

**Agenda for Quarterly Meeting on
MDUFA IV (FY 2018-2022) Performance**
September 7, 2022, 2:00 – 3:00 pm
Zoom

Welcome –

Guidance Development

FDA MDUFA Performance — Actions through June 30, 2022

- Report on decision goals for 3rd Quarter FY 2022

Registration and Listing

Qualitative Update on Finances – 3rd Quarter FY 2022

- User fee receipts through the 3rd Quarter FY 2022

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-designation15	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

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
5	Q1	Surgical Staplers and Staples for Internal Use - Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-staplers-and-staples-internal-use-labeling-recommendations	10/8/2021	Yes	No	N/A	A-List
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

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
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 www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations	12/23/21	Yes	No	N/A	No
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

#	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
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
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

#	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
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
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
28	Q3	Use of Whole Slide Imaging in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/use-whole-slide-imaging-nonclinical-toxicology-studies-questions-and-answers	4/8/22	Yes	No	N/A	No
29	Q3	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions	4/8/22	Yes	No	N/A	A-List
30	Q3	⁵ Surgical Sutures - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-sutures-performance-criteria-safety-and-performance-based-pathway	4/11/22	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
31	Q3	⁵ Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/orthopedic-fracture-fixation-plates-performance-criteria-safety-and-performance-based-pathway	4/11/22	Yes	No	N/A	No
32	Q3	Facet Screw Systems - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/facet-screw-systems-performance-criteria-safety-and-performance-based-pathway	4/13/22	Yes	No	N/A	No
33	Q3	Denture Base Resins - Performance Criteria for Safety and Performance Based Pathway www.fda.gov/regulatory-information/search-fda-guidance-documents/denture-base-resins-performance-criteria-safety-and-performance-based-pathway	4/13/22	Yes	No	N/A	No
34	Q3	Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations	4/14/22	Yes	No	N/A	No
35	Q3	⁴ Refuse to Accept Policy for 510(k)s www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks	4/21/22	Yes	No	N/A	No
36	Q3	⁵ Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/supplements-approved-premarket-approval-pma-or-humanitarian-device-exemption-hde-submissions-during	5/4/22	Yes	No	N/A	No
37	Q3	Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program www.fda.gov/regulatory-information/search-fda-guidance-documents/fostering-medical-device-improvement-fda-activities-and-engagement-voluntary-improvement-program	5/6/22	No	No	N/A	A-List

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
38	Q3	Feasibility and Early Feasibility Clinical Studies for Certain Medical Devices Intended to Therapeutically Improve Glycemic Control in Patients with Type 2 Diabetes Mellitus www.fda.gov/regulatory-information/search-fda-guidance-documents/feasibility-and-early-feasibility-clinical-studies-certain-medical-devices-intended-therapeutically	5/6/22	Yes	No	N/A	No
39	Q3	Electromagnetic Compatibility (EMC) of Medical Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices	6/6/22	Yes	No	N/A	No
40	Q3	Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-performance-assessment-quantitative-imaging-radiological-device-premarket-submissions	6/16/22	Yes	No	N/A	No
41	Q3	Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-performance-assessment-tissue-containment-systems-used-during-power-morcellation	6/21/22	Yes	No	N/A	No

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CDRH Performance Data ----
Actions through 30 June 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

OHT8: Office of Radiological Health

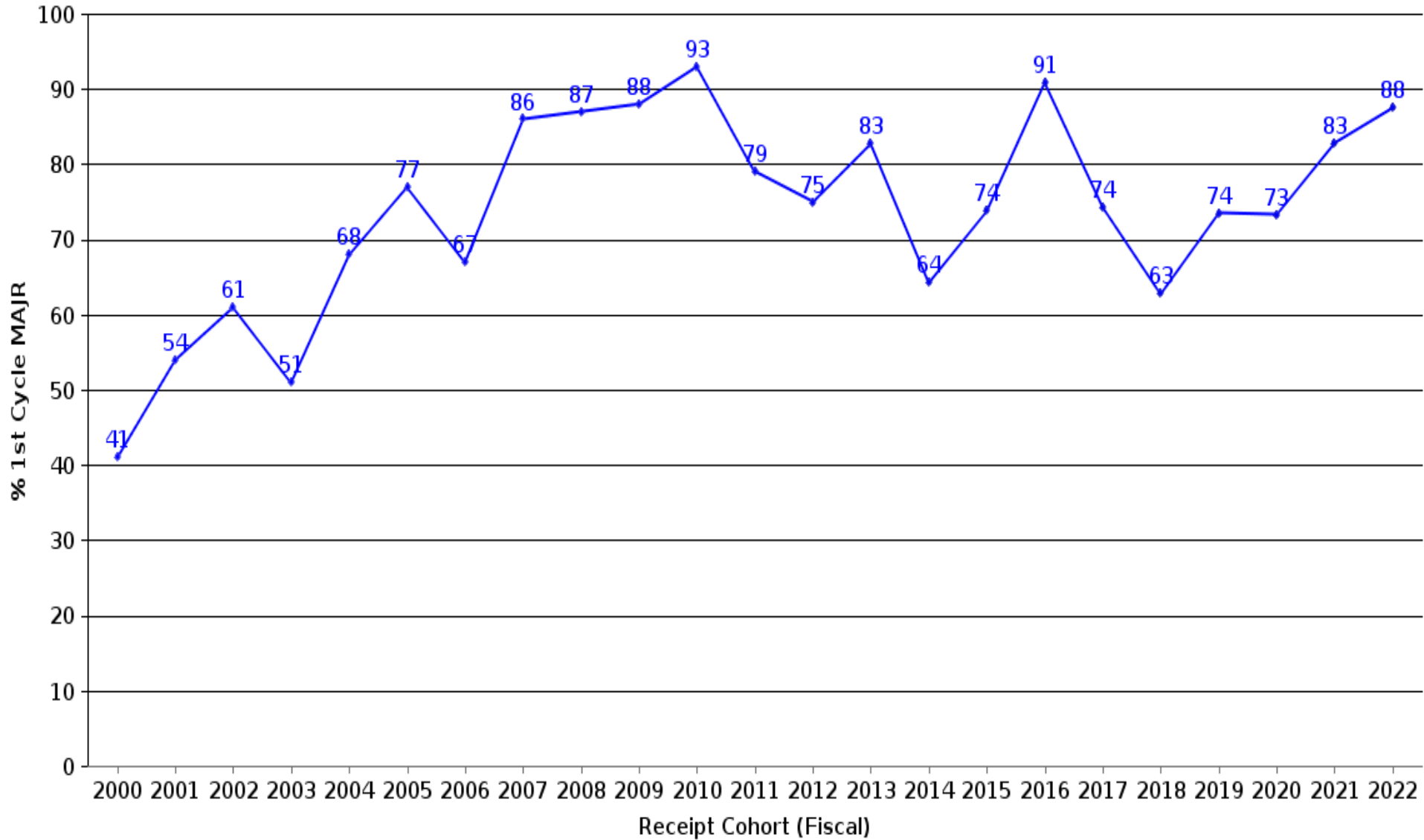
Note: Data may change in subsequent quarterly and annual reports.

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PMA's

Q3FY2022

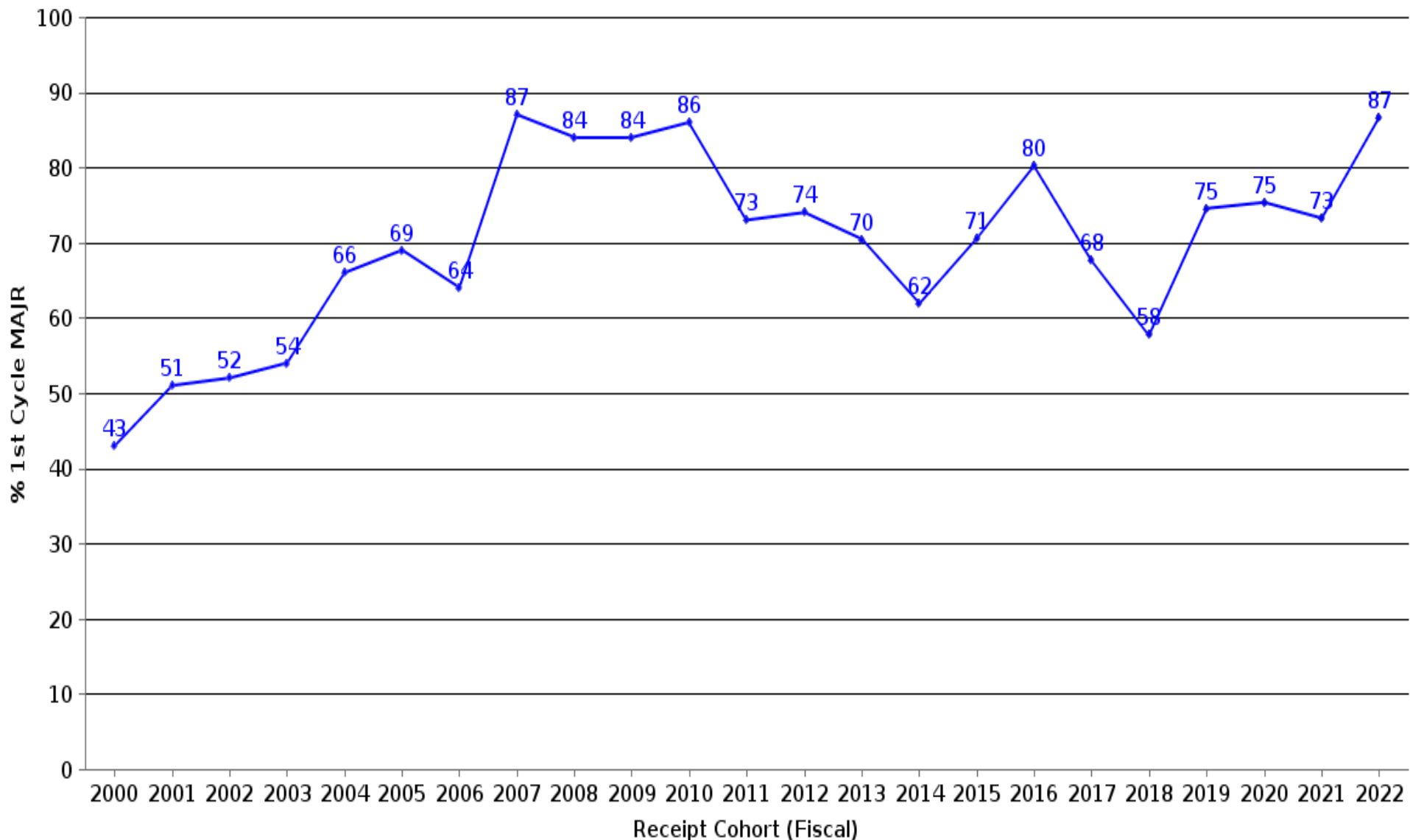
PMA Originals Filed As Of 3/31/22: 1st Cycle Major Deficiency Rate as of 6/30/22



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 3/31/22.

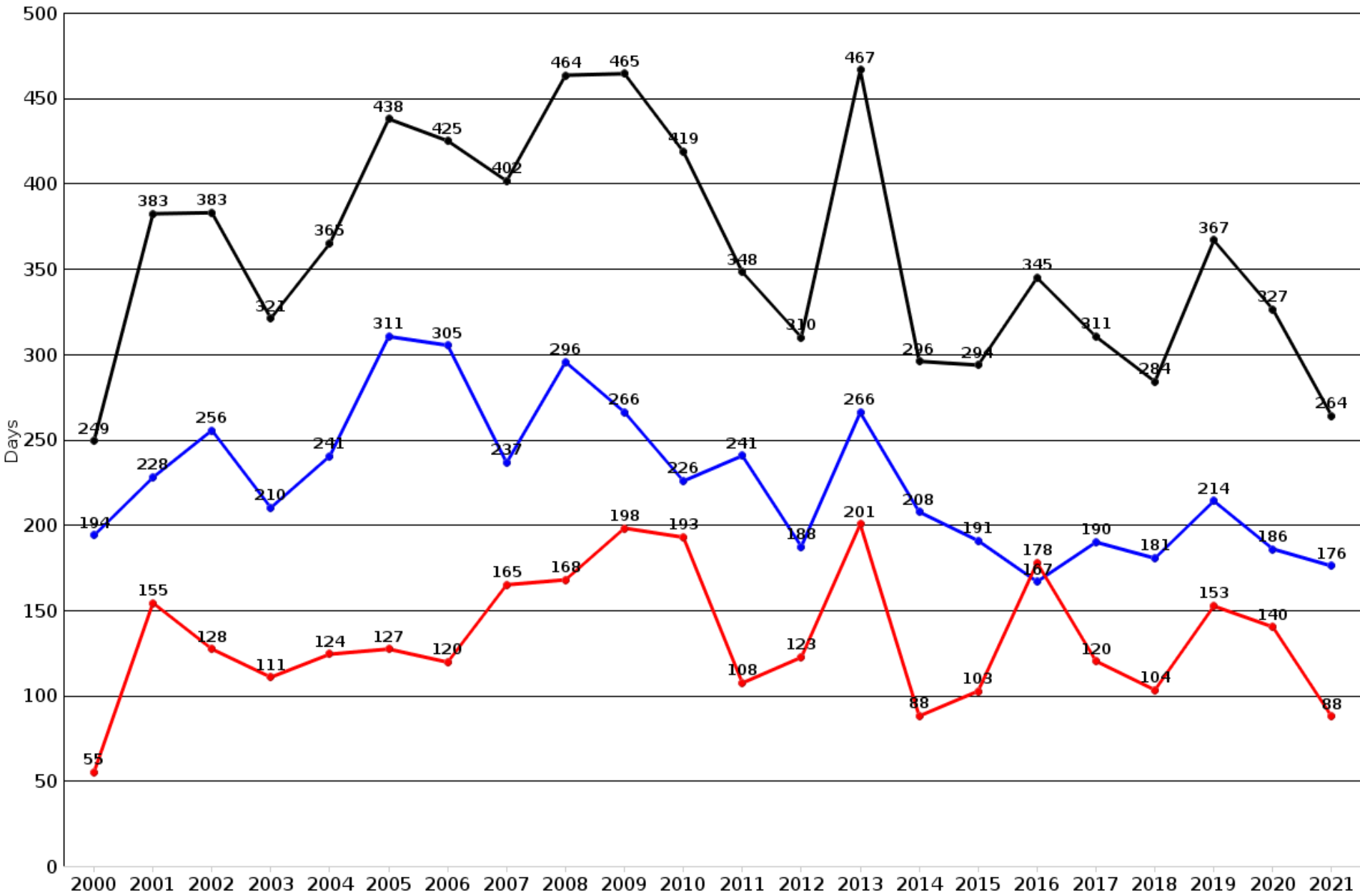
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

PMA Originals and Panel Track Supplements Filed As Of 3/31/22: 1st Cycle Major Deficiency Rate as of 6/30/22



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 3/31/22. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

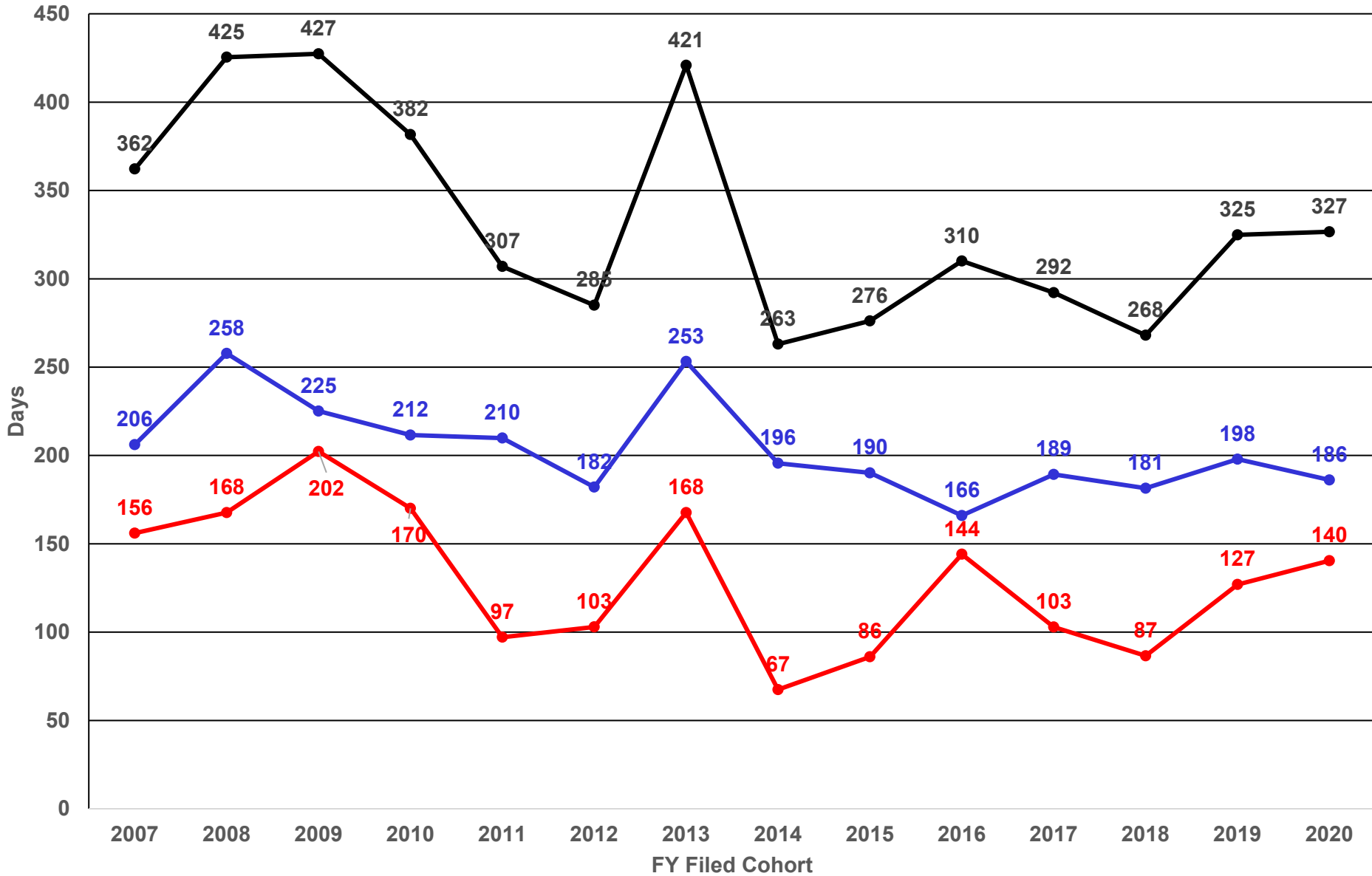
PMA Originals Filed As Of 06/30/2022: Average Time to MDUFA Decision



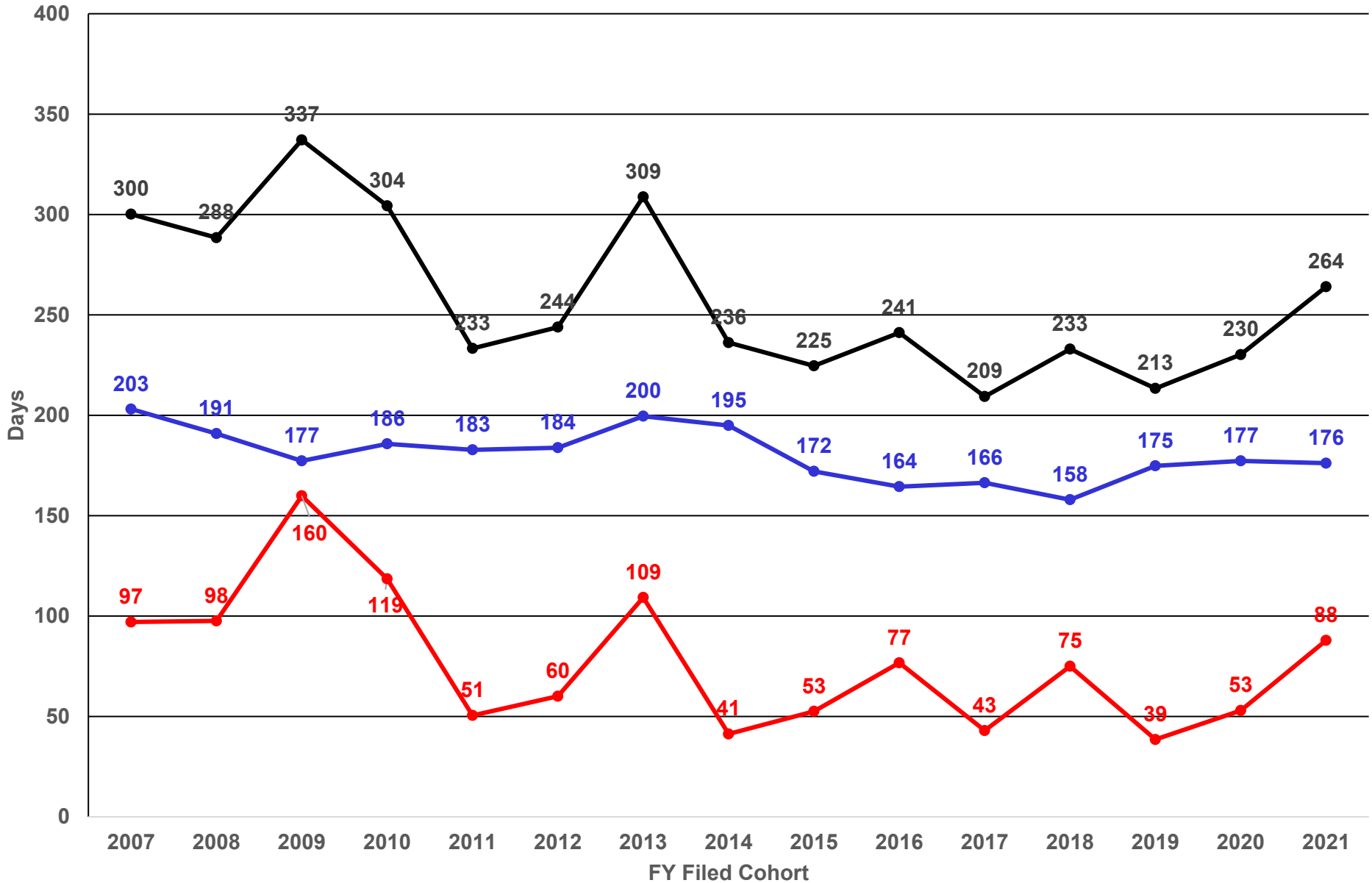
Cohorts not yet closed: 2020: 93.33%; 2021: 57.14%

