 |
| 80th Percentile FDA Days to Substantive Interaction | 60 | 60 | 60 | 60 | 60 |
| Maximum FDA Days to Substantive Interaction | 83 | 71 | 101 | 89 | 65 |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 341 | 366 | 368 | 374 | 140 | | | | | |
| Non-MDUFA IV Decision | 32 | 52 | 28 | 14 | 5 | | | | | |
| MDUFA IV Decision (SE/NSE) | 309 | 314 | 331 | 265 | 28 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 303 | 303 | 317 | 261 | 28 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 9 | 95 | 107 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 1 | 2 | 0 | | | | | |
| Current Performance Percent Within 90 FDA Days | 98.06% | 96.50% | 95.48% | 97.75% | 100.00% | | | | | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.71 | 1.70 | 1.81 | 1.71 | 1.36 |
| Number With MDUFA IV Decision | 309 | 314 | 331 | 265 | 28 |
| Average Number of FDA Days to MDUFA IV Decision | 71.68 | 71.37 | 74.86 | 70.56 | 52.82 |
| 20th Percentile FDA Days to MDUFA IV Decision | 50 | 49 | 55 | 36 | 28 |
| 40th Percentile FDA Days to MDUFA IV Decision | 80 | 80 | 86 | 75 | 41 |
| 60th Percentile FDA Days to MDUFA IV Decision | 88 | 88 | 89 | 88 | 56 |
| 80th Percentile FDA Days to MDUFA IV Decision | 90 | 90 | 90 | 90 | 88 |
| Maximum FDA Days to MDUFA IV Decision | 159 | 117 | 245 | 293 | 90 |
| Average Number of Industry Days to MDUFA IV Decision | 64.80 | 66.25 | 84.83 | 62.54 | 8.93 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 19 | 20 | 28 | 20 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 65 | 68 | 77 | 58 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 146 | 140 | 154 | 127 | 11 |
| Maximum Industry Days to MDUFA IV Decision | 292 | 359 | 571 | 386 | 66 |
| Average Number of Total Days to MDUFA IV Decision | 136.48 | 137.61 | 159.69 | 133.10 | 61.75 |
| 20th Percentile Total Days to MDUFA IV Decision | 55 | 51 | 56 | 40 | 28 |
| 40th Percentile Total Days to MDUFA IV Decision | 102 | 98 | 117 | 101 | 44 |
| 60th Percentile Total Days to MDUFA IV Decision | 150 | 148 | 161 | 142 | 58 |
| 80th Percentile Total Days to MDUFA IV Decision | 228 | 227 | 247 | 211 | 99 |
| Maximum Total Days to MDUFA IV Decision | 370 | 447 | 672 | 476 | 156 |

Table 6.6 OHT2 - Office of Cardiovascular Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 341 | 366 | 368 | 374 | 140 |
| Number With MDUFA IV Decision | 309 | 314 | 331 | 265 | 28 |
| Number of SE Decision | 291 | 289 | 307 | 242 | 25 |
| Number of NSE Decision | 18 | 25 | 24 | 23 | 3 |
| Number of Withdrawal | 20 | 31 | 19 | 12 | 5 |
| Number of Deleted | 10 | 20 | 9 | 2 | 0 |
| Rate of SE Decision | 94.17% | 92.04% | 92.75% | 91.32% | 89.29% |
| Rate of NSE Decision | 5.83% | 7.96% | 7.25% | 8.68% | 10.71% |
| Rate of Withdrawal | 5.87% | 8.47% | 5.16% | 3.21% | 3.57% |
| Rate of Deleted | 2.93% | 5.46% | 2.45% | 0.53% | 0.00% |

Table 6.7 OHT2 - Office of Cardiovascular Devices

510(k) Performance Metric - Submissions Missing Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 6 | 11 | 14 | 4 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 107.17 | 99.82 | 110.86 | 145.75 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 131.50 | 159.09 | 236.93 | 139.00 | 0.00 |

Table 6.8 OHT2 - Office of Cardiovascular Devices

LDT 510(k) MDUFA IV Decision Metric

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

**Table 6.9 OHT2 - Office of Cardiovascular Devices
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|---|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0.00% | | 0.00% | | 0.00% | | 0.00% | | 0.00% | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 455 | 477 | 440 | 511 | 200 |
| Closed Before RTA Action | 3 | 4 | 4 | 6 | 0 |
| Number Accepted | 334 | 350 | 287 | 292 | 99 |
| Number Without a RTA Review and > 15 Days Since Date Received | 2 | 6 | 2 | 14 | 18 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 13 |
| Number Not Accepted | 116 | 117 | 147 | 199 | 70 |
| Rate of Submissions Not Accepted for Review | 25.66% | 24.74% | 33.72% | 39.41% | 37.43% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 436 | 454 | 416 | 456 | 149 |
| Deleted or Withdrawn Prior to SI | 0 | 1 | 1 | 2 | 0 |
| SI Within 60 FDA Days | 427 | 448 | 401 | 415 | 89 |
| SI Over 60 FDA Days | 6 | 4 | 13 | 24 | 6 |
| SI Pending Within 60 FDA Days | 0 | 0 | 1 | 6 | 54 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 7 | 0 |
| 510(k)s NSE Without SI | 3 | 1 | 0 | 2 | 0 |
| Current SI Performance Percent Within 60 FDA Days | 97.94% | 98.90% | 96.86% | 92.63% | 93.68% |

**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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 433 | 452 | 414 | 439 | 95 |
| Average Number of FDA Days to Substantive Interaction | 51.10 | 52.60 | 53.35 | 53.94 | 55.00 |
| 20th Percentile FDA Days to Substantive Interaction | 44 | 48 | 51 | 53 | 55 |
| 40th Percentile FDA Days to Substantive Interaction | 55 | 57 | 57 | 57 | 58 |
| 60th Percentile FDA Days to Substantive Interaction | 58 | 58 | 59 | 59 | 59 |
| 80th Percentile FDA Days to Substantive Interaction | 60 | 60 | 60 | 60 | 60 |
| Maximum FDA Days to Substantive Interaction | 67 | 78 | 68 | 77 | 75 |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 436 | 454 | 416 | 456 | 149 | | | | | |
| Non-MDUFA IV Decision | 50 | 77 | 51 | 21 | 0 | | | | | |
| MDUFA IV Decision (SE/NSE) | 386 | 377 | 351 | 310 | 27 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 382 | 372 | 344 | 307 | 27 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 14 | 125 | 122 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 2 | 8 | 0 | | | | | |
| Current Performance Percent Within 90 FDA Days | 98.96% | 98.67% | 97.45% | 96.54% | 100.00% | | | | | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.74 | 1.84 | 1.82 | 1.75 | 1.37 |
| Number With MDUFA IV Decision | 386 | 377 | 351 | 310 | 27 |
| Average Number of FDA Days to MDUFA IV Decision | 75.68 | 78.18 | 78.46 | 78.35 | 63.41 |
| 20th Percentile FDA Days to MDUFA IV Decision | 58 | 60 | 65 | 60 | 31 |
| 40th Percentile FDA Days to MDUFA IV Decision | 84 | 87 | 87 | 87 | 59 |
| 60th Percentile FDA Days to MDUFA IV Decision | 88 | 88 | 89 | 89 | 78 |
| 80th Percentile FDA Days to MDUFA IV Decision | 89 | 90 | 90 | 90 | 90 |
| Maximum FDA Days to MDUFA IV Decision | 118 | 150 | 135 | 199 | 90 |
| Average Number of Industry Days to MDUFA IV Decision | 74.93 | 95.65 | 101.62 | 74.52 | 10.48 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 5 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 29 | 53 | 53 | 42 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 94 | 118 | 123 | 78 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 165 | 174 | 178 | 138 | 24 |
| Maximum Industry Days to MDUFA IV Decision | 214 | 444 | 490 | 361 | 57 |
| Average Number of Total Days to MDUFA IV Decision | 150.61 | 173.83 | 180.08 | 152.87 | 73.89 |
| 20th Percentile Total Days to MDUFA IV Decision | 64 | 87 | 87 | 80 | 31 |
| 40th Percentile Total Days to MDUFA IV Decision | 113 | 140 | 137 | 129 | 64 |
| 60th Percentile Total Days to MDUFA IV Decision | 177 | 205 | 210 | 167 | 87 |
| 80th Percentile Total Days to MDUFA IV Decision | 248 | 261 | 266 | 226 | 93 |
| Maximum Total Days to MDUFA IV Decision | 304 | 540 | 580 | 449 | 143 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 436 | 454 | 416 | 456 | 149 |
| Number With MDUFA IV Decision | 386 | 377 | 351 | 310 | 27 |
| Number of SE Decision | 361 | 354 | 331 | 287 | 27 |
| Number of NSE Decision | 25 | 23 | 20 | 23 | 0 |
| Number of Withdrawal | 20 | 31 | 25 | 14 | 0 |
| Number of Deleted | 30 | 44 | 25 | 7 | 0 |
| Rate of SE Decision | 93.52% | 93.90% | 94.30% | 92.58% | 100.00% |
| Rate of NSE Decision | 6.48% | 6.10% | 5.70% | 7.42% | 0.00% |
| Rate of Withdrawal | 4.59% | 6.83% | 6.01% | 3.07% | 0.00% |
| Rate of Deleted | 6.88% | 9.69% | 6.01% | 1.54% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 4 | 5 | 7 | 3 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 100.00 | 111.20 | 108.57 | 174.33 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 117.00 | 332.20 | 145.00 | 84.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|---|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | 0 | | 0 | | 0 | | 0 | | 0 | |
| Non-MDUFA IV Decision | 0 | | 0 | | 0 | | 0 | | 0 | |
| MDUFA IV Decision (SE/NSE) | 0 | | 0 | | 0 | | 0 | | 0 | |
| MDUFA IV Decision Within 90 FDA Days | 0 | | 0 | | 0 | | 0 | | 0 | |
| 510(k)s Pending MDUFA IV Decision | 0 | | 0 | | 0 | | 0 | | 0 | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | | 0 | | 0 | | 0 | | 0 | |
| Current Performance Percent Within 90 FDA Days | 0.00% | | 0.00% | | 0.00% | | 0.00% | | 0.00% | |

Table 6.1 OHT4 - Office of Surgical and Infection Control Devices

510(k) Acceptance Review Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 552 | 604 | 720 | 1,026 | 356 |
| Closed Before RTA Action | 2 | 0 | 3 | 4 | 0 |
| Number Accepted | 368 | 392 | 447 | 601 | 205 |
| Number Without a RTA Review and > 15 Days Since Date Received | 6 | 7 | 5 | 36 | 35 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 15 |
| Number Not Accepted | 176 | 205 | 265 | 385 | 101 |
| Rate of Submissions Not Accepted for Review | 32.00% | 33.94% | 36.96% | 37.67% | 29.62% |

Table 6.2 OHT4 - Office of Surgical and Infection Control Devices

510(k) Substantive Interaction Performance Goal

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 516 | 559 | 654 | 921 | 278 |
| Deleted or Withdrawn Prior to SI | 0 | 3 | 2 | 3 | 0 |
| SI Within 60 FDA Days | 512 | 543 | 626 | 741 | 155 |
| SI Over 60 FDA Days | 4 | 12 | 24 | 161 | 33 |
| SI Pending Within 60 FDA Days | 0 | 0 | 1 | 4 | 84 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 12 | 5 |
| 510(k)s NSE Without SI | 0 | 1 | 1 | 0 | 1 |
| Current SI Performance Percent Within 60 FDA Days | 99.22% | 97.66% | 96.16% | 81.07% | 79.90% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 516 | 555 | 650 | 902 | 188 |
| Average Number of FDA Days to Substantive Interaction | 52.60 | 52.19 | 53.93 | 57.24 | 55.39 |
| 20th Percentile FDA Days to Substantive Interaction | 50 | 48 | 52 | 54 | 49 |
| 40th Percentile FDA Days to Substantive Interaction | 57 | 56 | 57 | 57 | 57 |
| 60th Percentile FDA Days to Substantive Interaction | 58 | 58 | 59 | 59 | 59 |
| 80th Percentile FDA Days to Substantive Interaction | 60 | 60 | 60 | 60 | 60 |
| Maximum FDA Days to Substantive Interaction | 69 | 90 | 91 | 146 | 139 |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 516 | 559 | 654 | 921 | 278 | | | | | |
| Non-MDUFA IV Decision | 68 | 74 | 77 | 32 | 1 | | | | | |
| MDUFA IV Decision (SE/NSE) | 448 | 484 | 563 | 695 | 87 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 440 | 480 | 536 | 534 | 77 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 1 | 14 | 194 | 190 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 5 | 31 | 5 | | | | | |
| Current Performance Percent Within 90 FDA Days | 98.21% | 99.17% | 94.37% | 73.55% | 83.70% | | | | | |

Table 6.5 OHT4 - Office of Surgical and Infection Control Devices

510(k) Time to MDUFA IV Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.56 | 1.58 | 1.67 | 1.62 | 1.33 |
| Number With MDUFA IV Decision | 448 | 484 | 563 | 695 | 87 |
| Average Number of FDA Days to MDUFA IV Decision | 73.88 | 73.11 | 76.55 | 82.18 | 68.46 |
| 20th Percentile FDA Days to MDUFA IV Decision | 57 | 55 | 59 | 69 | 46 |
| 40th Percentile FDA Days to MDUFA IV Decision | 79 | 81 | 84 | 87 | 59 |
| 60th Percentile FDA Days to MDUFA IV Decision | 87 | 87 | 87 | 89 | 86 |
| 80th Percentile FDA Days to MDUFA IV Decision | 89 | 89 | 89 | 91 | 89 |
| Maximum FDA Days to MDUFA IV Decision | 220 | 207 | 179 | 242 | 114 |
| Average Number of Industry Days to MDUFA IV Decision | 48.98 | 54.82 | 65.06 | 44.99 | 9.54 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 10 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 31 | 41 | 61 | 33 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 110 | 128 | 137 | 87 | 19 |
| Maximum Industry Days to MDUFA IV Decision | 563 | 355 | 391 | 404 | 64 |
| Average Number of Total Days to MDUFA IV Decision | 122.86 | 127.93 | 141.61 | 127.17 | 78.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 59 | 57 | 60 | 79 | 51 |
| 40th Percentile Total Days to MDUFA IV Decision | 88 | 87 | 91 | 91 | 65 |
| 60th Percentile Total Days to MDUFA IV Decision | 110 | 125 | 145 | 122 | 89 |
| 80th Percentile Total Days to MDUFA IV Decision | 193 | 210 | 227 | 180 | 106 |
| Maximum Total Days to MDUFA IV Decision | 783 | 511 | 497 | 493 | 148 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 516 | 559 | 654 | 921 | 278 |
| Number With MDUFA IV Decision | 448 | 484 | 563 | 695 | 87 |
| Number of SE Decision | 437 | 470 | 551 | 687 | 86 |
| Number of NSE Decision | 11 | 14 | 12 | 8 | 1 |
| Number of Withdrawal | 36 | 37 | 37 | 20 | 1 |
| Number of Deleted | 31 | 35 | 38 | 11 | 0 |
| Rate of SE Decision | 97.54% | 97.11% | 97.87% | 98.85% | 98.85% |
| Rate of NSE Decision | 2.46% | 2.89% | 2.13% | 1.15% | 1.15% |
| Rate of Withdrawal | 6.98% | 6.62% | 5.66% | 2.17% | 0.36% |
| Rate of Deleted | 6.01% | 6.26% | 5.81% | 1.19% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 8 | 4 | 27 | 161 | 10 |
| Mean FDA Days for Submissions that Missed the Goal | 119.50 | 121.00 | 103.93 | 103.12 | 99.50 |
| Mean Industry Days for Submissions that Missed the Goal | 168.63 | 132.50 | 132.67 | 60.64 | 12.30 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|---------|--------------------|---------|--------------------|---------|--------------------|---------|--------------------|---------|--------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | 0 | | 0 | | 0 | | 0 | | 0 | |
| Non-MDUFA IV Decision | 0 | | 0 | | 0 | | 0 | | 0 | |
| MDUFA IV Decision (SE/NSE) | 0 | | 0 | | 0 | | 0 | | 0 | |
| MDUFA IV Decision Within 90 FDA Days | 0 | | 0 | | 0 | | 0 | | 0 | |
| 510(k)s Pending MDUFA IV Decision | 0 | | 0 | | 0 | | 0 | | 0 | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | | 0 | | 0 | | 0 | | 0 | |
| Current Performance Percent Within 90 FDA Days | 0.00% | | 0.00% | | 0.00% | | 0.00% | | 0.00% | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 260 | 274 | 261 | 276 | 131 |
| Closed Before RTA Action | 3 | 0 | 3 | 1 | 0 |
| Number Accepted | 147 | 155 | 110 | 135 | 68 |
| Number Without a RTA Review and > 15 Days Since Date Received | 3 | 7 | 5 | 8 | 7 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 8 |
| Number Not Accepted | 107 | 112 | 143 | 132 | 48 |
| Rate of Submissions Not Accepted for Review | 41.63% | 40.88% | 55.43% | 48.00% | 39.02% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 236 | 260 | 237 | 249 | 90 |
| Deleted or Withdrawn Prior to SI | 0 | 0 | 0 | 0 | 0 |
| SI Within 60 FDA Days | 232 | 257 | 228 | 243 | 62 |
| SI Over 60 FDA Days | 4 | 3 | 9 | 2 | 2 |
| SI Pending Within 60 FDA Days | 0 | 0 | 0 | 4 | 26 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s NSE Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Within 60 FDA Days | 98.31% | 98.85% | 96.20% | 99.18% | 96.88% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 236 | 260 | 237 | 245 | 64 |
| Average Number of FDA Days to Substantive Interaction | 53.91 | 54.53 | 53.49 | 53.54 | 54.98 |
| 20th Percentile FDA Days to Substantive Interaction | 53 | 54 | 50 | 53 | 56 |
| 40th Percentile FDA Days to Substantive Interaction | 58 | 58 | 58 | 58 | 58 |
| 60th Percentile FDA Days to Substantive Interaction | 60 | 60 | 59 | 59 | 60 |
| 80th Percentile FDA Days to Substantive Interaction | 60 | 60 | 60 | 60 | 60 |
| Maximum FDA Days to Substantive Interaction | 86 | 63 | 87 | 66 | 62 |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 236 | 260 | 237 | 249 | 90 | | | | | |
| Non-MDUFA IV Decision | 30 | 30 | 16 | 13 | 1 | | | | | |
| MDUFA IV Decision (SE/NSE) | 206 | 229 | 219 | 180 | 23 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 201 | 222 | 219 | 179 | 23 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 1 | 2 | 56 | 66 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 | | | | | |
| Current Performance Percent Within 90 FDA Days | 97.57% | 96.94% | 100.00% | 99.44% | 100.00% | | | | | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.52 | 1.60 | 1.46 | 1.51 | 1.17 |
| Number With MDUFA IV Decision | 206 | 229 | 219 | 180 | 23 |
| Average Number of FDA Days to MDUFA IV Decision | 76.47 | 80.32 | 75.72 | 73.52 | 62.52 |
| 20th Percentile FDA Days to MDUFA IV Decision | 60 | 69 | 64 | 52 | 40 |
| 40th Percentile FDA Days to MDUFA IV Decision | 86 | 88 | 87 | 84 | 58 |
| 60th Percentile FDA Days to MDUFA IV Decision | 89 | 90 | 89 | 88 | 72 |
| 80th Percentile FDA Days to MDUFA IV Decision | 90 | 90 | 90 | 90 | 87 |
| Maximum FDA Days to MDUFA IV Decision | 170 | 152 | 90 | 131 | 90 |
| Average Number of Industry Days to MDUFA IV Decision | 42.60 | 55.79 | 60.06 | 43.97 | 5.26 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 38 | 39 | 26 | 28 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 84 | 129 | 124 | 91 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 187 | 391 | 360 | 348 | 62 |
| Average Number of Total Days to MDUFA IV Decision | 119.07 | 136.10 | 135.78 | 117.49 | 67.78 |
| 20th Percentile Total Days to MDUFA IV Decision | 61 | 83 | 64 | 57 | 40 |
| 40th Percentile Total Days to MDUFA IV Decision | 89 | 90 | 89 | 87 | 58 |
| 60th Percentile Total Days to MDUFA IV Decision | 117 | 125 | 113 | 105 | 73 |
| 80th Percentile Total Days to MDUFA IV Decision | 171 | 219 | 210 | 176 | 87 |
| Maximum Total Days to MDUFA IV Decision | 346 | 543 | 449 | 438 | 151 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 236 | 260 | 237 | 249 | 90 |
| Number With MDUFA IV Decision | 206 | 229 | 219 | 180 | 23 |
| Number of SE Decision | 198 | 222 | 208 | 173 | 22 |
| Number of NSE Decision | 8 | 7 | 11 | 7 | 1 |
| Number of Withdrawal | 17 | 16 | 13 | 10 | 1 |
| Number of Deleted | 10 | 13 | 3 | 3 | 0 |
| Rate of SE Decision | 96.12% | 96.94% | 94.98% | 96.11% | 95.65% |
| Rate of NSE Decision | 3.88% | 3.06% | 5.02% | 3.89% | 4.35% |
| Rate of Withdrawal | 7.20% | 6.15% | 5.49% | 4.02% | 1.11% |
| Rate of Deleted | 4.24% | 5.00% | 1.27% | 1.20% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 5 | 7 | 0 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 111.40 | 119.43 | 0.00 | 131.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 80.60 | 110.29 | 0.00 | 153.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|---|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | 0 | | 0 | | 0 | | 0 | | 0 | |
| Non-MDUFA IV Decision | 0 | | 0 | | 0 | | 0 | | 0 | |
| MDUFA IV Decision (SE/NSE) | 0 | | 0 | | 0 | | 0 | | 0 | |
| MDUFA IV Decision Within 90 FDA Days | 0 | | 0 | | 0 | | 0 | | 0 | |
| 510(k)s Pending MDUFA IV Decision | 0 | | 0 | | 0 | | 0 | | 0 | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | | 0 | | 0 | | 0 | | 0 | |
| Current Performance Percent Within 90 FDA Days | 0.00% | | 0.00% | | 0.00% | | 0.00% | | 0.00% | |

Table 6.1 OHT6 - Office of Orthopedic Devices

510(k) Acceptance Review Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 606 | 634 | 655 | 578 | 269 |
| Closed Before RTA Action | 2 | 4 | 5 | 2 | 0 |
| Number Accepted | 466 | 489 | 493 | 435 | 161 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 5 | 6 | 6 | 16 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 28 |
| Number Not Accepted | 138 | 136 | 151 | 135 | 64 |
| Rate of Submissions Not Accepted for Review | 22.85% | 21.59% | 23.23% | 23.44% | 26.56% |

Table 6.2 OHT6 - Office of Orthopedic Devices

510(k) Substantive Interaction Performance Goal

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 594 | 622 | 638 | 552 | 212 |
| Deleted or Withdrawn Prior to SI | 0 | 2 | 3 | 1 | 1 |
| SI Within 60 FDA Days | 575 | 617 | 634 | 548 | 142 |
| SI Over 60 FDA Days | 19 | 3 | 1 | 1 | 0 |
| SI Pending Within 60 FDA Days | 0 | 0 | 0 | 2 | 68 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s NSE Without SI | 0 | 0 | 0 | 0 | 1 |
| Current SI Performance Percent Within 60 FDA Days | 96.80% | 99.52% | 99.84% | 99.82% | 99.30% |

Table 6.3 OHT6 - Office of Orthopedic Devices

510(k) Substantive Interaction Metric - Time to Substantive Interaction

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 594 | 620 | 635 | 549 | 142 |
| Average Number of FDA Days to Substantive Interaction | 50.43 | 49.80 | 49.83 | 50.18 | 49.84 |
| 20th Percentile FDA Days to Substantive Interaction | 39 | 30 | 30 | 31 | 30 |
| 40th Percentile FDA Days to Substantive Interaction | 55 | 56 | 56 | 55 | 55 |
| 60th Percentile FDA Days to Substantive Interaction | 57 | 58 | 58 | 58 | 58 |
| 80th Percentile FDA Days to Substantive Interaction | 59 | 60 | 60 | 59 | 59 |
| Maximum FDA Days to Substantive Interaction | 78 | 64 | 61 | 90 | 60 |

Table 6.4 OHT6 - Office of Orthopedic Devices

510(k) MDUFA IV Decision Performance Goal

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 594 | 622 | 638 | 552 | 212 | | | | | |
| Non-MDUFA IV Decision | 40 | 47 | 61 | 25 | 2 | | | | | |
| MDUFA IV Decision (SE/NSE) | 554 | 575 | 574 | 449 | 81 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 552 | 574 | 574 | 448 | 81 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 3 | 78 | 129 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 | | | | | |
| Current Performance Percent Within 90 FDA Days | 99.64% | 99.83% | 100.00% | 99.78% | 100.00% | | | | | |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.67 | 1.62 | 1.51 | 1.45 | 1.15 |
| Number With MDUFA IV Decision | 554 | 575 | 574 | 449 | 81 |
| Average Number of FDA Days to MDUFA IV Decision | 71.36 | 70.57 | 66.87 | 63.75 | 54.98 |
| 20th Percentile FDA Days to MDUFA IV Decision | 52 | 51 | 36 | 32 | 29 |
| 40th Percentile FDA Days to MDUFA IV Decision | 74 | 76 | 60 | 58 | 51 |
| 60th Percentile FDA Days to MDUFA IV Decision | 86 | 87 | 86 | 78 | 60 |
| 80th Percentile FDA Days to MDUFA IV Decision | 89 | 89 | 89 | 88 | 85 |
| Maximum FDA Days to MDUFA IV Decision | 135 | 91 | 90 | 151 | 90 |
| Average Number of Industry Days to MDUFA IV Decision | 48.84 | 50.98 | 51.43 | 32.51 | 5.11 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 10 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 34 | 29 | 20 | 13 | - |
| 80th Percentile Industry Days to MDUFA IV Decision | 103 | 103 | 96 | 63 | - |
| Maximum Industry Days to MDUFA IV Decision | 340 | 444 | 468 | 359 | 77 |
| Average Number of Total Days to MDUFA IV Decision | 120.19 | 121.55 | 118.31 | 96.26 | 60.09 |
| 20th Percentile Total Days to MDUFA IV Decision | 57 | 56 | 38 | 39 | 29 |
| 40th Percentile Total Days to MDUFA IV Decision | 86 | 87 | 66 | 59 | 51 |
| 60th Percentile Total Days to MDUFA IV Decision | 115 | 111 | 103 | 90 | 60 |
| 80th Percentile Total Days to MDUFA IV Decision | 189 | 185 | 183 | 144 | 87 |
| Maximum Total Days to MDUFA IV Decision | 430 | 533 | 557 | 448 | 164 |

Table 6.6 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 594 | 622 | 638 | 552 | 212 |
| Number With MDUFA IV Decision | 554 | 575 | 574 | 449 | 81 |
| Number of SE Decision | 540 | 563 | 570 | 447 | 80 |
| Number of NSE Decision | 14 | 12 | 4 | 2 | 1 |
| Number of Withdrawal | 24 | 28 | 38 | 21 | 2 |
| Number of Deleted | 16 | 19 | 23 | 4 | 0 |
| Rate of SE Decision | 97.47% | 97.91% | 99.30% | 99.55% | 98.77% |
| Rate of NSE Decision | 2.53% | 2.09% | 0.70% | 0.45% | 1.23% |
| Rate of Withdrawal | 4.04% | 4.50% | 5.96% | 3.80% | 0.94% |
| Rate of Deleted | 2.69% | 3.05% | 3.61% | 0.72% | 0.00% |