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

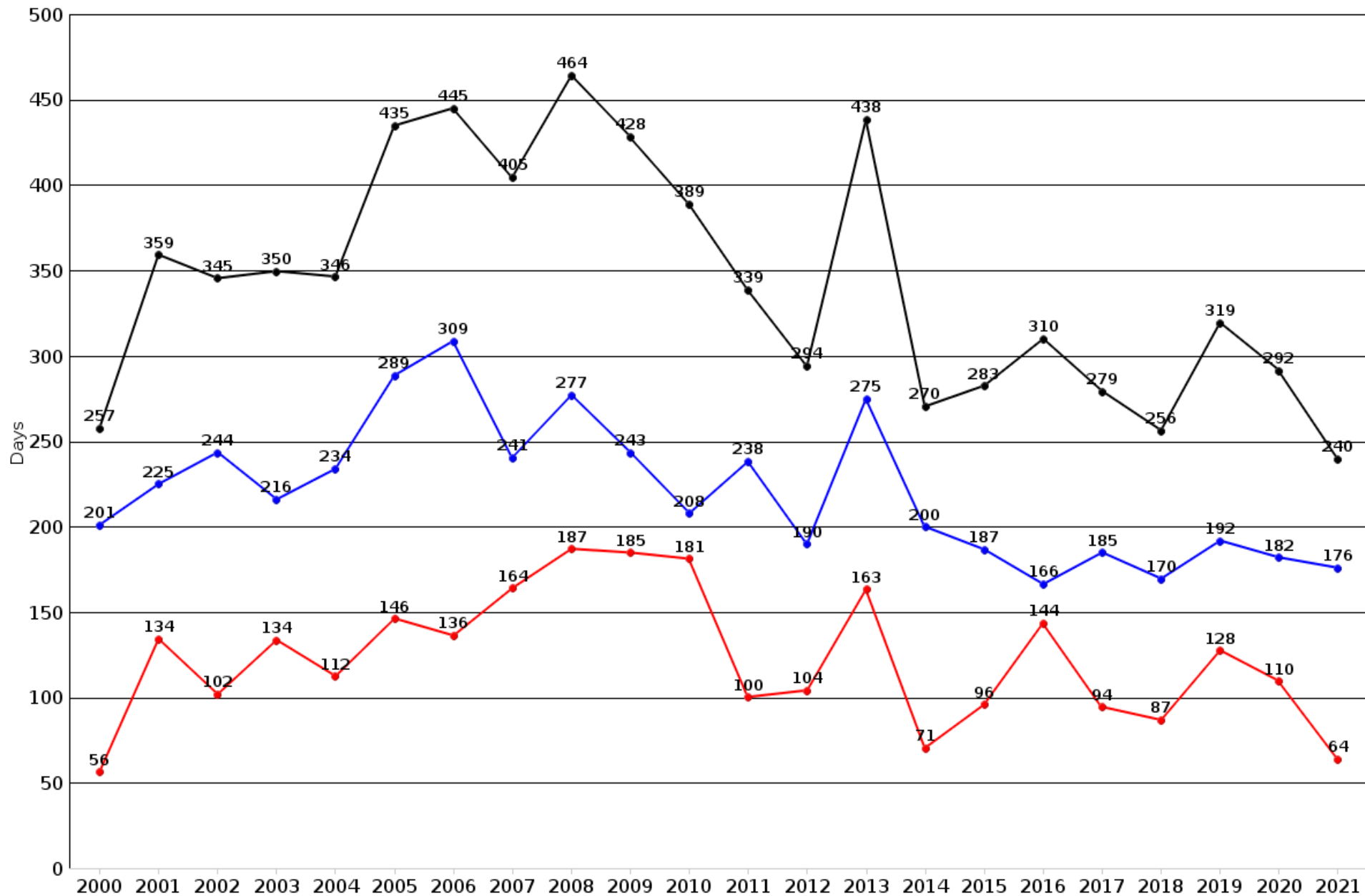
PMA Originals Filed as of 6/30/2022: Average Time to MDUFA Decision Comparison of Cohorts at 93.3% Closure



PMA Originals Filed as of 6/30/2022: Average Time to MDUFA Decision Comparison of Cohorts at 57.1% Closure



PMA Originals and Panel Track Supplements Filed As Of 06/30/2022: Average Time to MDUFA Decision

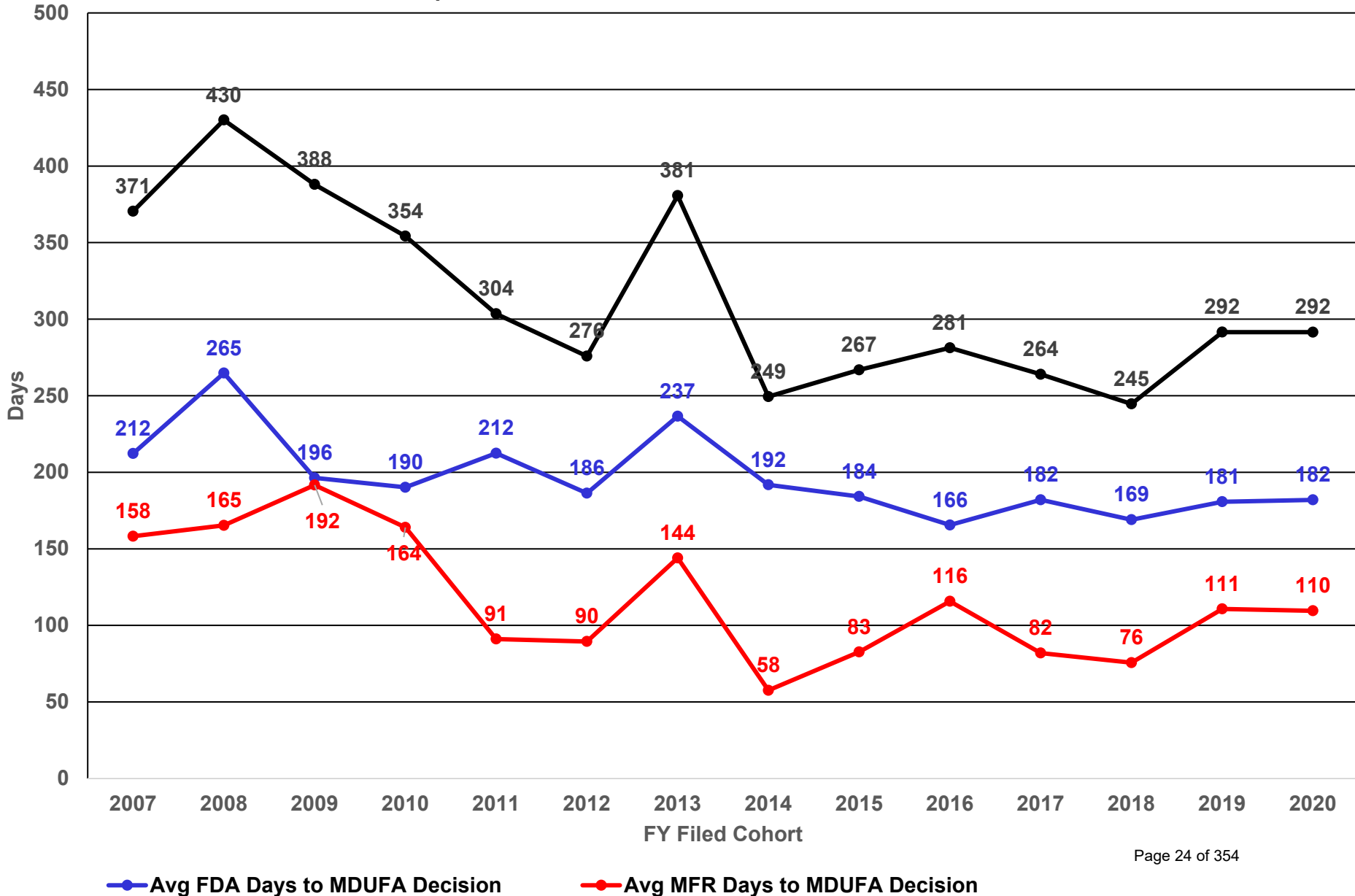


Cohorts not yet closed: 2018: 98.59%; 2020: 94.52%; 2021: 67.61%

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

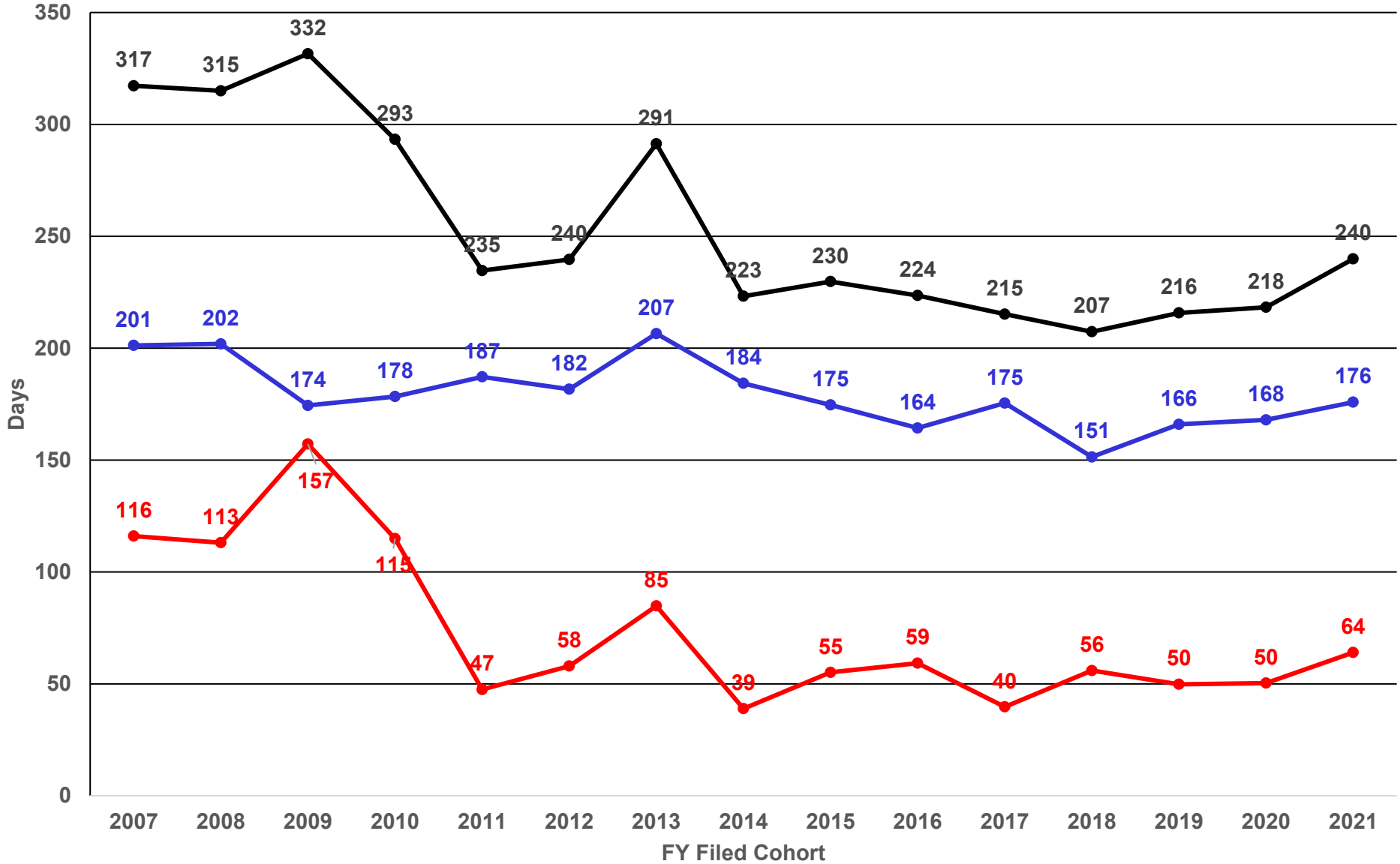
PMA Originals and Panel Track Supplements Filed as of 6/30/2022: Average Time to MDUFA Decision

Comparison of Cohorts at 94.5% Closure

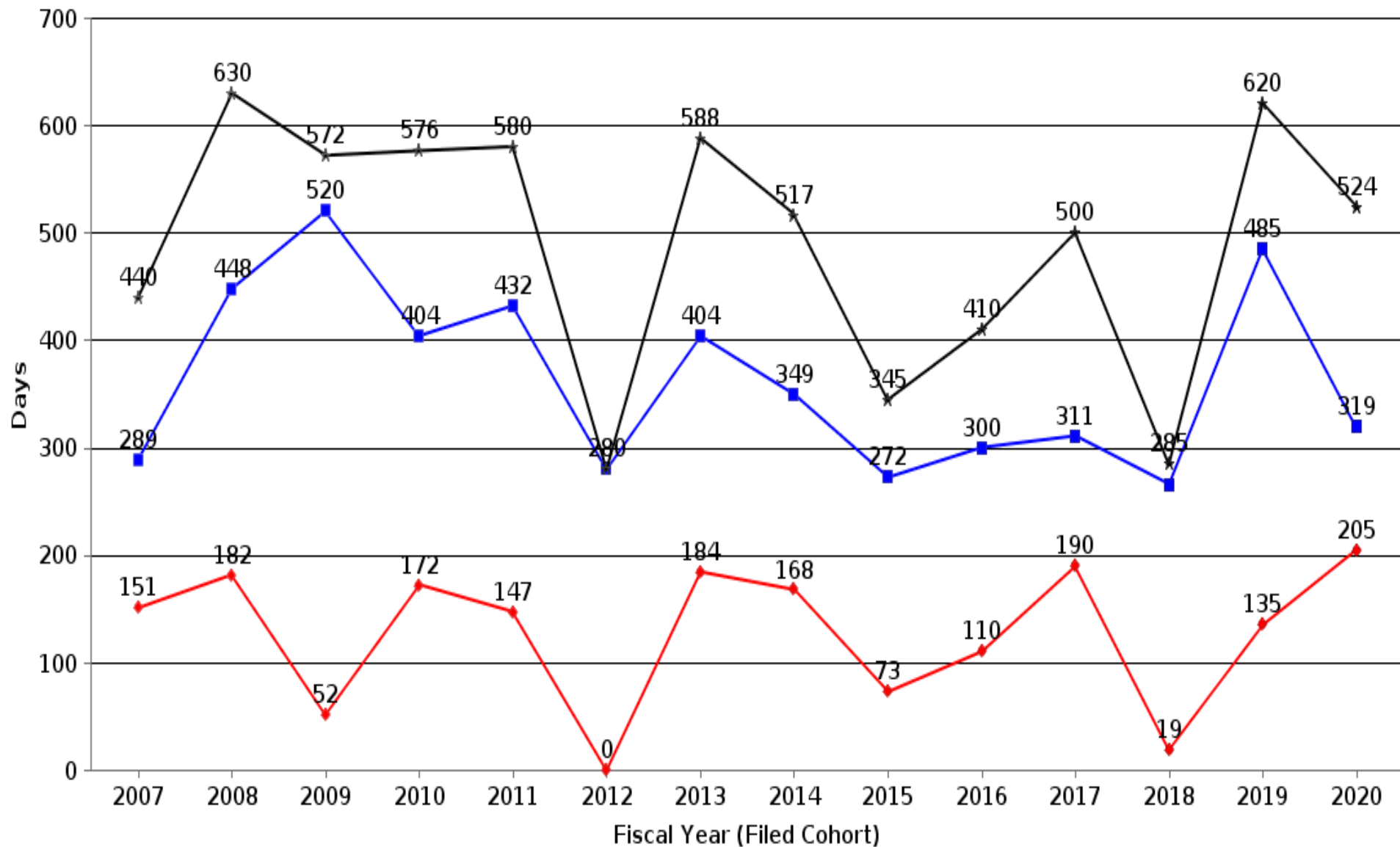


PMA Originals and Panel Track Supplements Filed as of 6/30/2022: Average Time to MDUFA Decision

Comparison of Cohorts at 67.6% Closure



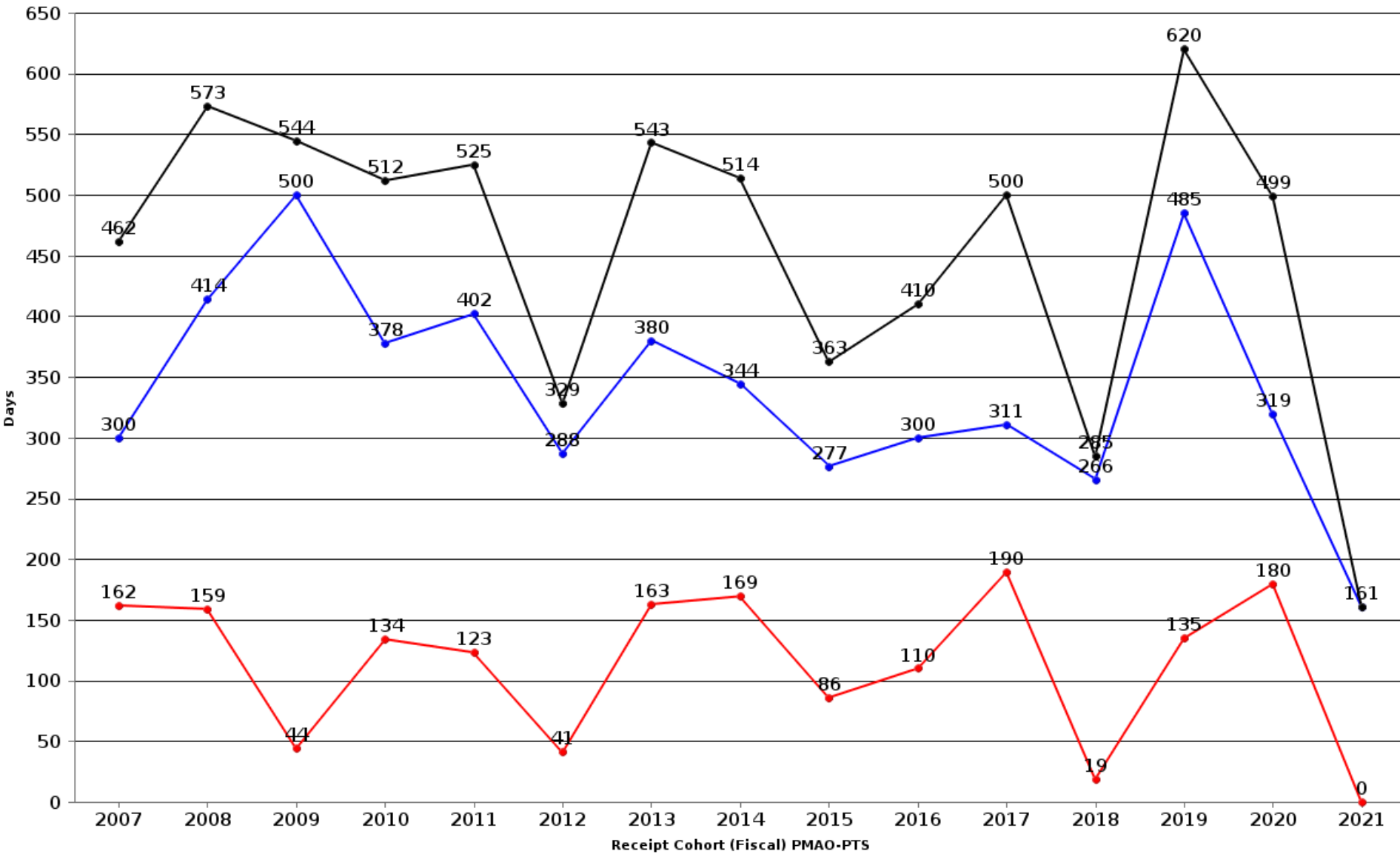
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2022/06/30



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: 2022/06/30

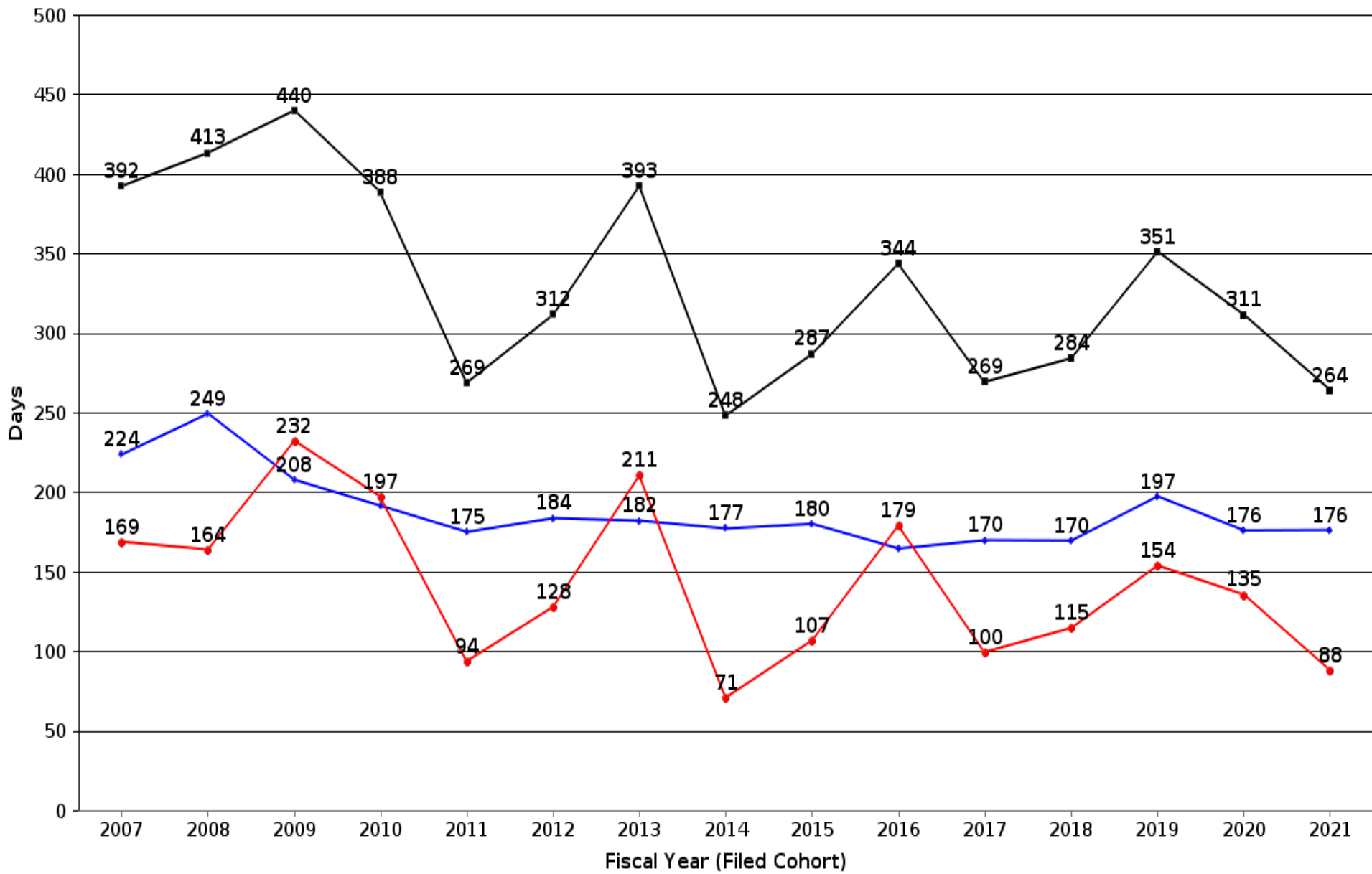


Numbers Filed/Closed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; +2012 = 2/2; 2013 = 17/17; + 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/4; 2021 = 2/1

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

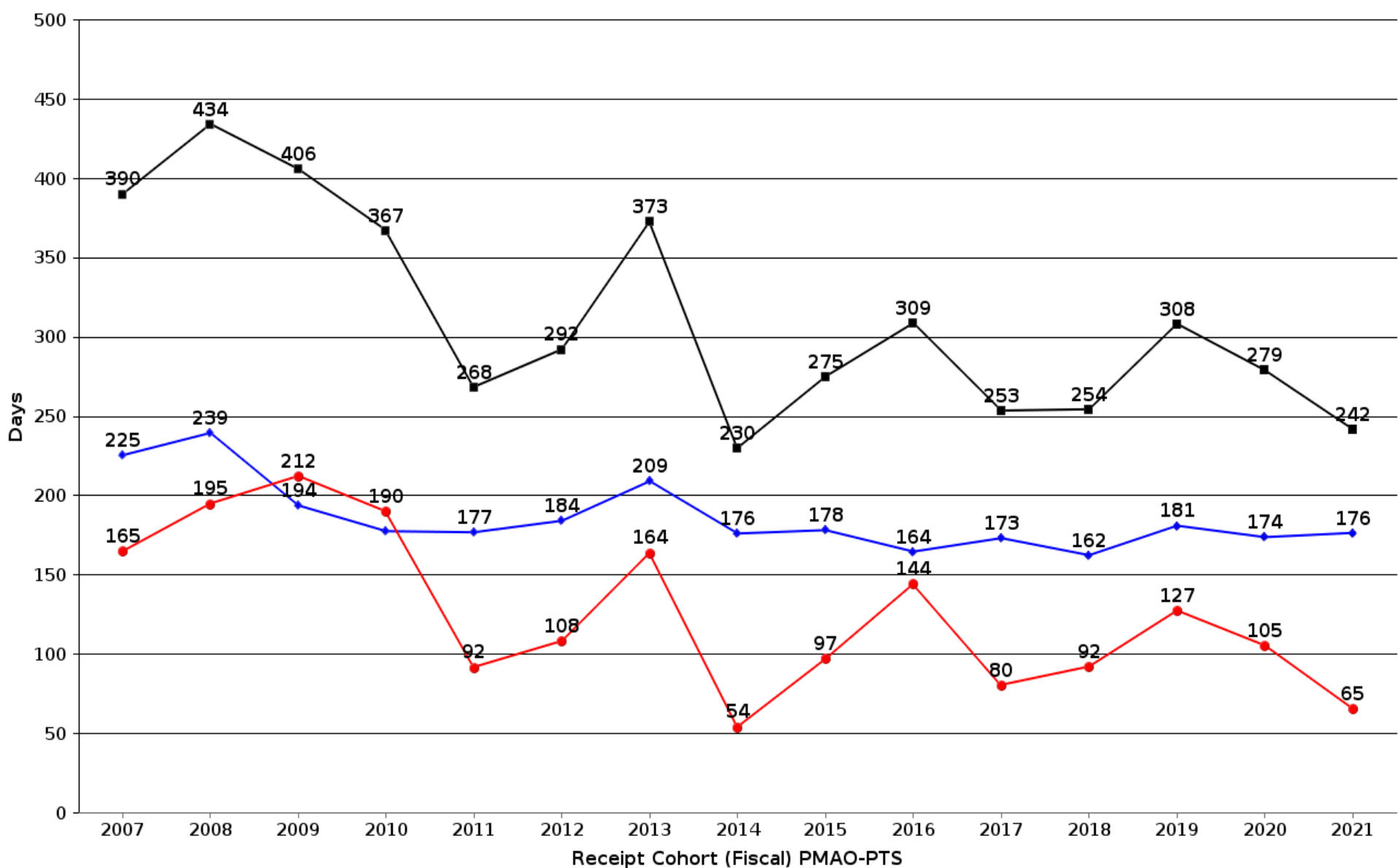
Performance data from FY13 onward map to Table 1.8. Numbers filed map to table 1.6.

PMA Originals: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2022/06/30



Numbers Filed/Closed: 2007 = 28/28; 2008 = 23/23; 2009 = 26/26; 2010 = 36/36; 2011 = 32/32; 2012 = 23/23; 2013 = 18/18; 2014 = 23/23; 2015 = 37/37; 2016 = 54/54; 2017 = 34/34; 2018 = 38/38; 2019 = 32/32; 2020 = 42/39; 2021 = 42/20

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

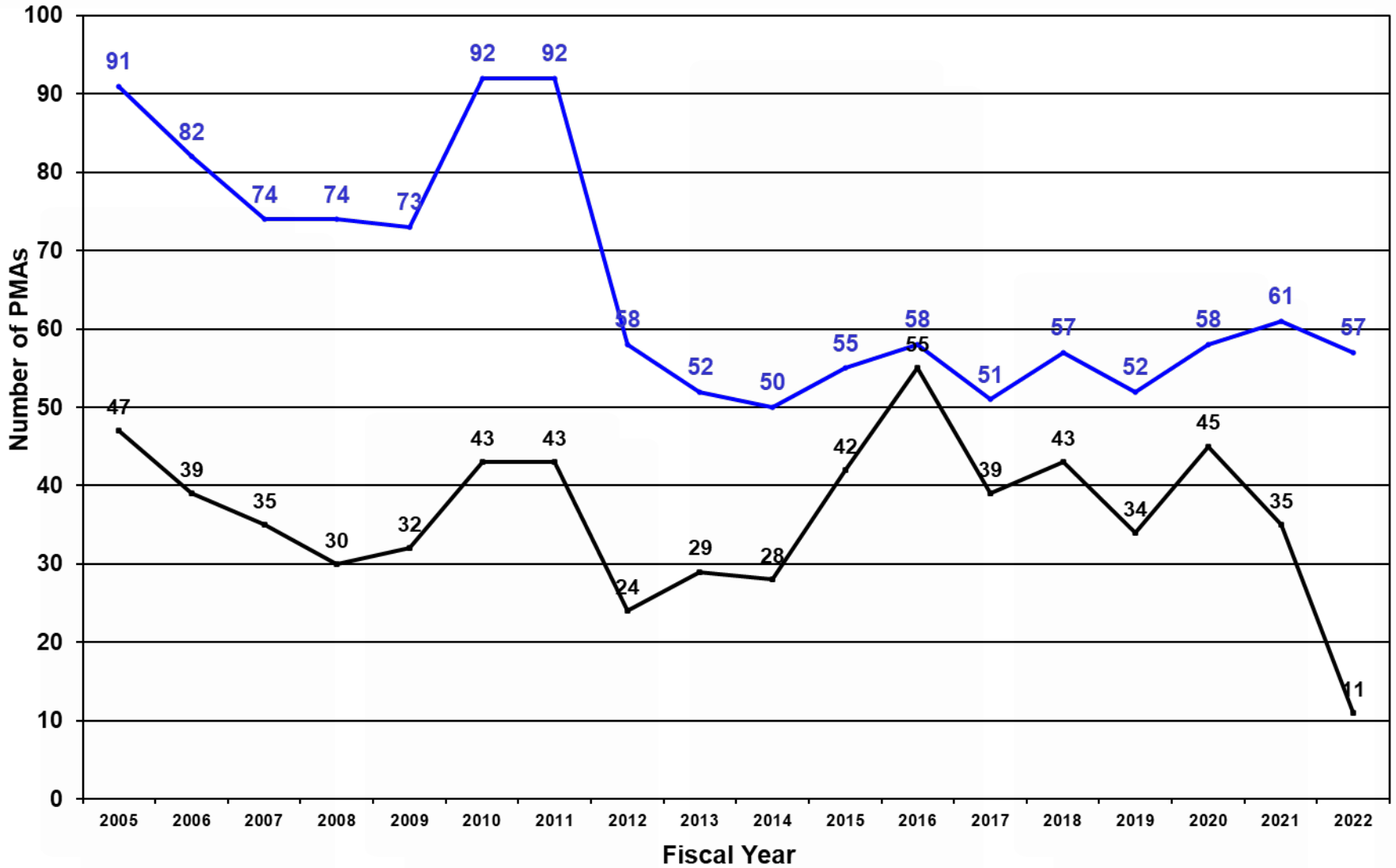


Numbers Filed/Closed: 2007 = 31/31; 2008 = 29/29; 2009 = 36/36; 2010 = 50/50; 2011 = 37/37; 2012 = 32/32; 2013 = 27/27; 2014 = 36/36; 2015 = 62/62; 2016 = 70/70; 2017 = 60/60; 2018 = 66/65; 2019 = 53/53; 2020 = 69/65; 2021 = 70/47

◆ Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ■ Avg Total Days to MDUFA Decision PMAO-PTS Page 29 of 354

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

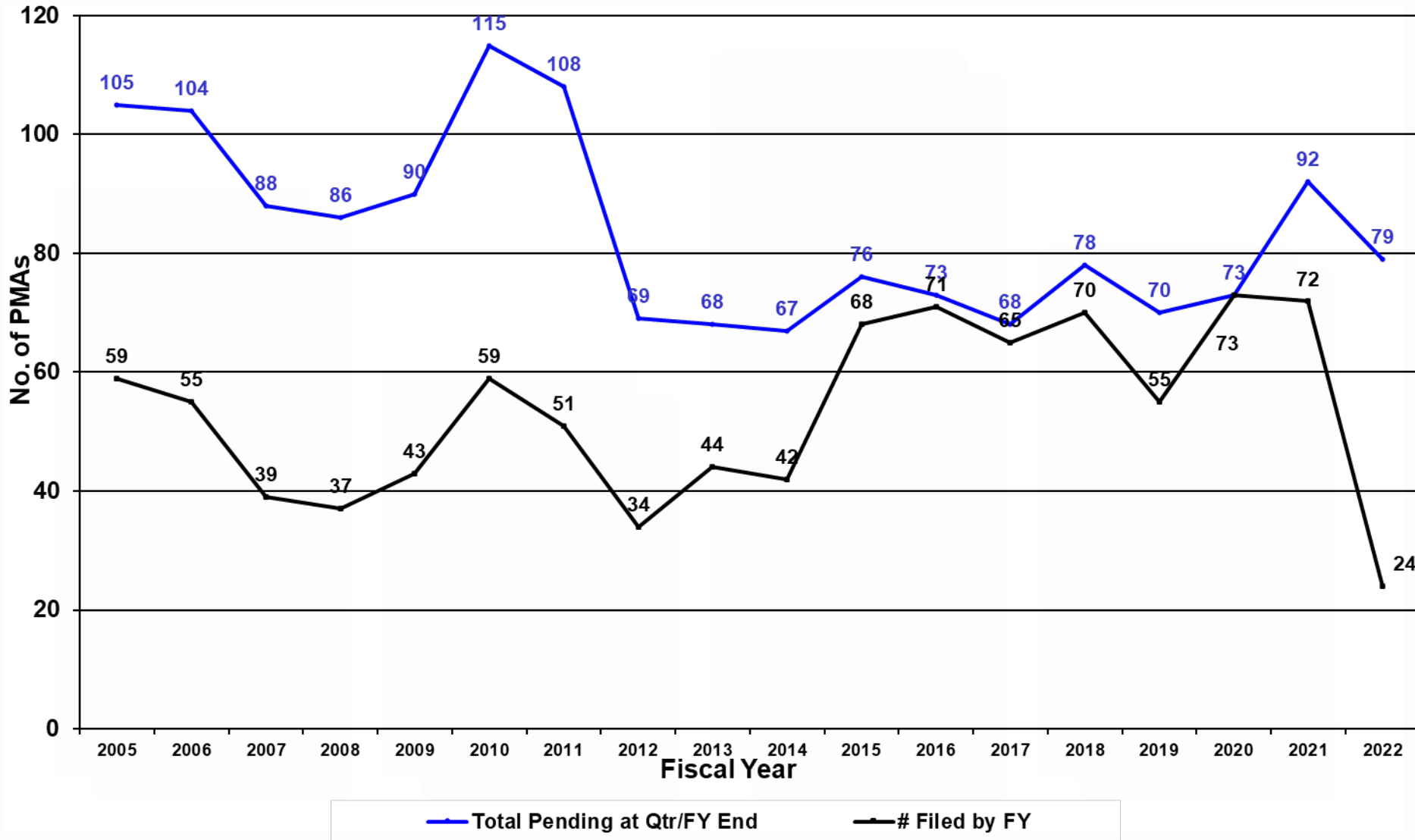
PMA Originals Pending* at End of Quarter/Year



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

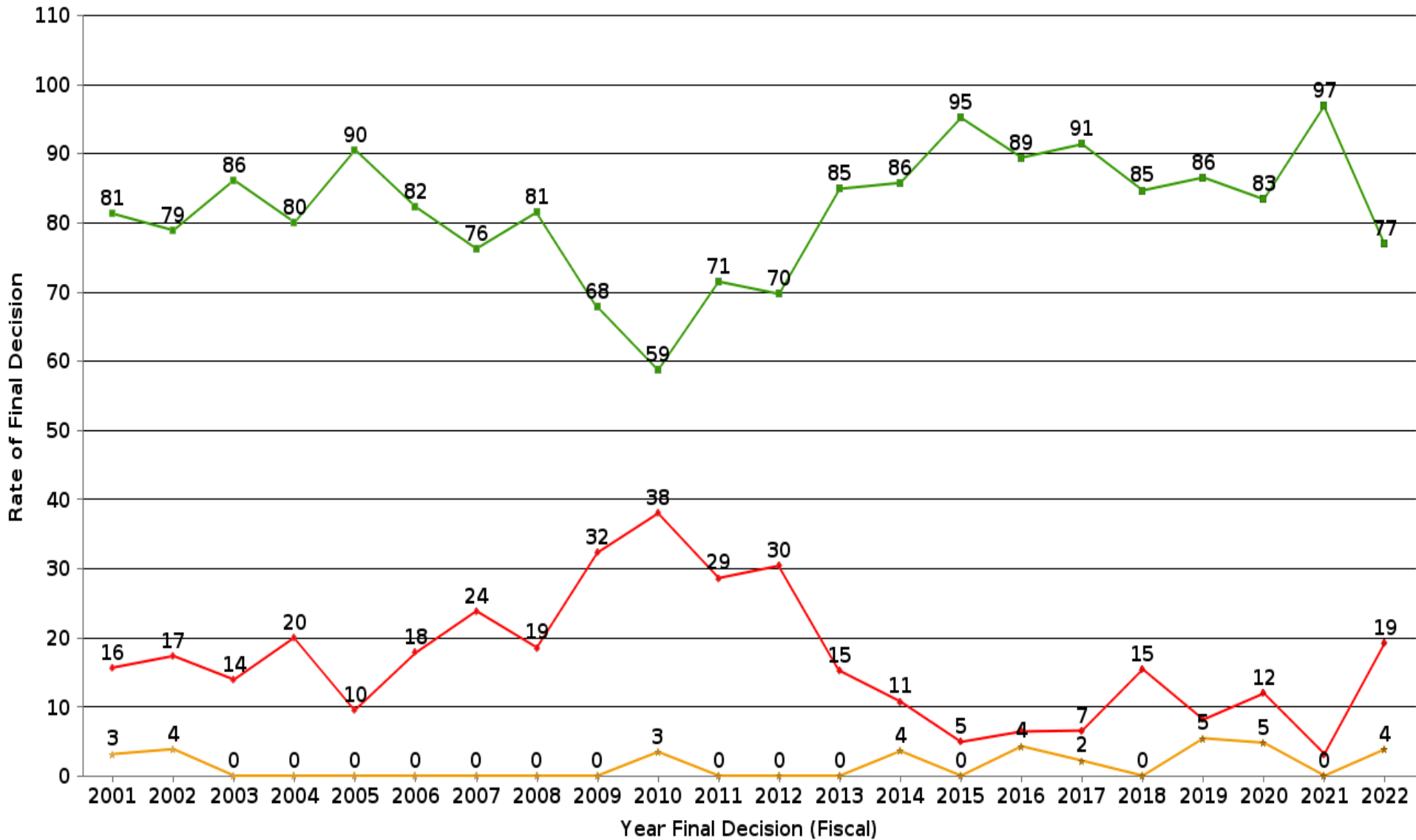
*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year. For the current FY, numbers filed are updated starting in Q2.

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

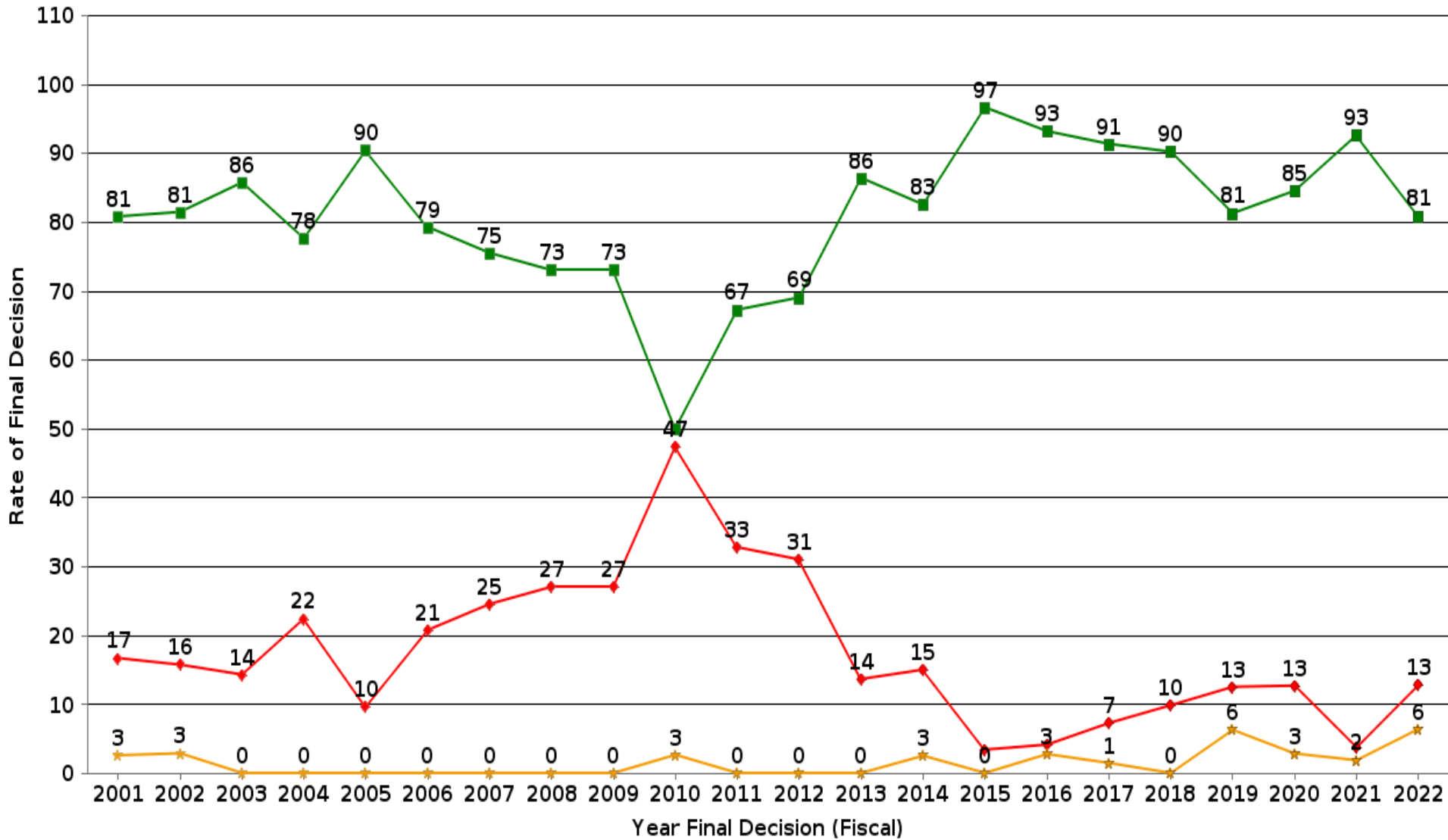


Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

■ % 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



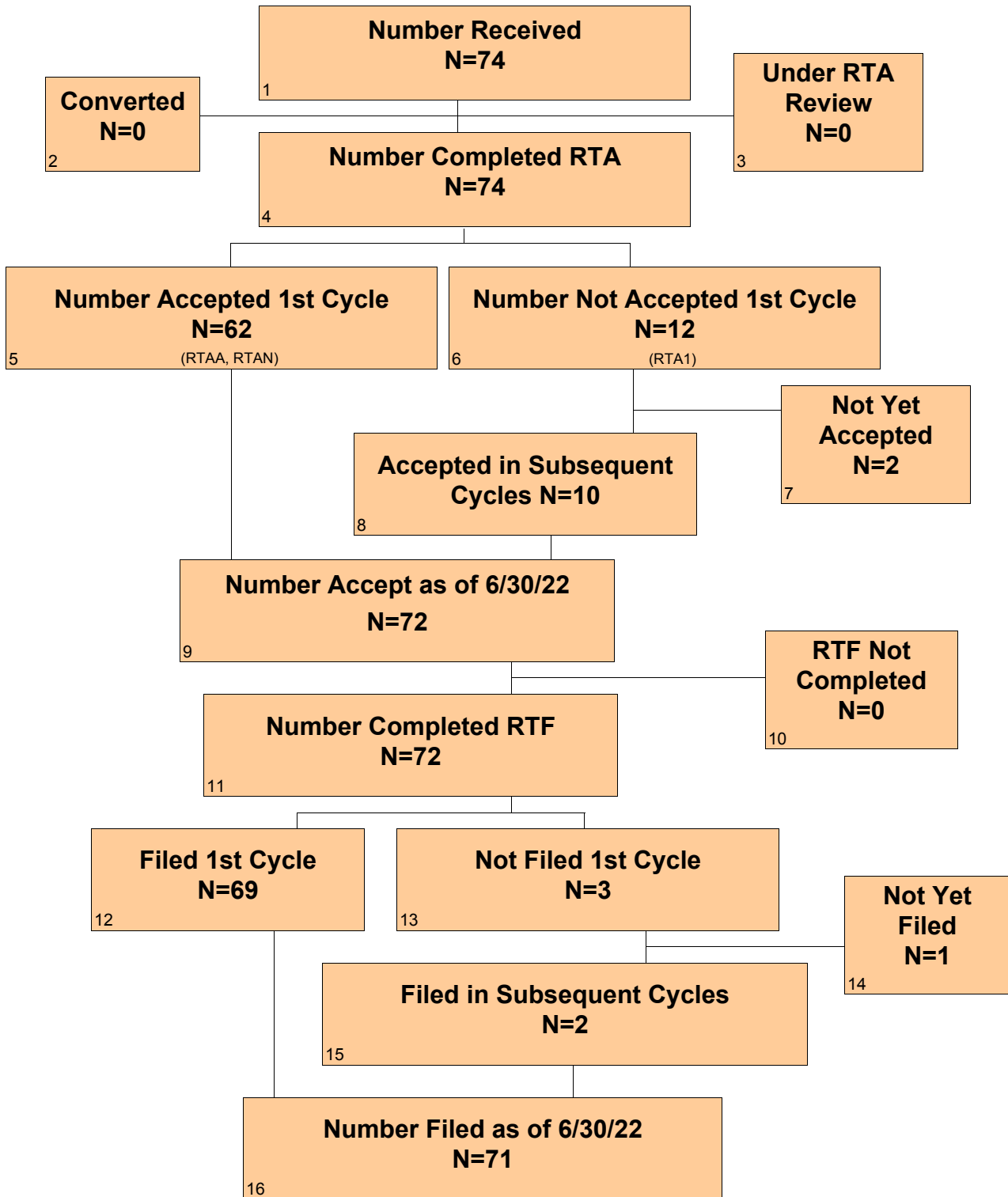
Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