Table 6.7 OHT6 - Office of Orthopedic Devices

510(k) Performance Metric - Submissions Missing Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 2 | 1 | 0 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 118 | 91 | 0 | 151 | 0 |
| Mean Industry Days for Submissions that Missed the Goal | 209 | 260 | 0 | 109 | 0 |

Table 6.8 OHT6 - Office of Orthopedic Devices

LDT 510(k) MDUFA IV Decision Metric

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

**Table 6.9 OHT6 -Office of Orthopedic Devices
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|---|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | | 0 | | 0 | | 0 | | 0 | | 0 |
| Non-MDUFA IV Decision | | 0 | | 0 | | 0 | | 0 | | 0 |
| MDUFA IV Decision (SE/NSE) | | 0 | | 0 | | 0 | | 0 | | 0 |
| MDUFA IV Decision Within 90 FDA Days | | 0 | | 0 | | 0 | | 0 | | 0 |
| 510(k)s Pending MDUFA IV Decision | | 0 | | 0 | | 0 | | 0 | | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | | 0 | | 0 | | 0 | | 0 | | 0 |
| Current Performance Percent Within 90 FDA Days | | 0.00% | | 0.00% | | 0.00% | | 0.00% | | 0.00% |

Table 6.1 OHT7 - Office of In Vitro Diagnostics and Radiological Health

510(k) Acceptance Review Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number Received | 681 | 684 | 705 | 656 | 338 |
| Closed Before RTA Action | 3 | 4 | 5 | 2 | 2 |
| Number Accepted | 593 | 544 | 552 | 417 | 207 |
| Number Without a RTA Review and > 15 Days Since Date Received | 2 | 7 | 19 | 128 | 51 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 25 |
| Number Not Accepted | 83 | 129 | 129 | 109 | 53 |
| Rate of Submissions Not Accepted for Review | 12.24% | 18.97% | 18.43% | 16.67% | 17.04% |

Table 6.2 OHT7 - Office of In Vitro Diagnostics and Radiological Health

510(k) Substantive Interaction Performance Goal

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 659 | 652 | 679 | 629 | 274 |
| Deleted or Withdrawn Prior to SI | 2 | 1 | 3 | 6 | 1 |
| SI Within 60 FDA Days | 655 | 646 | 626 | 448 | 138 |
| SI Over 60 FDA Days | 1 | 2 | 50 | 165 | 22 |
| SI Pending Within 60 FDA Days | 0 | 0 | 0 | 2 | 77 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 5 | 35 |
| 510(k)s NSE Without SI | 1 | 3 | 0 | 3 | 1 |
| Current SI Performance Percent Within 60 FDA Days | 99.70% | 99.23% | 92.60% | 72.14% | 70.41% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 656 | 648 | 676 | 613 | 160 |
| Average Number of FDA Days to Substantive Interaction | 46.54 | 46.73 | 64.05 | 82.80 | 57.19 |
| 20th Percentile FDA Days to Substantive Interaction | 30 | 29 | 30 | 46 | 40 |
| 40th Percentile FDA Days to Substantive Interaction | 48 | 49 | 51 | 55 | 54 |
| 60th Percentile FDA Days to Substantive Interaction | 56 | 56 | 57 | 59 | 58 |
| 80th Percentile FDA Days to Substantive Interaction | 58 | 59 | 59 | 122 | 60 |
| Maximum FDA Days to Substantive Interaction | 61 | 61 | 496 | 381 | 140 |

**Table 6.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
510(k) MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 659 | 652 | 679 | 629 | 274 | | | | | |
| Non-MDUFA IV Decision | 56 | 59 | 57 | 23 | 1 | | | | | |
| MDUFA IV Decision (SE/NSE) | 603 | 593 | 590 | 461 | 76 | | | | | |
| MDUFA IV Decision Within 90 FDA Days | 602 | 589 | 526 | 389 | 74 | | | | | |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 32 | 145 | 197 | | | | | |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 31 | 94 | 38 | | | | | |
| Current Performance Percent Within 90 FDA Days | 99.83% | 99.33% | 84.70% | 70.09% | 64.91% | | | | | |

Table 6.5 OHT7 - Office of In Vitro Diagnostics and Radiological Health

510(k) Time to MDUFA IV Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.51 | 1.44 | 1.54 | 1.46 | 1.22 |
| Number With MDUFA IV Decision | 603 | 593 | 590 | 461 | 76 |
| Average Number of FDA Days to MDUFA IV Decision | 64.21 | 65.35 | 89.39 | 89.17 | 53.92 |
| 20th Percentile FDA Days to MDUFA IV Decision | 30 | 30 | 30 | 48 | 25 |
| 40th Percentile FDA Days to MDUFA IV Decision | 59 | 59 | 66 | 76 | 50 |
| 60th Percentile FDA Days to MDUFA IV Decision | 81 | 81 | 85 | 87 | 59 |
| 80th Percentile FDA Days to MDUFA IV Decision | 88 | 88 | 89 | 90 | 85 |
| Maximum FDA Days to MDUFA IV Decision | 93 | 655 | 673 | 381 | 132 |
| Average Number of Industry Days to MDUFA IV Decision | 42.78 | 42.94 | 51.90 | 36.54 | 7.13 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 25 | 13 | 35 | 22 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 91 | 90 | 108 | 68 | 13 |
| Maximum Industry Days to MDUFA IV Decision | 231 | 448 | 360 | 360 | 77 |
| Average Number of Total Days to MDUFA IV Decision | 106.99 | 108.29 | 141.29 | 125.71 | 61.05 |
| 20th Percentile Total Days to MDUFA IV Decision | 30 | 30 | 31 | 49 | 25 |
| 40th Percentile Total Days to MDUFA IV Decision | 72 | 61 | 78 | 86 | 50 |
| 60th Percentile Total Days to MDUFA IV Decision | 104 | 90 | 120 | 125 | 59 |
| 80th Percentile Total Days to MDUFA IV Decision | 177 | 173 | 217 | 198 | 99 |
| Maximum Total Days to MDUFA IV Decision | 321 | 871 | 775 | 471 | 167 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| 510(k) Accepted | 659 | 652 | 679 | 629 | 274 |
| Number With MDUFA IV Decision | 603 | 593 | 590 | 461 | 76 |
| Number of SE Decision | 581 | 582 | 581 | 452 | 75 |
| Number of NSE Decision | 22 | 11 | 9 | 9 | 1 |
| Number of Withdrawal | 33 | 22 | 35 | 19 | 1 |
| Number of Deleted | 20 | 28 | 20 | 4 | 0 |
| Rate of SE Decision | 96.35% | 98.15% | 98.47% | 98.05% | 98.68% |
| Rate of NSE Decision | 3.65% | 1.85% | 1.53% | 1.95% | 1.32% |
| Rate of Withdrawal | 5.01% | 3.37% | 5.15% | 3.02% | 0.36% |
| Rate of Deleted | 3.03% | 4.29% | 2.95% | 0.64% | 0.00% |

**Table 6.7 OHT7 - Office of In Vitro Diagnostics and Radiological Health
510(k) Performance Metric - Submissions Missing Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 1 | 4 | 64 | 72 | 2 |
| Mean FDA Days for Submissions that Missed the Goal | 93.00 | 370.00 | 298.73 | 212.31 | 119.00 |
| Mean Industry Days for Submissions that Missed the Goal | 202.00 | 268.00 | 123.34 | 27.33 | 0.00 |

**Table 6.8 OHT7 - Office of In Vitro Diagnostics and Radiological Health
LDT 510(k) MDUFA IV Decision Metric**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 2 | 1 | 4 | 2 | 2 |
| Non-MDUFA IV Decision | 1 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 1 | 1 | 4 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 1 | 1 | 2 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 2 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 2 | 0 |
| Current Performance Percent Within 90 FDA Days | 100.00% | 100.00% | 50.00% | 0.00% | 0.00% |

**Table 6.9 OHT7 - Office of In Vitro Diagnostics and Radiological Health
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

| Performance Metric | FY 2018 | | FY 2019 | | FY 2020 | | FY 2021 | | FY 2022 | |
|--|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|---------|-----------------------|
| | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days | 95% | Within 90 FDA Days |
| 510(k)s Accepted | | 272 | | 278 | | 253 | | 193 | | 88 |
| Non-MDUFA IV Decision | | 41 | | 37 | | 38 | | 11 | | 1 |
| MDUFA IV Decision (SE/NSE) | | 231 | | 241 | | 184 | | 85 | | 4 |
| MDUFA IV Decision Within 90 FDA Days | | 230 | | 237 | | 122 | | 13 | | 2 |
| 510(k)s Pending MDUFA IV Decision | | 0 | | 0 | | 31 | | 97 | | 83 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | | 0 | | 0 | | 31 | | 92 | | 38 |
| Current Performance Percent Within 90 FDA Days | | 99.57% | | 98.34% | | 56.74% | | 7.34% | | 4.76% |

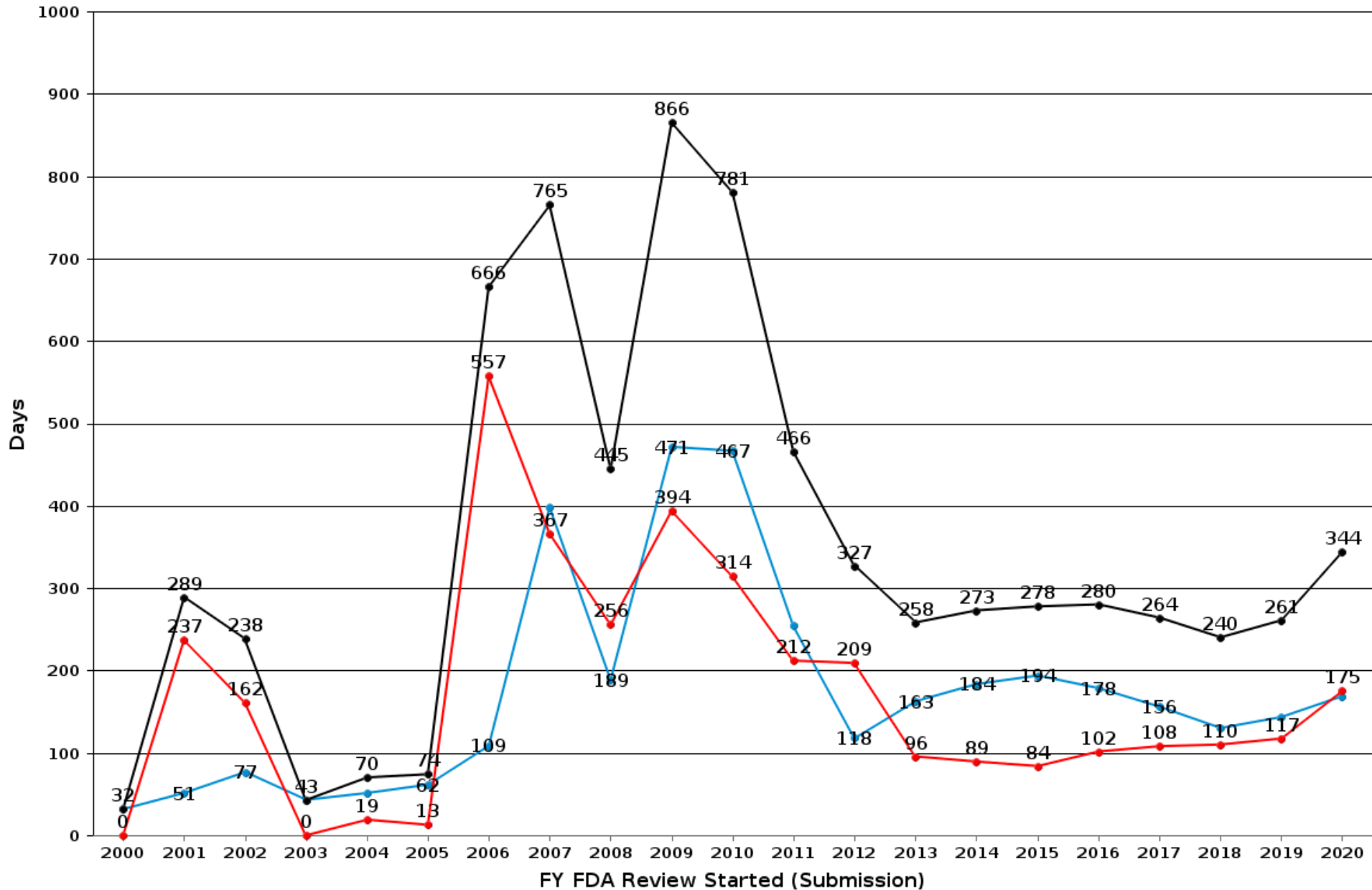
Section 7 510(k) Annual General Metrics - Annual Metrics and Goals will be reported in the Annual Report.

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De Novos

Q2FY2022

De Novo Average Days to MDUFA Decision as of: 3/31/22

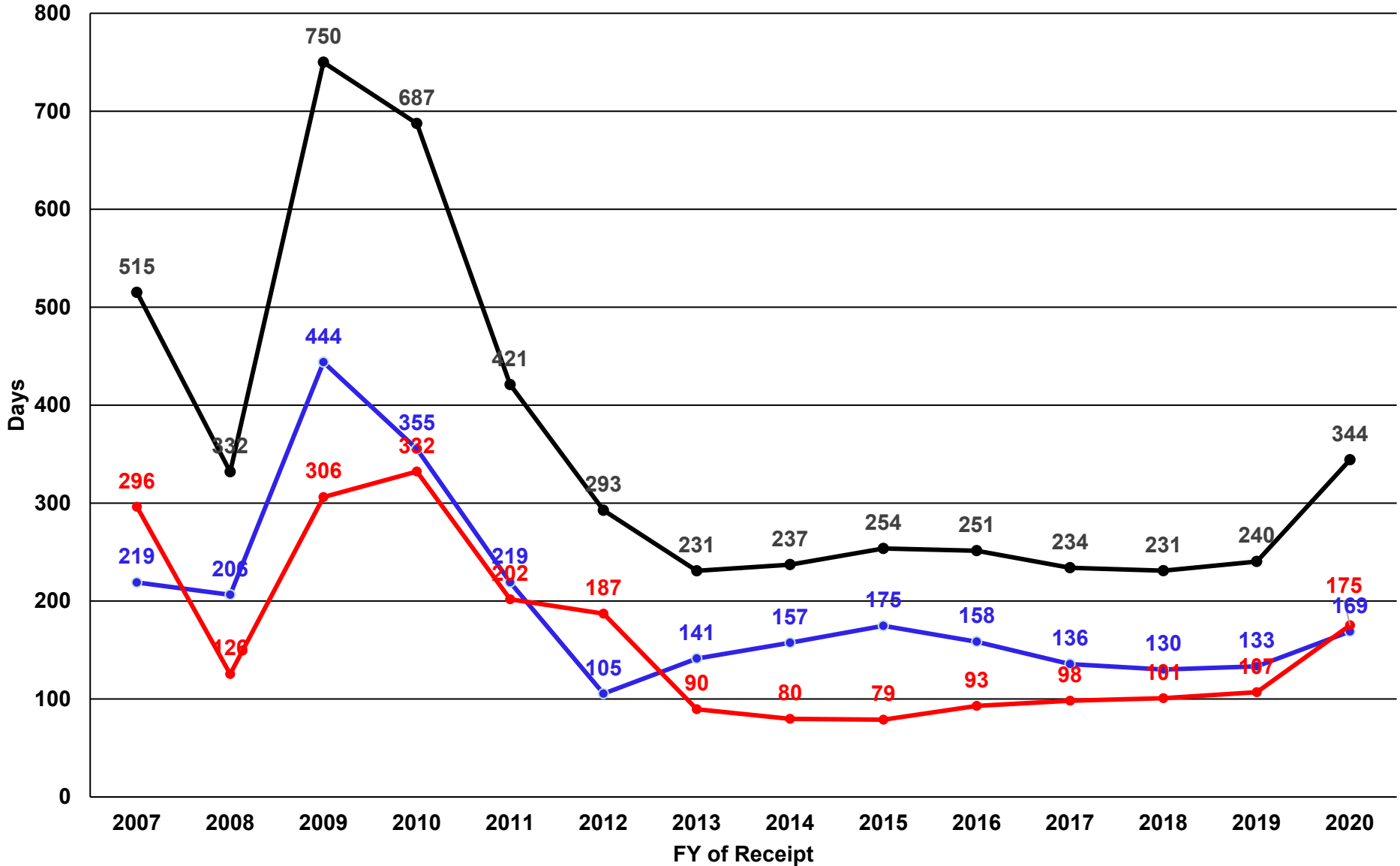


Cohorts not yet closed: 2020: 93.75%

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

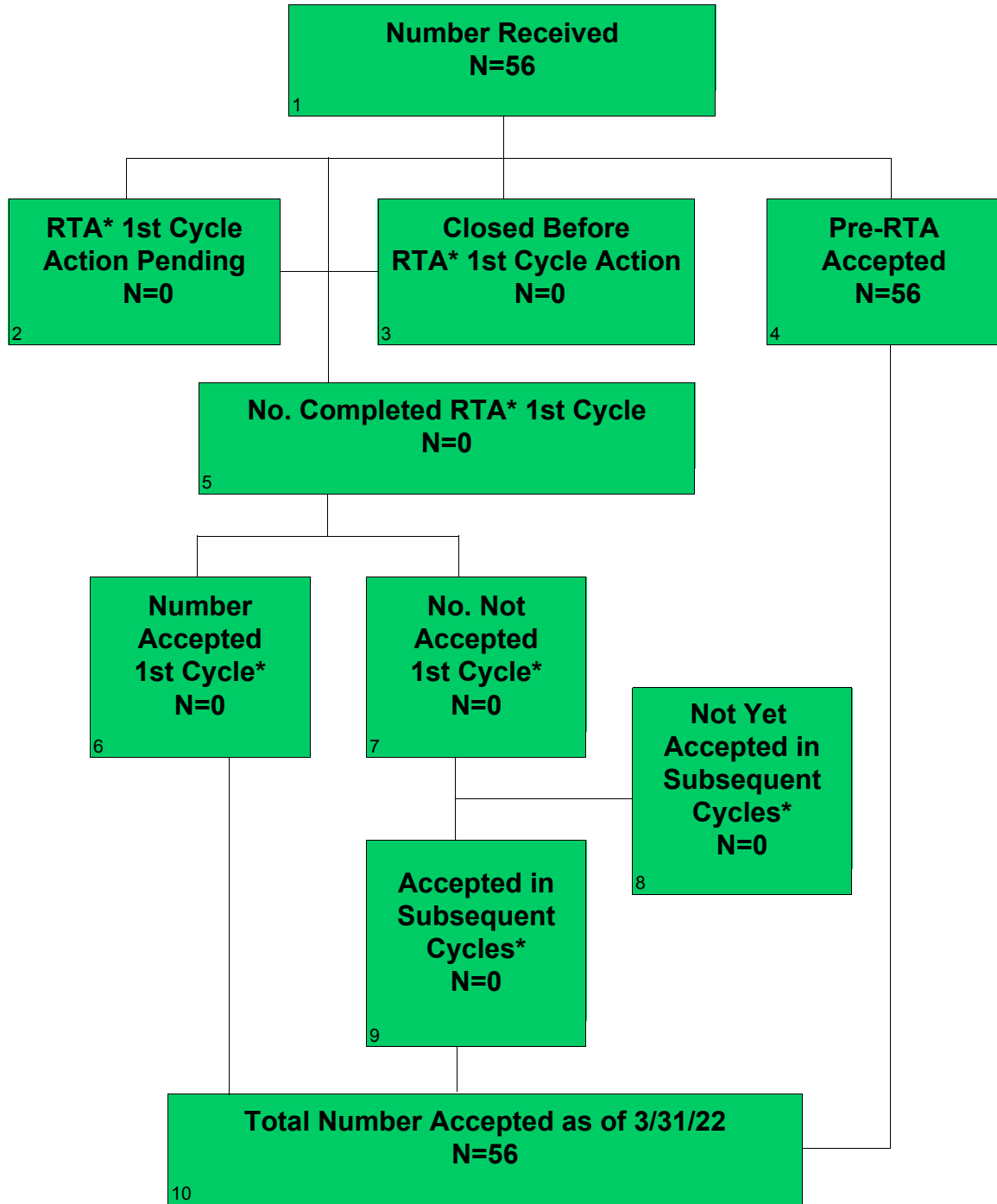
Average Time to MDUFA Decision: De Novos

(93.8% closure comparison)



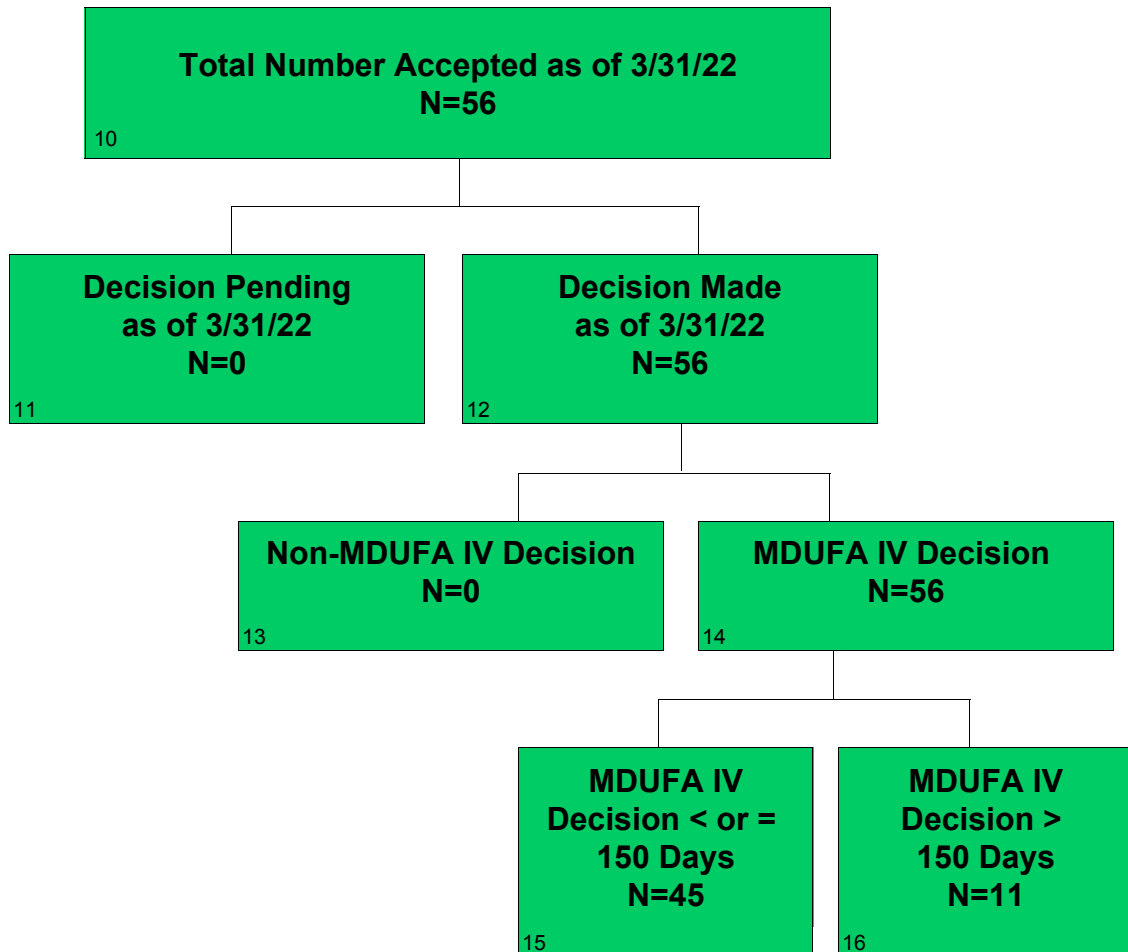
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CDRH De Novo - FY 2018 as of 3/31/22