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

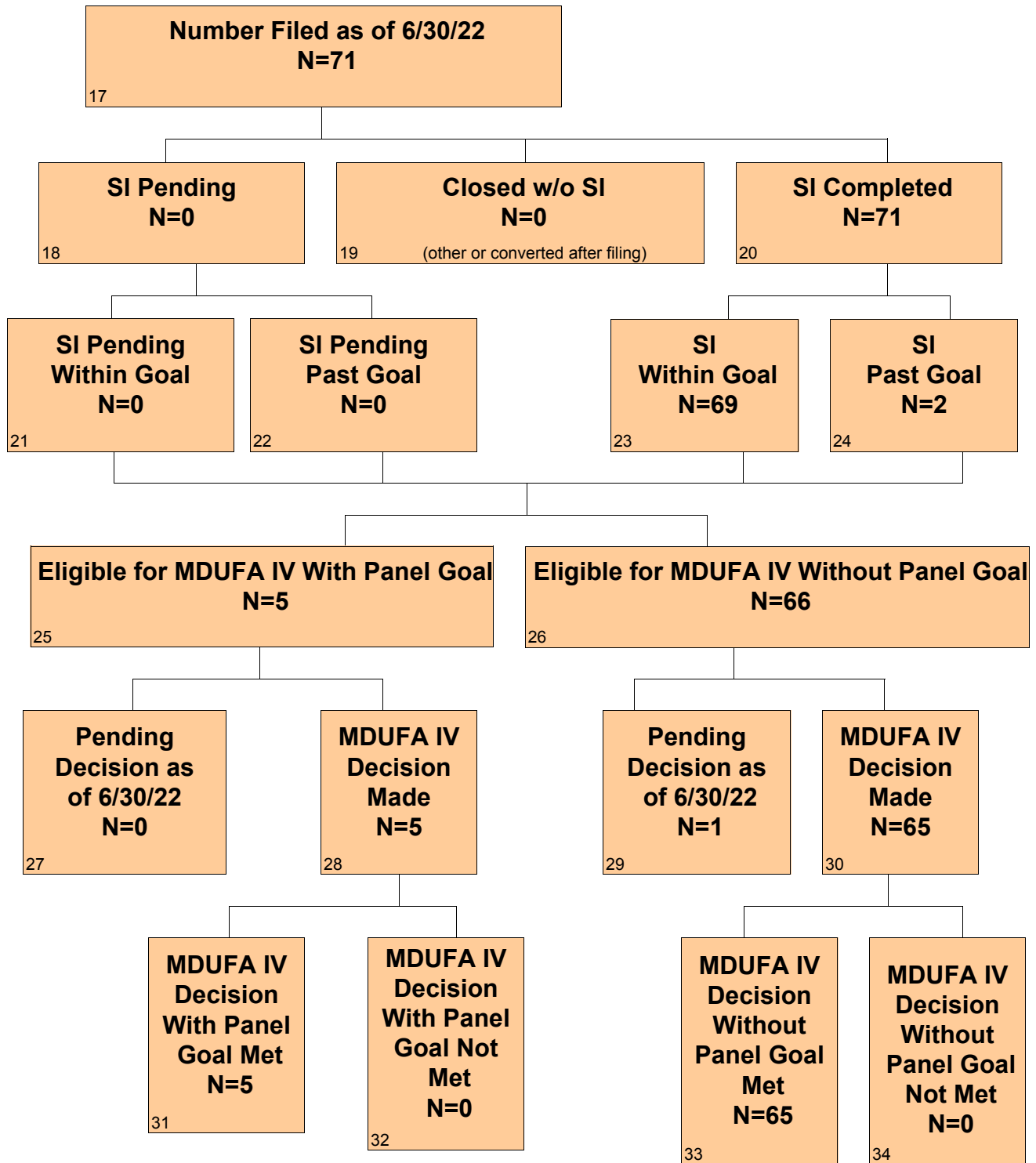
Submissions deleted due to lack of response were counted as “withdrawals” prior to FY16. Submissions deleted due to lack of response prior to MDUFA decision are counted as “withdrawals” from FY16 onward. Submissions deleted due to lack of response post-MDUFA decision are considered “other” decisions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

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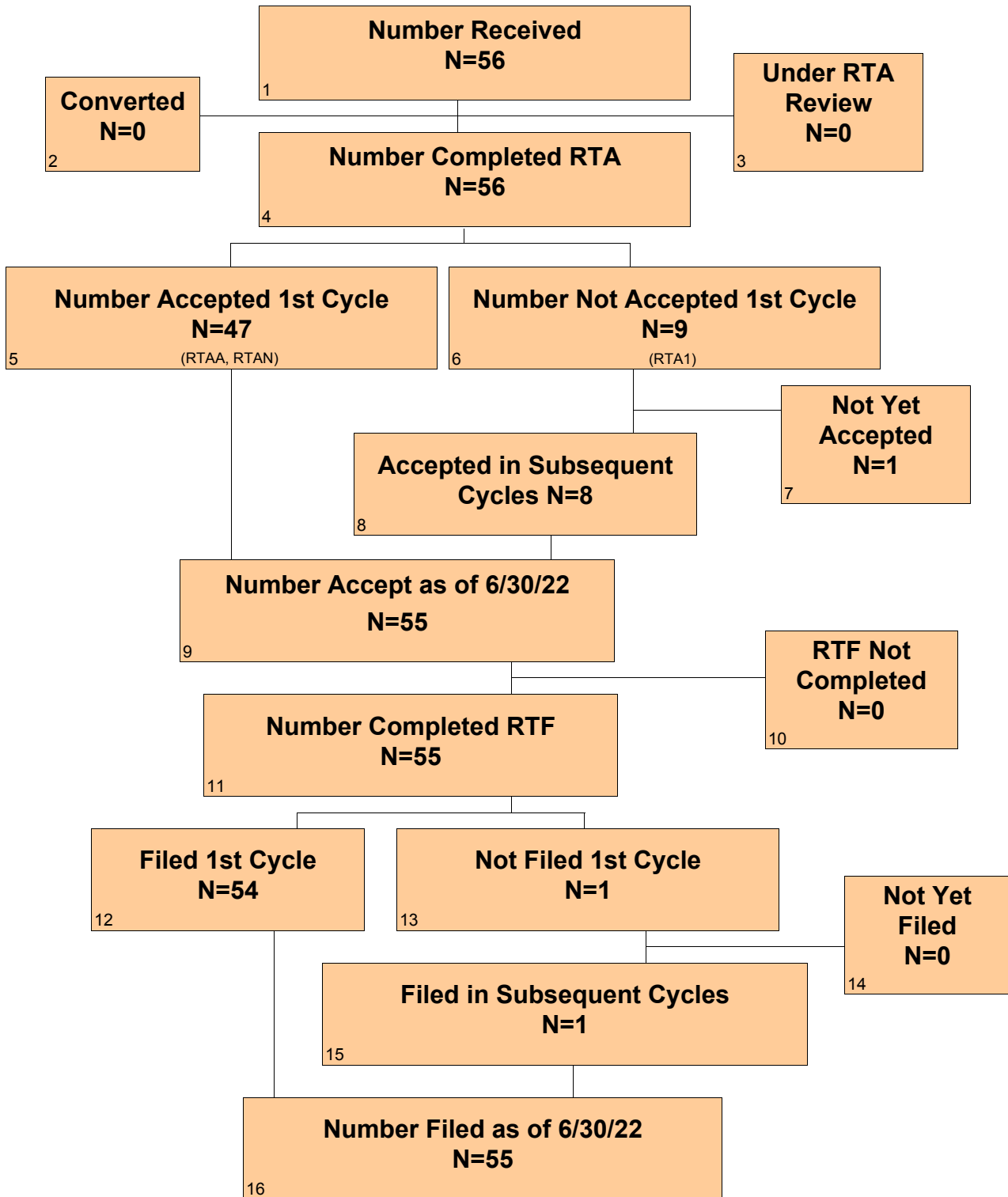
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 6/30/22



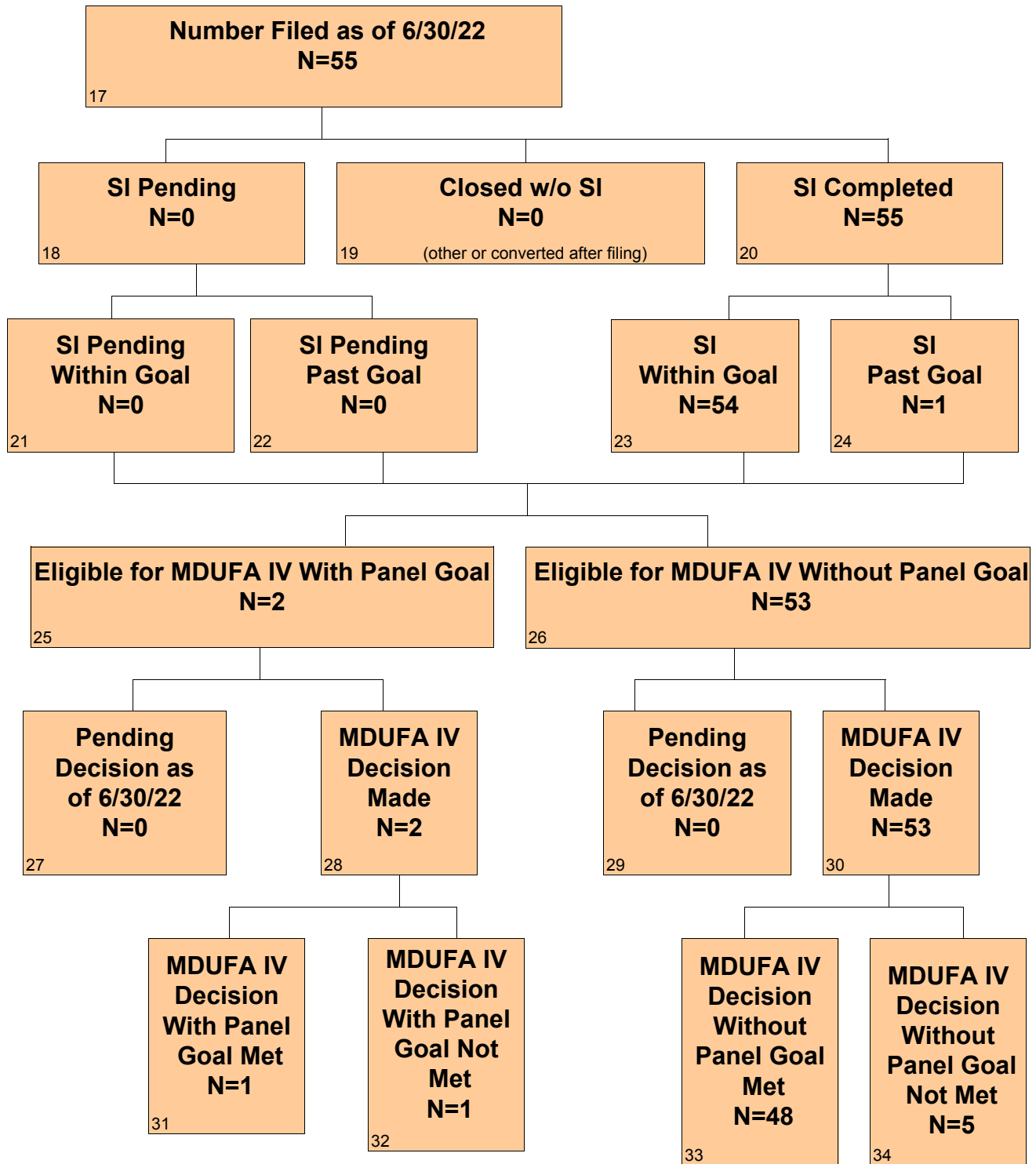
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 6/30/22 Continued



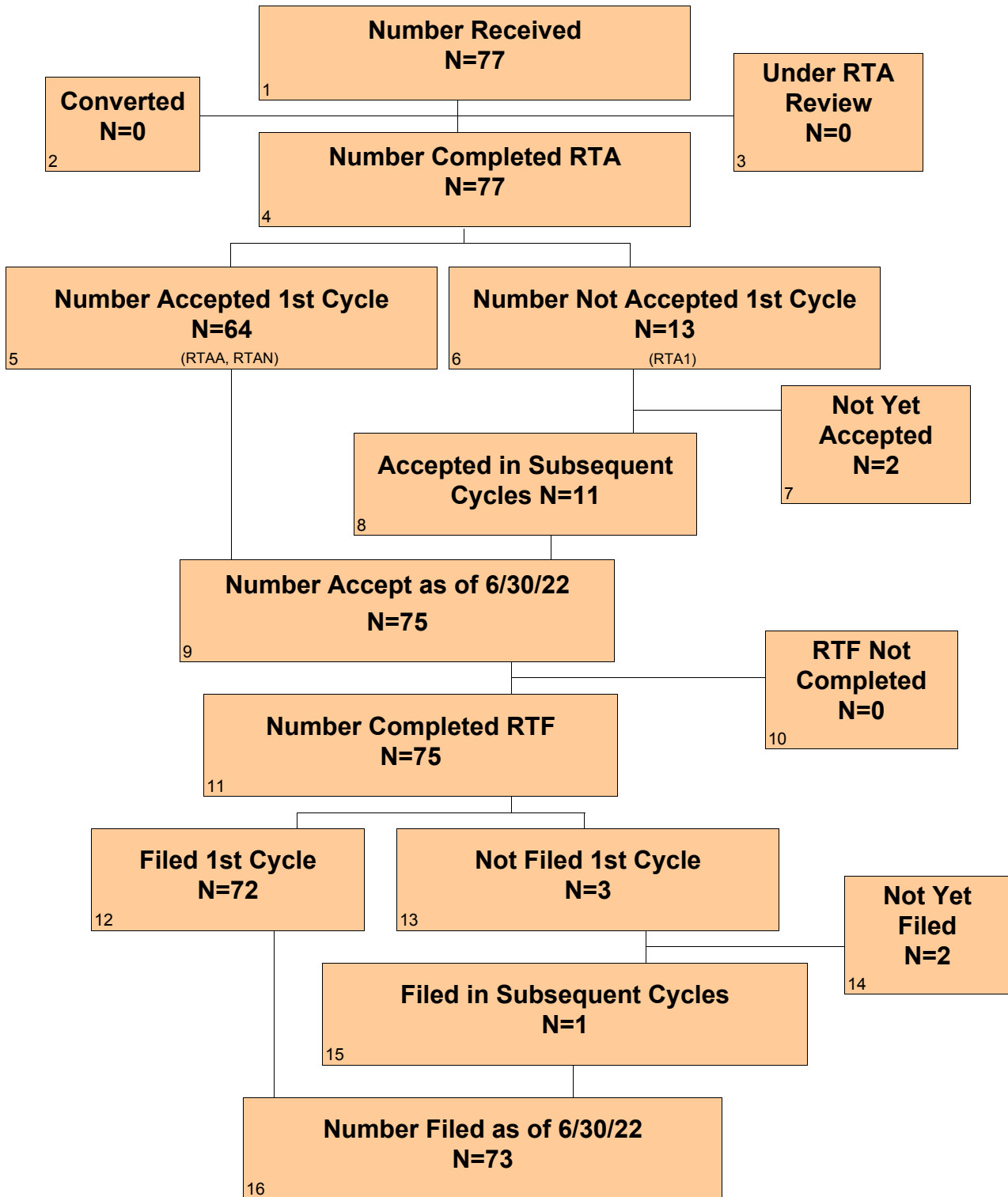
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 6/30/22



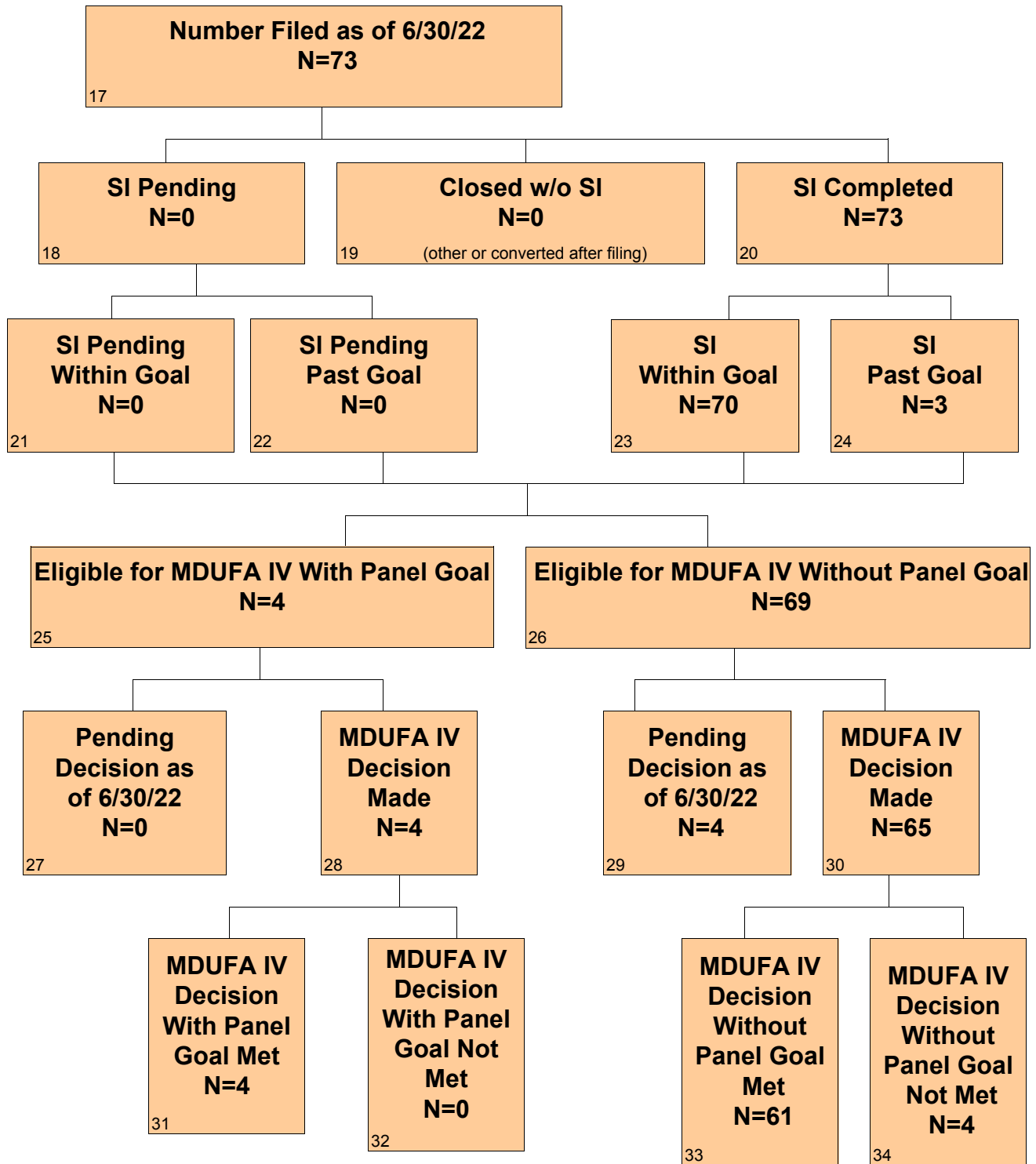
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 6/30/22 Continued



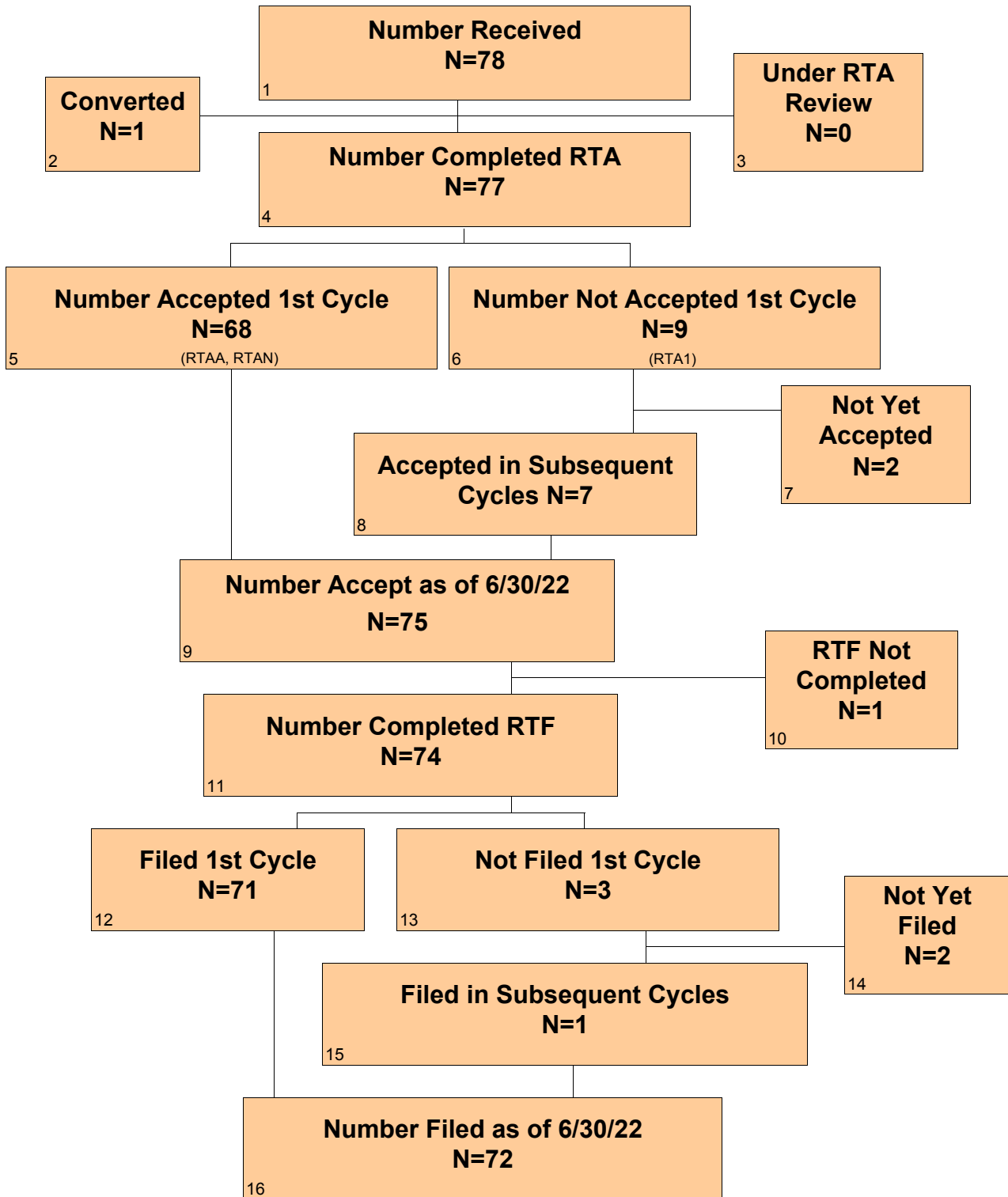
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 6/30/22