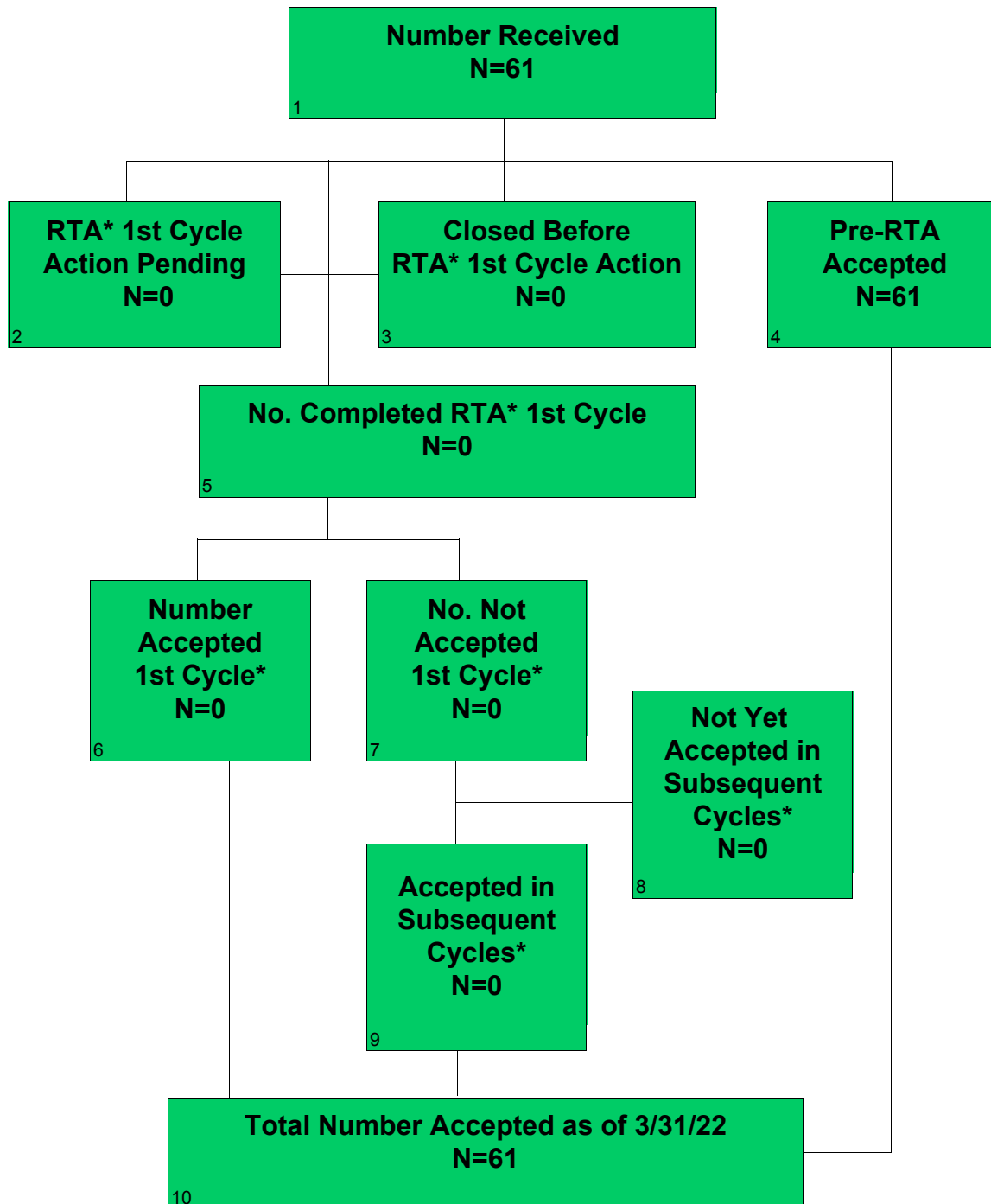


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018 as of 3/31/22 Continued

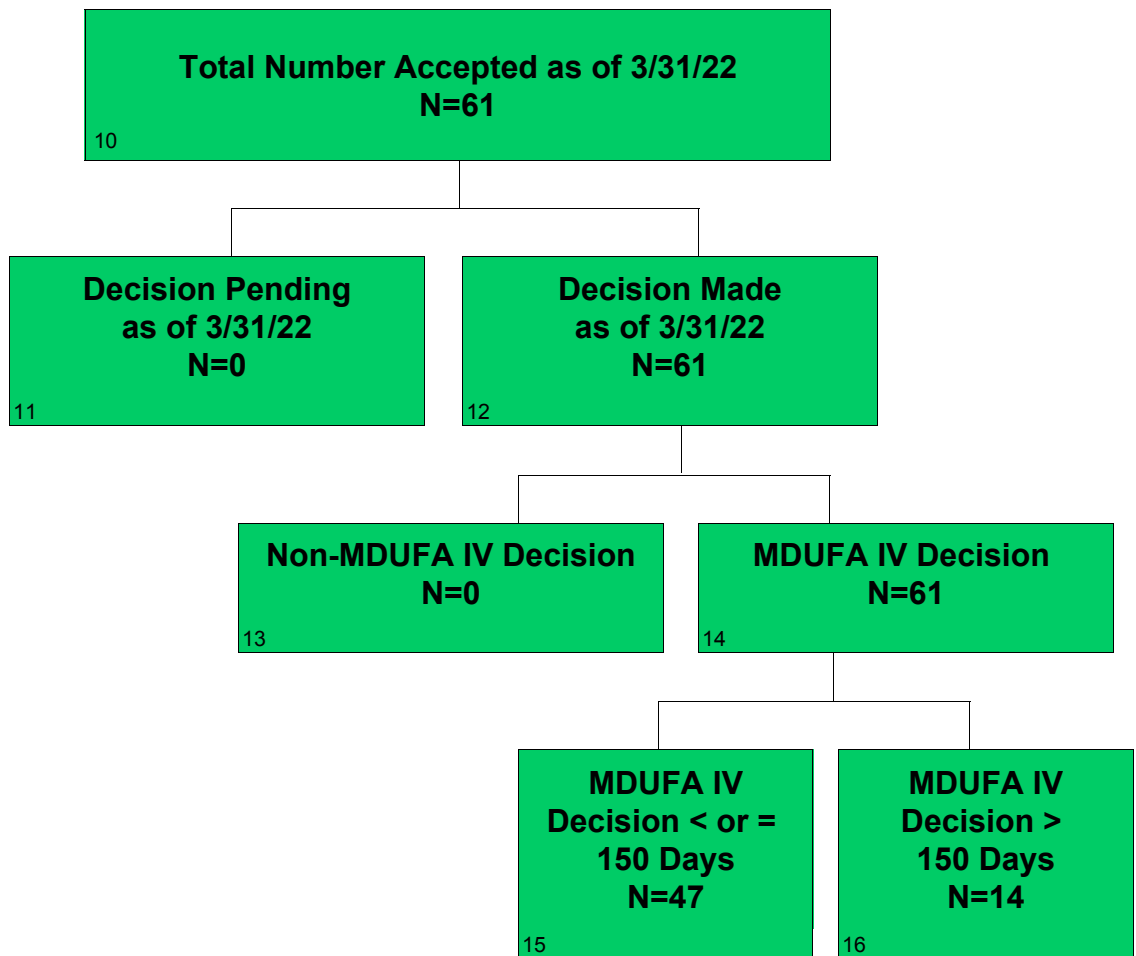


CDRH De Novo - FY 2019 as of 3/31/22

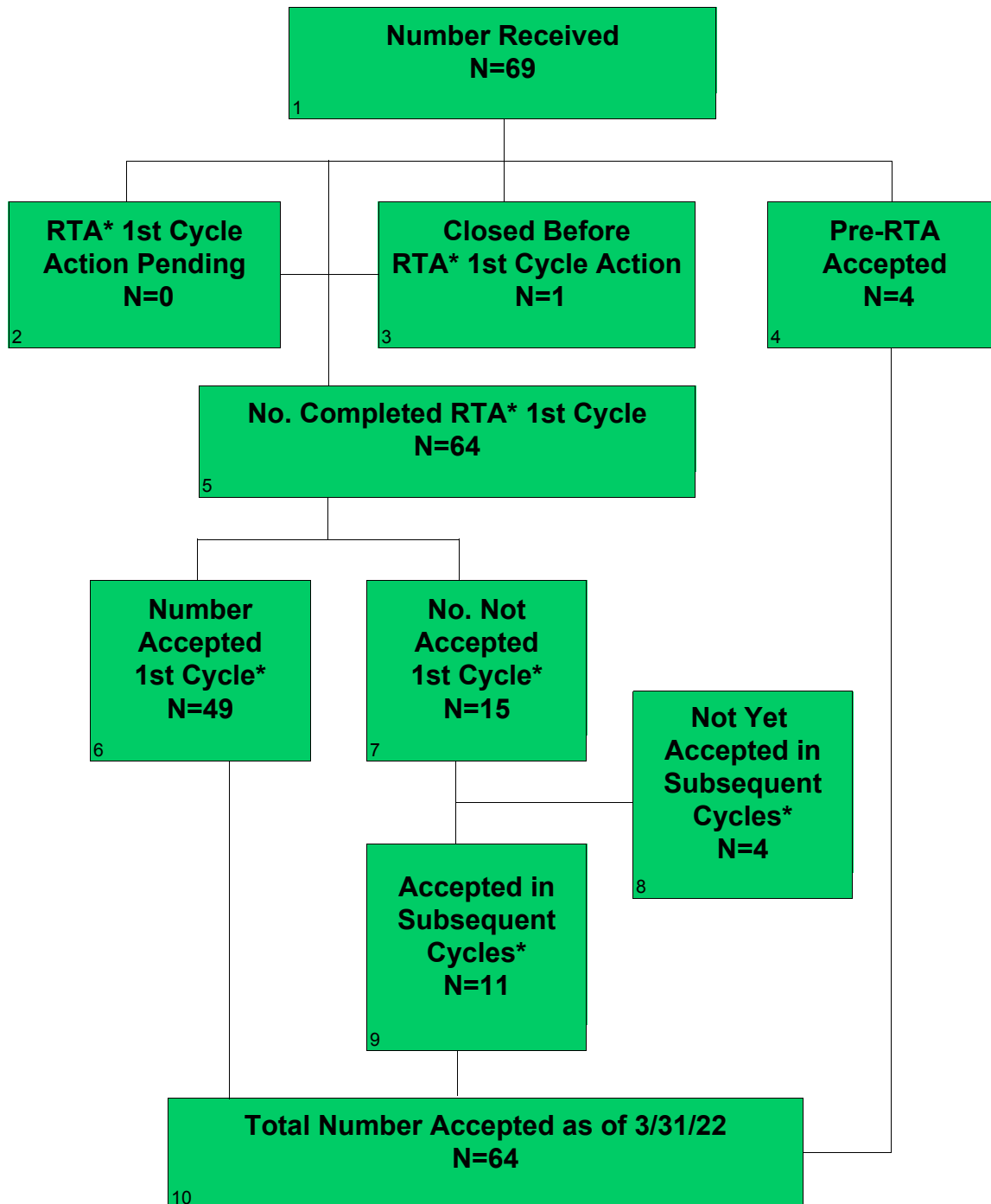


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019 as of 3/31/22 Continued

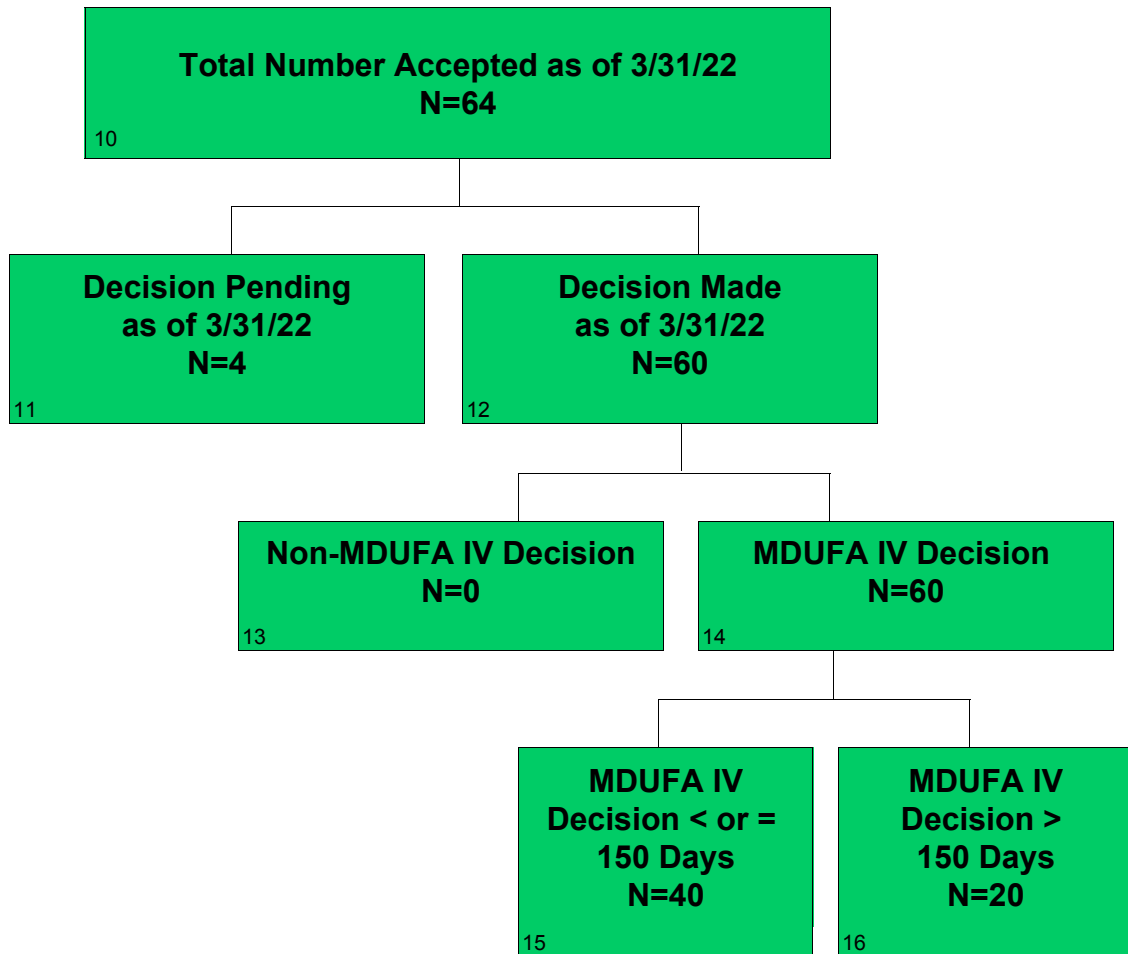


CDRH De Novo - FY 2020 as of 3/31/22

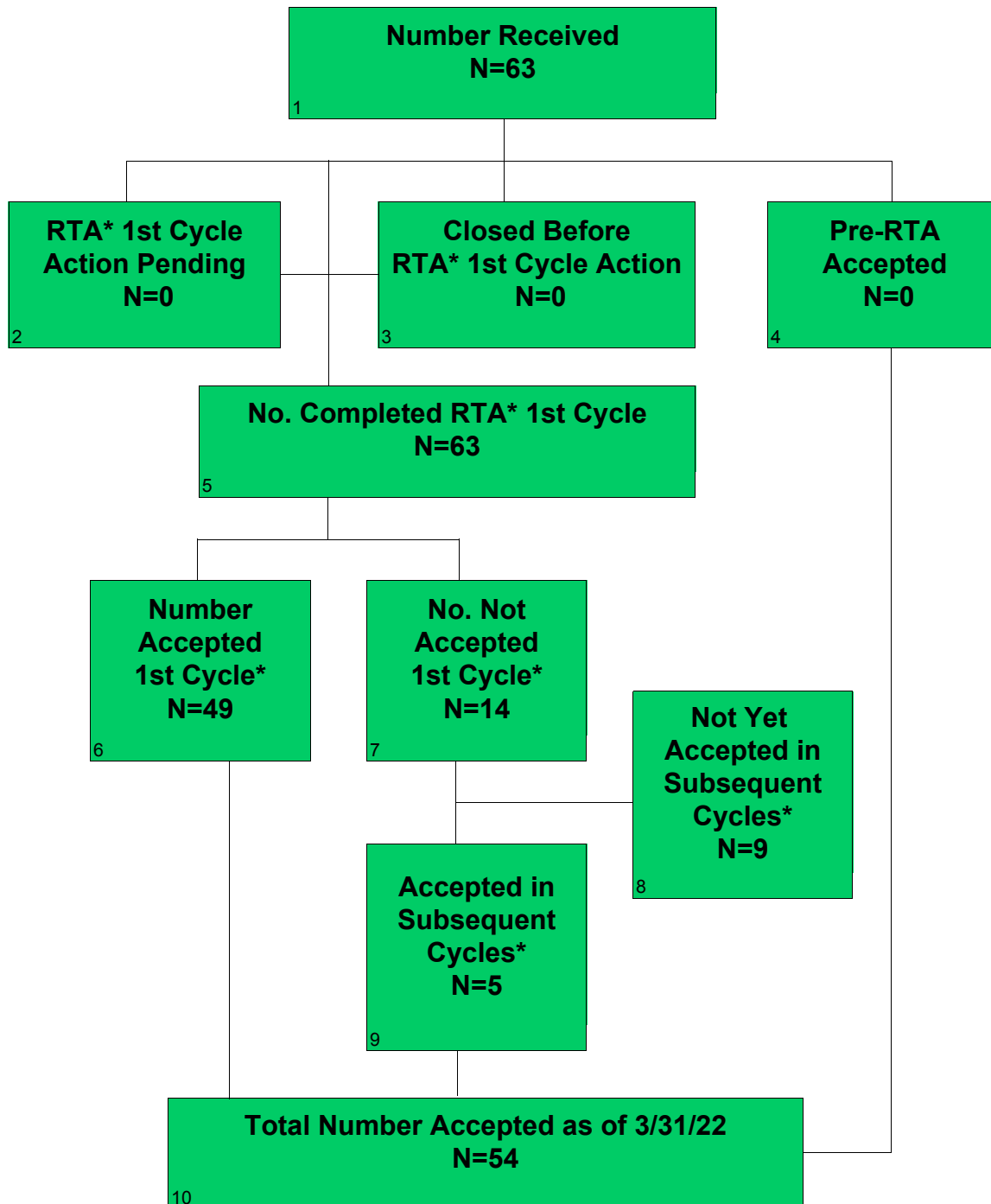


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020 as of 3/31/22 Continued

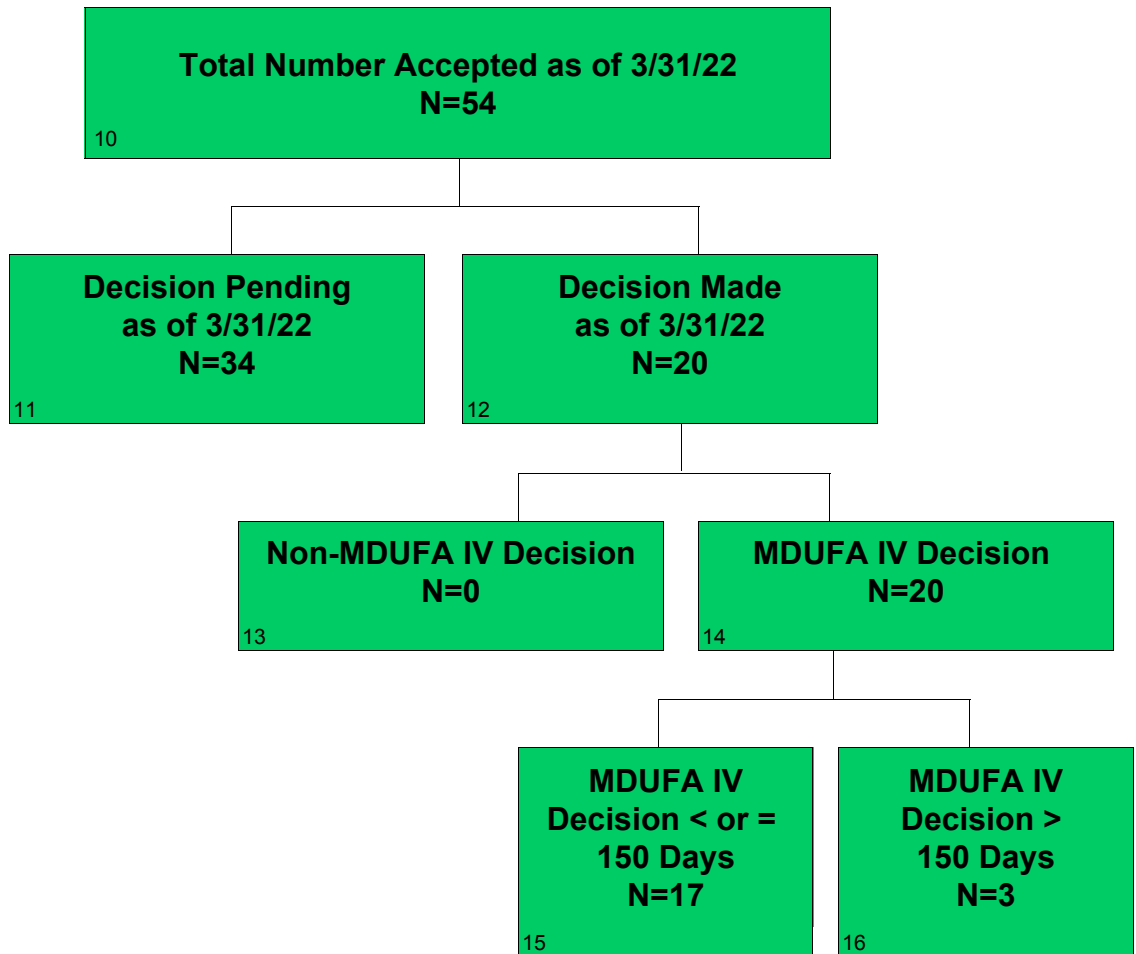


CDRH De Novo - FY 2021 as of 3/31/22

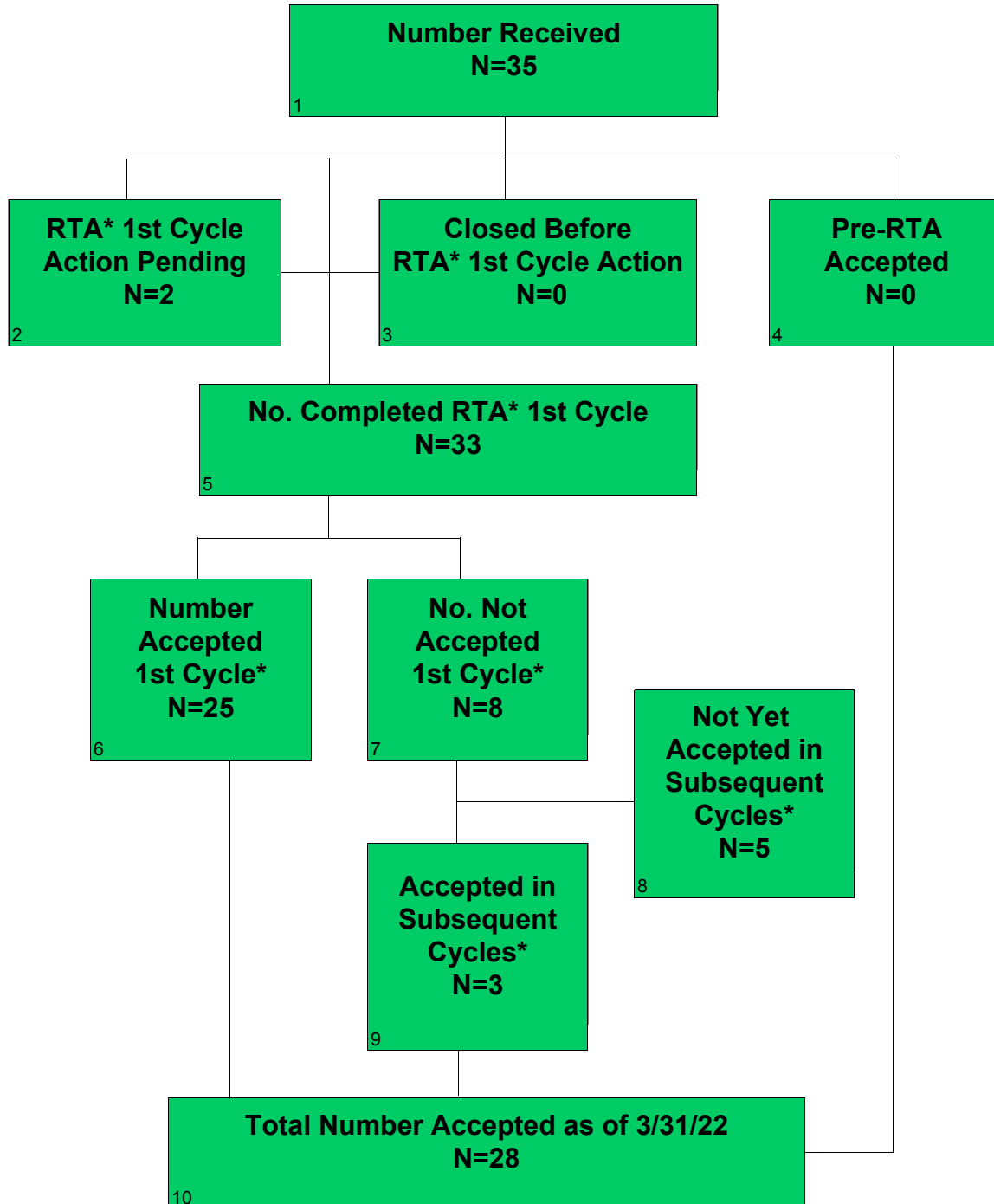


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2021 as of 3/31/22 Continued

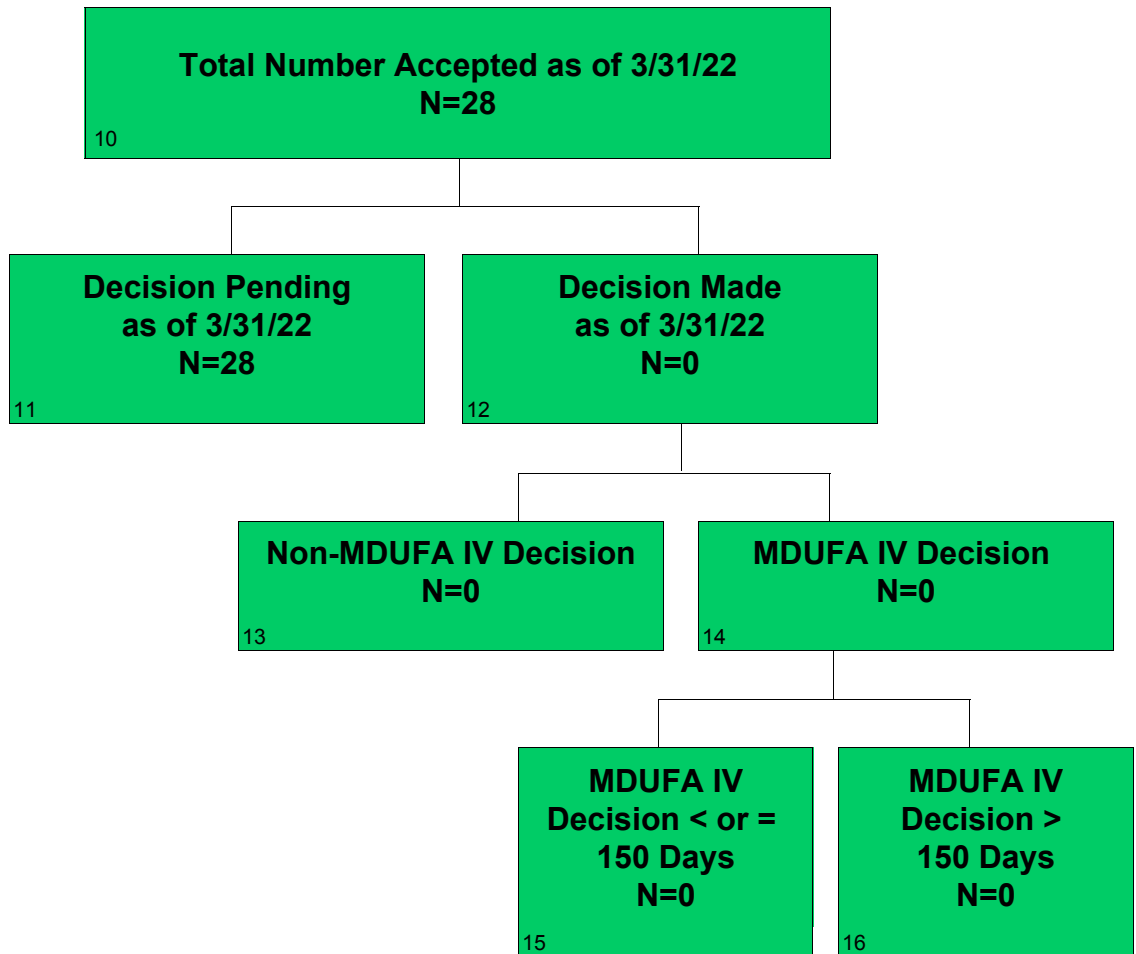


CDRH De Novo - FY 2022 as of 3/31/22



*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2022 as of 3/31/22 Continued



Section 8 De Novo Center Level Metrics

Table 8.1 CDRH - De Novo Acceptance Review Decision*

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 56 | 61 | 69 | 63 | 35 |
| Closed Before RTA Action | N/A | N/A | 1 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 46 | 41 | 21 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 3 | 8 | 4 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 2 |
| Number Not Accepted | N/A | N/A | 15 | 14 | 8 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 23.44% | 22.22% | 24.24% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

Table 8.2 CDRH - De Novo MDUFA IV Decision Performance Goals

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 65% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 56 | 61 | 64 | 54 | 28 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 56 | 61 | 60 | 20 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 45 | 47 | 40 | 17 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 4 | 34 | 28 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 4 | 10 | 0 |
| Current Performance Percent Within 150 FDA Days | 80.36% | 77.05% | 62.50% | 56.67% | 0.00% |

Table 8.3 CDRH - De Novo Time to MDUFA IV Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.57 | 1.61 | 1.77 | 1.80 | 0.00 |
| Number With MDUFA IV Decision | 56 | 61 | 60 | 20 | 0 |
| Average FDA Days to MDUFA IV Decision | 130.13 | 143.57 | 168.93 | 151.30 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 75 | 76 | 114 | 141 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 145 | 130 | 149 | 149 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 150 | 148 | 150 | 149 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 150 | 180 | 211 | 150 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 254 | 485 | 467 | 270 | 0 |
| Average Industry Days to MDUFA IV Decision | 110.13 | 117.44 | 175.30 | 80.95 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 23 | 36 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 89 | 29 | 132 | 69 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 166 | 177 | 209 | 86 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 180 | 204 | 320 | 133 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 389 | 373 | 427 | 177 | 0 |
| Average Total Days to MDUFA IV Decision | 240.25 | 261.02 | 344.23 | 232.25 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 145 | 107 | 210 | 181 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 251 | 179 | 311 | 220 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 292 | 304 | 390 | 244 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 324 | 388 | 468 | 282 | 0 |
| Maximum Total Days to MDUFA IV Decision | 463 | 680 | 668 | 436 | 0 |

Table 8.4 CDRH - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 56 | 61 | 64 | 54 | 28 |
| Number With MDUFA IV Decisions | 56 | 61 | 60 | 20 | 0 |
| Number With Granted Decisions | 25 | 28 | 31 | 12 | 0 |
| Number With Declined Decisions | 15 | 15 | 16 | 4 | 0 |
| Number of Withdrawals | 10 | 13 | 8 | 4 | 0 |
| Number Deleted | 6 | 5 | 5 | 0 | 0 |
| Rate of Granted Decisions | 44.64% | 45.90% | 51.67% | 60.00% | 0.00% |
| Rate of Declined Decisions | 26.79% | 24.59% | 26.67% | 20.00% | 0.00% |
| Rate of Withdrawals | 17.86% | 21.31% | 13.33% | 20.00% | 0.00% |
| Rate of Deleted | 10.71% | 8.20% | 8.33% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 11 | 14 | 20 | 3 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 192.45 | 248.29 | 258.95 | 232.33 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 127.27 | 218.64 | 185.05 | 101.67 | 0.00 |

Table 8.6 CDRH - LDT De Novo MDUFA IV Decision Metrics

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 1 | 5 | 2 | 0 | 1 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 1 | 5 | 1 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 1 | 2 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 1 | 0 | 1 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 1 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 100.00% | 40.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 15 | 14 | 16 | 13 | 4 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 15 | 14 | 14 | 2 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 15 | 14 | 9 | 1 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 2 | 11 | 4 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 2 | 8 | 0 |
| Current Performance Percent Within 150 FDA Days | 100.00% | 100.00% | 56.25% | 10.00% | 0.00% |

Section 8 De Novo Office Level Metrics

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 8 | 5 | 13 | 11 | 6 |
| Closed Before RTA Action | N/A | N/A | 0 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 10 | 8 | 2 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Not Accepted | N/A | N/A | 2 | 3 | 4 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 16.67% | 27.27% | 66.67% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 60% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 8 | 5 | 13 | 10 | 4 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 8 | 5 | 12 | 3 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 5 | 4 | 10 | 3 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 1 | 7 | 4 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 1 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 62.50% | 80.00% | 76.92% | 100.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.63 | 1.80 | 1.75 | 2.00 | 0.00 |
| Number With MDUFA IV Decision | 8 | 5 | 12 | 3 | 0 |
| Average FDA Days to MDUFA IV Decision | 141.25 | 124.80 | 138.17 | 149.33 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 110 | 75 | 74 | 149 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 149 | 119 | 148 | 149 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 153 | 148 | 149 | 149 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 165 | 154 | 150 | 150 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 194 | 180 | 287 | 150 | 0 |
| Average Industry Days to MDUFA IV Decision | 106.13 | 195.20 | 197.50 | 96.33 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 9 | 185 | 108 | 78 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 45 | 192 | 152 | 81 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 75 | 199 | 259 | 93 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 167 | 206 | 312 | 112 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 389 | 212 | 366 | 131 | 0 |
| Average Total Days to MDUFA IV Decision | 247.38 | 320.00 | 335.67 | 245.67 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 157 | 268 | 262 | 228 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 199 | 304 | 313 | 231 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 260 | 336 | 370 | 242 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 332 | 360 | 435 | 261 | 0 |
| Maximum Total Days to MDUFA IV Decision | 463 | 392 | 653 | 280 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 8 | 5 | 13 | 10 | 4 |
| Number With MDUFA IV Decisions | 8 | 5 | 12 | 3 | 0 |
| Number With Granted Decisions | 5 | 2 | 5 | 2 | 0 |
| Number With Declined Decisions | 2 | 1 | 4 | 1 | 0 |
| Number of Withdrawals | 0 | 0 | 2 | 0 | 0 |
| Number Deleted | 1 | 2 | 1 | 0 | 0 |
| Rate of Granted Decisions | 62.50% | 40.00% | 41.67% | 66.67% | 0.00% |
| Rate of Declined Decisions | 25.00% | 20.00% | 33.33% | 33.33% | 0.00% |
| Rate of Withdrawals | 0.00% | 0.00% | 16.67% | 0.00% | 0.00% |
| Rate of Deleted | 12.50% | 40.00% | 8.33% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 3 | 1 | 2 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 174.67 | 180.00 | 243.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 127.00 | 212.00 | 242.50 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 5 | 9 | 8 | 6 | 3 |
| Closed Before RTA Action | N/A | N/A | 0 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 6 | 4 | 1 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 0 | 0 | 2 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Not Accepted | N/A | N/A | 1 | 2 | 0 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 14.29% | 33.33% | 0.00% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 OHT2 - Office of Cardiovascular Devices
De Novo MDUFA IV Decision Performance Goals**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 60% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 5 | 9 | 8 | 5 | 3 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 5 | 9 | 8 | 3 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 5 | 8 | 3 | 3 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 2 | 3 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 100.00% | 88.89% | 37.50% | 100.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.20 | 1.44 | 2.00 | 1.67 | 0.00 |
| Number With MDUFA IV Decision | 5 | 9 | 8 | 3 | 0 |
| Average FDA Days to MDUFA IV Decision | 74.00 | 144.00 | 200.50 | 122.33 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 32 | 86 | 150 | 102 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 58 | 132 | 162 | 129 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 79 | 148 | 214 | 144 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 98 | 150 | 253 | 147 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 148 | 348 | 357 | 150 | 0 |
| Average Industry Days to MDUFA IV Decision | 112.40 | 71.11 | 161.75 | 106.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 24 | 64 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 98 | 6 | 96 | 91 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 171 | 64 | 177 | 119 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 188 | 163 | 279 | 148 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 217 | 207 | 427 | 177 | 0 |
| Average Total Days to MDUFA IV Decision | 186.40 | 215.11 | 362.25 | 228.33 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 32 | 117 | 286 | 208 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 173 | 153 | 350 | 237 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 277 | 213 | 363 | 252 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 296 | 281 | 448 | 253 | 0 |
| Maximum Total Days to MDUFA IV Decision | 312 | 526 | 651 | 254 | 0 |

Table 8.4 OHT2 - Office of Cardiovascular Devices

De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 5 | 9 | 8 | 5 | 3 |
| Number With MDUFA IV Decisions | 5 | 9 | 8 | 3 | 0 |
| Number With Granted Decisions | 3 | 2 | 5 | 2 | 0 |
| Number With Declined Decisions | 0 | 5 | 2 | 0 | 0 |
| Number of Withdrawals | 0 | 1 | 1 | 1 | 0 |
| Number Deleted | 2 | 1 | 0 | 0 | 0 |
| Rate of Granted Decisions | 60.00% | 22.22% | 62.50% | 66.67% | 0.00% |
| Rate of Declined Decisions | 0.00% | 55.56% | 25.00% | 0.00% | 0.00% |
| Rate of Withdrawals | 0.00% | 11.11% | 12.50% | 33.33% | 0.00% |
| Rate of Deleted | 40.00% | 11.11% | 0.00% | 0.00% | 0.00% |

Table 8.5 OHT2 - Office of Cardiovascular Devices

De Novo Performance Metrics-Submissions Missing Performance Goals

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 1 | 5 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 348.00 | 246.20 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 178.00 | 170.00 | 0.00 | 0.00 |

Table 8.6 OHT2 - Office of Cardiovascular Devices

LDT De Novo MDUFA IV Decision Metrics

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

Table 8.7 OHT2 - Office of Cardiovascular Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 4 | 11 | 6 | 6 | 5 |
| Closed Before RTA Action | N/A | N/A | 0 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 4 | 5 | 4 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Not Accepted | N/A | N/A | 2 | 1 | 1 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 33.33% | 16.67% | 20.00% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 60% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 4 | 11 | 6 | 6 | 4 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 4 | 11 | 6 | 2 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 3 | 5 | 4 | 2 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 4 | 4 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 75.00% | 45.45% | 66.67% | 100.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.50 | 1.82 | 1.83 | 2.00 | 0.00 |
| Number With MDUFA IV Decision | 4 | 11 | 6 | 2 | 0 |
| Average FDA Days to MDUFA IV Decision | 100.00 | 186.55 | 161.50 | 148.50 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 57 | 148 | 148 | 148 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 97 | 150 | 150 | 148 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 135 | 191 | 150 | 149 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 149 | 211 | 203 | 149 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 151 | 327 | 243 | 150 | 0 |
| Average Industry Days to MDUFA IV Decision | 136.75 | 168.45 | 116.83 | 61.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 100 | 136 | 21 | 43 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 169 | 175 | 24 | 55 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 175 | 177 | 61 | 67 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 187 | 241 | 222 | 79 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 203 | 338 | 363 | 91 | 0 |
| Average Total Days to MDUFA IV Decision | 236.75 | 355.00 | 278.33 | 209.50 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 179 | 283 | 209 | 192 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 293 | 347 | 213 | 204 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 312 | 368 | 267 | 215 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 321 | 416 | 372 | 227 | 0 |
| Maximum Total Days to MDUFA IV Decision | 325 | 617 | 438 | 238 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 4 | 11 | 6 | 6 | 4 |
| Number With MDUFA IV Decisions | 4 | 11 | 6 | 2 | 0 |
| Number With Granted Decisions | 0 | 8 | 3 | 2 | 0 |
| Number With Declined Decisions | 3 | 3 | 2 | 0 | 0 |
| Number of Withdrawals | 0 | 0 | 0 | 0 | 0 |
| Number Deleted | 1 | 0 | 1 | 0 | 0 |
| Rate of Granted Decisions | 0.00% | 72.73% | 50.00% | 100.00% | 0.00% |
| Rate of Declined Decisions | 75.00% | 27.27% | 33.33% | 0.00% | 0.00% |
| Rate of Withdrawals | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| Rate of Deleted | 25.00% | 0.00% | 16.67% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 1 | 6 | 2 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 151.00 | 230.33 | 223.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 167.00 | 212.00 | 17.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 5 | 6 | 8 | 8 | 3 |
| Closed Before RTA Action | N/A | N/A | 0 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 3 | 4 | 2 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 1 | 1 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Not Accepted | N/A | N/A | 3 | 3 | 1 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 42.86% | 37.50% | 33.33% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 60% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 5 | 6 | 7 | 5 | 3 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 5 | 6 | 7 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 3 | 4 | 3 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 5 | 3 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 1 | 0 |
| Current Performance Percent Within 150 FDA Days | 60.00% | 66.67% | 42.86% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.80 | 1.50 | 1.57 | 0.00 | 0.00 |
| Number With MDUFA IV Decision | 5 | 6 | 7 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 147.40 | 182.50 | 165.14 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 133 | 93 | 113 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 150 | 98 | 146 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 151 | 107 | 174 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 167 | 236 | 189 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 221 | 485 | 323 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 90.80 | 125.83 | 231.86 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 12 | 0 | 161 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 65 | 0 | 248 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 124 | 187 | 267 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 165 | 195 | 331 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 179 | 373 | 365 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 238.20 | 308.33 | 397.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 145 | 93 | 331 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 215 | 107 | 408 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 275 | 285 | 436 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 332 | 609 | 469 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 400 | 680 | 668 | 0 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 5 | 6 | 7 | 5 | 3 |
| Number With MDUFA IV Decisions | 5 | 6 | 7 | 0 | 0 |
| Number With Granted Decisions | 3 | 1 | 1 | 0 | 0 |
| Number With Declined Decisions | 1 | 3 | 3 | 0 | 0 |
| Number of Withdrawals | 1 | 1 | 2 | 0 | 0 |
| Number Deleted | 0 | 1 | 1 | 0 | 0 |
| Rate of Granted Decisions | 60.00% | 16.67% | 14.29% | 0.00% | 0.00% |
| Rate of Declined Decisions | 20.00% | 50.00% | 42.86% | 0.00% | 0.00% |
| Rate of Withdrawals | 20.00% | 16.67% | 28.57% | 0.00% | 0.00% |
| Rate of Deleted | 0.00% | 16.67% | 14.29% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 2 | 2 | 4 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 187.00 | 360.50 | 215.50 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 170.50 | 284.00 | 246.25 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 13 | 6 | 7 | 9 | 4 |
| Closed Before RTA Action | N/A | N/A | 0 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 5 | 7 | 3 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 1 |
| Number Not Accepted | N/A | N/A | 2 | 2 | 0 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 28.57% | 22.22% | 0.00% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 60% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 13 | 6 | 6 | 7 | 3 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 13 | 6 | 6 | 6 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 9 | 6 | 5 | 5 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 1 | 3 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 69.23% | 100.00% | 83.33% | 83.33% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.77 | 1.33 | 1.83 | 1.83 | 0.00 |
| Number With MDUFA IV Decision | 13 | 6 | 6 | 6 | 0 |
| Average FDA Days to MDUFA IV Decision | 153.00 | 113.33 | 138.67 | 156.33 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 104 | 76 | 149 | 148 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 148 | 127 | 149 | 149 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 150 | 136 | 150 | 150 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 219 | 149 | 150 | 150 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 254 | 150 | 175 | 270 | 0 |
| Average Industry Days to MDUFA IV Decision | 106.08 | 20.17 | 134.67 | 83.33 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 39 | 0 | 14 | 51 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 82 | 0 | 84 | 62 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 164 | 0 | 125 | 80 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 174 | 45 | 169 | 141 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 183 | 76 | 416 | 166 | 0 |
| Average Total Days to MDUFA IV Decision | 259.08 | 133.50 | 273.33 | 239.67 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 226 | 76 | 163 | 201 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 266 | 127 | 234 | 211 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 316 | 136 | 274 | 230 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 323 | 195 | 344 | 289 | 0 |
| Maximum Total Days to MDUFA IV Decision | 371 | 225 | 566 | 436 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 13 | 6 | 6 | 7 | 3 |
| Number With MDUFA IV Decisions | 13 | 6 | 6 | 6 | 0 |
| Number With Granted Decisions | 3 | 2 | 6 | 3 | 0 |
| Number With Declined Decisions | 7 | 0 | 0 | 2 | 0 |
| Number of Withdrawals | 3 | 4 | 0 | 1 | 0 |
| Number Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Granted Decisions | 23.08% | 33.33% | 100.00% | 50.00% | 0.00% |
| Rate of Declined Decisions | 53.85% | 0.00% | 0.00% | 33.33% | 0.00% |
| Rate of Withdrawals | 23.08% | 66.67% | 0.00% | 16.67% | 0.00% |
| Rate of Deleted | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 4 | 0 | 1 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 229.25 | 0.00 | 175.00 | 270.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 82.75 | 0.00 | 169.00 | 166.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 4 | 4 | 5 | 6 | 4 |
| Closed Before RTA Action | N/A | N/A | 0 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 5 | 5 | 3 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 0 | 0 | 1 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Not Accepted | N/A | N/A | 0 | 1 | 0 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 0.00% | 16.67% | 0.00% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 OHT6 - Office of Orthopedic Devices
De Novo MDUFA IV Decision Performance Goals**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 60% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 4 | 4 | 5 | 6 | 4 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 4 | 4 | 5 | 3 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 3 | 3 | 5 | 2 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 3 | 4 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 1 | 0 |
| Current Performance Percent Within 150 FDA Days | 75.00% | 75.00% | 100.00% | 50.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.50 | 1.75 | 2.00 | 1.67 | 0.00 |
| Number With MDUFA IV Decision | 4 | 4 | 5 | 3 | 0 |
| Average FDA Days to MDUFA IV Decision | 133.25 | 144.75 | 147.40 | 161.33 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 122 | 116 | 147 | 140 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 148 | 143 | 150 | 141 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 150 | 144 | 150 | 154 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 150 | 173 | 150 | 179 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 151 | 217 | 150 | 204 | 0 |
| Average Industry Days to MDUFA IV Decision | 161.00 | 178.50 | 132.60 | 57.33 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 149 | 104 | 62 | 30 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 179 | 175 | 107 | 59 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 180 | 177 | 146 | 79 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 180 | 252 | 179 | 88 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 181 | 362 | 245 | 98 | 0 |
| Average Total Days to MDUFA IV Decision | 294.25 | 323.25 | 280.00 | 218.67 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 260 | 221 | 209 | 170 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 278 | 333 | 256 | 199 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 316 | 380 | 296 | 231 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 330 | 439 | 329 | 266 | 0 |
| Maximum Total Days to MDUFA IV Decision | 331 | 505 | 395 | 302 | 0 |

Table 8.4 OHT6 - Office of Orthopedic Devices

De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 4 | 4 | 5 | 6 | 4 |
| Number With MDUFA IV Decisions | 4 | 4 | 5 | 3 | 0 |
| Number With Granted Decisions | 1 | 1 | 3 | 2 | 0 |
| Number With Declined Decisions | 1 | 3 | 2 | 0 | 0 |
| Number of Withdrawals | 1 | 0 | 0 | 1 | 0 |
| Number Deleted | 1 | 0 | 0 | 0 | 0 |
| Rate of Granted Decisions | 25.00% | 25.00% | 60.00% | 66.67% | 0.00% |
| Rate of Declined Decisions | 25.00% | 75.00% | 40.00% | 0.00% | 0.00% |
| Rate of Withdrawals | 25.00% | 0.00% | 0.00% | 33.33% | 0.00% |
| Rate of Deleted | 25.00% | 0.00% | 0.00% | 0.00% | 0.00% |

Table 8.5 OHT6 - Office of Orthopedic Devices

De Novo Performance Metrics-Submissions Missing Performance Goals

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 1 | 1 | 0 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 151.00 | 217.00 | 0.00 | 204.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 180.00 | 178.00 | 0.00 | 98.00 | 0.00 |

Table 8.6 OHT6 - Office of Orthopedic Devices

LDT De Novo MDUFA IV Decision Metrics

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

Table 8.7 OHT6 - Office of Orthopedic Devices

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 17 | 20 | 22 | 17 | 10 |
| Closed Before RTA Action | N/A | N/A | 1 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 13 | 8 | 6 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 2 | 7 | 1 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 1 |
| Number Not Accepted | N/A | N/A | 5 | 2 | 2 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 25.00% | 11.76% | 22.22% |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

**Table 8.2 OHT7 - Office of In Vitro Diagnostics and Radiological Health
De Novo MDUFA IV Decision Performance Goals**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 60% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 17 | 20 | 19 | 15 | 7 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 17 | 20 | 16 | 3 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 17 | 17 | 10 | 2 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 3 | 12 | 7 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 3 | 8 | 0 |
| Current Performance Percent Within 150 FDA Days | 100.00% | 85.00% | 52.63% | 18.18% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.47 | 1.60 | 1.63 | 1.67 | 0.00 |
| Number With MDUFA IV Decision | 17 | 20 | 16 | 3 | 0 |
| Average FDA Days to MDUFA IV Decision | 125.18 | 121.60 | 198.75 | 164.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 108 | 73 | 115 | 132 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 127 | 121 | 147 | 143 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 146 | 148 | 150 | 164 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 150 | 150 | 303 | 193 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 150 | 243 | 467 | 223 | 0 |
| Average Industry Days to MDUFA IV Decision | 101.88 | 105.25 | 191.19 | 72.67 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 71 | 16 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 84 | 0 | 171 | 33 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 169 | 168 | 232 | 68 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 179 | 220 | 326 | 123 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 189 | 276 | 364 | 177 | 0 |
| Average Total Days to MDUFA IV Decision | 227.06 | 226.85 | 389.94 | 236.67 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 137 | 99 | 210 | 178 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 183 | 150 | 402 | 235 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 277 | 278 | 441 | 276 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 313 | 337 | 502 | 301 | 0 |
| Maximum Total Days to MDUFA IV Decision | 327 | 509 | 668 | 326 | 0 |

**Table 8.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 17 | 20 | 19 | 15 | 7 |
| Number With MDUFA IV Decisions | 17 | 20 | 16 | 3 | 0 |
| Number With Granted Decisions | 10 | 12 | 8 | 1 | 0 |
| Number With Declined Decisions | 1 | 0 | 3 | 1 | 0 |
| Number of Withdrawals | 5 | 7 | 3 | 1 | 0 |
| Number Deleted | 1 | 1 | 2 | 0 | 0 |
| Rate of Granted Decisions | 58.82% | 60.00% | 50.00% | 33.33% | 0.00% |
| Rate of Declined Decisions | 5.88% | 0.00% | 18.75% | 33.33% | 0.00% |
| Rate of Withdrawals | 29.41% | 35.00% | 18.75% | 33.33% | 0.00% |
| Rate of Deleted | 5.88% | 5.00% | 12.50% | 0.00% | 0.00% |

**Table 8.5 OHT7 - Office of In Vitro Diagnostics and Radiological Health
De Novo Performance Metrics-Submissions Missing Performance Goals**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 3 | 6 | 1 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 209.33 | 329.83 | 223.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 217.67 | 196.33 | 41.00 | 0.00 |

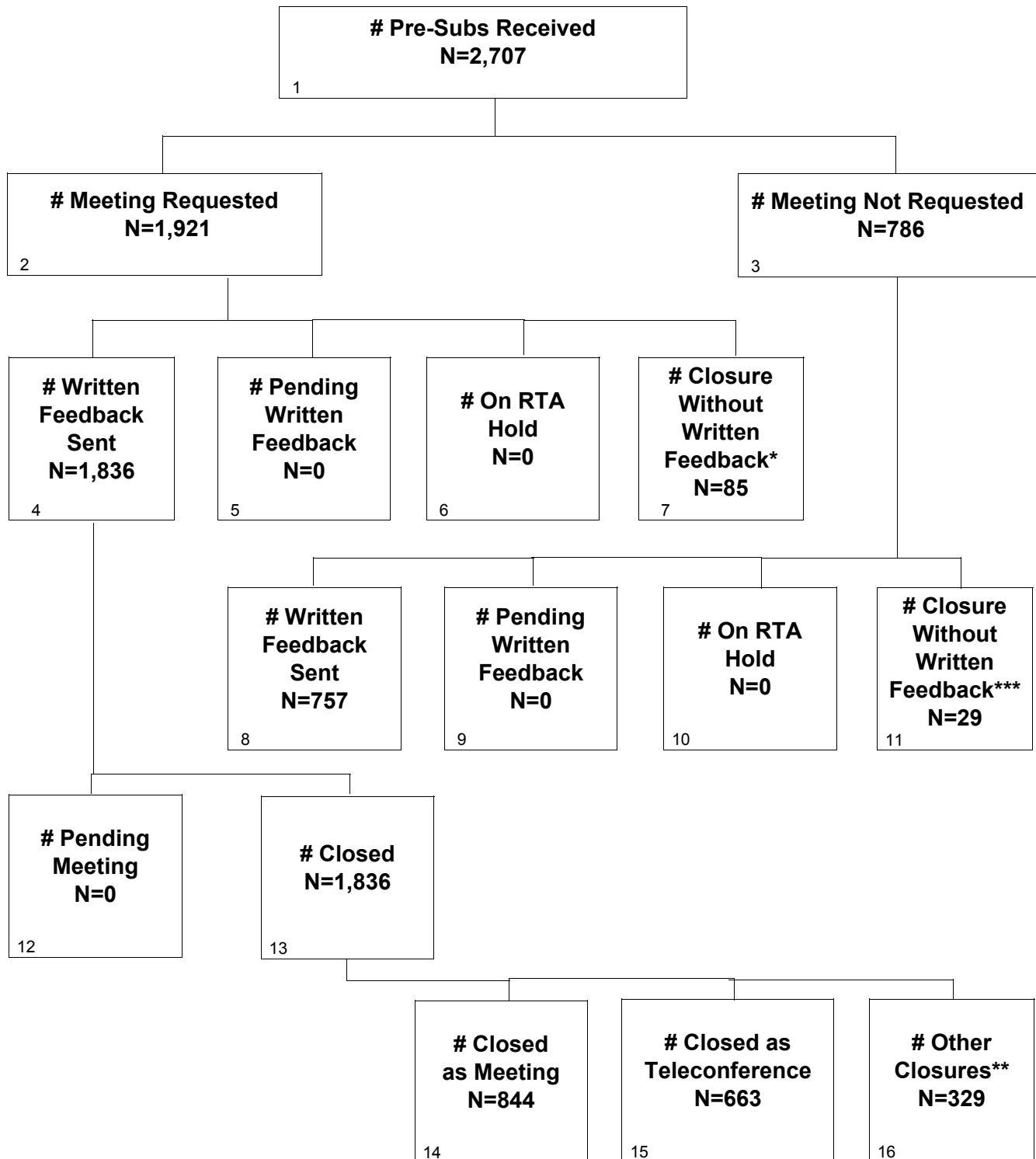
**Table 8.6 OHT7 - Office of In Vitro Diagnostics and Radiological Health
LDT De Novo MDUFA IV Decision Metrics**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 1 | 5 | 2 | 0 | 1 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 1 | 5 | 1 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 1 | 2 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 1 | 0 | 1 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 1 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | 100.00% | 40.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| De Novos Accepted | 15 | 14 | 16 | 13 | 4 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 15 | 14 | 14 | 2 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 15 | 14 | 9 | 1 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 2 | 11 | 4 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 2 | 8 | 0 |
| Current Performance Percent Within 150 FDA Days | 100.00% | 100.00% | 56.25% | 10.00% | 0.00% |