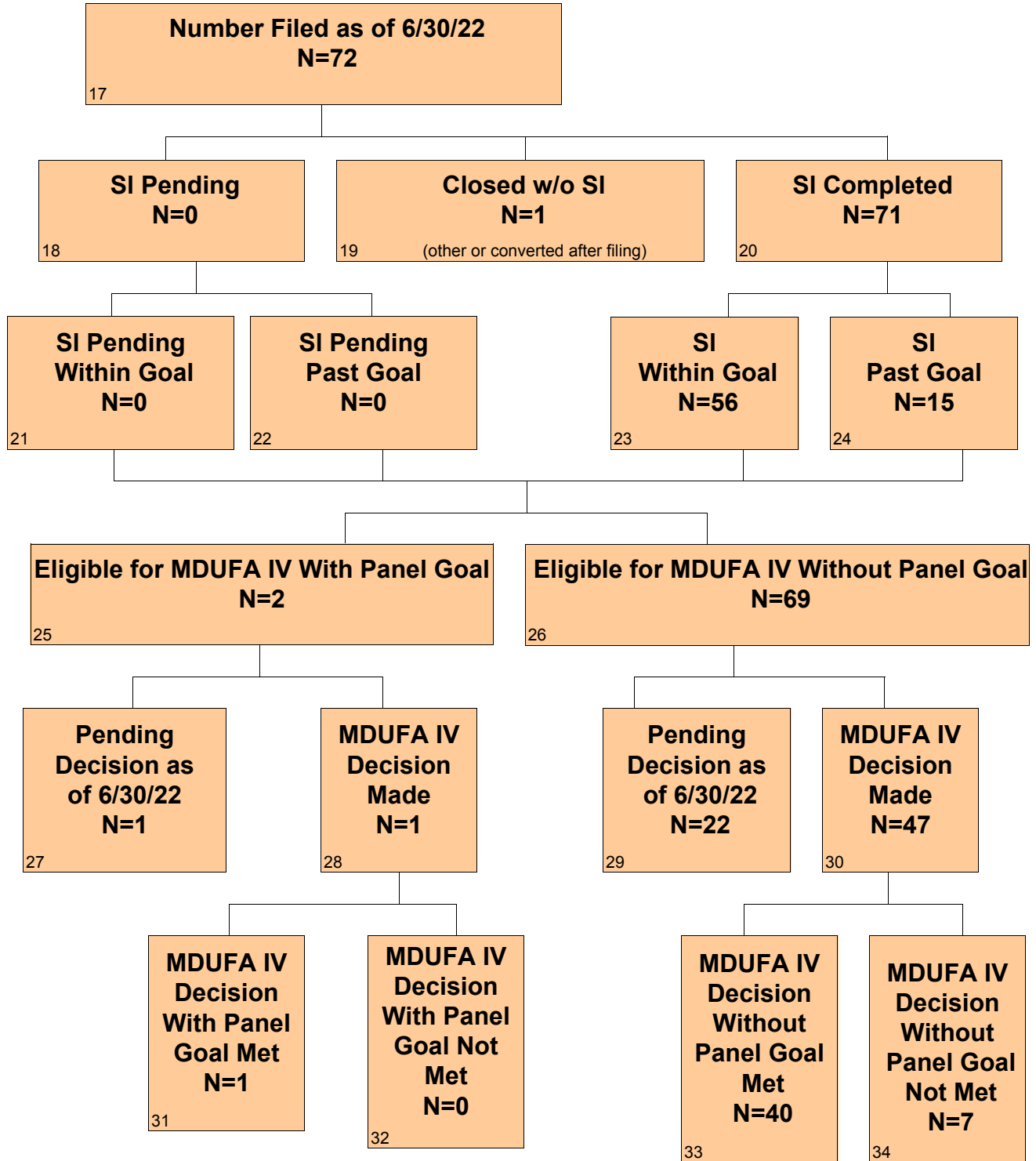
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 6/30/22 Continued



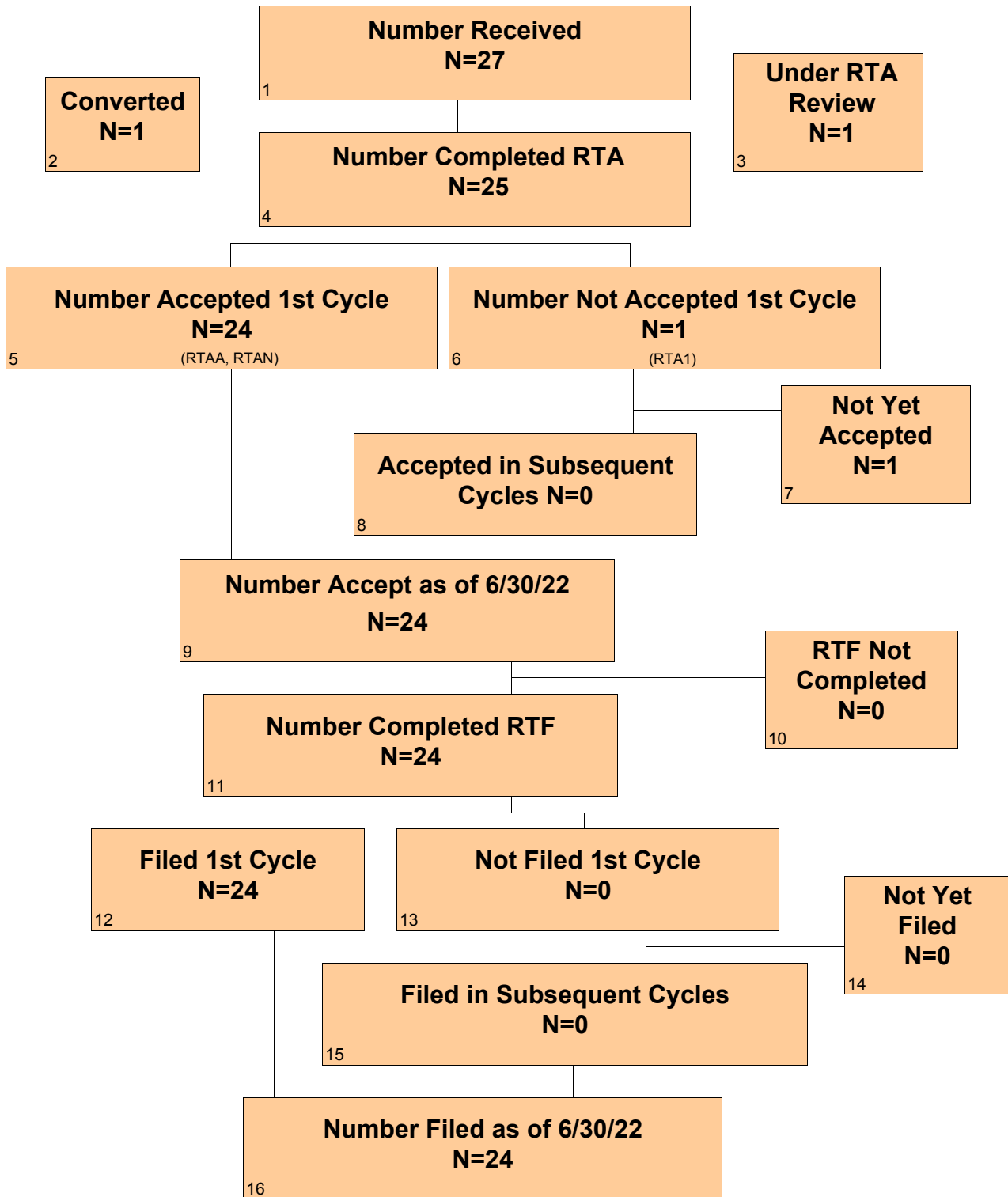
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 6/30/22



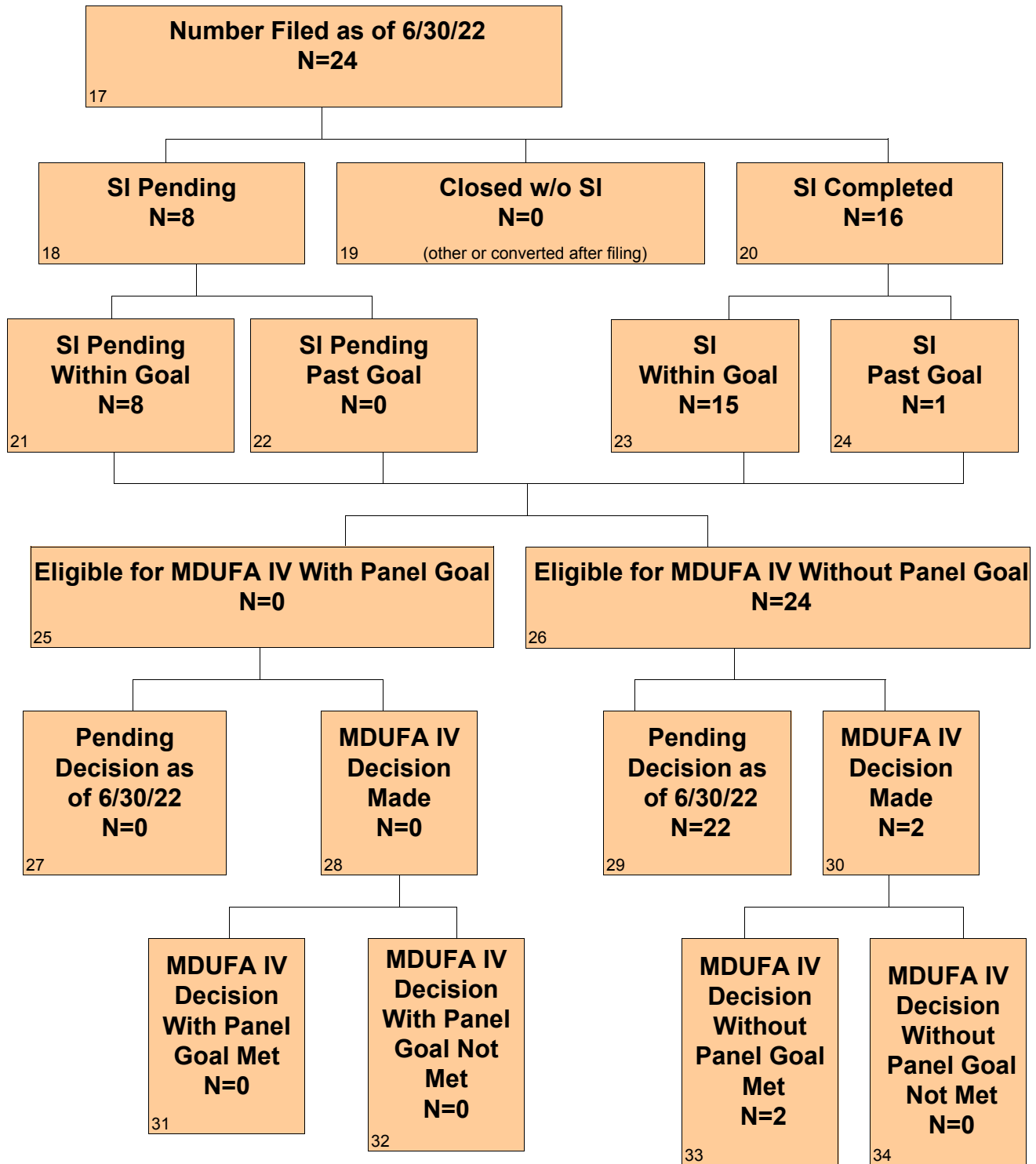
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 6/30/22 Continued



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 6/30/22



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 6/30/22 Continued



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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	74	56	77	78	27
Closed Before RTA Action	0	0	0	1	1
Number with Accepted RTA Review	62	46	63	59	24
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	1
Number Not Accepted for Filing Review	12	9	13	9	1
Rate of Submissions Not Accepted for Filing Review	16.22%	16.07%	16.88%	11.69%	4.00%

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	27
Number Accepted	62	47	64	68	24
Completed RTF	72	55	75	74	24
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	24
SI Goal Met	69	54	70	56	15
SI Goal Not Met	2	1	3	15	1
SI Pending Within Goal	0	0	0	0	8
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	97.18%	98.18%	95.89%	78.87%	93.75%

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	71	16
Average Number of FDA Days to Substantive Interaction	87.03	89.95	91.74	125.73	89.44
20th Percentile FDA Days to Substantive Interaction	84	87	88	87	86
40th Percentile FDA Days to Substantive Interaction	88	88	88	89	88
60th Percentile FDA Days to Substantive Interaction	90	89	90	90	90
80th Percentile FDA Days to Substantive Interaction	90	90	90	91	90
Maximum FDA Days to Substantive Interaction	178	246	325	598	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	24
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	65	53	65	47	2
MDUFA IV Decision Goal Met	65	48	61	40	2
PMAs Pending MDUFA IV Decision	1	0	4	22	22
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	9	0
Current Performance Percent Goal Met	100.00%	90.57%	92.42%	71.43%	100.00%

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	65	47	2
Average FDA Days to MDUFA IV Decision	162.15	180.74	173.51	176.19	175.00
20th Percentile FDA Days to MDUFA IV Decision	144	147	175	150	172
40th Percentile FDA Days to MDUFA IV Decision	177	178	179	178	174
60th Percentile FDA Days to MDUFA IV Decision	178	180	180	180	176
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	178
Maximum FDA Days to MDUFA IV Decision	279	338	406	490	180
Average Industry Days to MDUFA IV Decision	93.18	127.28	105.23	65.38	11.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	4
40th Percentile Industry Days to MDUFA IV Decision	18	31	35	24	9
60th Percentile Industry Days to MDUFA IV Decision	88	130	74	47	13
80th Percentile Industry Days to MDUFA IV Decision	162	192	183	89	18
Maximum Industry Days to MDUFA IV Decision	360	540	521	387	22
Average Total Days to MDUFA IV Decision	255.34	308.02	278.74	241.57	186.00
20th Percentile Total Days to MDUFA IV Decision	167	175	177	177	176
40th Percentile Total Days to MDUFA IV Decision	180	204	211	203	183
60th Percentile Total Days to MDUFA IV Decision	257	310	261	229	189
80th Percentile Total Days to MDUFA IV Decision	342	440	389	288	196
Maximum Total Days to MDUFA IV Decision	540	718	633	588	202

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	24
Number with MDUFA IV Decision	65	53	65	47	2
Number of Withdrawal	6	3	5	3	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%	7.69%	6.38%	0.00%
Rate of Not Approvable	12.31%	13.21%	7.69%	2.13%	0.00%

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	16	0
Mean FDA Days for Submissions that Missed the Goal	0.00	266.60	265.20	294.25	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	235.00	135.00	117.44	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	4
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	4
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	6
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	11	0
MDUFA IV Decision Goal Met	15	13	12	7	0
PMAs Pending MDUFA IV Decision	0	0	1	8	6
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	6	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	41.18%	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	2
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	1
Rate of Submissions Not Accepted for Filing Review	31.25%	14.29%	33.33%	25.00%	100.00%

**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	2
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	6	0
MDUFA IV Decision Goal Met	15	7	6	5	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%	100.00%	100.00%	83.33%	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	6	0
Average FDA Days to MDUFA IV Decision	177.33	179.14	180.00	168.17	0.00
20th Percentile FDA Days to MDUFA IV Decision	176	179	180	178	0
40th Percentile FDA Days to MDUFA IV Decision	178	180	180	180	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	201	0
Average Industry Days to MDUFA IV Decision	130.93	65.43	160.17	174.17	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	4	68	47	0
40th Percentile Industry Days to MDUFA IV Decision	52	20	81	90	0
60th Percentile Industry Days to MDUFA IV Decision	141	50	108	138	0
80th Percentile Industry Days to MDUFA IV Decision	278	148	277	355	0
Maximum Industry Days to MDUFA IV Decision	360	180	400	387	0
Average Total Days to MDUFA IV Decision	308.27	244.57	340.17	342.33	0.00
20th Percentile Total Days to MDUFA IV Decision	178	184	248	227	0
40th Percentile Total Days to MDUFA IV Decision	232	200	261	268	0
60th Percentile Total Days to MDUFA IV Decision	321	230	288	318	0
80th Percentile Total Days to MDUFA IV Decision	450	328	457	445	0
Maximum Total Days to MDUFA IV Decision	528	359	580	588	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	6	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%	16.67%	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	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	201.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	387.00	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	8
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	20	11	21	18	8
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	8
Number Accepted	20	11	21	18	8
Completed RTF	22	14	23	19	8
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	8
SI Goal Met	22	14	23	19	5
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	3
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	5
Average Number of FDA Days to Substantive Interaction	83.36	85.21	88.26	88.74	88.40
20th Percentile FDA Days to Substantive Interaction	84	85	87	88	87
40th Percentile FDA Days to Substantive Interaction	87	88	88	89	89
60th Percentile FDA Days to Substantive Interaction	89	89	90	90	90
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	90
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	8
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	21	12	20	16	1
MDUFA IV Decision Goal Met	21	12	20	16	1
PMAs Pending MDUFA IV Decision	0	0	2	3	7
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%	100.00%

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	20	16	1
Average FDA Days to MDUFA IV Decision	174.00	178.92	178.15	175.13	170.00
20th Percentile FDA Days to MDUFA IV Decision	161	159	176	177	170
40th Percentile FDA Days to MDUFA IV Decision	178	178	179	178	170
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	178	170
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	170
Maximum FDA Days to MDUFA IV Decision	279	295	180	180	170
Average Industry Days to MDUFA IV Decision	51.48	107.00	100.70	51.63	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	18	37	0
60th Percentile Industry Days to MDUFA IV Decision	45	122	62	53	0
80th Percentile Industry Days to MDUFA IV Decision	91	171	160	78	0
Maximum Industry Days to MDUFA IV Decision	162	322	453	238	0
Average Total Days to MDUFA IV Decision	225.48	285.92	278.85	226.75	170.00
20th Percentile Total Days to MDUFA IV Decision	168	170	177	178	170
40th Percentile Total Days to MDUFA IV Decision	180	245	197	217	170
60th Percentile Total Days to MDUFA IV Decision	229	302	240	231	170
80th Percentile Total Days to MDUFA IV Decision	324	363	339	258	170
Maximum Total Days to MDUFA IV Decision	340	501	633	418	170

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	8
Number with MDUFA IV Decision	21	12	20	16	1
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%	5.00%	0.00%	0.00%
Rate of Not Approvable	4.76%	8.33%	5.00%	6.25%	0.00%

**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	402.00	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	1
SI Goal Not Met	1	0	0	1	1
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	50.00%	100.00%	100.00%	80.00%	50.00%

**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	2
Average Number of FDA Days to Substantive Interaction	93.50	90.00	89.25	108.20	109.50
20th Percentile FDA Days to Substantive Interaction	90	90	89	86	98
40th Percentile FDA Days to Substantive Interaction	92	90	89	88	106
60th Percentile FDA Days to Substantive Interaction	95	90	90	90	113
80th Percentile FDA Days to Substantive Interaction	97	90	90	110	121
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	2	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	4	0
Mean FDA Days for Submissions that Missed the Goal	0.00	184.00	208.00	196.50	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	21.00	46.00	142.00	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	4	2
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 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	4	2
Average Number of FDA Days to Substantive Interaction	86.50	88.67	88.50	85.50	87.00
20th Percentile FDA Days to Substantive Interaction	84	88	88	81	86
40th Percentile FDA Days to Substantive Interaction	86	89	88	84	87
60th Percentile FDA Days to Substantive Interaction	87	89	89	88	87
80th Percentile FDA Days to Substantive Interaction	89	90	89	90	88
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	1
MDUFA IV Decision Goal Met	2	3	2	2	1
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%	100.00%

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	1
Average FDA Days to MDUFA IV Decision	180.00	146.33	178.50	168.00	180.00
20th Percentile FDA Days to MDUFA IV Decision	180	121	178	161	180
40th Percentile FDA Days to MDUFA IV Decision	180	156	178	166	180
60th Percentile FDA Days to MDUFA IV Decision	180	174	179	170	180
80th Percentile FDA Days to MDUFA IV Decision	180	177	179	175	180
Maximum FDA Days to MDUFA IV Decision	180	179	180	180	180
Average Industry Days to MDUFA IV Decision	141.50	203.67	103.50	0.00	22.00
20th Percentile Industry Days to MDUFA IV Decision	57	67	41	0	22
40th Percentile Industry Days to MDUFA IV Decision	113	122	83	0	22
60th Percentile Industry Days to MDUFA IV Decision	170	209	124	0	22
80th Percentile Industry Days to MDUFA IV Decision	226	330	166	0	22
Maximum Industry Days to MDUFA IV Decision	283	450	207	0	22
Average Total Days to MDUFA IV Decision	321.50	350.00	282.00	168.00	202.00
20th Percentile Total Days to MDUFA IV Decision	237	191	219	161	202
40th Percentile Total Days to MDUFA IV Decision	293	282	261	166	202
60th Percentile Total Days to MDUFA IV Decision	350	387	303	170	202
80th Percentile Total Days to MDUFA IV Decision	406	505	345	175	202
Maximum Total Days to MDUFA IV Decision	463	623	387	180	202

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	1
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%	0.00%
Rate of Not Approvable	0.00%	33.33%	0.00%	0.00%	0.00%

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
PMA Original and Panel-Track Supplements - Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	21	27	28	11
Closed Before RTA Action	0	0	0	1	0
Number with Accepted RTA Review	16	19	23	17	10
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	1
Number Not Accepted for Filing Review	0	2	4	1	0
Rate of Submissions Not Accepted for Filing Review	0.00%	9.52%	14.81%	3.70%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	21	27	28	11
Number Accepted	16	19	23	26	10
Completed RTF	16	21	27	26	10
Number Not Filed	0	0	2	2	0
Rate of Submissions Not Filed	0.00%	0.00%	7.41%	7.69%	0.00%

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

Substantive Interaction (SI) Goal	FY 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	21	26	25	10
SI Goal Met	16	20	23	11	5
SI Goal Not Met	0	1	3	13	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	1	0
Current SI Performance Percent Goal Met	100.00%	95.24%	88.46%	45.83%	100.00%

Table 1.4 OHT7 - Office of In Vitro Diagnostics

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	16	21	26	24	5
Average Number of FDA Days to Substantive Interaction	85.63	87.76	97.35	192.25	83.20
20th Percentile FDA Days to Substantive Interaction	84	87	86	88	82
40th Percentile FDA Days to Substantive Interaction	88	88	88	90	87
60th Percentile FDA Days to Substantive Interaction	90	89	90	178	87
80th Percentile FDA Days to Substantive Interaction	90	90	90	283	88
Maximum FDA Days to Substantive Interaction	90	91	325	598	90

Table 1.5 OHT7 - Office of In Vitro Diagnostics

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	16	21	26	24	10
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	16	21	25	13	0
MDUFA IV Decision Goal Met	16	17	23	9	0
PMAs Pending MDUFA IV Decision	0	0	1	10	10
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	7	0
Current Performance Percent Goal Met	100.00%	80.95%	92.00%	45.00%	N/A

Table 1.6 OHT7 - Office of In Vitro Diagnostics

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

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	16	21	25	13	0
Average FDA Days to MDUFA IV Decision	127.13	178.67	170.04	178.23	0.00
20th Percentile FDA Days to MDUFA IV Decision	90	134	129	100	0
40th Percentile FDA Days to MDUFA IV Decision	112	173	179	120	0
60th Percentile FDA Days to MDUFA IV Decision	146	177	180	155	0
80th Percentile FDA Days to MDUFA IV Decision	175	180	180	245	0
Maximum FDA Days to MDUFA IV Decision	180	299	406	490	0
Average Industry Days to MDUFA IV Decision	91.56	142.38	65.20	54.54	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	22	0	0
60th Percentile Industry Days to MDUFA IV Decision	75	81	58	34	0
80th Percentile Industry Days to MDUFA IV Decision	158	325	127	100	0
Maximum Industry Days to MDUFA IV Decision	336	540	257	318	0
Average Total Days to MDUFA IV Decision	218.69	321.05	235.24	232.77	0.00
20th Percentile Total Days to MDUFA IV Decision	90	155	156	127	0
40th Percentile Total Days to MDUFA IV Decision	146	179	182	181	0
60th Percentile Total Days to MDUFA IV Decision	225	257	242	231	0
80th Percentile Total Days to MDUFA IV Decision	270	619	307	298	0
Maximum Total Days to MDUFA IV Decision	511	718	573	490	0