CDRH Pre-Sub - FY 2018 as of 3/31/22

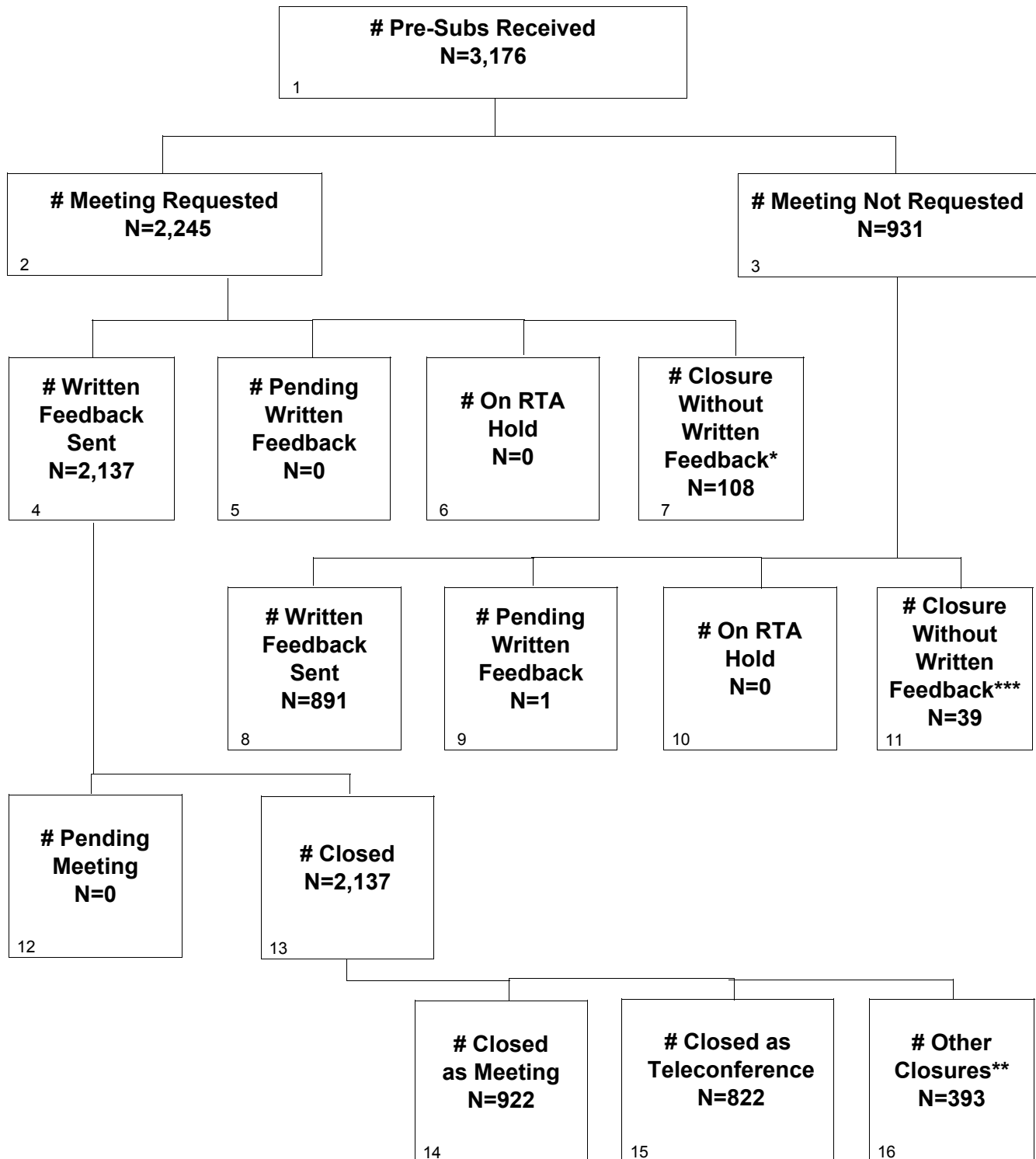


* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

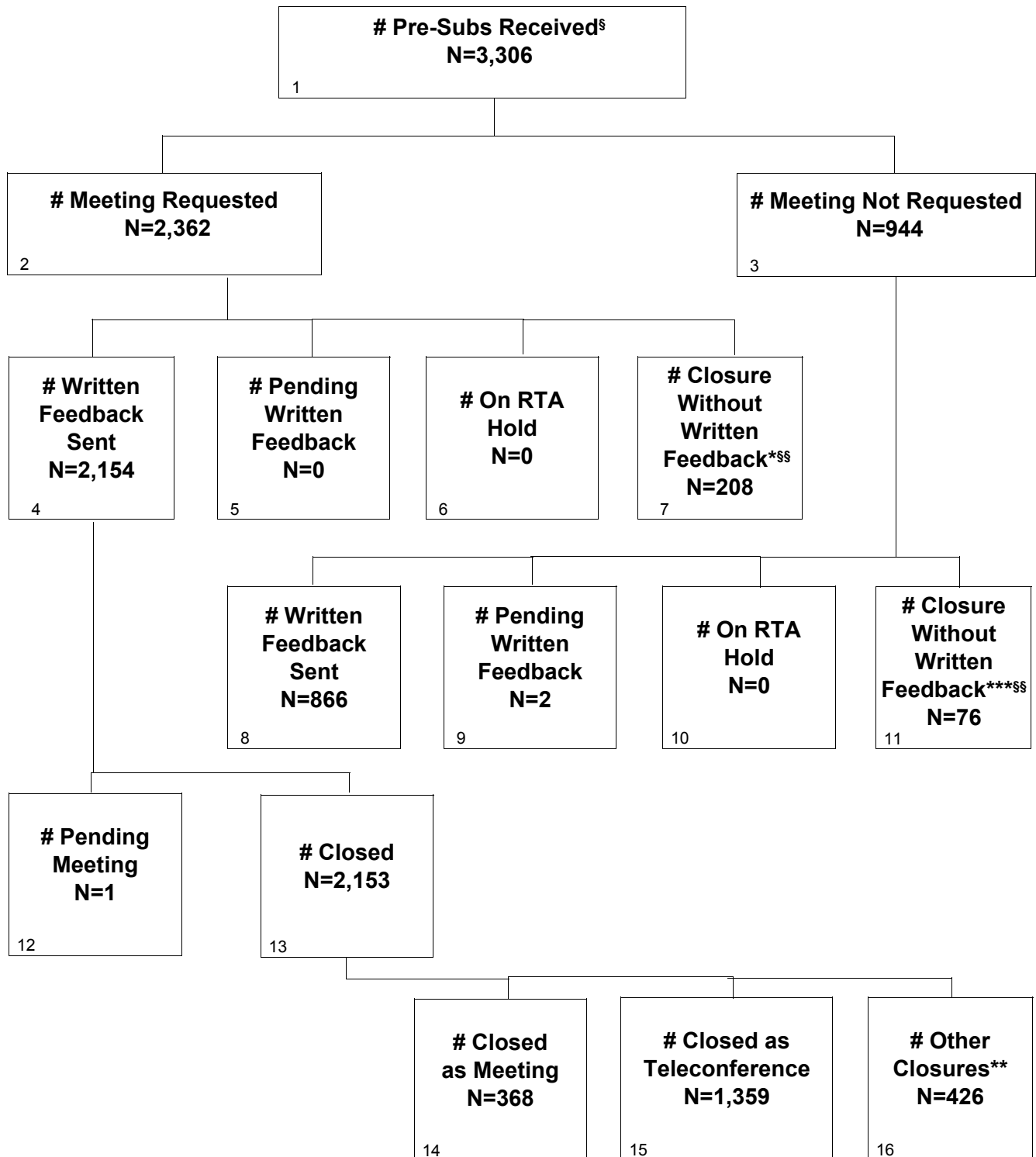
*** Closures include JTRX, JPND, DELE & WTDR

CDRH Pre-Sub - FY 2019 as of 3/31/22



* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE, WTDR & CCOV
 ** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR
 *** Closures include JTRX, JPND, DELE & WTDR

CDRH Pre-Sub - FY 2020 as of 3/31/22



* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE, WTDR & CCOV

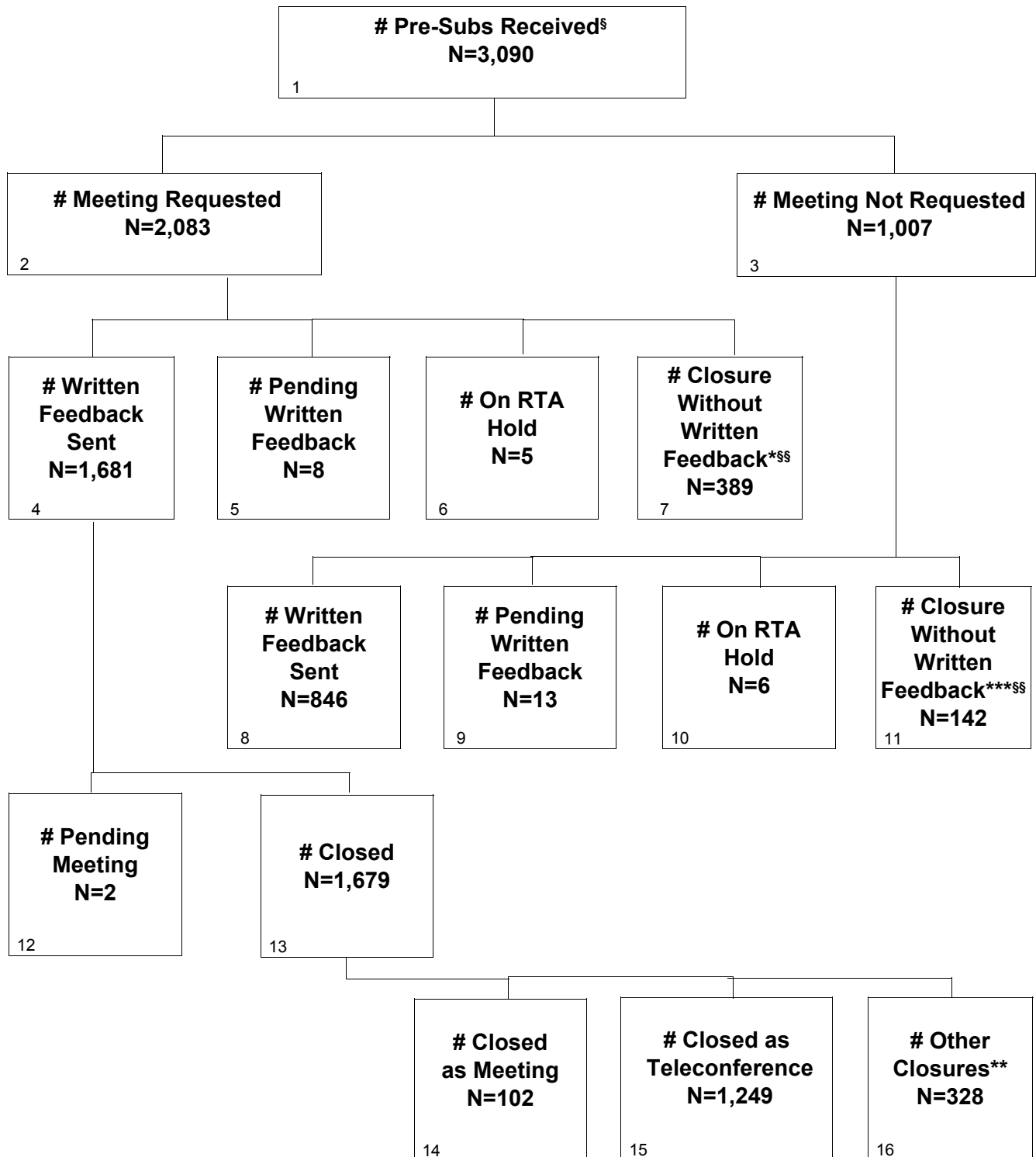
** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

*** Closures include JTRX, JPND, DELE & WTDR

§ Does not include data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

§§ Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

CDRH Pre-Sub - FY 2021 as of 3/31/22



* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE, WTDR & CCOV

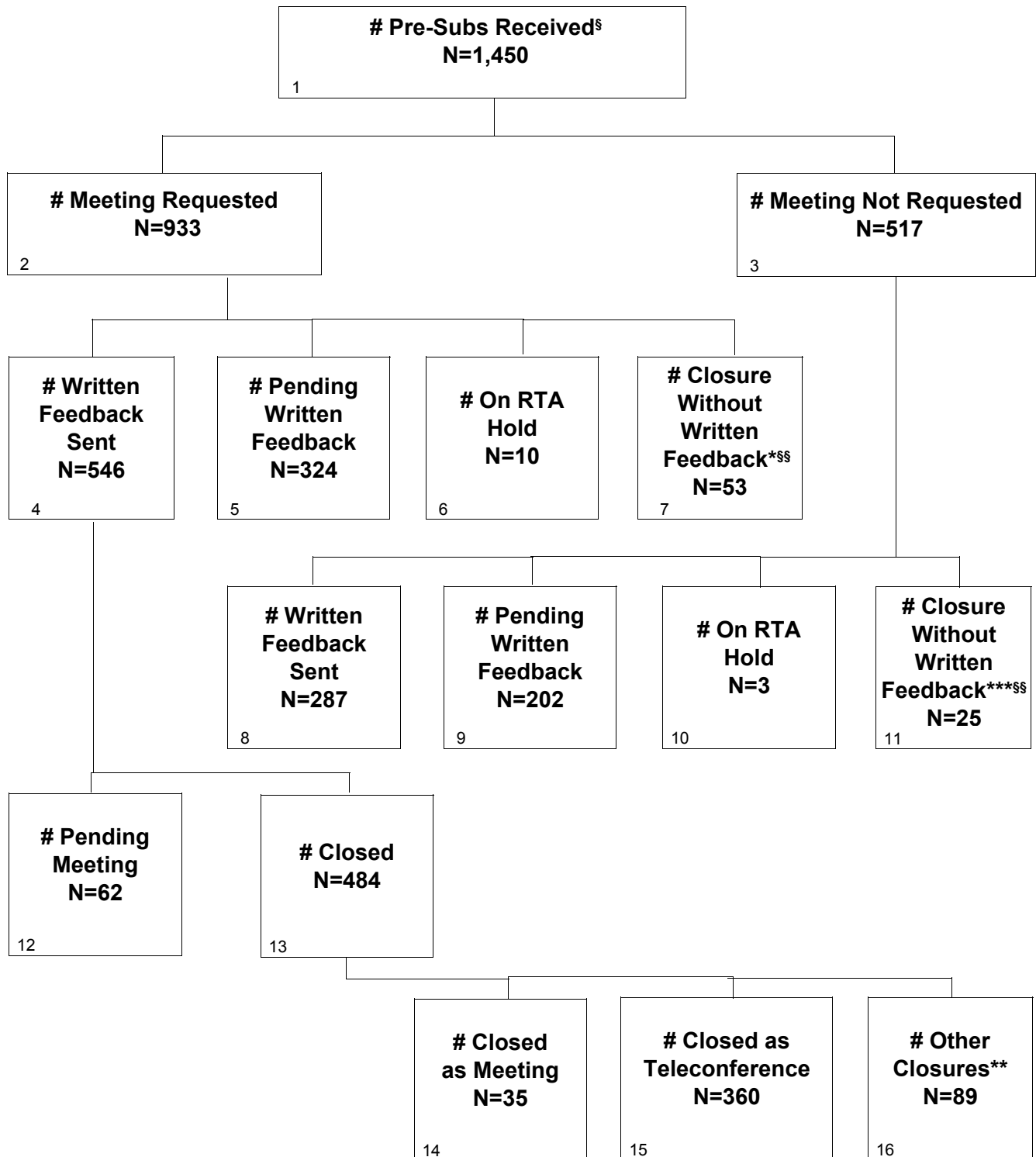
** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

*** Closures include JTRX, JPND, DELE & WTDR

§ Does not include data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

§§ Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

CDRH Pre-Sub - FY 2022 as of 3/31/22



* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, CCOV, DELE & WTDR

** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

*** Closures include JTRX, JPND, CCOV, DELE & WTDR

§ Does not include data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

§§ Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

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Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision*

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 2,707 | 3,176 | 3,306 | 3,090 | 1,450 |
| Closed Before RTA Action** | 27 | 41 | 109 | 388 | 40 |
| Number Accepted First RTA Cycle** | 2,565 | 3,004 | 3,035 | 2,449 | 1,190 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 49 | 71 | 121 | 223 | 115 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 83 |
| Number Not Accepted | 66 | 60 | 41 | 29 | 22 |
| Rate of Submissions Not Accepted for Review | 2.46% | 1.91% | 1.28% | 1.07% | 1.66% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

Table 9.2 CDRH - MDUFA IV Pre-Sub Performance Goals*

| Performance Metric | MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|--|---|--------------------|--------------------|--------------------|--------------------|
| | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
| | ≥ 1530 Submissions | ≥ 1645 Submissions | ≥ 1765 Submissions | ≥ 1880 Submissions | ≥ 1950 Submissions |
| Written Feedback Sent | 2,594 | 3,028 | 3,020 | 2,527 | 833 |
| Written Feedback Provided Within MDUFA IV Goal | 2,439 | 2,848 | 2,652 | 2,022 | 664 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

Table 9.3 CDRH - Pre-Sub Time to MDUFA IV Decision*

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 2,594 | 3,028 | 3,020 | 2,527 | 833 |
| Average FDA Days to Written Feedback | 58.86 | 59.93 | 63.26 | 66.94 | 63.65 |
| 20th Percentile FDA Days to Written Feedback | 49 | 49 | 52 | 52 | 52 |
| 40th Percentile FDA Days to Written Feedback | 59 | 60 | 62 | 63 | 63 |
| 60th Percentile FDA Days to Written Feedback | 65 | 65 | 66 | 67 | 67 |
| 80th Percentile FDA Days to Written Feedback | 69 | 70 | 70 | 70 | 70 |
| Maximum FDA Days to Written Feedback | 172 | 397 | 389 | 307 | 174 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

Table 9.4 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 37 | 45 | 30 | 89 | 49 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 35.59 | 36.62 | 43.33 | 48.15 | 49.53 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

Table 9.5 CDRH - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes*

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 1,507 | 1,744 | 1,727 | 1,351 | 395 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 971 | 1,113 | 1,110 | 890 | 244 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 35 |
| Meeting Minutes Past 15 Days of Meeting | 483 | 560 | 539 | 418 | 96 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 53 | 71 | 78 | 43 | 20 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 64.43% | 63.82% | 64.27% | 65.88% | 67.78% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 319 | 389 | 429 | 401 | 189 |
| Closed Before RTA Action** | 0 | 6 | 5 | 8 | 1 |
| Number Accepted First RTA Cycle** | 284 | 359 | 406 | 376 | 168 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 8 | 9 | 10 | 13 | 7 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 9 |
| Number Not Accepted | 27 | 15 | 8 | 4 | 4 |
| Rate of Submissions Not Accepted for Review | 8.46% | 3.92% | 1.89% | 1.02% | 2.23% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 298 | 359 | 401 | 378 | 124 |
| Written Feedback Provided Within MDUFA IV Goal | 256 | 314 | 279 | 225 | 70 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Pre-Sub Time to MDUFA IV Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 298 | 359 | 401 | 378 | 124 |
| Average FDA Days to Written Feedback | 64.18 | 64.05 | 73.33 | 73.35 | 71.66 |
| 20th Percentile FDA Days to Written Feedback | 56 | 57 | 62 | 63 | 62 |
| 40th Percentile FDA Days to Written Feedback | 64 | 65 | 66 | 67 | 68 |
| 60th Percentile FDA Days to Written Feedback | 69 | 69 | 70 | 70 | 70 |
| 80th Percentile FDA Days to Written Feedback | 70 | 70 | 74 | 81 | 80 |
| Maximum FDA Days to Written Feedback | 168 | 119 | 389 | 219 | 140 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.4 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 8 | 4 | 10 | 18 | 11 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 44.75 | 34.00 | 42.40 | 60.50 | 48.64 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.5 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 183 | 224 | 242 | 222 | 67 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 126 | 151 | 151 | 143 | 38 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 8 |
| Meeting Minutes Past 15 Days of Meeting | 50 | 68 | 80 | 75 | 18 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 7 | 5 | 11 | 4 | 3 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 68.85% | 67.41% | 62.40% | 64.41% | 64.41% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.1 OHT2 - Office of Cardiovascular Devices
Pre-Sub Acceptance Review Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 530 | 582 | 675 | 774 | 321 |
| Closed Before RTA Action** | 6 | 7 | 4 | 7 | 0 |
| Number Accepted First RTA Cycle** | 506 | 555 | 648 | 739 | 294 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 12 | 14 | 14 | 24 | 10 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 14 |
| Number Not Accepted | 6 | 6 | 9 | 4 | 3 |
| Rate of Submissions Not Accepted for Review | 1.15% | 1.04% | 1.34% | 0.52% | 0.98% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 512 | 563 | 660 | 747 | 218 |
| Written Feedback Provided Within MDUFA IV Goal | 482 | 535 | 610 | 676 | 203 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.3 OHT2 - Office of Cardiovascular Devices
Pre-Sub Time to MDUFA IV Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 512 | 563 | 660 | 747 | 218 |
| Average FDA Days to Written Feedback | 53.02 | 55.51 | 56.18 | 58.82 | 58.56 |
| 20th Percentile FDA Days to Written Feedback | 39 | 44 | 45 | 45 | 47 |
| 40th Percentile FDA Days to Written Feedback | 50 | 53 | 55 | 57 | 59 |
| 60th Percentile FDA Days to Written Feedback | 59 | 63 | 63 | 64 | 65 |
| 80th Percentile FDA Days to Written Feedback | 67 | 69 | 69 | 69 | 69 |
| Maximum FDA Days to Written Feedback | 91 | 115 | 143 | 222 | 86 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.4 OHT2 - Office of Cardiovascular Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 8 | 9 | 4 | 20 | 6 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 32.13 | 39.89 | 38.75 | 41.00 | 49.83 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.5 OHT2 - Office of Cardiovascular Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 313 | 324 | 357 | 385 | 101 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 183 | 199 | 212 | 248 | 63 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 5 |
| Meeting Minutes Past 15 Days of Meeting | 119 | 105 | 123 | 126 | 29 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 11 | 20 | 22 | 11 | 4 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 58.47% | 61.42% | 59.38% | 64.42% | 65.63% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 334 | 382 | 399 | 377 | 188 |
| Closed Before RTA Action** | 5 | 7 | 11 | 30 | 1 |
| Number Accepted First RTA Cycle** | 307 | 359 | 376 | 326 | 159 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 11 | 7 | 3 | 16 | 13 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 10 |
| Number Not Accepted | 11 | 9 | 9 | 5 | 5 |
| Rate of Submissions Not Accepted for Review | 3.34% | 2.40% | 2.32% | 1.44% | 2.82% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 313 | 354 | 372 | 336 | 104 |
| Written Feedback Provided Within MDUFA IV Goal | 300 | 344 | 352 | 294 | 94 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.3 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Pre-Sub Time to MDUFA IV Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 313 | 354 | 372 | 336 | 104 |
| Average FDA Days to Written Feedback | 60.53 | 60.85 | 61.36 | 65.67 | 62.50 |
| 20th Percentile FDA Days to Written Feedback | 53 | 53 | 51 | 58 | 59 |
| 40th Percentile FDA Days to Written Feedback | 61 | 61 | 61 | 64 | 65 |
| 60th Percentile FDA Days to Written Feedback | 65 | 66 | 66 | 67 | 67 |
| 80th Percentile FDA Days to Written Feedback | 69 | 69 | 70 | 70 | 70 |
| Maximum FDA Days to Written Feedback | 156 | 148 | 168 | 204 | 90 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.4 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 3 | 8 | 1 | 9 | 5 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 32.00 | 36.88 | 36.00 | 52.11 | 38.60 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.5 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 178 | 204 | 220 | 197 | 52 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 112 | 125 | 156 | 141 | 37 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 3 |
| Meeting Minutes Past 15 Days of Meeting | 64 | 73 | 61 | 52 | 11 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 2 | 6 | 3 | 4 | 1 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 62.92% | 61.27% | 70.91% | 71.57% | 75.51% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.1 OHT4 - Office of Surgical and Infection Control Devices
Pre-Sub Acceptance Review Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 251 | 275 | 337 | 315 | 152 |
| Closed Before RTA Action** | 4 | 5 | 21 | 119 | 1 |
| Number Accepted First RTA Cycle** | 234 | 250 | 304 | 164 | 134 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 6 | 11 | 7 | 29 | 9 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 5 |
| Number Not Accepted | 7 | 9 | 5 | 3 | 3 |
| Rate of Submissions Not Accepted for Review | 2.83% | 3.33% | 1.58% | 1.53% | 2.05% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 234 | 253 | 300 | 178 | 91 |
| Written Feedback Provided Within MDUFA IV Goal | 215 | 221 | 264 | 118 | 54 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.3 OHT4 - Office of Surgical and Infection Control Devices
Pre-Sub Time to MDUFA IV Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 234 | 253 | 300 | 178 | 91 |
| Average FDA Days to Written Feedback | 60.70 | 62.60 | 63.10 | 70.48 | 70.68 |
| 20th Percentile FDA Days to Written Feedback | 52 | 55 | 56 | 55 | 56 |
| 40th Percentile FDA Days to Written Feedback | 59 | 63 | 62 | 64 | 64 |
| 60th Percentile FDA Days to Written Feedback | 65 | 66 | 66 | 69 | 70 |
| 80th Percentile FDA Days to Written Feedback | 69 | 70 | 70 | 80 | 81 |
| Maximum FDA Days to Written Feedback | 121 | 106 | 268 | 237 | 174 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.4 OHT4 - Office of Surgical and Infection Control Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 4 | 8 | 5 | 19 | 7 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 33.25 | 34.25 | 42.80 | 42.84 | 55.43 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.5 OHT4 - Office of Surgical and Infection Control Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 124 | 141 | 180 | 96 | 41 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 92 | 95 | 118 | 69 | 22 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 6 |
| Meeting Minutes Past 15 Days of Meeting | 26 | 41 | 50 | 23 | 9 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 6 | 5 | 12 | 4 | 4 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 74.19% | 67.38% | 65.56% | 71.88% | 62.86% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 249 | 277 | 308 | 340 | 158 |
| Closed Before RTA Action** | 3 | 2 | 2 | 1 | 1 |
| Number Accepted First RTA Cycle** | 232 | 253 | 285 | 316 | 135 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 7 | 10 | 16 | 14 | 7 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 10 |
| Number Not Accepted | 7 | 12 | 5 | 8 | 5 |
| Rate of Submissions Not Accepted for Review | 2.85% | 4.36% | 1.63% | 2.37% | 3.40% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 235 | 260 | 297 | 321 | 85 |
| Written Feedback Provided Within MDUFA IV Goal | 202 | 219 | 184 | 216 | 59 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.3 OHT5 - Office of Neurological and Physical Medicine Devices
Pre-Sub Time to MDUFA IV Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 235 | 260 | 297 | 321 | 85 |
| Average FDA Days to Written Feedback | 64.73 | 72.86 | 80.73 | 79.76 | 67.82 |
| 20th Percentile FDA Days to Written Feedback | 58 | 63 | 65 | 64 | 59 |
| 40th Percentile FDA Days to Written Feedback | 65 | 68 | 70 | 69 | 67 |
| 60th Percentile FDA Days to Written Feedback | 69 | 70 | 70 | 70 | 70 |
| 80th Percentile FDA Days to Written Feedback | 70 | 70 | 84 | 85 | 77 |
| Maximum FDA Days to Written Feedback | 172 | 397 | 385 | 307 | 113 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.4 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 5 | 7 | 4 | 16 | 11 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 34.20 | 33.00 | 37.50 | 38.50 | 40.27 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.5 OHT5 - Office of Neurological and Physical Medicine Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 156 | 174 | 176 | 173 | 41 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 99 | 103 | 107 | 107 | 22 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 4 |
| Meeting Minutes Past 15 Days of Meeting | 50 | 59 | 62 | 56 | 12 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 7 | 12 | 7 | 10 | 3 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 63.46% | 59.20% | 60.80% | 61.85% | 59.46% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.1 OHT6 - Office of Orthopedic Devices
Pre-Sub Acceptance Review Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 133 | 173 | 179 | 241 | 123 |
| Closed Before RTA Action** | 1 | 3 | 1 | 2 | 1 |
| Number Accepted First RTA Cycle** | 127 | 162 | 168 | 230 | 111 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 5 | 6 | 7 | 6 | 2 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 8 |
| Number Not Accepted | 0 | 2 | 3 | 3 | 1 |
| Rate of Submissions Not Accepted for Review | 0.0% | 1.18% | 1.69% | 1.26% | 0.88% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 129 | 167 | 173 | 227 | 79 |
| Written Feedback Provided Within MDUFA IV Goal | 115 | 154 | 169 | 224 | 79 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.3 OHT6 - Office of Orthopedic Devices
Pre-Sub Time to MDUFA IV Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 129 | 167 | 173 | 227 | 79 |
| Average FDA Days to Written Feedback | 61.91 | 61.18 | 62.34 | 58.92 | 53.49 |
| 20th Percentile FDA Days to Written Feedback | 52 | 55 | 57 | 45 | 43 |
| 40th Percentile FDA Days to Written Feedback | 62 | 62 | 63 | 60 | 51 |
| 60th Percentile FDA Days to Written Feedback | 67 | 66 | 69 | 65 | 59 |
| 80th Percentile FDA Days to Written Feedback | 70 | 70 | 70 | 70 | 66 |
| Maximum FDA Days to Written Feedback | 106 | 92 | 105 | 78 | 70 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.4 OHT6 - Office of Orthopedic Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 3 | 4 | 0 | 2 | 1 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 33.00 | 43.75 | 0.00 | 31.00 | 37.00 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.5 OHT6 - Office of Orthopedic Devices
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 77 | 87 | 79 | 100 | 34 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 55 | 53 | 61 | 63 | 24 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 4 |
| Meeting Minutes Past 15 Days of Meeting | 19 | 29 | 15 | 35 | 4 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 3 | 5 | 3 | 2 | 2 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 71.43% | 60.92% | 77.22% | 63.00% | 80.00% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.1 OHT7 - Office of In Vitro Diagnostics and Radiological Health
Pre-Sub Acceptance Review Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number Received | 891 | 1,098 | 979 | 642 | 319 |
| Closed Before RTA Action** | 8 | 11 | 65 | 221 | 35 |
| Number Accepted First RTA Cycle** | 875 | 1,066 | 848 | 298 | 189 |
| Number Without a RTA Review and > 15 Days Since Date Received** | 0 | 14 | 64 | 121 | 67 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 27 |
| Number Not Accepted | 8 | 7 | 2 | 2 | 1 |
| Rate of Submissions Not Accepted for Review | 0.91% | 0.64% | 0.22% | 0.48% | 0.39% |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Includes Q-Submissions closed due to reallocation of resources to COVID-19 activities.

**Table 9.2 OHT7 - Office of In Vitro Diagnostics and Radiological Health
MDUFA IV Pre-Sub Performance Goals***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 873 | 1,072 | 817 | 340 | 132 |
| Written Feedback Provided Within MDUFA IV Goal | 869 | 1,061 | 794 | 269 | 105 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
Pre-Sub Time to MDUFA IV Decision***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 873 | 1,072 | 817 | 340 | 132 |
| Average FDA Days to Written Feedback | 57.35 | 56.61 | 58.79 | 70.32 | 63.96 |
| 20th Percentile FDA Days to Written Feedback | 48 | 45 | 50 | 51 | 50 |
| 40th Percentile FDA Days to Written Feedback | 57 | 56 | 58 | 58 | 59 |
| 60th Percentile FDA Days to Written Feedback | 63 | 63 | 64 | 65 | 66 |
| 80th Percentile FDA Days to Written Feedback | 68 | 68 | 69 | 71 | 70 |
| Maximum FDA Days to Written Feedback | 85 | 307 | 190 | 295 | 136 |

*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Meetings Not Scheduled By Day 30 | 6 | 5 | 6 | 5 | 8 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 33.83 | 35.60 | 53.50 | 83.00 | 66.50 |

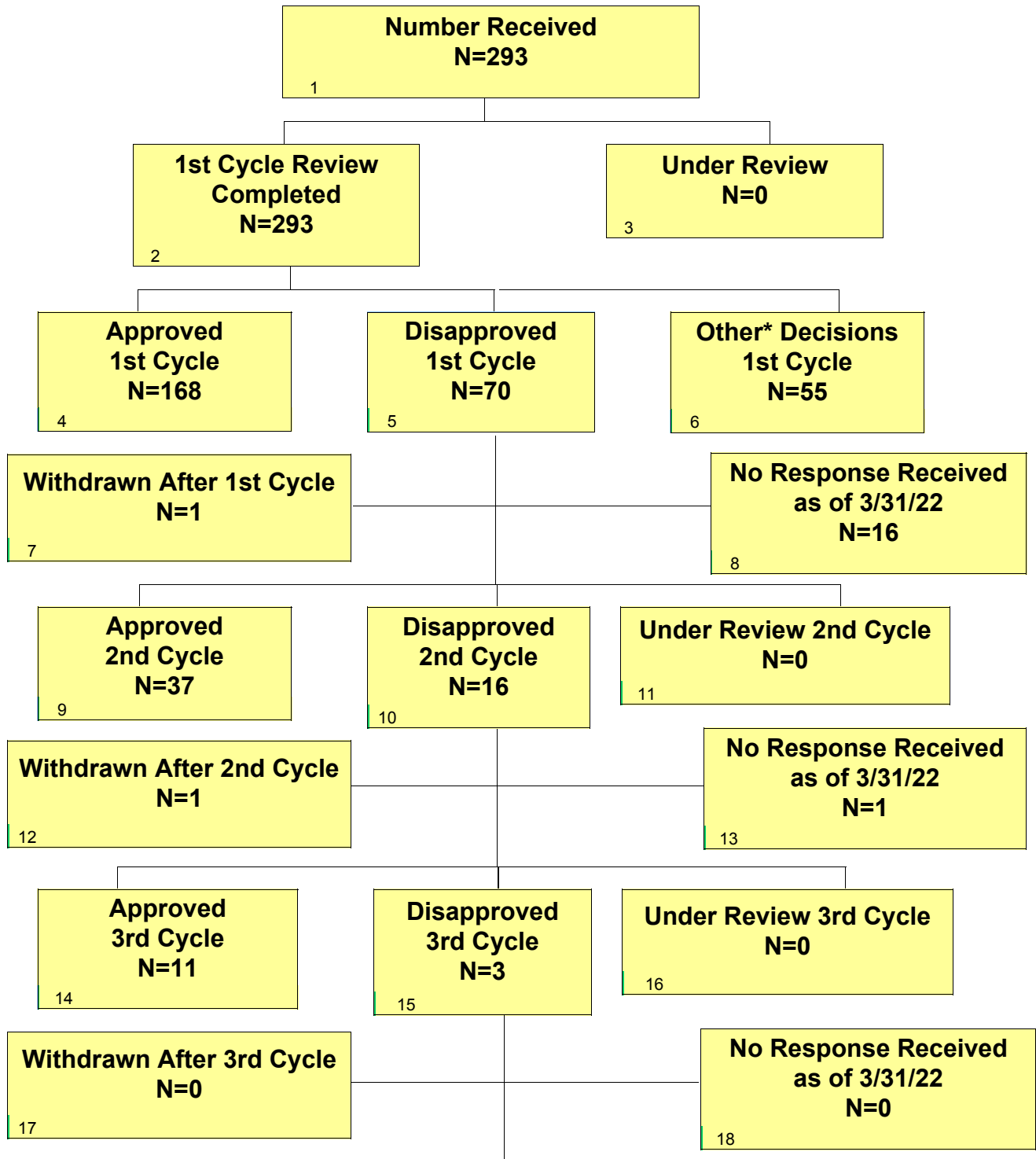
*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

**Table 9.5 OHT7 - Office of In Vitro Diagnostics and Radiological Health
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 476 | 590 | 473 | 178 | 59 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 304 | 387 | 305 | 119 | 38 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 5 |
| Meeting Minutes Past 15 Days of Meeting | 155 | 185 | 148 | 51 | 13 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 17 | 18 | 20 | 8 | 3 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 63.87% | 65.59% | 64.48% | 66.85% | 70.37% |

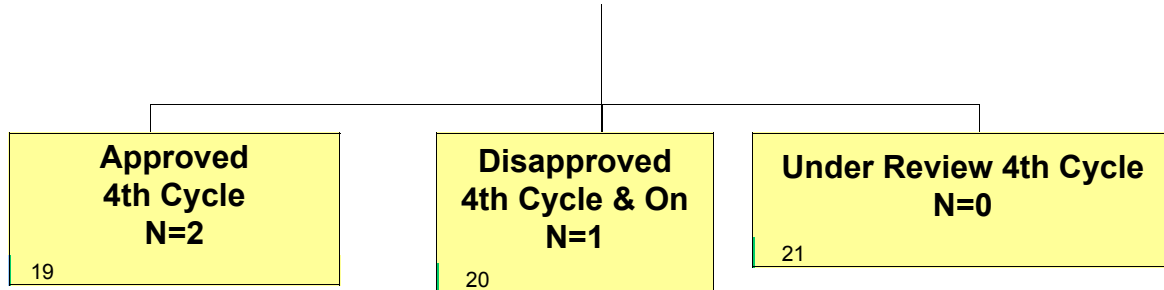
*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

CDRH IDEs - FY 2018 as of 3/31/22

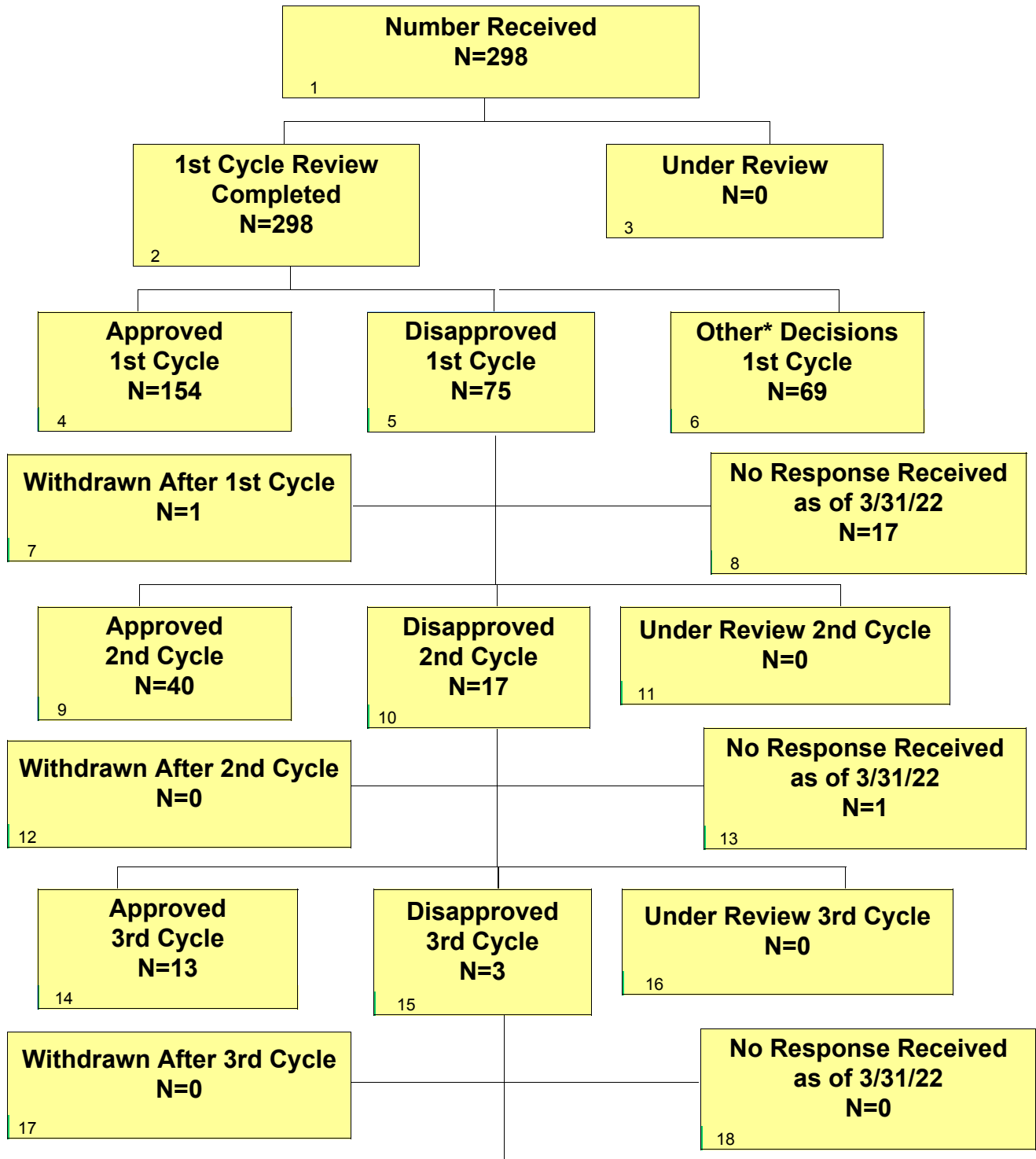


* Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

CDRH IDEs - FY 2018 as of 3/31/22

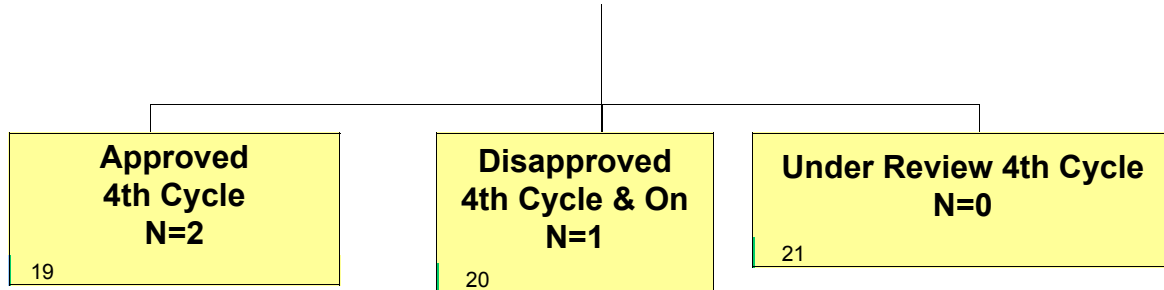


CDRH IDEs - FY 2019 as of 3/31/22

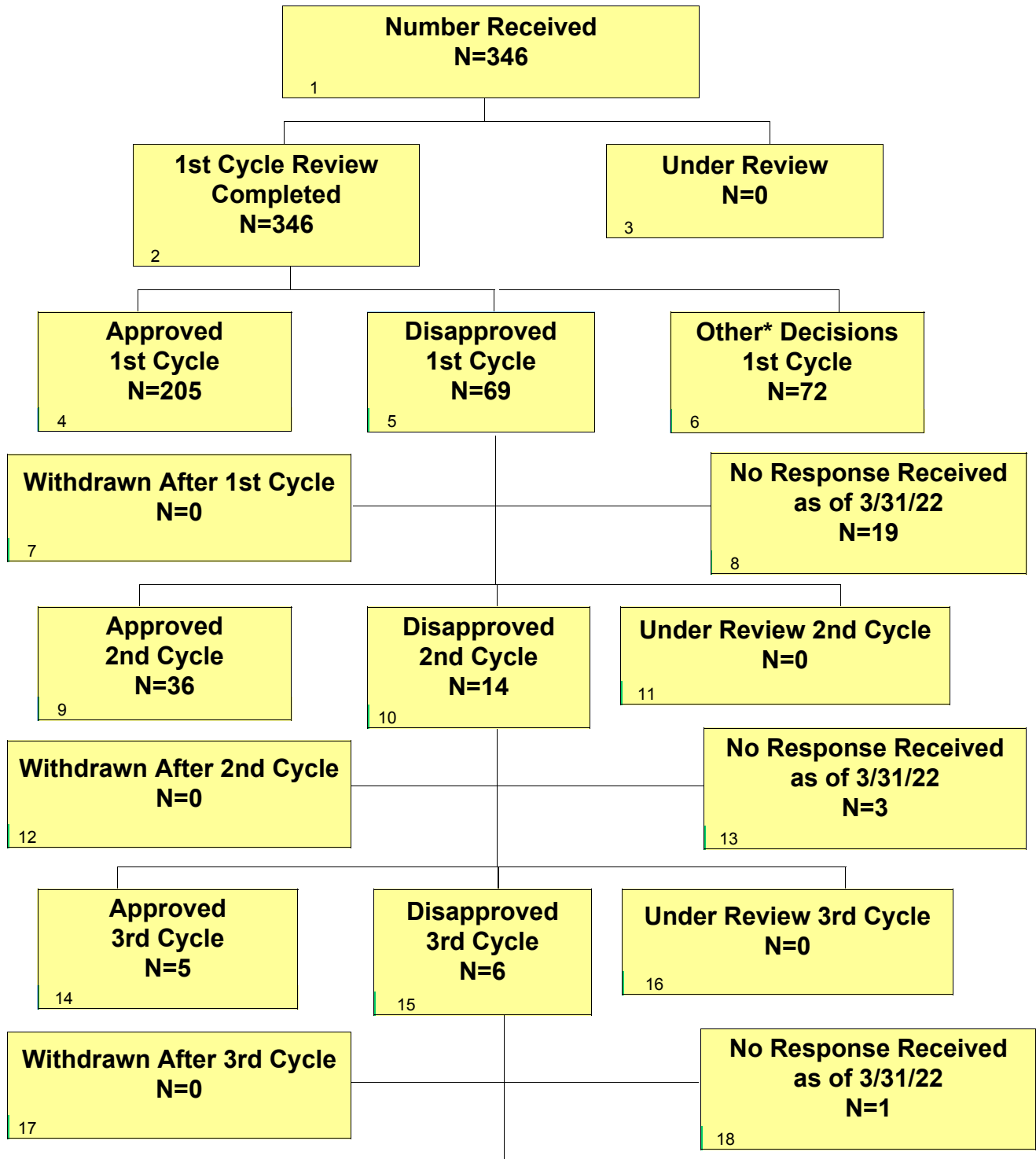


* Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).

CDRH IDEs - FY 2019 as of 3/31/22

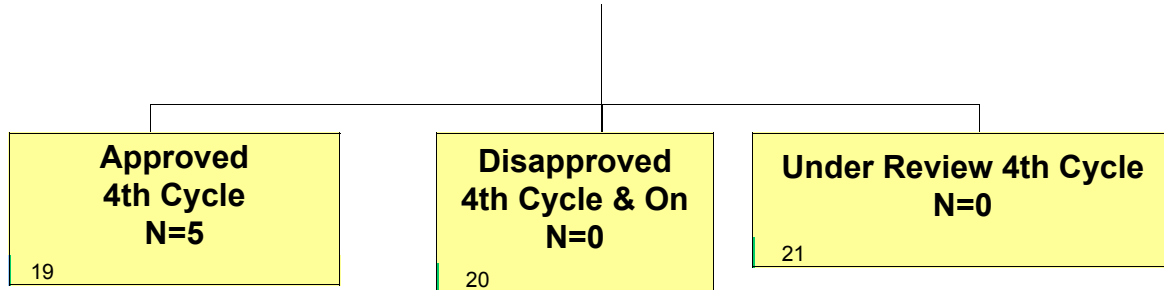


CDRH IDEs - FY 2020 as of 3/31/22

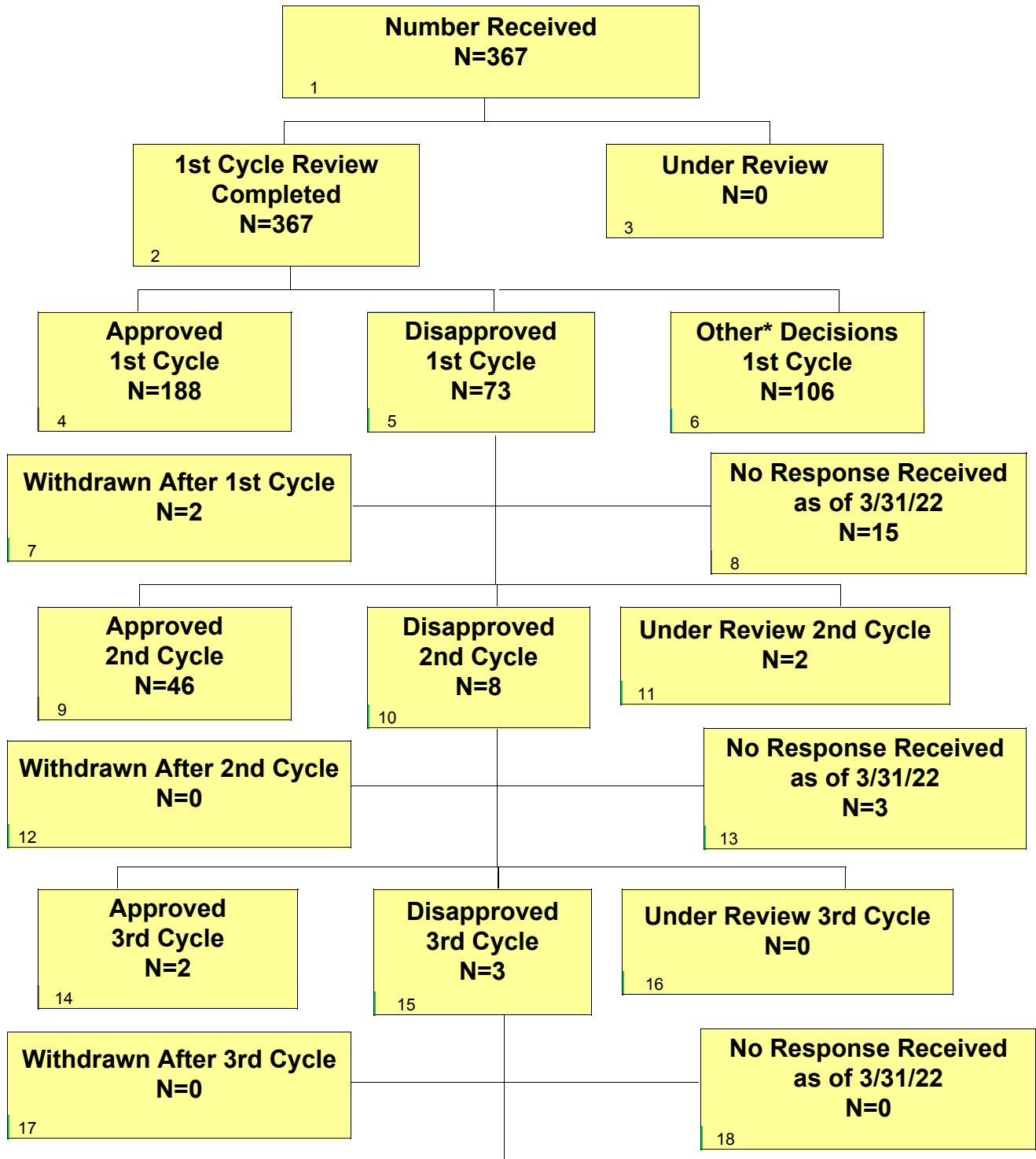


* Other decisions include withdrawn (N=12), withdrawn and converted (N=37), RTA (N=0), nonsignificant risk device (N=15), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).

CDRH IDEs - FY 2020 as of 3/31/22

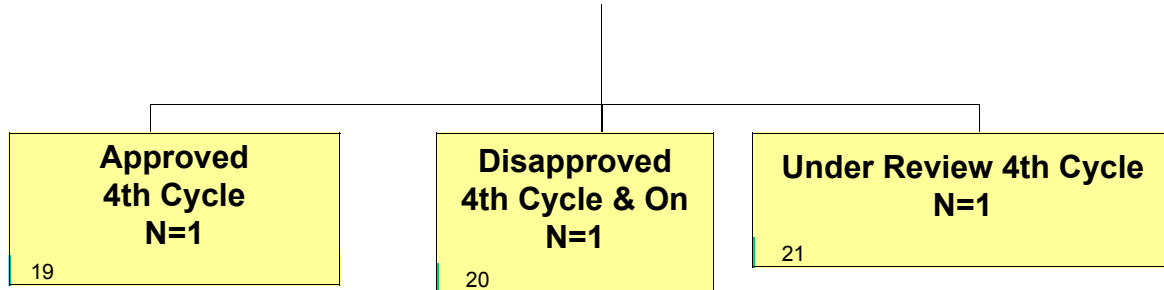


CDRH IDEs - FY 2021 as of 3/31/22

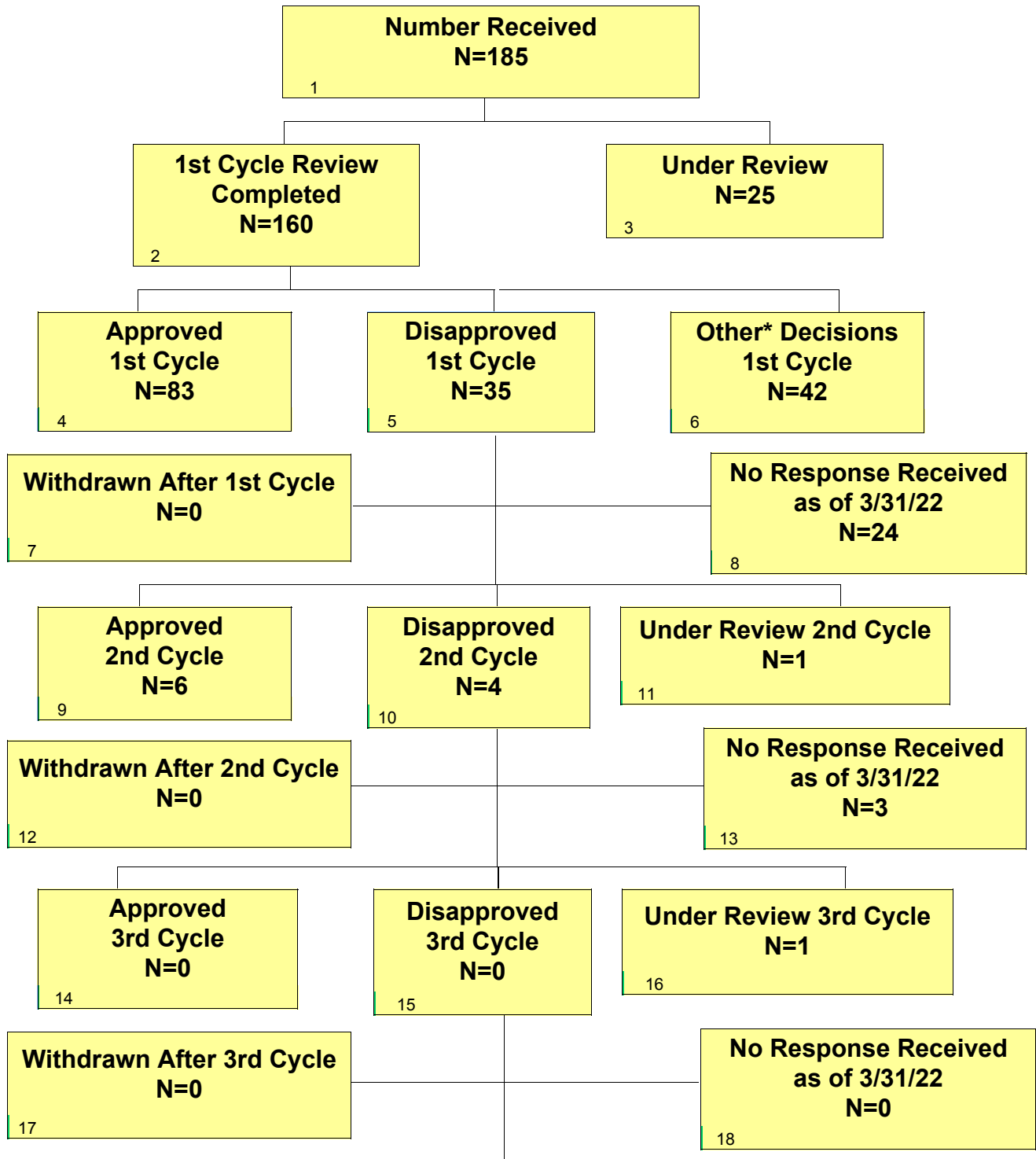


* Other decisions include withdrawn (N=26), withdrawn and converted (N=56), RTA (N=0), nonsignificant risk device (N=17), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=3), Basic Physiological Research (N=0).

CDRH IDEs - FY 2021 as of 3/31/22

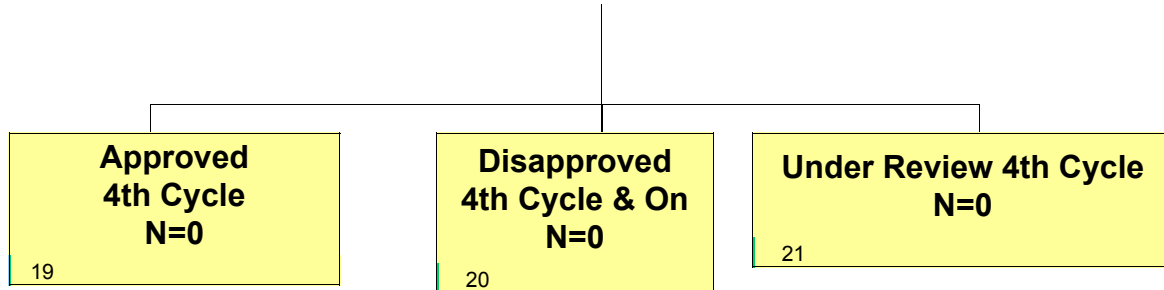


CDRH IDEs - FY 2022 as of 3/31/22



* Other decisions include withdrawn (N=5), withdrawn and converted (N=27), RTA (N=0), nonsignificant risk device (N=5), exempt (N=1), product jurisdiction pending (N=1), or product jurisdiction transferred (N=3), Basic Physiological Research (N=0).