Table 1.8 OHT7 - Office of In Vitro Diagnostics

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

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	16	21	26	24	10
Number with MDUFA IV Decision	16	21	25	13	0
Number of Withdrawal	4	1	2	2	0
Number of Not Approvable	2	1	1	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	25.00%	4.76%	8.00%	15.38%	N/A
Rate of Not Approvable	12.50%	4.76%	4.00%	0.00%	N/A

Table 1.10 OHT7 - Office of In Vitro Diagnostics

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

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	11	0
Mean FDA Days for Submissions that Missed the Goal	0.00	287.25	254.00	338.27	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	288.50	124.00	84.00	0.00

Table 1.12 OHT7 - Office of In Vitro Diagnostics

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

Performance Metric	FY 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 OHT7 - Office of In Vitro Diagnostics
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	4
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	4
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
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	6
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	11	0
MDUFA IV Decision Goal Met	15	13	12	7	0
PMAs Pending MDUFA IV Decision	0	0	1	8	6
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	6	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	41.18%	N/A

*Includes submission that went to panel

Table 1.1 OHT8 - Office of Radiological Health

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0	3	0	1
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	1	0	3	0	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	0	0	0	0	0
Rate of Submissions Not Accepted for Filing Review	0.00%	N/A	0.00%	N/A	0.00%

Table 1.2 OHT8 - Office of Radiological Health

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	0	3	0	1
Number Accepted	1	0	3	0	1
Completed RTF	1	0	3	0	1
Number Not Filed	0	0	0	0	0
Rate of Submissions Not Filed	0.00%	N/A	0.00%	N/A	0.00%

Table 1.3 OHT8 - Office of Radiological Health

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	1	0	3	0	1
SI Goal Met	1	0	3	0	1
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%	N/A	100.00%	N/A	100.00%

**Table 1.4 OHT8 - Office of 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	1	0	3	0	1
Average Number of FDA Days to Substantive Interaction	63.00	0.00	89.67	0.00	90.00
20th Percentile FDA Days to Substantive Interaction	63	0	89	0	90
40th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
60th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
80th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
Maximum FDA Days to Substantive Interaction	63	0	90	0	90

**Table 1.5 OHT8 - Office of 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	1	0	3	0	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	0	3	0	0
MDUFA IV Decision Goal Met	1	0	3	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%	N/A	100.00%	N/A	N/A

**Table 1.6 OHT8 - Office of 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	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 OHT8 - Office of 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	1	0	3	0	0
Average FDA Days to MDUFA IV Decision	63.00	0.00	179.67	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	63	0	179	0	0
40th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
60th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
80th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
Maximum FDA Days to MDUFA IV Decision	63	0	180	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	157.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	118	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	150	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	177	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	198	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	219	0	0
Average Total Days to MDUFA IV Decision	63.00	0.00	336.67	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	63	0	298	0	0
40th Percentile Total Days to MDUFA IV Decision	63	0	330	0	0
60th Percentile Total Days to MDUFA IV Decision	63	0	356	0	0
80th Percentile Total Days to MDUFA IV Decision	63	0	377	0	0
Maximum Total Days to MDUFA IV Decision	63	0	398	0	0

Table 1.8 OHT8 - Office of 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	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 OHT8 - Office of 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	1	0	3	0	1
Number with MDUFA IV Decision	1	0	3	0	0
Number of Withdrawal	1	0	0	0	0
Number of Not Approvable	0	0	0	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	100.00%	N/A	0.00%	N/A	N/A
Rate of Not Approvable	0.00%	N/A	0.00%	N/A	N/A

**Table 1.10 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (with Panel Review) 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 OHT8 - Office of 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	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 OHT8 - Office of 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	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

**Table 1.13 OHT8 - Office of 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	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

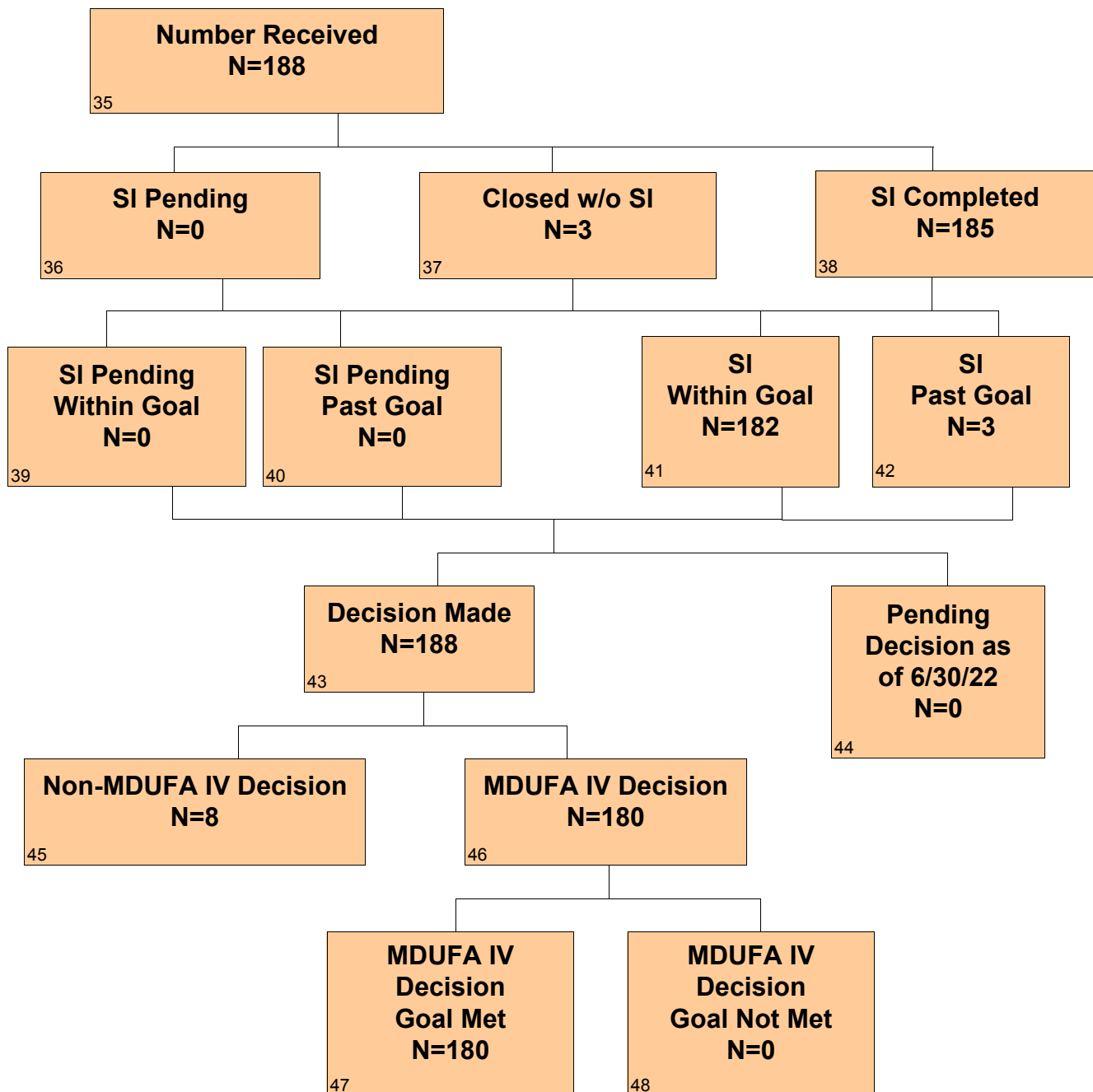
*Includes submission that went to panel

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

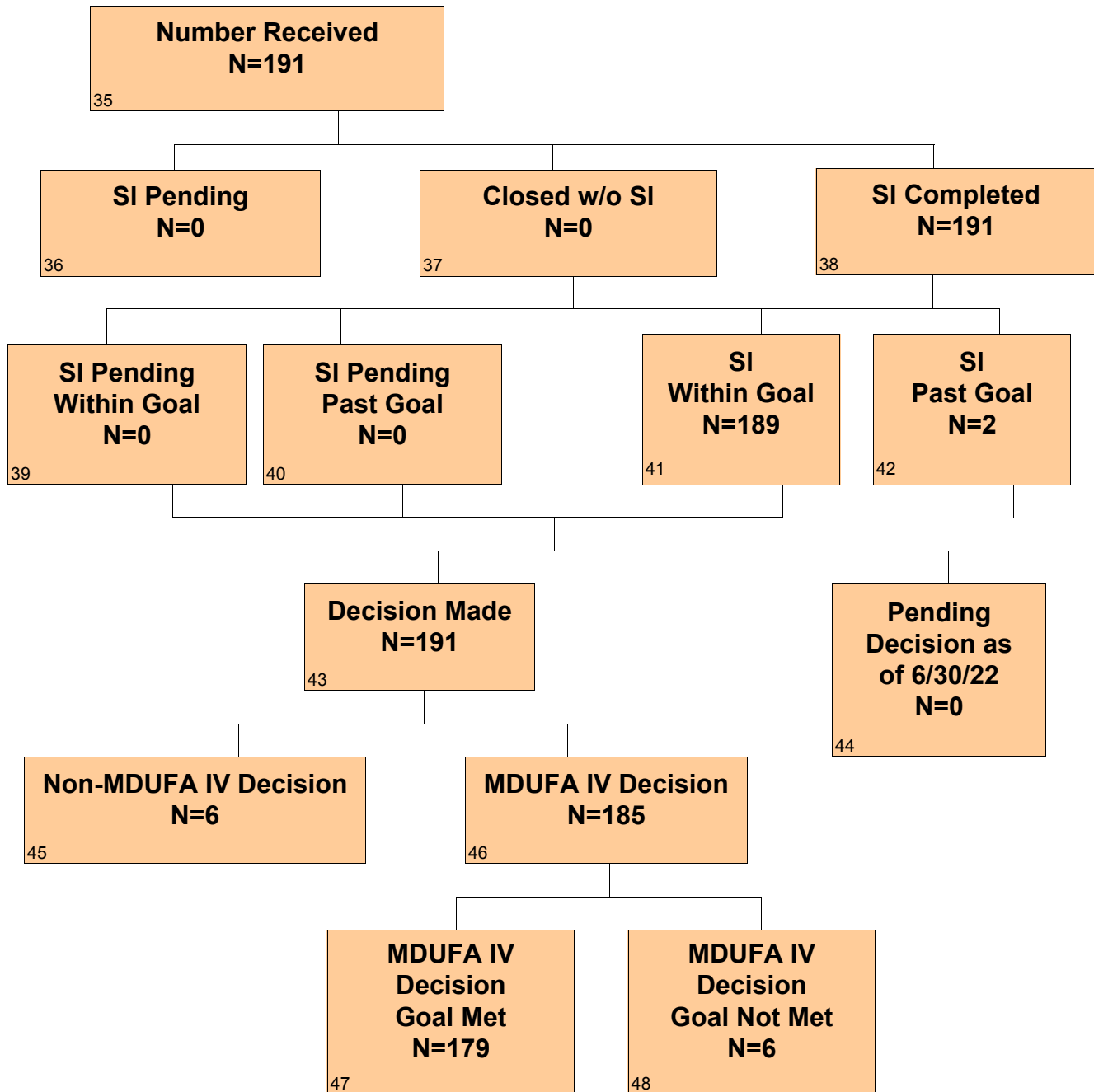
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
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

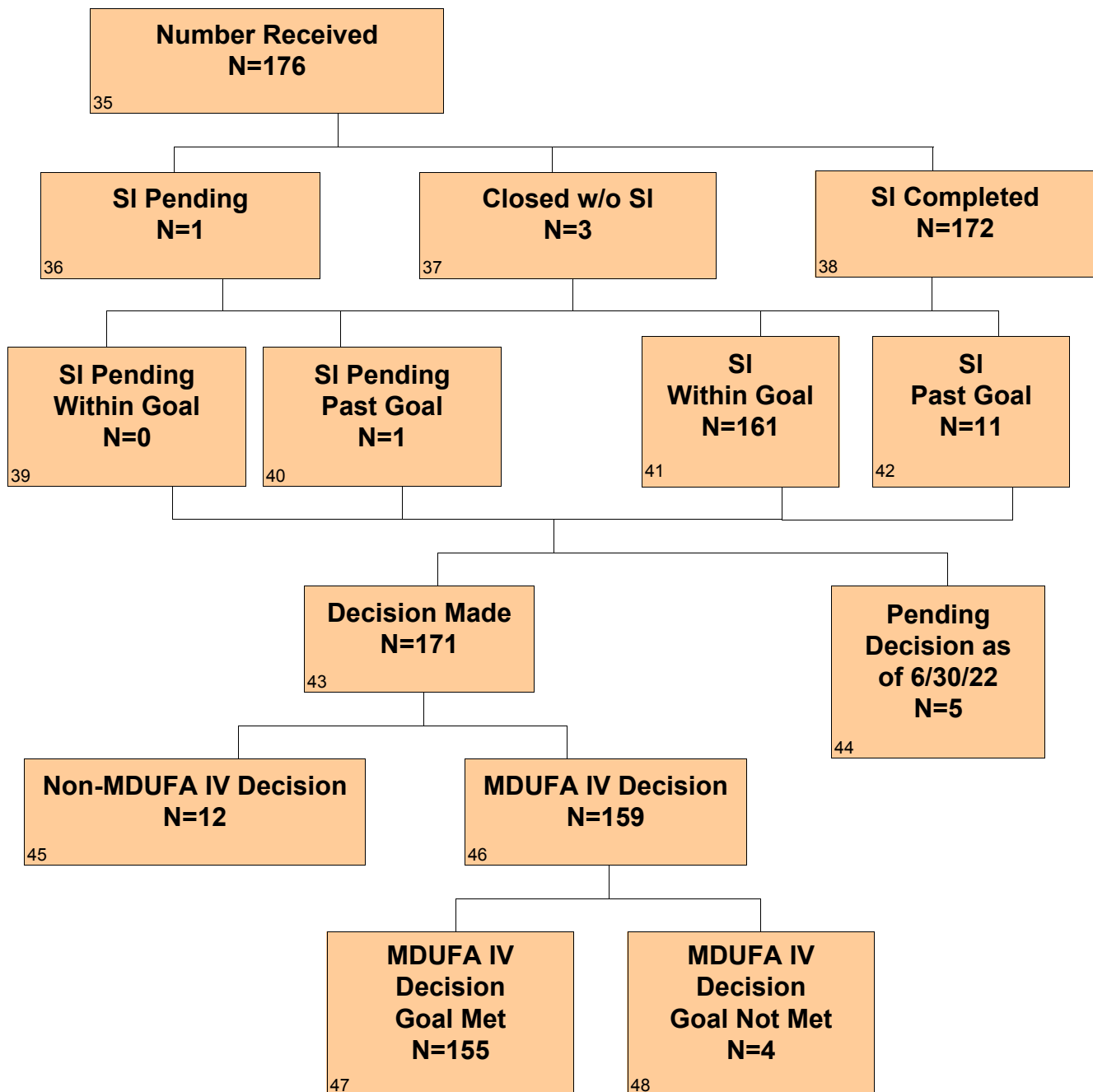
CDRH PMA 180 Day Supplements - FY 2018 as of 6/30/22



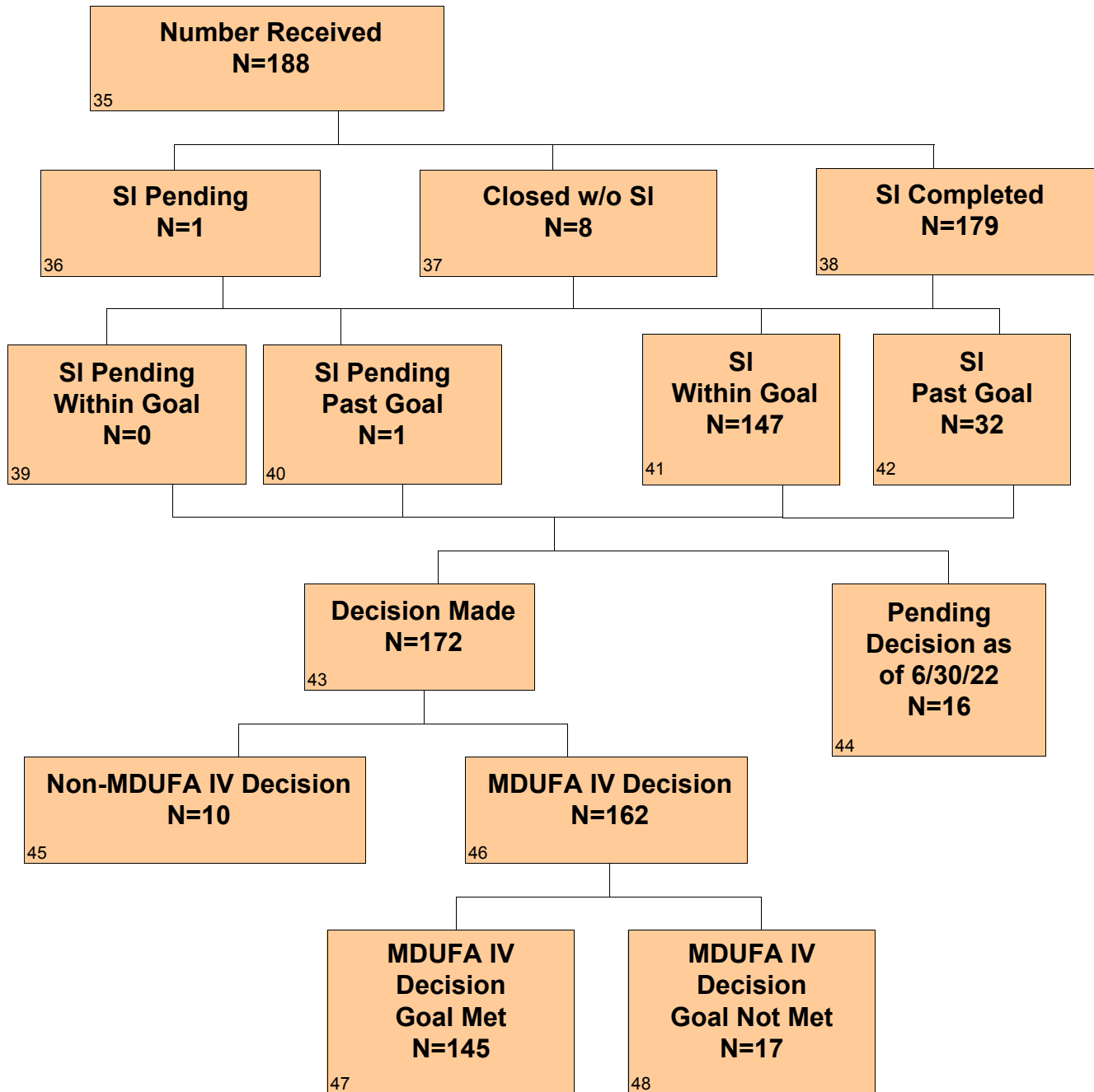
CDRH PMA 180 Day Supplements - FY 2019 as of 6/30/22



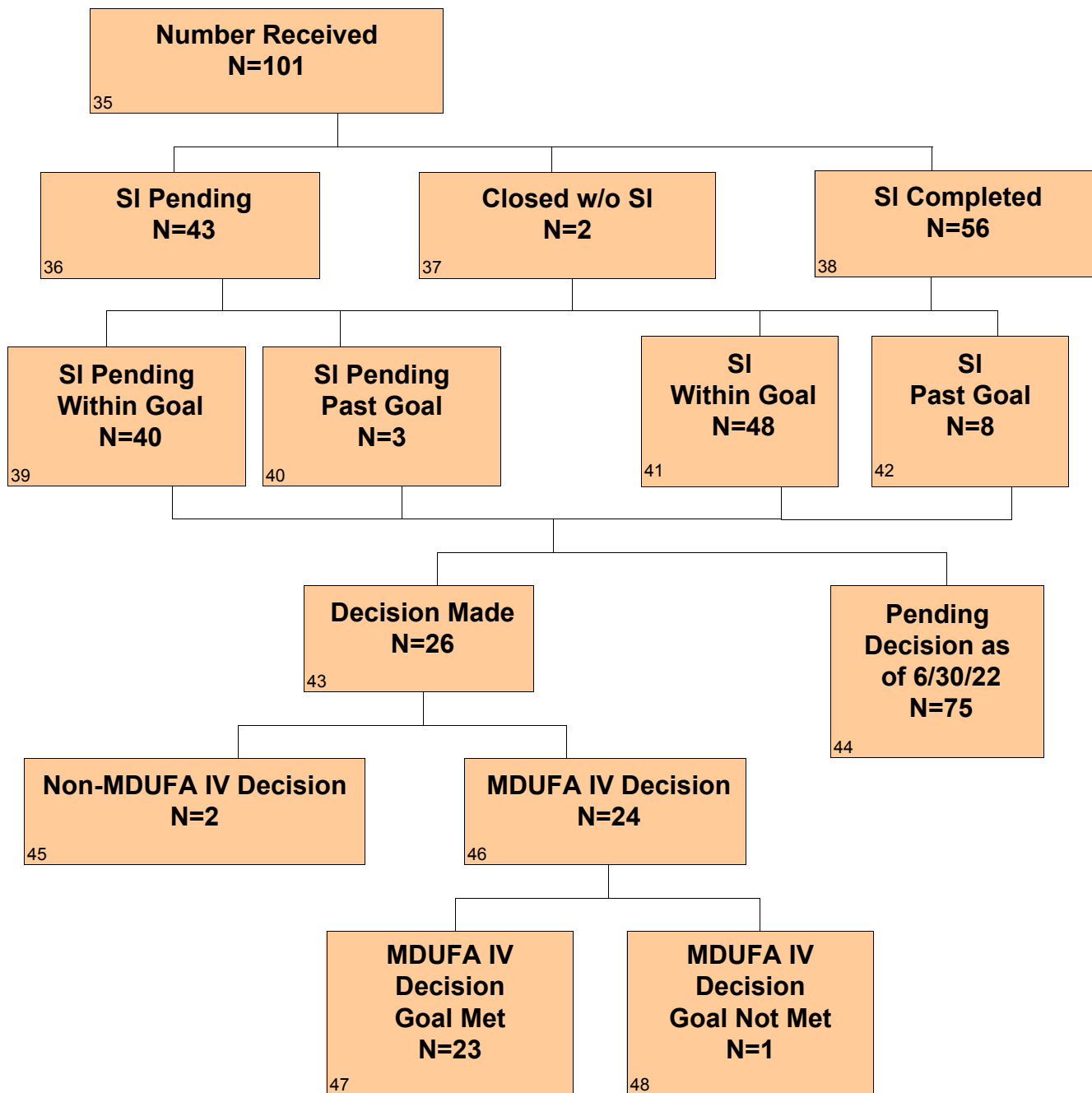
CDRH PMA 180 Day Supplements - FY 2020 as of 6/30/22



CDRH PMA 180 Day Supplements - FY 2021 as of 6/30/22



CDRH PMA 180 Day Supplements - FY 2022 as of 6/30/22



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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	101
SI Goal Met	182	189	161	147	48
SI Goal Not Met	3	2	11	32	8
SI Pending Within Goal	0	0	0	0	40
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%	81.36%

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	101
Non-MDUFA IV Decision	8	6	12	10	2
MDUFA IV Decision	180	185	159	162	24
MDUFA IV Decision Goal Met	180	179	155	145	23
Supplements Pending MDUFA IV Decision	0	0	5	16	75
Supplements Pending MDUFA IV Decision Past Goal	0	0	1	3	1
Current Performance Percent Goal Met	100.00%	96.76%	96.88%	87.88%	92.00%

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	101
Number with MDUFA IV Decision	180	185	159	162	24
Number of Not Approvable	13	10	8	9	1
Rate of Not Approvable	7.22%	5.41%	5.03%	5.56%	4.17%

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	20	2
Mean FDA Days for Submissions that Missed the Goal	0.00	263.33	404.40	230.60	195.50
Mean Industry Days for Submissions that Missed the Goal	0.00	69.67	69.60	39.30	35.50

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	16
SI Goal Met	20	36	28	14	7
SI Goal Not Met	0	0	0	1	0
SI Pending Within Goal	0	0	0	0	9
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	16
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	20	36	28	13	3
MDUFA IV Decision Goal Met	20	35	28	13	3
Supplements Pending MDUFA IV Decision	0	0	0	1	13
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	16
Number with MDUFA IV Decision	20	36	28	13	3
Number of Not Approvable	1	1	1	2	1
Rate of Not Approvable	5.00%	2.78%	3.57%	15.38%	33.33%

**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	38
SI Goal Met	91	81	66	79	18
SI Goal Not Met	1	0	4	7	3
SI Pending Within Goal	0	0	0	0	17
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	2	0	0	8	0
Current SI Performance Percent Goal Met	98.91%	100.00%	94.29%	91.86%	85.71%

**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	38
Non-MDUFA IV Decision	2	3	2	8	0
MDUFA IV Decision	92	78	65	81	10
MDUFA IV Decision Goal Met	92	78	65	81	10
Supplements Pending MDUFA IV Decision	0	0	3	5	28
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	38
Number with MDUFA IV Decision	92	78	65	81	10
Number of Not Approvable	6	6	4	7	0
Rate of Not Approvable	6.52%	7.69%	6.15%	8.64%	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	12
SI Goal Met	14	15	16	18	5
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%	100.00%

**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	12
Non-MDUFA IV Decision	0	2	7	1	2
MDUFA IV Decision	15	14	11	17	1
MDUFA IV Decision Goal Met	15	14	11	16	1
Supplements Pending MDUFA IV Decision	0	0	1	1	9
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%	100.00%

**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	12
Number with MDUFA IV Decision	15	14	11	17	1
Number of Not Approvable	0	2	2	0	0
Rate of Not Approvable	0.00%	14.29%	18.18%	0.00%	0.00%

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

Performance Metric	FY 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	7
SI Goal Met	9	9	6	5	3
SI Goal Not Met	0	1	1	9	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	1	1
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	90.00%	85.71%	33.33%	75.00%

**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	7
Non-MDUFA IV Decision	1	1	0	0	0
MDUFA IV Decision	8	9	7	13	0
MDUFA IV Decision Goal Met	8	5	6	8	0
Supplements Pending MDUFA IV Decision	0	0	0	2	7
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	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	7
Number with MDUFA IV Decision	8	9	7	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	383.00	239.67	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	11
SI Goal Met	12	16	23	19	8
SI Goal Not Met	0	0	0	1	0
SI Pending Within Goal	0	0	0	0	3
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	11
Non-MDUFA IV Decision	2	0	2	0	0
MDUFA IV Decision	11	16	21	16	3
MDUFA IV Decision Goal Met	11	15	21	15	3
Supplements Pending MDUFA IV Decision	0	0	0	4	8
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	93.75%	100.00%	93.75%	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	11
Number with MDUFA IV Decision	11	16	21	16	3
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	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	244.00	0.00	181.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	13.00	0.00	75.00	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	1
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	1
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	1
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	1
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	1
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
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	35	23	25	21	15
SI Goal Met	34	23	18	8	6
SI Goal Not Met	1	0	6	13	5
SI Pending Within Goal	0	0	0	0	2
SI Pending Past Goal	0	0	1	0	2
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	97.14%	100.00%	72.00%	38.10%	46.15%

**Table 2.2 OHT7 - Office of In Vitro Diagnostics
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	35	23	25	21	15
Non-MDUFA IV Decision	2	0	0	0	0
MDUFA IV Decision	33	23	24	19	6
MDUFA IV Decision Goal Met	33	23	21	9	5
Supplements Pending MDUFA IV Decision	0	0	1	2	9
Supplements Pending MDUFA IV Decision Past Goal	0	0	1	2	1
Current Performance Percent Goal Met	100.00%	100.00%	84.00%	42.86%	71.43%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	35	23	25	21	15
Number with MDUFA IV Decision	33	23	24	19	6
Number of Not Approvable	4	1	0	0	0
Rate of Not Approvable	12.12%	4.35%	0.00%	0.00%	0.00%

**Table 2.4 OHT7 - Office of In Vitro Diagnostics
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	2
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	409.75	230.00	195.50
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	31.25	49.17	35.50

**Table 2.1 OHT8 - Office of 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	2	3	2	0	1
SI Goal Met	2	3	2	0	1
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%	N/A	100.00%

**Table 2.2 OHT8 - Office of 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	2	3	2	0	1
Non-MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision	1	3	2	0	1
MDUFA IV Decision Goal Met	1	3	2	0	1
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	N/A	100.00%

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

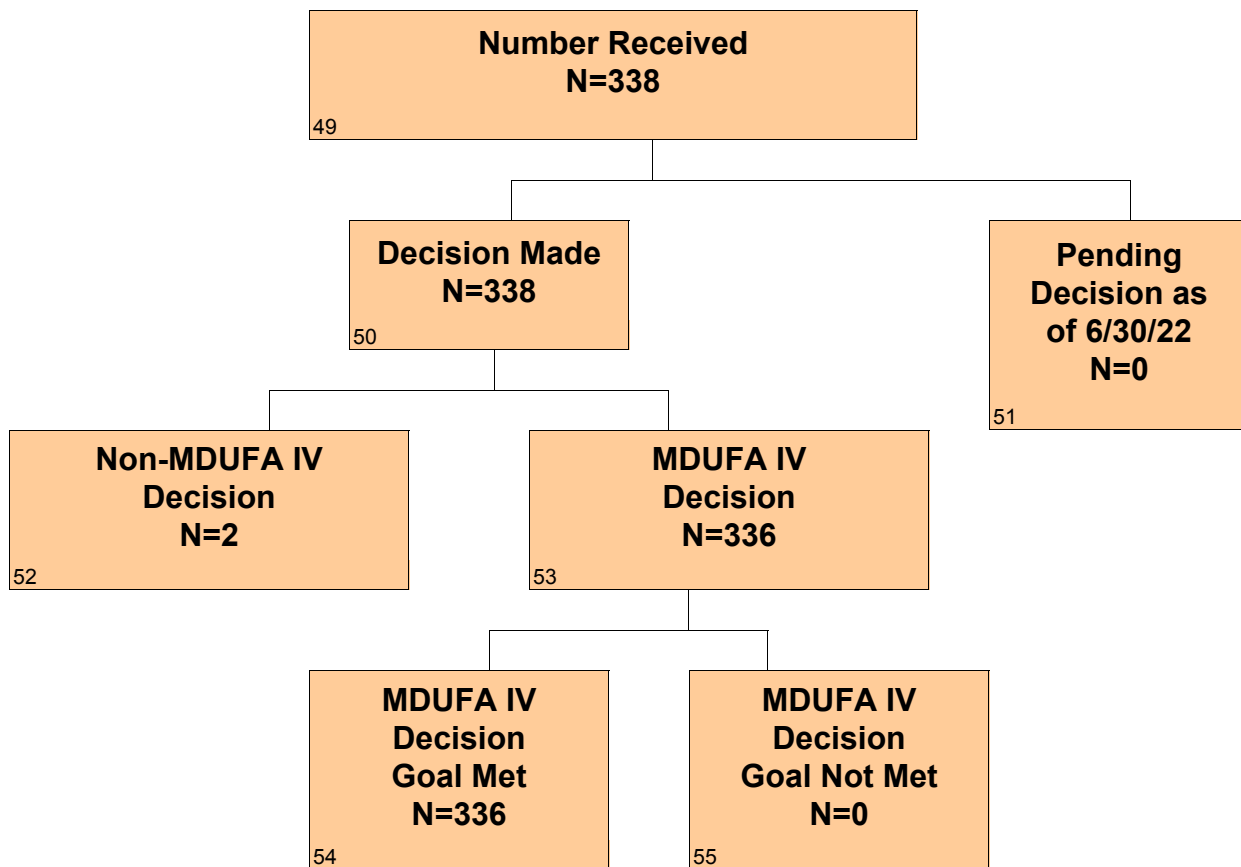
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2	3	2	0	1
Number with MDUFA IV Decision	1	3	2	0	1
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.00%	0.00%	0.00%	N/A	0.00%

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

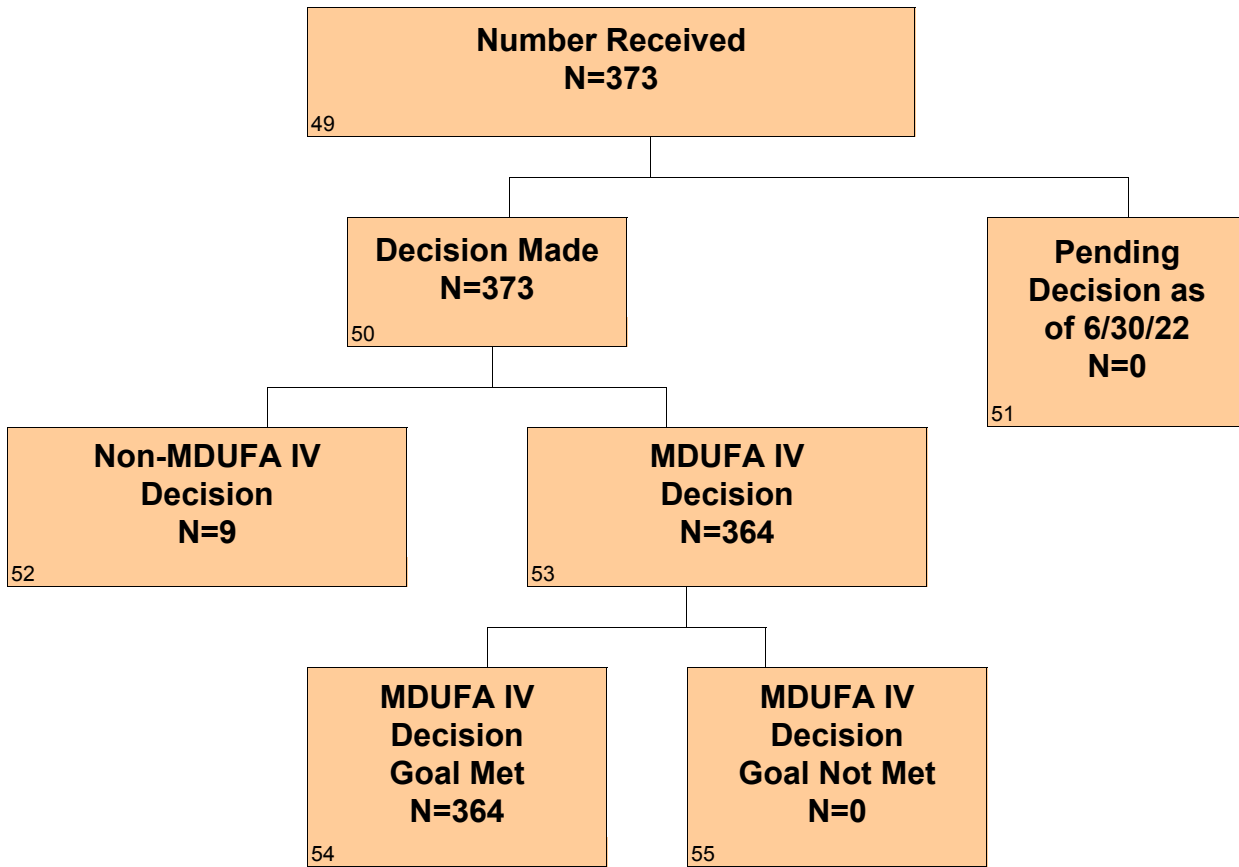
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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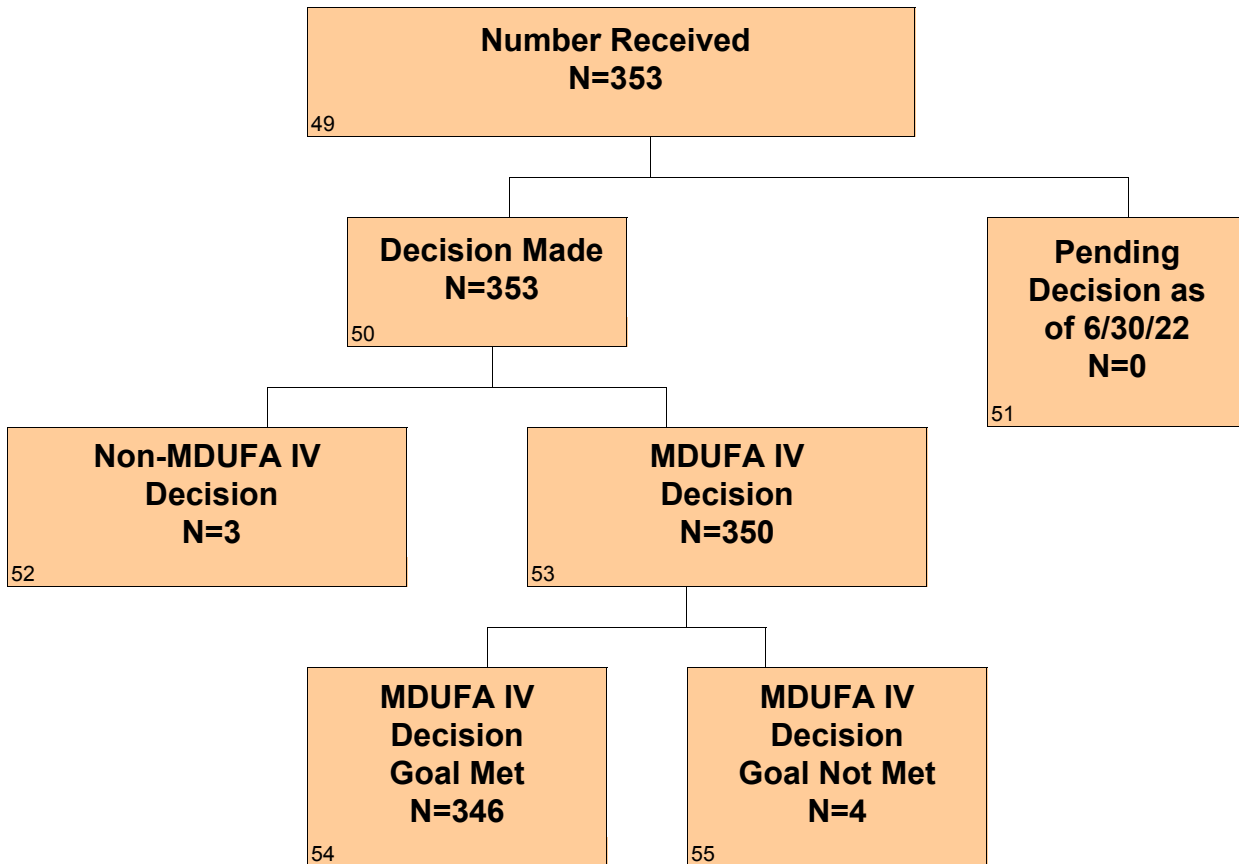
CDRH PMA Real Time Supplements - FY 2018 as of 6/30/22



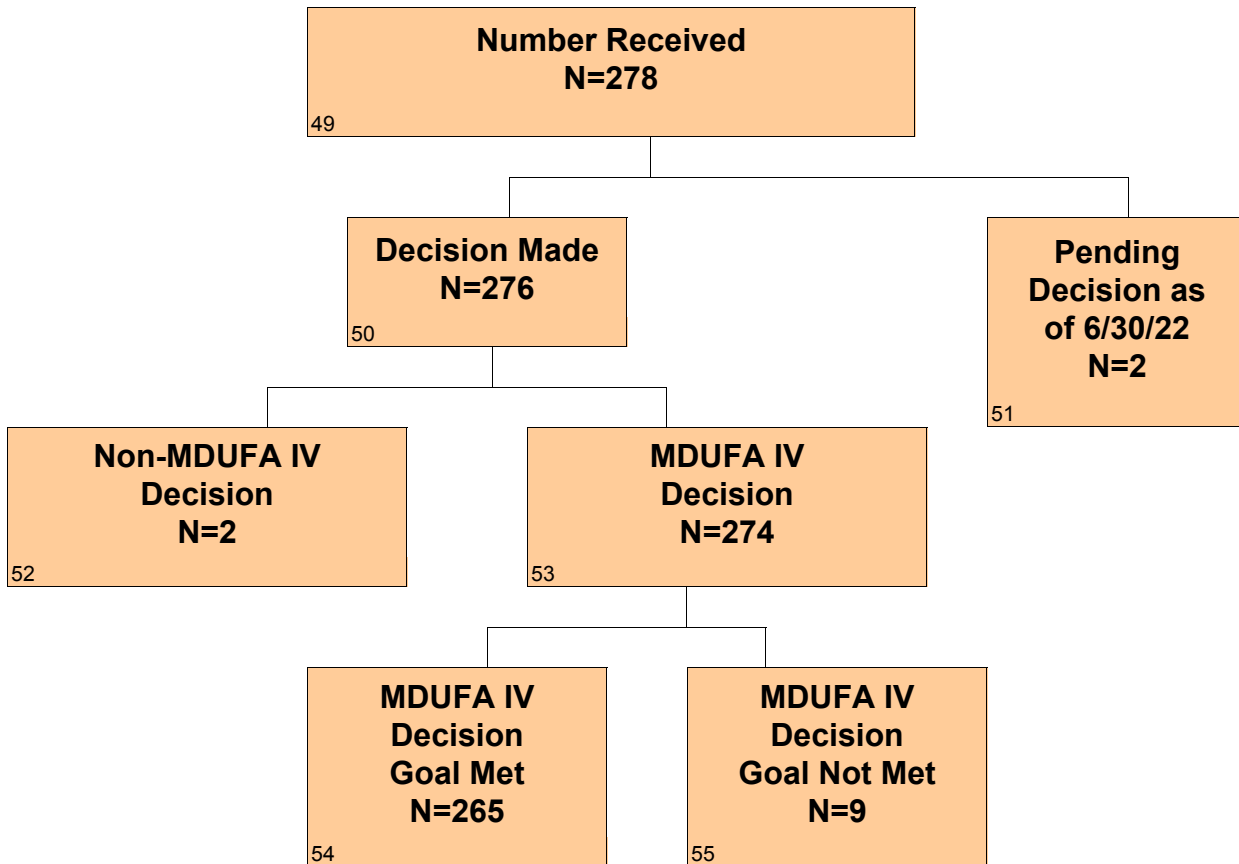
CDRH PMA Real Time Supplements - FY 2019 as of 6/30/22



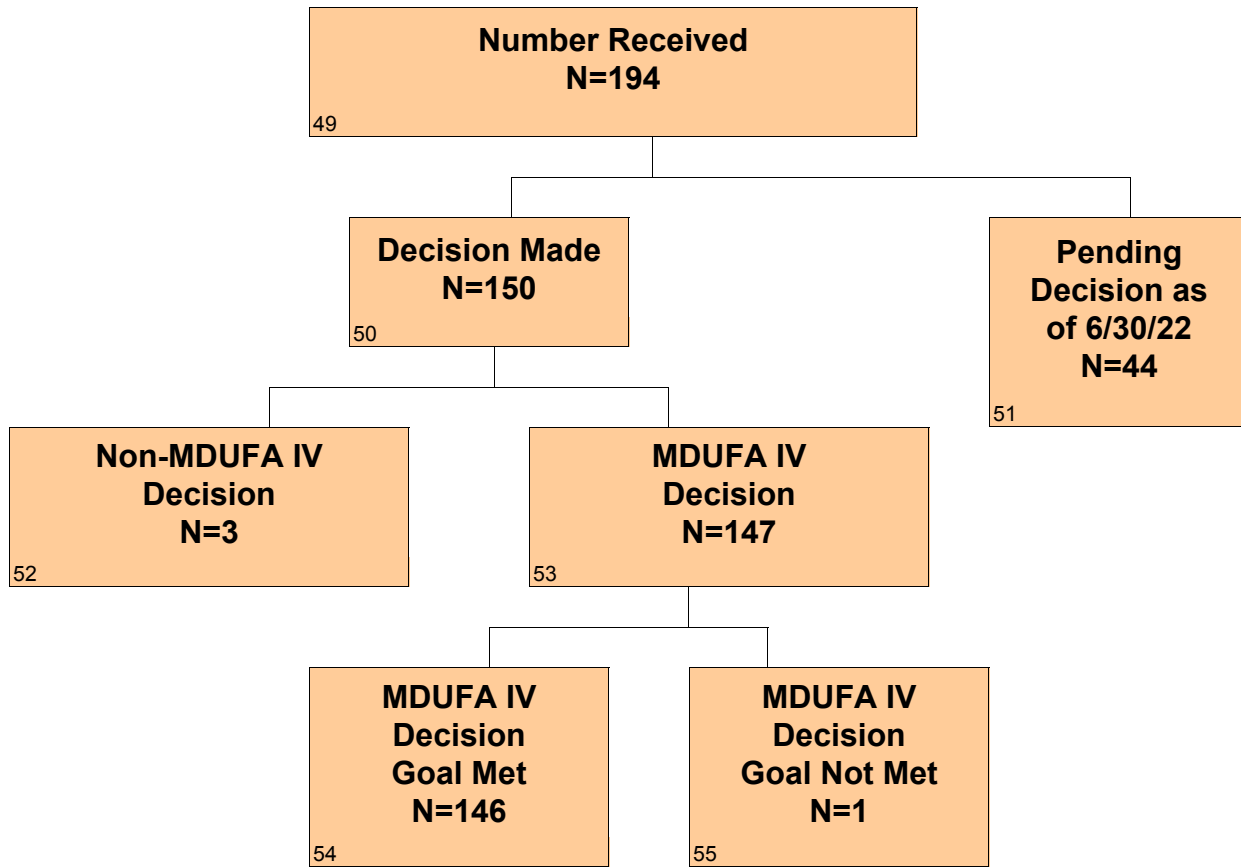
CDRH PMA Real Time Supplements - FY 2020 as of 6/30/22