CDRH IDEs - FY 2022 as of 3/31/22



Section 10 IDE- Center Level Metric

Table 10.1 CDRH - IDE MDUFA IV Decision Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number of IDEs Received | 293 | 298 | 346 | 367 | 185 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.32 | 1.34 | 1.24 | 1.22 | 1.07 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.32 | 0.34 | 0.24 | 0.22 | 0.07 |

Section 10 IDE - Office Level Metric

**Table 10.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
IDE MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of IDEs Received | 44 | 35 | 41 | 37 | 17 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.41 | 1.36 | 1.32 | 1.43 | 1.14 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.41 | 0.36 | 0.32 | 0.43 | 0.14 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of IDEs Received | 57 | 57 | 70 | 77 | 42 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.58 | 1.43 | 1.45 | 1.39 | 1.20 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.58 | 0.43 | 0.45 | 0.39 | 0.20 |

**Table 10.1 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
IDE MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of IDEs Received | 33 | 43 | 47 | 47 | 25 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.60 | 1.50 | 1.45 | 1.41 | 1.00 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.60 | 0.50 | 0.45 | 0.41 | 0.00 |

**Table 10.1 OHT4 - Office of Surgical and Infection Control Devices
IDE MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of IDEs Received | 29 | 32 | 42 | 42 | 22 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.29 | 1.21 | 1.11 | 1.15 | 1.08 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.29 | 0.21 | 0.11 | 0.15 | 0.08 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of IDEs Received | 62 | 70 | 66 | 59 | 35 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.16 | 1.47 | 1.17 | 1.12 | 1.06 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.16 | 0.47 | 0.17 | 0.12 | 0.06 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of IDEs Received | 16 | 11 | 17 | 19 | 7 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.18 | 1.20 | 1.00 | 1.00 | 1.00 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.18 | 0.20 | 0.00 | 0.00 | 0.00 |

**Table 10.1 OHT7 - Office of In Vitro Diagnostics and Radiological Health
IDE MDUFA IV Decision Performance Goal**

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number of IDEs Received | 52 | 50 | 63 | 86 | 37 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.00 | 1.03 | 1.00 | 1.00 | 1.00 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.00 | 0.03 | 0.00 | 0.00 | 0.00 |

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Section 11 CLIA Waiver Annual Metrics

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

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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.

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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 | Closed before RTA action | Number Received (line 1) that were closed with a final decision before RTA action. |
| 3 | Number with accepted RTA review | Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer. |
| 4 | Number without 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 RTA Review and <= 15 Days since Date Received | Number Received (line 1) that are still in the first RTA review cycle. |
| 6 | Number Not Accepted for Filing Review | 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 | 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 Original 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 | Number with 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 & Panel Track Supplements Substantive Interaction Performance Goals - 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 Metrics – Time to Substantive Interaction - Definitions**

| # | Measure | Description |
|---|---|--|
| 1 | Number of Substantive Interactions | Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI. |
| 2 | Average number of FDA days to Substantive Interaction | Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1). |
| 3 | 20 th Percentile FDA days to Substantive Interaction | 20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 4 | 40 th Percentile FDA days to Substantive Interaction | 40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 5 | 60 th Percentile FDA days to Substantive Interaction | 60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 6 | 80 th Percentile FDA days to Substantive Interaction | 80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 7 | Maximum FDA days to Substantive Interaction | Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1). |

**Tables 1.5 and Tables 1.5.x PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals - 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 IV Decisions | Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA). |
| 3 | MDUFA IV Decisions | Submissions filed (line 1) and closed with a MDUFA IV decision. |
| 4 | MDUFA IV Decisions Goal Met | Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date. |
| 5 | PMAs pending MDUFA IV Decision | Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision. |
| 6 | PMAs pending MDUFA IV Decision Past Goal | Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Goal Met | Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6). |

Table 1.6 and Tables 1.6.x PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals - 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 IV Decisions | Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA). |
| 3 | MDUFA IV Decisions | Submissions filed (line 1) and closed with a MDUFA IV decision. |
| 4 | MDUFA IV Decisions Goal Met | Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date. |
| 5 | PMAs pending MDUFA IV Decision | Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision. |
| 6 | PMAs pending MDUFA IV Decision Past Goal | Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Goal Met | Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6). |

Table 1.7 and Tables 1.7.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions

| # | Measure | Description |
|---|-------------------------------|--|
| 1 | Number with MDUFA IV 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 IV 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 Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision - Definitions**

| # | Measure | Description |
|---|-------------------------------|--|
| 1 | Number with MDUFA IV 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 IV 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)
Performance Metrics – Rate of Withdrawal and Not Approvable -
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 IV decision | Number submissions filed (line 1) that also had a MDUFA decision. |
| 3 | Number of Withdrawals | 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 Withdrawals | 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 Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - 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 Withdrawals | 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 Withdrawals | 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 (line2). |

Table 1.11 and Tables 1.11.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - 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 FDA days to MDUFA IV decision exceeding number of goal 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 goal | Mean industry days for submissions that missed the goal (line 1). |

Table 1.12 and Tables 1.12.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - 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 IV decision exceeding number of goal 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 goal | Mean industry days for submissions that missed the goal (line 1). |

Tables 1.13 and Tables 1.13.x LDT PMA Originals & Panel-Track Supplements Metric* MDUFA Decision Performance Goals - 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 IV Decisions | Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA). |
| 3 | MDUFA IV Decisions | Submissions filed (line 1) and closed with a MDUFA IV decision. |
| 4 | MDUFA IV Decisions Goal Met | Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date. |
| 5 | PMAs pending MDUFA IV Decision | Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision. |
| 6 | PMAs pending MDUFA IV Decision Past Goal | Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Goal Met | Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV 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 Metric* MDUFA Decision Performance Goals - 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 IV Decisions | Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA). |
| 3 | MDUFA IV Decisions | Submissions filed (line 1) and closed with a MDUFA IV decision. |
| 4 | MDUFA IV Decisions Goal Met | Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date. |
| 5 | PMAs pending MDUFA IV Decision | Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision. |
| 6 | PMAs pending MDUFA IV Decision Past Goal | Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Goal Met | Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV 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 Goals – 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 Decision Performance Goals – Definitions

| # | Measure | Description |
|---|---|--|
| 1 | Supplements filed | Number of 180 day PMA supplements received in this fiscal year. |
| 2 | Non-MDUFA IV Decisions | Supplements received (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMa). |
| 3 | MDUFA IV Decisions | Supplements received (line 1) and closed with a MDUFA IV decision. |
| 4 | MDUFA IV Decisions Goal Met | Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date. |
| 5 | Supplements pending MDUFA IV Decision | Number of supplements received (line 1) that do not have a MDUFA IV decision or a final decision. |
| 6 | Supplements pending MDUFA IV Decision Past Goal | Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Goal Met | Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV 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 Performance Metrics – 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 Performance Metrics – Submissions Missing Performance Goals – 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 IV 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 Real Time PMA Supplements MDUFA Performance Goals – Definitions

| # | Measure | Description |
|---|---|--|
| 1 | Supplements received | Number of Real Time PMA supplements that were received in this fiscal year. |
| 2 | Non-MDUFA IV Decisions | Supplements received in this fiscal year (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA). |
| 3 | MDUFA IV Decisions | Supplements received in this fiscal year (line 1) and closed with a MDUFA IV decision. |
| 4 | MDUFA IV Decisions Goal Met | Submissions with MDUFA IV decisions (line 3) within goal. |
| 5 | Supplements pending MDUFA IV Decision | Number of supplements received in this fiscal year (line 1) that do not have a MDUFA IV decision and are not closed with a final decision. |
| 6 | Supplements pending MDUFA IV Decision Past Goal | Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Goal Met | Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6). |

Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – 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

Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals – 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 MDUFA decision | Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision. |
| 2 | Number with 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 IV decision and 5% of submissions with the highest number of Total Days to MDUFA IV 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 IV 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 RTA action | Number Received (line 1) that were closed with a final decision before RTA action. |
| 3 | Number Accepted | Number Received (line 1) that received an “RTA Accepted” (RTAA) decision in the first RTA review cycle. |
| 4 | Number Without a RTA Review and > 15 days since Date Received | Number Received (line 1) that received a “Did not perform RTA” (RTAN, RTAS or RTAW) decision in the first RTA review cycle. An RTAN decision is automatically recorded by CTS at the end of day 15 of RTA review, if no other RTA decision is made. This RTA decision means that the 510(k) is deemed accepted. |
| 5 | Number Without a RTA Review and <= 15 days since Date Received | Number Received (line 1) that are still in the first RTA review cycle and have not yet reached the 15 th day of that cycle.. |
| 6 | Number Not Accepted | Number of submissions received in this fiscal year (line 1) that got a “Not Accepted” decision in the first RTA review cycle. |
| 7 | Rate of Submissions Not Accepted for Review | Number Not Accepted (line 6) expressed as a percentage of the sum of the Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (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 deemed accepted via the RTA process as of quarter end date (RTAA, RTAN, RTAW or RTAS). |
| 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 under review over 60 FDA days and that do not have an SI. |
| 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 either had an SI (line 3 and line 4), the number of submissions that received an SI after 60 days had elapsed (line 6), and the number of submissions that were found NSE without first 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 accepted in this fiscal year that had an SI. |
| 2 | Average number of FDA days to Substantive Interaction | Average number of FDA days to substantive interaction across all 510(k) submissions with SI (line 1). |
| 3 | 20 th Percentile FDA days to Substantive Interaction | 20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 4 | 40 th Percentile FDA days to Substantive Interaction | 40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 5 | 60 th Percentile FDA days to Substantive Interaction | 60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 6 | 80 th Percentile FDA days to Substantive Interaction | 80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1). |
| 7 | Maximum FDA days to Substantive Interaction | Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1). |

Tables 6.4 and Tables 6.4.x 510(k) MDUFA Decision Performance Goal – Definitions

| # | Measure | Description |
|---|---|---|
| 1 | 510(k)s Accepted | Number of 510(k) submissions accepted in this fiscal year. |
| 2 | Non-MDUFA IV Decisions | Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE). |
| 3 | MDUFA IV Decision (SE/NSE) | Number of submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE). |
| 4 | MDUFA IV Decision within 90 FDA Days | Number of submissions with MDUFA IV decision (line 3) made within 90 FDA days. |
| 5 | 510(k)s Pending MDUFA IV Decision | Number of submissions accepted (line 1) and still under review. |
| 6 | 510(k) Pending MDUFA IV Decision Over 90 FDA Days | Number of submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Within 90 FDA Days | Number of submissions with MDUFA IV Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6). |

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA IV 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 IV Decision | Number of submissions accepted in this fiscal year that had a MDUFA decision. |
| | Days to MDUFA IV Decision | Table shall show Average Days to MDUFA IV 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 IV decision. |

Table 6.6 and Tables 6.6.x**510(k) Performance Metrics – Rate 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 IV Decision | Number submissions accepted (line 1) that had a MDUFA decision. |
| 3 | Number of SE Decision | Number of submissions accepted (line 1) that had an SE MDUFA decision. |
| 4 | Number of NSE Decision | Number of submissions accepted (line 1) that had an NSE MDUFA decision. |
| 5 | Number of Withdrawal | Number of submissions accepted (line 1) and closed with Withdrawal final decision. |
| 6 | Number Deleted | Number of submissions accepted (line 1) and closed with Delete final decision. |
| 7 | Rate of SE Decision | Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2). |
| 8 | Rate of NSE Decision | Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2). |
| 9 | Rate of Withdrawal | Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1). |
| 10 | Rate of Deleted | Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1). |

Table 6.7 and Tables 6.7.x**510(k) Performance Metric – Submissions Missing Performance Goal – Definitions**

| # | Measure | Description |
|---|---|---|
| 1 | Number of Submissions that Missed the Goal | Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days. |
| 2 | Mean FDA Days for Submissions that Missed the Goal | Mean FDA days for submissions that missed the goal (line 1). |
| 3 | Mean Industry Days for Submissions that missed goal | Mean industry days for submissions that missed the goal (line 1). |

Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA IV 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 IV Decision | Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE). |
| 3 | MDUFA IV Decision (SE/NSE) | Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE). |
| 4 | MDUFA IV Decision within 90 FDA Days | Number of LDT submissions with MDUFA IV decisions (line 3) made within 90 FDA days. |
| 5 | 510(k)s pending MDUFA IV Decision | Number of submissions accepted (line 1) and still under review. |
| 6 | 510(k) pending MDUFA IV Decision over 90 FDA days | Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent within 90 FDA Days | Number of LDT submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6). |

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA IV 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 IV Decision | Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE). |
| 3 | MDUFA IV Decision (SE/NSE) | Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE). |
| 4 | MDUFA IV Decision within 90 FDA Days | Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 90 FDA days. |
| 5 | 510(k)s Pending MDUFA IV Decision | Number of non-LDT IVD submissions accepted (line 1) and still under review. |
| 6 | 510(k) Pending MDUFA IV Decision Over 90 FDA Days | Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent within 90 FDA Days | Number of non-LDT IVD submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed 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 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 IV decision | Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision. |
| 4 | Number with MDUFA IV Decision | Number of 510(k) submissions accepted (line 1) that had a MDUFA IV decision. |
| 5 | Percent of cohort closed | Number with MDUFA decision (line 4) expressed as a percentage of the sum of Number Under Review (line 2) and Number with MDUFA Decision (line 4). |
| 6 | Number with MDUFA IV decision after trimming the upper and lower 2% | Number of 510(k) submissions with MDUFA IV Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA IV decision and the 2% of submissions with the highest number of Total Days to MDUFA IV decision. |
| 7 | Average Total Time to MDUFA IV 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 IV Decision | The 90 th percentile of FDA days to MDUFA IV decision on 3 rd Party 510(k) submissions received in this fiscal year |

Section 8 De Novo MDUFA IV 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 RTA action | Number Received (line 1) that were closed with a final decision before RTA action. |
| 3 | Number Accepted First RTA Cycle | Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer. |
| 4 | Number Without a 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 RTA Review and <= 15 days since Date Received | Number Received (line 1) that are still in the first RTA review cycle. |
| 6 | Number Not Accepted | Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle. |
| 7 | Rate of Submissions Not Accepted for Review | Number Not Accepted (line 6) expressed as a percentage the sum of the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6). |

*RTA was implemented on November 8, 2019, thus RTA metrics in table 8.1 include only De Novos received on or after November 8, 2019. All other tables include De Novos received on or after October 1, 2017.

Tables 8.2 and Tables 8.2.x De Novo MDUFA IV Decision Performance Goals – Definitions

| # | Measure | Description |
|---|--|--|
| 1 | De Novos Accepted | Number of De Novo submissions accepted in this fiscal year. |
| 2 | Non-MDUFA IV Decisions | Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted/Declined, Withdrawn or Deleted). |
| 3 | MDUFA IV Decisions | Number of submissions accepted (line 1) and closed with a MDUFA IV decision (Granted/Declined, Withdrawn or Deleted). |
| 4 | MDUFA IV Decisions within 150 FDA Days | Number of submissions with MDUFA IV decisions (line 3) made within 150 FDA days. |
| 5 | De Novos pending MDUFA IV Decision | Number of submissions accepted (line 1) and still under review. |
| 6 | De Novos pending MDUFA IV Decision over 150 FDA days | Number of submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent within 150 FDA Days | Number of submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6). |

Table 8.3 and Tables 8.3.x De Novo Time to MDUFA IV 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 IV decision (line 2). |
| 2 | Number with MDUFA IV Decision | Number of submissions accepted in this fiscal year that had a MDUFA IV decision. |
| | Days to MDUFA IV Decision | Table shall show Average Days to MDUFA IV 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 IV decision. |

Table 8.4 and Tables 8.4.x**De Novo Performance Metrics – Rate of Grant, Decline, Withdrawal and Delete Decisions – Definitions**

| # | Measure | Description |
|----|--------------------------------|--|
| 1 | De Novos Accepted | Number of De Novos submissions accepted in this fiscal year. |
| 2 | Number with MDUFA IV Decisions | Number submissions accepted (line 1) that had a MDUFA IV decision. |
| 3 | Number with Granted Decisions | Number of submissions accepted (line 1) that had a Granted MDUFA IV decision. |
| 4 | Number with Declined Decisions | Number of submissions accepted (line 1) that had a Declined MDUFA IV decision. |
| 5 | Number of Withdrawals | Number of submissions accepted (line 1) that had a Withdrawn MDUFA IV decision. |
| 6 | Number of Deleted | Number of submissions accepted (line 1) and closed that had a Deleted MDUFA IV decision |
| 7 | Rate of Granted Decisions | Number of Granted decisions (line 3) divided by Number with MDUFA IV decision (line 2). |
| 8 | Rate of Declined Decisions | Number of Declined decisions (line 4) divided by Number with MDUFA IV decision (line 2). |
| 9 | Rate of Withdrawals | Number of Withdrawals (line 5) divided by Number with MDUFA IV decision (line 2). |
| 10 | Rate of Deleted | Number of Deleted (line 6) divided by Number with MDUFA IV 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 De Novo submissions accepted in this fiscal year that had a MDUFA IV decision with more than 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 IV Decision Metrics – Definitions

| # | Measure | Description |
|---|--|--|
| 1 | De Novos accepted | Number of De Novo submissions for LDTs accepted in this fiscal year. |
| 2 | Non-MDUFA IV Decisions | Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted). |
| 3 | MDUFA IV Decisions | Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted). |
| 4 | MDUFA IV Decisions Within 150 FDA Days | Number of LDT submissions with MDUFA IV decisions (line 3) made within 150 FDA days. |
| 5 | De Novos Pending MDUFA IV Decision | Number of LDT submissions accepted (line 1) and still under review. |
| 6 | De Novos Pending MDUFA IV Decision over 150 FDA days | Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent within 150 FDA Days | Number of LDT submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6). |

Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA IV 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 IV Decisions | Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted). |
| 3 | MDUFA IV Decisions | Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted). |
| 4 | MDUFA IV Decisions within 150 FDA Days | Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 150 FDA days. |
| 5 | De Novos Pending MDUFA IV Decision | Number of non-LDT IVD submissions accepted (line 1) and still under review. |
| 6 | De Novos Pending MDUFA IV Decision Over 150 FDA Days | Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal. |
| 7 | Current Performance Percent Within 150 FDA Days | Number of non-LDT IVD submissions with MDUFA IV 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 IV Decisions (line 3) and pending non-LDT IVD submissions that already failed 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 First RTA Cycle | Number of De Novo submissions accepted in the first RTA cycle in this fiscal year as of the report cutoff date. |
| 4 | Average Number of Days to Accept/Refuse to Accept* | Average number of days in the first RTA review cycle De Novo submissions.. |

*RTA will be implemented when the guidance, including the submission checklist, is finalized.

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 submissions received in this fiscal year. |
| 2 | Closed before RTA Action | Number Received (line 1) that were closed with a final decision before RTA action. |
| 3 | Number Accepted First RTA Cycle | Number Received (line 1) that had “RTA Accepted” (RTAA) decision in the first RTA review cycle entered by reviewer. |
| 4 | Number Without a RTA Review and > 15 days Since Date Received | Number Received (line 1) that had “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. |
| 5 | Number Without a RTA Review and <= 15 days Since Date Received | Number Received (line 1) that are still in the first RTA review cycle at the quarter end date. |
| 6 | Number Not Accepted | Number of submissions received in this fiscal year (line 1) that had “Refuse to accept” (RTA1) decision in the first RTA review cycle. |
| 7 | Rate of Submissions Not Accepted for Review | Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6). |

Table 9.2 and Tables 9.2.x Pre-Submissions Performance Metrics – Definitions

| # | Measure | Description |
|---|--|--|
| 1 | Written Feedback Sent | Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either “Email Reply” (EMAL) or “Email Feedback Sent Before Meeting” (EMFB) in CTS. EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested. |
| 2 | Written Feedback Provided Within MDUFA IV Goal | Number of Pre-Subs that had Written Feedback sent (line 1) by Day 70 (for Pre-Subs without a meeting request), or by 5 Days before the Meeting Date or Day 70, whichever is sooner (for Pre-Subs with a meeting request). |

Table 9.3 and Tables 9.3.x Pre-Sub Time to MDUFA IV Metrics – Definitions

| # | Measure | Description |
|---|--|--|
| 1 | Written Feedback Sent | Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV 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 IV Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1). |
| 3 | 20 th Percentile FDA Days to Written Feedback | 20 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1). |
| 4 | 40 th Percentile FDA Days to Written Feedback | 40 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1). |
| 5 | 60 th Percentile FDA Days to Written Feedback | 60 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1). |
| 6 | 80 th Percentile FDA Days to Written Feedback | 80 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1). |
| 7 | Maximum FDA Days to Written Feedback | Maximum FDA days (100 th percentile) to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1). |

Table 9.4 and Tables 9.4.x Pre-Submissions Performance Metrics Meeting Scheduling-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 Pre-Submissions Performance Metrics Meeting Minutes- Definitions

| # | Measure | Description |
|---|---|---|
| 1 | Meetings Held | Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date. |
| 2 | Meeting Minutes Submitted Within 15 Days of Meeting | Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received within 15 days after Meeting Date. |
| 3 | Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and it is still under 15 days since meeting (as of end of quarter). |
| 4 | Meeting Minutes Past 15 Days of Meeting | Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received more than 15 days after Meeting Date. |
| 5 | Meeting Minutes Not Submitted and >15 Days Since Meeting | Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and more than 15 days have passed since the Meeting Date (as of end of quarter). |
| 6 | Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | Number of Meeting Minutes received within 15 days (line 2) divided by the total of Number of Meeting Minutes received within 15 days (line 2), Number of Meeting Minutes received past 15 days (line 4), and Number of Meeting Minutes which have not been received and >15 days since Meeting Date (line 5). |

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

| # | Measure | Description |
|---|---|--|
| 1 | Number of IDEs received | Number of IDEs received in the fiscal year. |
| 2 | Average number of cycles to approval or conditional approval of the IDE | The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE. |
| 3 | Average number of amendments prior to approval or conditional approval of the IDE | The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter. |

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

Table 11.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

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

Table 11.3 CLIA Waiver (without Panel Review) MDUFA IV Decision Performance Goals – Definitions

| # | Measure | Description |
|---|--|---|
| 1 | Eligible for MDUFA IV Decisions | Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review. |
| 2 | Non-MDUFA IV Decisions | Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn). |
| 3 | MDUFA IV Decisions | Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn). |
| 4 | MDUFA IV Decisions within 150 FDA Days | Number of submissions with MDUFA IV decisions made within 150 FDA days. |
| 5 | CLIA Waiver Applications pending MDUFA IV Decision | Number of submissions still under review. |
| 6 | CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days | Number of submissions pending MDUFA IV Decision for more than 150 FDA days. These submissions already failed the MDUFA IV Decision goal. |
| 7 | Current Performance Percent within 150 FDA Days | Number of submissions with MDUFA IV Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6). |

Table 11.4 CLIA Waiver (with Panel Review) MDUFA IV Decision Performance Goals) – Definitions

| # | Measure | Description |
|---|--|---|
| 1 | Eligible for MDUFA IV Decisions | Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review. |
| 2 | Non-MDUFA IV Decisions | Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn). |
| 3 | MDUFA IV Decisions | Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn). |
| 4 | MDUFA IV Decisions within 320 FDA Days | Number of submissions with MDUFA IV decisions made within 320 FDA days. |
| 5 | CLIA Waiver Applications pending MDUFA IV Decision | Number of submissions still under review. |
| 6 | CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days | Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal. |
| 7 | Current Performance Percent within 320 FDA Days | Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6). |

Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA IV Decision – Definitions

| # | Measure | Description |
|---|-------------------------------|--|
| 1 | Number with MDUFA IV Decision | Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and did not have a panel review. |
| | Days to MDUFA IV Decision | Table shall show Average Days to MDUFA IV 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 IV Decision - Definitions

| # | Measure | Description |
|---|-------------------------------|--|
| 1 | Number with MDUFA IV Decision | Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and had a panel review. |
| | Days to MDUFA IV Decision | Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days. |

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

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

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

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

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

Table 12.3 Dual 510(k) and CLIA Waiver (without panel review) MDUFA IV Decision Performance Goals – Definitions

| # | Measure | Description |
|---|--|---|
| 1 | Eligible for MDUFA IV 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 IV Decisions | Number of submissions closed with non-MDUFA IV decisions. |
| 3 | MDUFA IV Decisions | Number of submissions closed with MDUFA IV decisions. |
| 4 | MDUFA IV Decisions within 180 FDA Days | Number of submissions with MDUFA IV decisions made within 180 FDA days. |
| 5 | Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision | Number of submissions still under review. |
| 6 | Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days | Number of submissions pending MDUFA IV Decision for more than 180 FDA days. These submissions already failed the MDUFA IV Decision goal. |
| 7 | Current Performance Percent within 180 FDA Days | Number of submissions with MDUFA IV Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6). |

Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA IV Decision Performance Goals – Definitions

| # | Measure | Description |
|---|--|---|
| 1 | Eligible for MDUFA IV 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 IV Decisions | Number of submissions closed with non-MDUFA IV decisions. |
| 3 | MDUFA IV Decisions | Number of submissions closed with MDUFA IV decisions. |
| 4 | MDUFA IV Decisions within 320FDA Days | Number of submissions with MDUFA IV decisions made within 320 FDA days. |
| 5 | Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision | Number of submissions still under review. |
| 6 | Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days | Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal. |
| 7 | Current Performance Percent within 320 FDA Days | Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6). |

Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA IV Decision – Definitions

| # | Measure | Description |
|---|-------------------------------|--|
| 1 | Number with MDUFA IV Decision | Number of submissions accepted in this fiscal year that had a MDUFA IV decision), and did not have a panel review. |
| | Days to MDUFA IV Decision | Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days. |

Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA IV Decision – Definitions

| # | Measure | Description |
|---|-------------------------------|--|
| 1 | Number with MDUFA IV Decision | Number of submissions accepted in this fiscal year that had a MDUFA IV decision, and had a panel review. |
| | Days to MDUFA IV Decision | Table shall show Average Days to MDUFA IV 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. |

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**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CBER Performance Data ----
Actions through 31 Mar 2022**

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 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 3 | 3 | 3 | 1 | 1 |
| Closed Before RTA Action | 0 | 0 | 0 | 0 | 0 |
| Number with Accepted RTA Review | 1 | 2 | 3 | 1 | 1 |
| Number Without a RTA Review and > 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 0 |
| Number Not Accepted for Filing Review | 2 | 1 | 0 | 0 | 0 |
| Rate of Submissions Not Accepted for Filing Review | 66.67% | 33.33% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 3 | 3 | 3 | 1 | 1 |
| Number Accepted | 1 | 2 | 3 | 1 | 1 |
| Completed RTF | 3 | 3 | 3 | 1 | 1 |
| Number Not Filed | 1 | 0 | 0 | 0 | 0 |
| Rate of Submissions Not Filed | 33.33% | 0.00% | 0.00% | 0.00% | 0.00% |

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

Performance Goal

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 2 | 3 | 3 | 1 | 1 |
| SI Goal Met | 2 | 3 | 2 | 1 | 1 |
| SI Goal Not Met | 0 | 0 | 1 | 0 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 0 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 66.67% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Substantive Interactions | 2 | 3 | 3 | 1 | 1 |
| Average Number of FDA Days to Substantive Interaction | 69.00 | 85.33 | 91.33 | 86.00 | 85.00 |
| 20th Percentile FDA Days to Substantive Interaction | 50 | 82 | 81 | 86 | 85 |
| 40th Percentile FDA Days to Substantive Interaction | 50 | 84 | 89 | 86 | 85 |
| 60th Percentile FDA Days to Substantive Interaction | 88 | 84 | 89 | 86 | 85 |
| 80th Percentile FDA Days to Substantive Interaction | 88 | 90 | 104 | 86 | 85 |
| Maximum FDA Days to Substantive Interaction | 88 | 90 | 104 | 86 | 85 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 2 | 3 | 3 | 1 | 1 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 2 | 3 | 3 | 1 | 0 |
| MDUFA IV Decision Goal Met | 2 | 3 | 3 | 1 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 1 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Goal Met | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Number with MDUFA IV Decision | 2 | 3 | 3 | 1 | 0 |
| Average FDA Days to MDUFA IV Decision | 164.50 | 162.33 | 164.67 | 177.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 156 | 140 | 150 | 177 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 156 | 171 | 169 | 177 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 173 | 171 | 169 | 177 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 173 | 176 | 175 | 177 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 173 | 176 | 175 | 177 | 0 |
| Average Industry Days to MDUFA IV Decision | 319.50 | 161.00 | 55.33 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 105 | 56 | 166 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 105 | 177 | 166 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 534 | 177 | 166 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 534 | 250 | 166 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 534 | 250 | 166 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 484.00 | 323.33 | 220.00 | 177.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 261 | 196 | 150 | 177 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 261 | 348 | 169 | 177 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 707 | 348 | 169 | 177 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 707 | 426 | 341 | 177 | 0 |
| Maximum Total Days to MDUFA IV Decision | 707 | 426 | 341 | 177 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number with MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 2 | 3 | 3 | 1 | 1 |
| Number with MDUFA IV Decision | 2 | 3 | 3 | 1 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 1 | 1 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | N/A | N/A | N/A | N/A | N/A |
| Rate of Not Approvable | 50.00% | 33.33% | N/A | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Filed | 0 | 0 | 0 | 0 | 0 |
| Number With MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| Number of Withdrawal | 0 | 0 | 0 | 0 | 0 |
| Number of Not Approvable | 0 | 0 | 0 | 0 | 0 |
| Number of Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Withdrawal | N/A | N/A | N/A | N/A | N/A |
| Rate of Not Approvable | N/A | N/A | N/A | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days | 90% Within 180 FDA Days |
| Number of PMAs Filed | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Goal Met | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | N/A | N/A | N/A | N/A | N/A |

*Includes submission that went to panel

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days | 90% Within 320 FDA Days |
| Number of PMAs Filed | 1 | 2 | 2 | 0 | 1 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 1 | 2 | 2 | 0 | 0 |
| MDUFA IV Decision Goal Met | 1 | 2 | 2 | 0 | 0 |
| PMAs Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 1 |
| PMAs Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | N/A | N/A |

*Includes submission that went to panel

Section 2 PMA 180-Day Supplements - Center Level Metric

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days | 95% SI Within 90 FDA Days |
| Eligible for SI | 8 | 5 | 8 | 7 | 5 |
| SI Goal Met | 8 | 5 | 8 | 4 | 0 |
| SI Goal Not Met | 0 | 0 | 0 | 0 | 0 |
| SI Pending Within Goal | 0 | 0 | 0 | 0 | 5 |
| SI Pending Past Goal | 0 | 0 | 0 | 0 | 0 |
| Closed Without SI | 0 | 0 | 0 | 3 | 0 |
| Current SI Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

Table 2.2 CBER - PMA 180-Day Supplements MDUFA IV Decision Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days | 95% SI Within 180 FDA Days |
| Supplements Received | 8 | 5 | 8 | 7 | 5 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 4 | 0 |
| MDUFA IV Decision | 8 | 5 | 8 | 2 | 0 |
| MDUFA IV Decision Goal Met | 8 | 5 | 8 | 2 | 0 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 1 | 5 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 8 | 5 | 8 | 7 | 5 |
| Number with MDUFA IV Decision | 8 | 5 | 8 | 2 | 0 |
| Number of Not Approvable | 0 | 0 | 1 | 0 | 0 |
| Rate of Not Approvable | 0.00% | 0.00% | 12.50% | 0.00% | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

Section 3 PMA Real-Time Supplements - Center Level Metric

Table 3.1 CBER - PMA Real-Time Supplements MDUFA IV Decision Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| Supplements Received | 3 | 2 | 5 | 9 | 6 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision | 3 | 2 | 5 | 9 | 3 |
| MDUFA IV Decision Goal Met | 3 | 2 | 5 | 9 | 3 |
| Supplements Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 3 |
| Supplements Pending MDUFA IV Decision Past Goal | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Goal Met | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|---------|---------|---------|---------|---------|
| Number Received | 3 | 2 | 5 | 9 | 6 |
| Number With MDUFA IV Decision | 3 | 2 | 5 | 9 | 3 |
| Number of Not Approvable | 0 | 0 | 0 | 0 | 0 |
| Rate of Not Approvable | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 53 | 54 | 50 | 45 | 19 |
| Closed Before RTA Action | 0 | 0 | 1 | 1 | 0 |
| Number Accepted | 40 | 38 | 34 | 36 | 14 |
| Number Without a RTA Review and > 15 Days Since Date Received | 2 | 1 | 1 | 3 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 1 |
| Number Not Accepted | 11 | 15 | 14 | 5 | 4 |
| Rate of Submissions Not Accepted for Review | 20.75% | 27.78% | 28.57% | 11.36% | 22.22% |

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

| Substantive Interaction (SI) Goal | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------------|
| | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days | 95% SI Within 60 FDA Days |
| Eligible for SI | 49 | 51 | 44 | 40 | 16 |
| Deleted or Withdrawn Prior to SI | 0 | 0 | 0 | 0 | 0 |
| SI Within 60 FDA Days | 49 | 51 | 43 | 40 | 11 |
| SI Over 60 FDA Days | 0 | 0 | 1 | 0 | 0 |
| SI Pending Within 60 FDA Days | 0 | 0 | 0 | 0 | 5 |
| SI Pending Over 60 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s NSE Without SI | 0 | 0 | 0 | 0 | 0 |
| Current SI Performance Percent Within 60 FDA Days | 100.00% | 100.00% | 97.73% | 100.00% | 100.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Substantive Interaction | 49 | 51 | 44 | 40 | 11 |
| Average Number of FDA Days to Substantive Interaction | 50.60 | 45.27 | 48.98 | 53.63 | 54.18 |
| 20th Percentile FDA Days to Substantive Interaction | 43 | 21 | 21 | 56 | 58 |
| 40th Percentile FDA Days to Substantive Interaction | 57 | 53 | 55 | 58 | 59 |
| 60th Percentile FDA Days to Substantive Interaction | 59 | 58 | 59 | 59 | 60 |
| 80th Percentile FDA Days to Substantive Interaction | 60 | 60 | 60 | 60 | 60 |
| Maximum FDA Days to Substantive Interaction | 60 | 60 | 64 | 60 | 60 |

Table 6.4 CBER - 510(k) MDUFA IV Decision Performance Goal

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 49 | 51 | 44 | 40 | 16 |
| Non-MDUFA IV Decision | 6 | 5 | 6 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 43 | 46 | 37 | 31 | 5 |
| MDUFA IV Decision Within 90 FDA Days | 43 | 46 | 37 | 31 | 5 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 1 | 9 | 11 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

Table 6.5 CBER - 510(k) Time to MDUFA IV Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 1.30 | 1.48 | 1.24 | 1.32 | 1.00 |
| Number With MDUFA IV Decision | 43 | 46 | 37 | 31 | 1 |
| Average Number of FDA Days to MDUFA IV Decision | 75.58 | 67.48 | 64.08 | 74.39 | 60.80 |
| 20th Percentile FDA Days to MDUFA IV Decision | 65 | 28 | 30 | 63 | 30 |
| 40th Percentile FDA Days to MDUFA IV Decision | 85 | 77 | 65 | 81 | 30 |
| 60th Percentile FDA Days to MDUFA IV Decision | 88 | 87 | 82 | 87 | 72 |
| 80th Percentile FDA Days to MDUFA IV Decision | 90 | 89 | 88 | 89 | 84 |
| Maximum FDA Days to MDUFA IV Decision | 90 | 206 | 90 | 96 | 88 |
| Average Number of Industry Days to MDUFA IV Decision | 25.26 | 75.76 | 16.95 | 39.74 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 78 | 0 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 59 | 179 | 29 | 73 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 178 | 389 | 199 | 360 | 0 |
| Average Number of Total Days to MDUFA IV Decision | 100.84 | 143.24 | 81.05 | 114.13 | 60.80 |
| 20th Percentile Total Days to MDUFA IV Decision | 76 | 59 | 30 | 63 | 30 |
| 40th Percentile Total Days to MDUFA IV Decision | 86 | 87 | 65 | 81 | 30 |
| 60th Percentile Total Days to MDUFA IV Decision | 90 | 141 | 82 | 89 | 72 |
| 80th Percentile Total Days to MDUFA IV Decision | 147 | 269 | 105 | 161 | 84 |
| Maximum Total Days to MDUFA IV Decision | 268 | 463 | 287 | 450 | 88 |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|-------------------------------|----------------|----------------|----------------|----------------|----------------|
| 510(k) Accepted | 49 | 51 | 44 | 40 | 16 |
| Number With MDUFA IV Decision | 43 | 46 | 37 | 31 | 5 |
| Number of SE Decision | 43 | 43 | 35 | 31 | 5 |
| Number of NSE Decision | 0 | 3 | 2 | 0 | 0 |
| Number of Withdrawal | 2 | 4 | 4 | 0 | 0 |
| Number of Deleted | 3 | 1 | 2 | 0 | 0 |
| Rate of SE Decision | 100.00% | 93.48% | 94.59% | 100.00% | 100.00% |
| Rate of NSE Decision | 0.00% | 6.52% | 5.41% | 0.00% | 0.00% |
| Rate of Withdrawal | 4.08% | 7.84% | 9.09% | 0.00% | 0.00% |
| Rate of Deleted | 6.12% | 1.96% | 4.55% | 0.00% | 0.00% |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean Industry Days for Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |

Table 6.8 CBER - LDT 510(k) MDUFA IV Decision Metric

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decision Within 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | N/A | N/A | N/A | N/A | N/A |

Table 6.9 CBER - Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|------------------------|------------------------|------------------------|------------------------|------------------------|
| | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days | 95% Within 90 FDA Days |
| 510(k)s Accepted | 15 | 17 | 7 | 19 | 4 |
| Non-MDUFA IV Decision | 0 | 1 | 0 | 0 | 0 |
| MDUFA IV Decision (SE/NSE) | 15 | 16 | 7 | 13 | 2 |
| MDUFA IV Decision Within 90 FDA Days | 15 | 16 | 7 | 13 | 2 |
| 510(k)s Pending MDUFA IV Decision | 0 | 0 | 0 | 6 | 2 |
| 510(k)s Pending MDUFA IV Decision Over 90 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 90 FDA Days | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |

Section 8 De Novo Center Level Metrics

Table 8.1 CBER - De Novo Acceptance Review Decision*

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 0 | 1 | 0 | 0 | 2 |
| Closed Before RTA Action | N/A | N/A | 0 | 0 | 0 |
| Number Accepted First RTA Cycle | N/A | N/A | 0 | 0 | 1 |
| Number Without a RTA Review and > 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Without a RTA Review and <= 15 Days Since Date Received | N/A | N/A | 0 | 0 | 0 |
| Number Not Accepted | N/A | N/A | 0 | 0 | 1 |
| Rate of Submissions Not Accepted for Review | N/A | N/A | 0.00% | 0.00% | 50.00% |

* RTA will be implemented when the guidance, including the submission checklist, is finalized.

Table 8.2 CBER - De Novo MDUFA IV Decision Performance Goals

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| | 50% Within 150 FDA Days | 55% Within 150 FDA Days | 60% Within 150 FDA Days | 65% Within 150 FDA Days | 70% Within 150 FDA Days |
| De Novos Accepted | 0 | 1 | 0 | 0 | 1 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 1 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 1 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 1 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | N/A | 100.00% | N/A | N/A | N/A |

Table 8.3 CBER - De Novo Time to MDUFA IV Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| Average Review Cycles | 0.00 | 2.00 | 0.00 | 0.00 | 0.00 |
| Number With MDUFA IV Decision | 0 | 1 | 0 | 0 | 0 |
| Average FDA Days to MDUFA IV Decision | 0.00 | 150.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile FDA Days to MDUFA IV Decision | 0 | 150 | 0 | 0 | 0 |
| 40th Percentile FDA Days to MDUFA IV Decision | 0 | 150 | 0 | 0 | 0 |
| 60th Percentile FDA Days to MDUFA IV Decision | 0 | 150 | 0 | 0 | 0 |
| 80th Percentile FDA Days to MDUFA IV Decision | 0 | 150 | 0 | 0 | 0 |
| Maximum FDA Days to MDUFA IV Decision | 0 | 150 | 0 | 0 | 0 |
| Average Industry Days to MDUFA IV Decision | 0.00 | 81.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Industry Days to MDUFA IV Decision | 0 | 81 | 0 | 0 | 0 |
| 40th Percentile Industry Days to MDUFA IV Decision | 0 | 81 | 0 | 0 | 0 |
| 60th Percentile Industry Days to MDUFA IV Decision | 0 | 81 | 0 | 0 | 0 |
| 80th Percentile Industry Days to MDUFA IV Decision | 0 | 81 | 0 | 0 | 0 |
| Maximum Industry Days to MDUFA IV Decision | 0 | 81 | 0 | 0 | 0 |
| Average Total Days to MDUFA IV Decision | 0.00 | 231.00 | 0.00 | 0.00 | 0.00 |
| 20th Percentile Total Days to MDUFA IV Decision | 0 | 231 | 0 | 0 | 0 |
| 40th Percentile Total Days to MDUFA IV Decision | 0 | 231 | 0 | 0 | 0 |
| 60th Percentile Total Days to MDUFA IV Decision | 0 | 231 | 0 | 0 | 0 |
| 80th Percentile Total Days to MDUFA IV Decision | 0 | 231 | 0 | 0 | 0 |
| Maximum Total Days to MDUFA IV Decision | 0 | 231 | 0 | 0 | 0 |

Table 8.4 CBER - De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--------------------------------|---------|---------|---------|---------|---------|
| De Novos Accepted | 0 | 1 | 0 | 0 | 1 |
| Number With MDUFA IV Decisions | 0 | 1 | 0 | 0 | 0 |
| Number With Granted Decisions | 0 | 1 | 0 | 0 | 0 |
| Number With Declined Decisions | 0 | 0 | 0 | 0 | 0 |
| Number of Withdrawals | 0 | 0 | 0 | 0 | 0 |
| Number Deleted | 0 | 0 | 0 | 0 | 0 |
| Rate of Granted Decisions | N/A | 100.00% | N/A | N/A | N/A |
| Rate of Declined Decisions | N/A | N/A | N/A | N/A | N/A |
| Rate of Withdrawals | N/A | N/A | N/A | N/A | N/A |
| Rate of Deleted | N/A | N/A | N/A | N/A | N/A |

Table 8.5 CBER - De Novo Performance Metrics-Submissions Missing Performance Goals

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|---------|---------|
| Number of Submissions that Missed the Goal | 0 | 0 | 0 | 0 | 0 |
| Mean FDA Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Mean Industry Days for Submissions that Missed the Goal | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

Table 8.6 CBER - LDT De Novo MDUFA IV Decision Metrics

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| De Novos Accepted | 0 | 0 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | N/A | N/A | N/A | N/A | N/A |

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

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|----------------|----------------|----------------|----------------|----------------|
| De Novos Accepted | 0 | 1 | 0 | 0 | 0 |
| Non-MDUFA IV Decisions | 0 | 0 | 0 | 0 | 0 |
| MDUFA IV Decisions | 0 | 1 | 0 | 0 | 0 |
| MDUFA IV Decisions Within 150 FDA Days | 0 | 1 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision | 0 | 0 | 0 | 0 | 0 |
| De Novos Pending MDUFA IV Decision Over 150 FDA Days | 0 | 0 | 0 | 0 | 0 |
| Current Performance Percent Within 150 FDA Days | N/A | 100.00% | N/A | N/A | N/A |

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CBER - Pre-Sub Acceptance Review Decision

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number Received | 76 | 77 | 77 | 80 | 24 |
| Closed Before RTA Action | 5 | 3 | 10 | 6 | 1 |
| Number Accepted First RTA Cycle | 69 | 70 | 65 | 67 | 17 |
| Number Without a RTA Review and > 15 Days Since Date Received | 1 | 3 | 1 | 6 | 3 |
| Number Without a RTA Review and <= 15 Days Since Date Received | 0 | 0 | 0 | 0 | 2 |
| Number Not Accepted | 1 | 1 | 1 | 1 | 1 |
| Rate of Submissions Not Accepted for Review | 1.41% | 1.35% | 1.49% | 1.35% | 4.76% |

Table 9.2 CBER - MDUFA IV Pre-Sub Performance Goals*

| Performance Metric | MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting) | | | | |
|--|---|--------------------|--------------------|--------------------|--------------------|
| | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
| | ≥ 1530 Submissions | ≥ 1645 Submissions | ≥ 1765 Submissions | ≥ 1880 Submissions | ≥ 1950 Submissions |
| Written Feedback Sent | 70 | 74 | 68 | 71 | 17 |
| Written Feedback Provided Within MDUFA IV Goal | 68 | 71 | 63 | 67 | 15 |

*Due to resource limitations related to COVID-19 activities, some Pre-Subs were reviewed with a delayed timeline which may have resulted in missed MDUFA goals

Table 9.3 CBER - Pre-Sub Time to MDUFA IV Decision*

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Written Feedback Sent | 70 | 74 | 68 | 71 | 17 |
| Average FDA Days to Written Feedback | 57.86 | 61.00 | 56.70 | 62.28 | 59.71 |
| 20th Percentile FDA Days to Written Feedback | 47 | 55 | 48 | 54 | 49 |
| 40th Percentile FDA Days to Written Feedback | 58 | 60 | 58 | 62 | 58 |
| 60th Percentile FDA Days to Written Feedback | 64 | 63 | 64 | 64 | 66 |
| 80th Percentile FDA Days to Written Feedback | 67 | 68 | 68 | 66 | 68 |
| Maximum FDA Days to Written Feedback | 72 | 75 | 77 | 156 | 80 |

*Due to resource limitations related to COVID-19 activities, some Pre-Subs were reviewed with a delayed timeline which may have resulted in missed MDUFA goals

Table 9.4 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Meetings Not Scheduled By Day 30 | 0 | 0 | 0 | 0 | 0 |
| Average Days to Scheduling for Meetings Scheduled After Day 30 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |

Table 9.5 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|---|----------------|----------------|----------------|----------------|----------------|
| Meeting Held | 42 | 33 | 27 | 39 | 8 |
| Meeting Minutes Submitted Within 15 Days of Meeting | 33 | 30 | 26 | 33 | 5 |
| Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date | 0 | 0 | 0 | 0 | 0 |
| Meeting Minutes Past 15 Days of Meeting | 9 | 2 | 1 | 6 | 3 |
| Meeting Minutes Not Submitted and >15 Days Since Meeting | 0 | 1 | 0 | 0 | 0 |
| Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days | 78.57% | 90.91% | 96.30% | 84.62% | 62.50% |

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

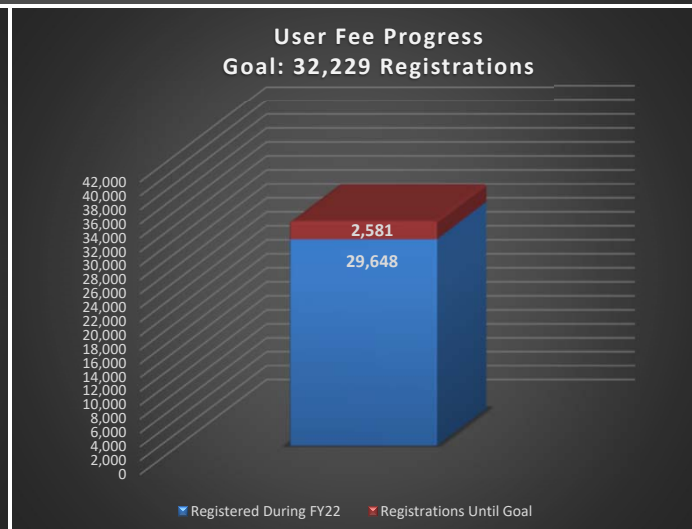
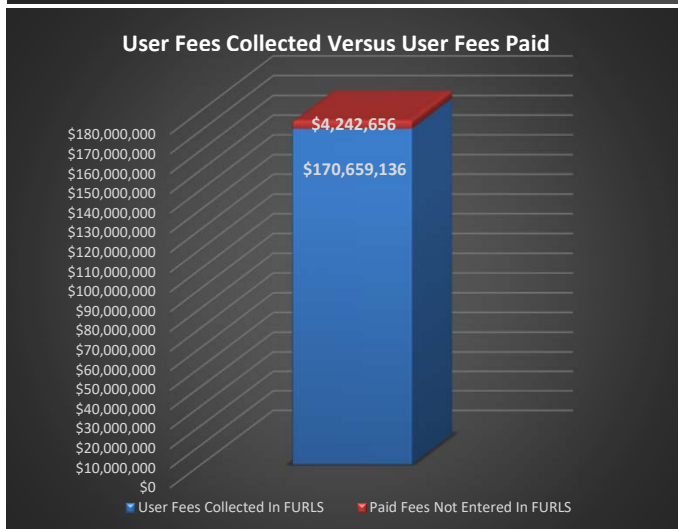
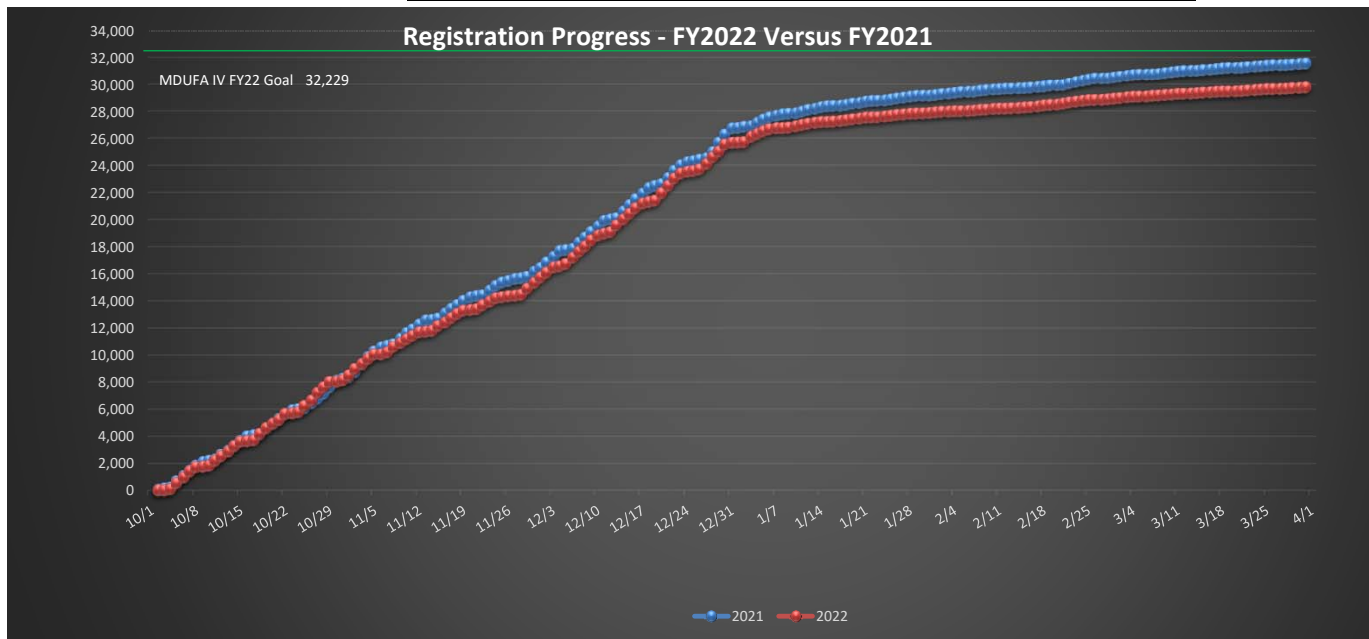
| Performance Metric | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
|--|---------|---------|---------|---------|---------|
| Number of IDEs Received | 15 | 15 | 21 | 20 | 6 |
| Average Number of Cycles to IDE Approval or Conditional Approval | 1.25 | 1.63 | 1.07 | 1.25 | 1.00 |
| Average Number of Amendments Prior to IDE Approval or Conditional Approval | 0.25 | 0.63 | 0.07 | 0.25 | 0.00 |

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MDUFA IV Registrations - 2nd Quarter Summary FY2022*

| Current Active Registrations by Type | FY22 Q2 | | | FY21 Year End Active Totals | | | FY22 vs End FY21 |
|--|---------------|---------------|---------------|-----------------------------|---------------|---------------|------------------|
| | Domestic | Foreign | Total | Domestic | Foreign | Total | |
| Manufacturer/ Complaint File Handler | 6,545 | 12,079 | 18,622 | 6,899 | 14,017 | 20,916 | 89.03% |
| Contract Manufacturer | 1,188 | 1,708 | 2,896 | 1,213 | 1,745 | 2,958 | 97.90% |
| Contract Sterilizer | 67 | 155 | 222 | 70 | 156 | 226 | 98.23% |
| Specification Developer | 1,648 | 557 | 2,205 | 1,785 | 594 | 2,379 | 92.69% |
| Reprocessor of Single Use Devices | 24 | 5 | 29 | 30 | 8 | 38 | 76.32% |
| U.S. Manufacturer of Export Only Devices | 129 | 0 | 129 | 133 | 0 | 133 | 96.99% |
| Repackager/Relabeler | 1,096 | 195 | 1,291 | 1,186 | 230 | 1,416 | 91.17% |
| Remanufacturer | 13 | 11 | 24 | 17 | 11 | 28 | 85.71% |
| Foreign Exporter/Private Label Distributor | | 1,075 | 1,075 | | 1,179 | 1,179 | 91.18% |
| Initial Importer | 3,412 | | 3,412 | 4,125 | | 4,125 | 82.72% |
| Unknown | 4 | 10 | 14 | 4 | 5 | 9 | 155.56% |
| Total: | 14,126 | 15,795 | 29,921 | 15,462 | 17,945 | 33,407 | 89.57% |

*Note: This data is current as of 4/1/2022



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| FY 2022 Medical Device User Fee Collections as of March 31st, 2022 Excludes Unearned Fees | | | | | |
|--|----------------------|-------------------|----------------------|----------------------|------------------------|
| | Receipts | Refunds | Net | Authorized | % of Authorized |
| Registration Fees | \$170,677,438 | -\$215,536 | \$170,461,902 | | |
| Application Fees | \$32,233,778 | -\$279,622 | \$31,954,157 | | |
| Total | \$202,911,216 | -\$495,158 | \$202,416,059 | \$243,473,000 | 83% |
| 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 | \$147,149,475 | \$137,778,305 |
| | | | | | |
| | FY 2018 | FY 2019 | FY 2020 | FY 2021 | FY 2022 |
| MD IV | \$193,456,432 | \$202,319,688 | \$290,488,757 | \$275,981,109 | \$202,416,059 |

MDUFA IV 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 2022 by Submission type | # Waived | # Reduced |
|---|-----------------|------------------|
| Full Fee applications^{2/} | | |
| PMA | 0 | 0 |
| PDP | 0 | 0 |
| PMR | 0 | 0 |
| BLA | | |
| BLA efficacy supplement | | |
| Panel Track Supplements | 0 | 0 |
| De Novo Classification | 2 | 20 |
| 180-Day Supplements | 0 | 8 |
| Real-Time Supplements | 0 | 18 |
| 510(k)s | 22 | 707 |
| 30-day Notices | 6 | 40 |
| 513(g)s | 0 | 22 |
| PMA Annual Report | 0 | 27 |
| Total | 30 | 842 |

^{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.