CDRH PMA Real Time Supplements - FY 2021 as of 6/30/22



CDRH PMA Real Time Supplements - FY 2022 as of 6/30/22



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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	194
Non-MDUFA IV Decision	2	9	3	2	3
MDUFA IV Decision	336	364	350	274	147
MDUFA IV Decision Goal Met	336	364	346	265	146
Supplements Pending MDUFA IV Decision	0	0	0	2	44
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	2	1
Current Performance Percent Goal Met	100.00%	100.00%	98.86%	96.01%	98.65%

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	194
Number With MDUFA IV Decision	336	364	350	274	147
Number of Not Approvable	20	29	6	10	4
Rate of Not Approvable	5.95%	7.97%	1.71%	3.65%	2.72%

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	2
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.25	188.36	128.50
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	14
Non-MDUFA IV Decision	0	2	1	0	0
MDUFA IV Decision	23	38	15	21	10
MDUFA IV Decision Goal Met	23	38	15	21	10
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 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	14
Number With MDUFA IV Decision	23	38	15	21	10
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	81
Non-MDUFA IV Decision	0	3	2	0	1
MDUFA IV Decision	154	170	191	147	69
MDUFA IV Decision Goal Met	154	170	190	146	69
Supplements Pending MDUFA IV Decision	0	0	0	0	11
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	81
Number With MDUFA IV Decision	154	170	191	147	69
Number of Not Approvable	12	15	1	2	2
Rate of Not Approvable	7.79%	8.82%	0.52%	1.36%	2.90%

**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	24
Non-MDUFA IV Decision	0	1	0	2	0
MDUFA IV Decision	20	38	36	14	19
MDUFA IV Decision Goal Met	20	38	36	14	19
Supplements Pending MDUFA IV Decision	0	0	0	0	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%	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	24
Number with MDUFA IV Decision	20	38	36	14	19
Number of Not Approvable	1	8	1	0	2
Rate of Not Approvable	5.00%	21.05%	2.78%	0.00%	10.53%

**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	6
Non-MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision	12	18	13	12	1
MDUFA IV Decision Goal Met	12	18	13	10	1
Supplements Pending MDUFA IV Decision	0	0	0	1	5
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	1
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	76.92%	50.00%

**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	6
Number with MDUFA IV Decision	12	18	13	12	1
Number of Not Approvable	4	0	0	1	0
Rate of Not Approvable	33.33%	0.00%	0.00%	8.33%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	3	1
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	196.67	153.00
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	26
Non-MDUFA IV Decision	0	0	0	0	1
MDUFA IV Decision	16	32	24	22	14
MDUFA IV Decision Goal Met	16	32	24	22	14
Supplements Pending MDUFA IV Decision	0	0	0	0	11
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	26
Number with MDUFA IV Decision	16	32	24	22	14
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	8
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	17	22	9	3	4
MDUFA IV Decision Goal Met	17	22	9	3	4
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 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	8
Number with MDUFA IV Decision	17	22	9	3	4
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
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	93	48	61	55	35
Non-MDUFA IV Decision	1	3	0	0	1
MDUFA IV Decision	92	45	61	54	30
MDUFA IV Decision Goal Met	92	45	58	48	29
Supplements Pending MDUFA IV Decision	0	0	0	1	4
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	0
Current Performance Percent Goal Met	100.00%	100.00%	95.08%	87.27%	96.67%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	93	48	61	55	35
Number with MDUFA IV Decision	92	45	61	54	30
Number of Not Approvable	0	1	0	5	0
Rate of Not Approvable	0.00%	2.22%	0.00%	9.26%	0.00%

Table 3.3 OHT7 - Office of In Vitro Diagnostics
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	1
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.00	192.57	104.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

**Table 3.1 OHT8 - Office of 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	2	1	1	1	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	2	1	1	1	0
MDUFA IV Decision Goal Met	2	1	1	1	0
Supplements Pending MDUFA IV Decision	0	0	0	0	0
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 3.2 OHT8 - Office of 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	2	1	1	1	0
Number with MDUFA IV Decision	2	1	1	1	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 3.3 OHT8 - Office of 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	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

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Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2021 and June 30, 2022.

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Section 5 PMA Annual Metrics and Goals

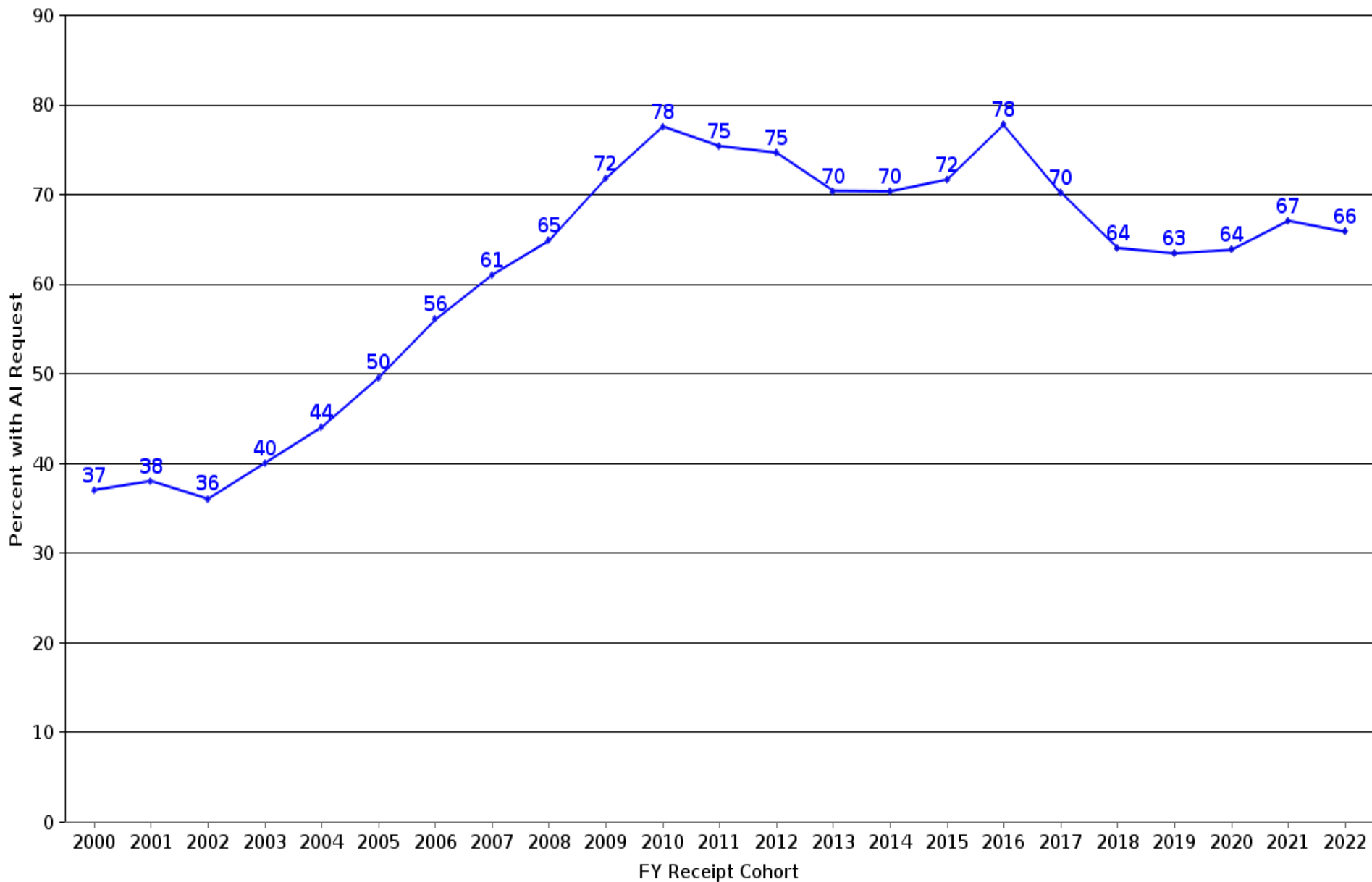
PMA Annual Metrics and Goals will be reported in the Annual Report.

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510(k)s

Q3FY2022

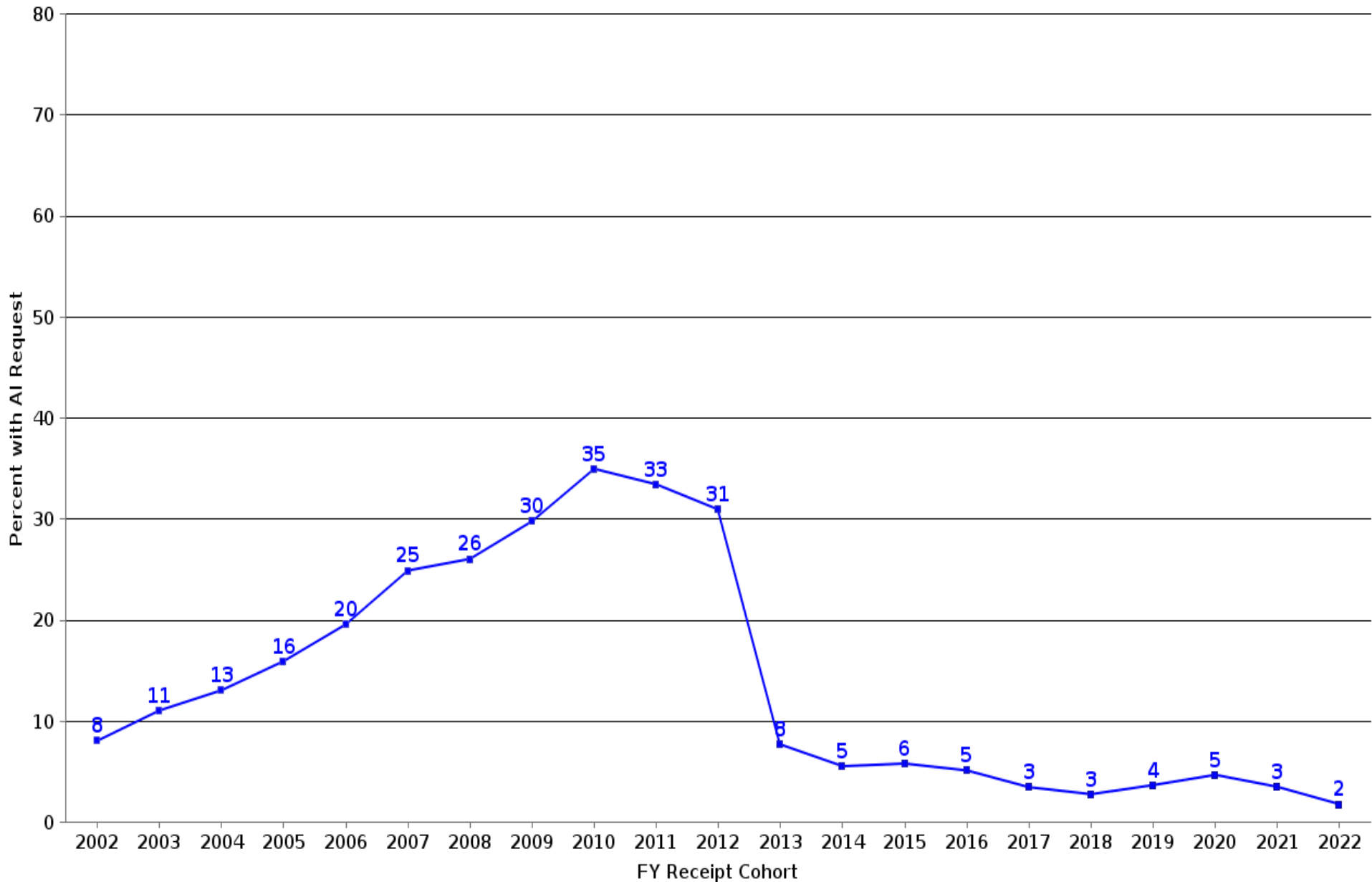
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 4/30/22

◆ % with 1st Cycle AI Request

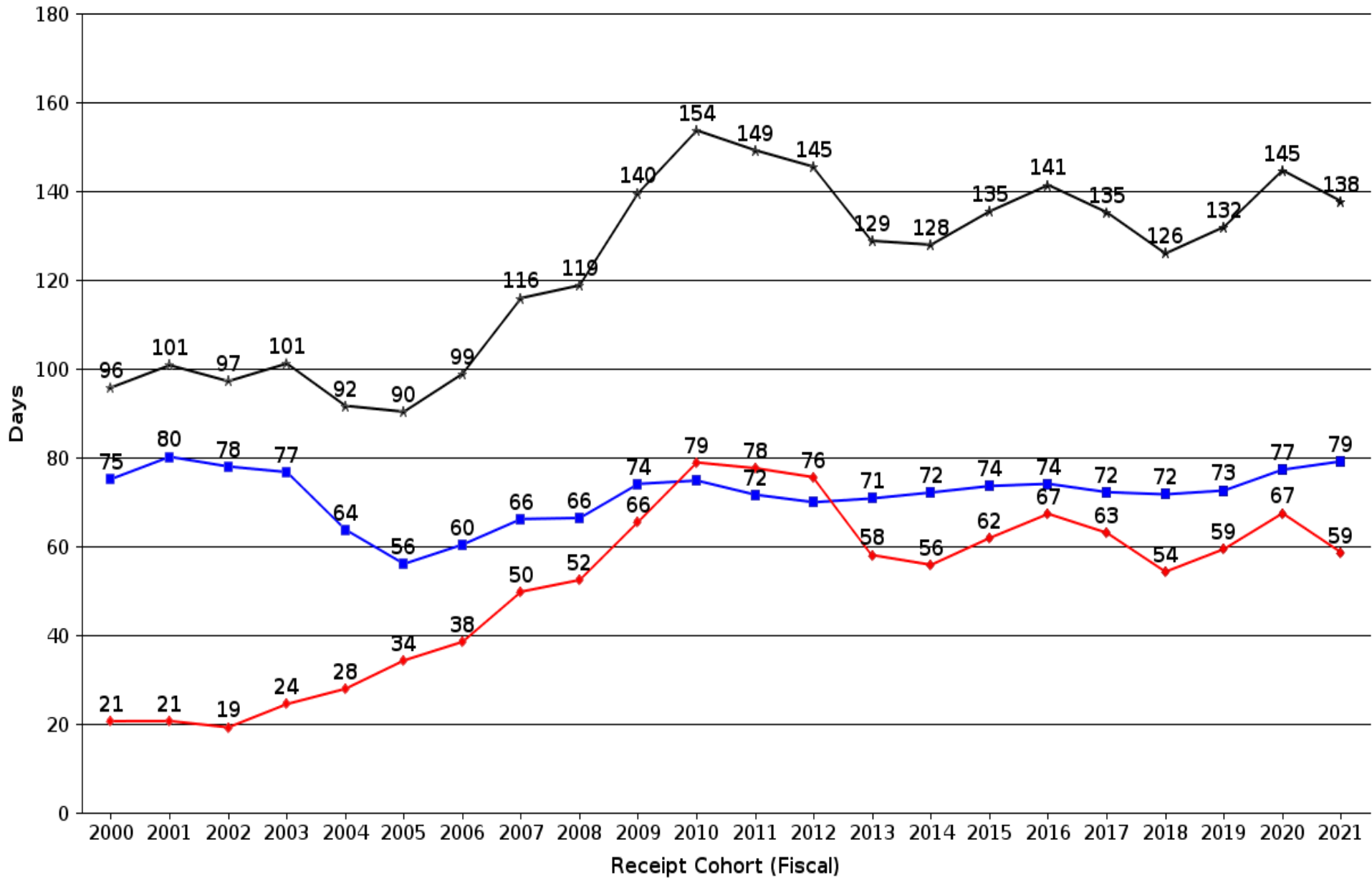
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 11/30/21

■ % with 2nd Cycle AI Request

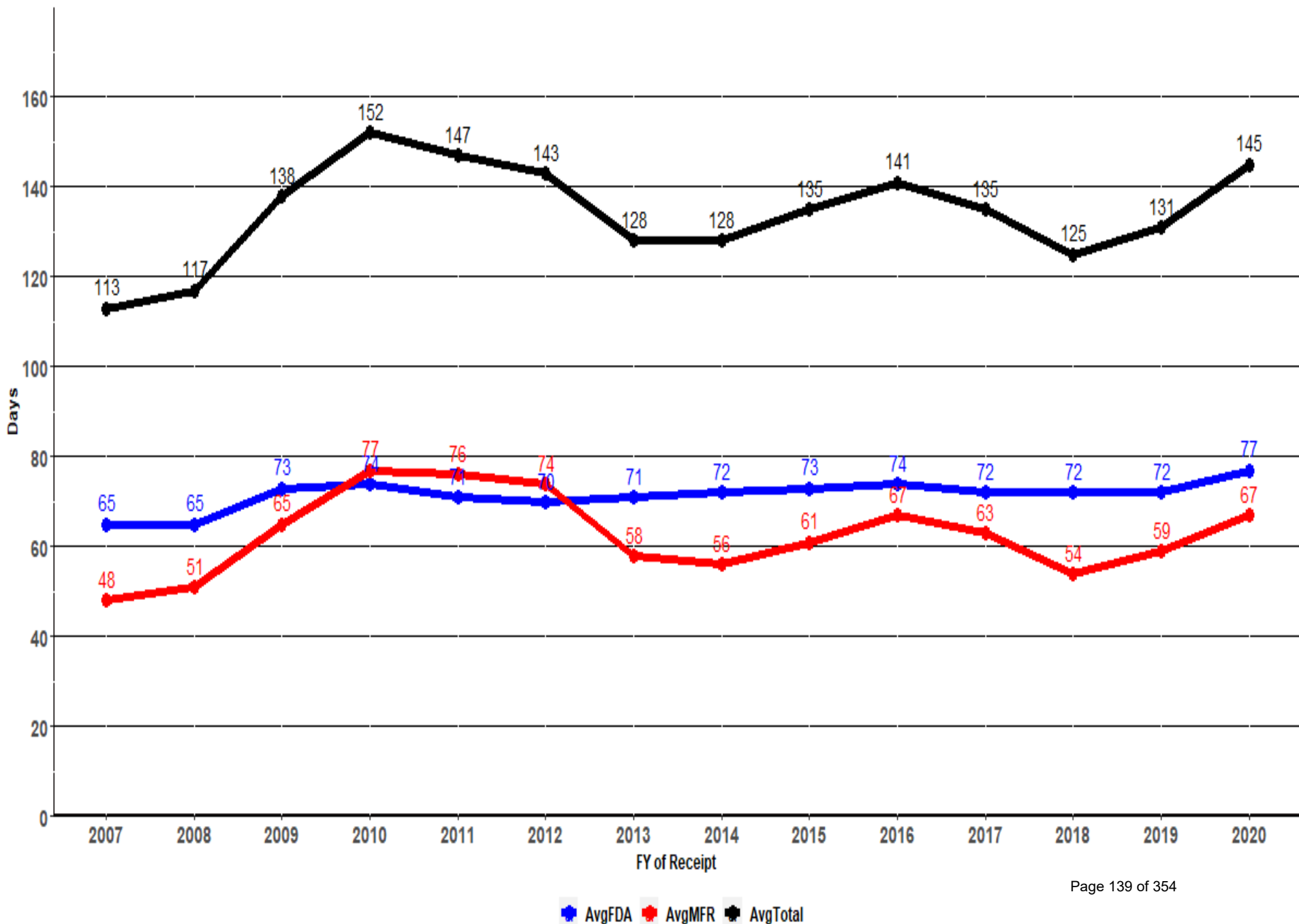
510(k) Average Days to MDUFA (SE/NSE) Decision as of: 6/30/22



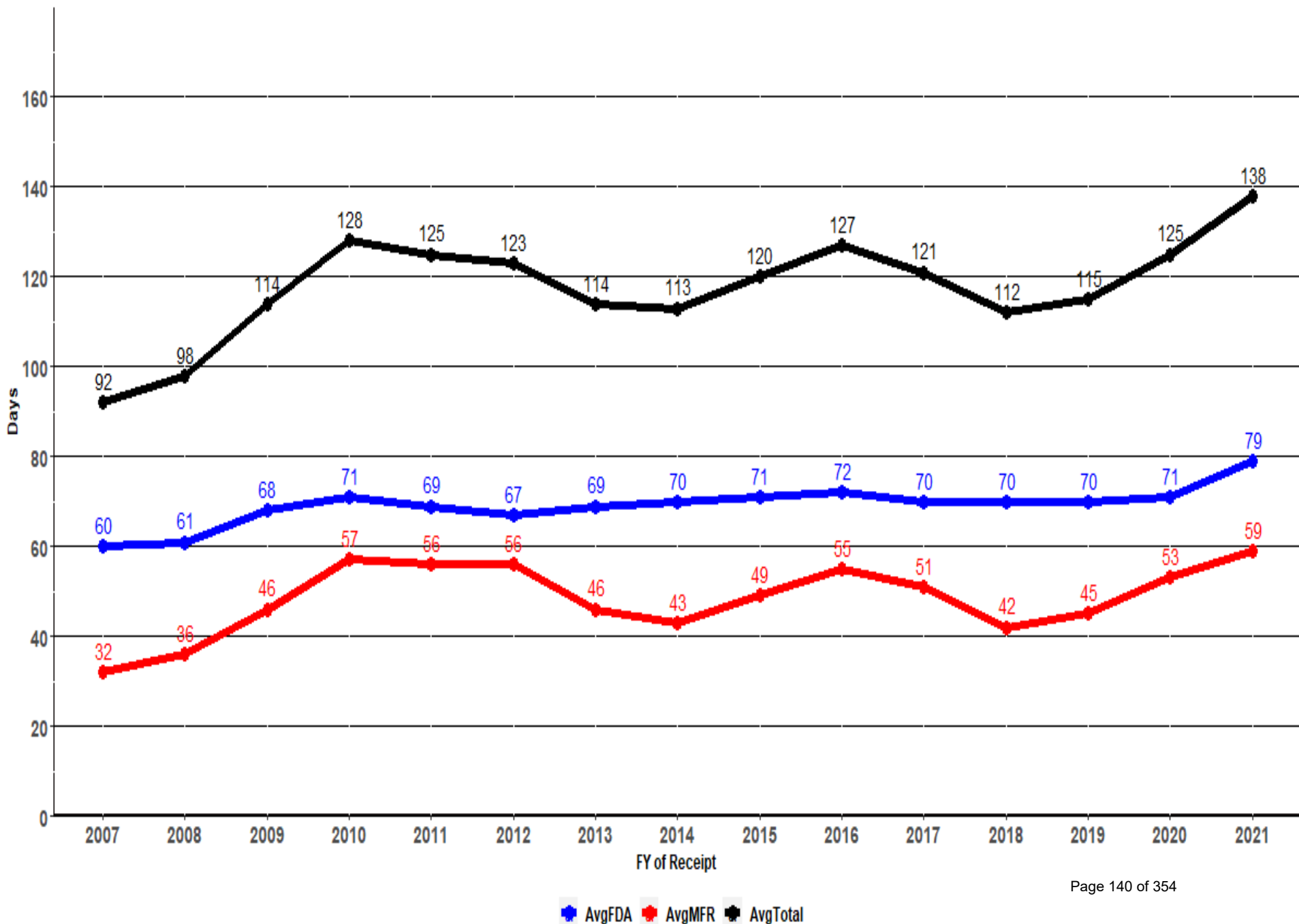
Cohorts not yet closed: 2019: 99.94%; 2020: 98.47%; 2021: 85.02%

■ 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 98.5 % Cohort Closure by FY of Receipt

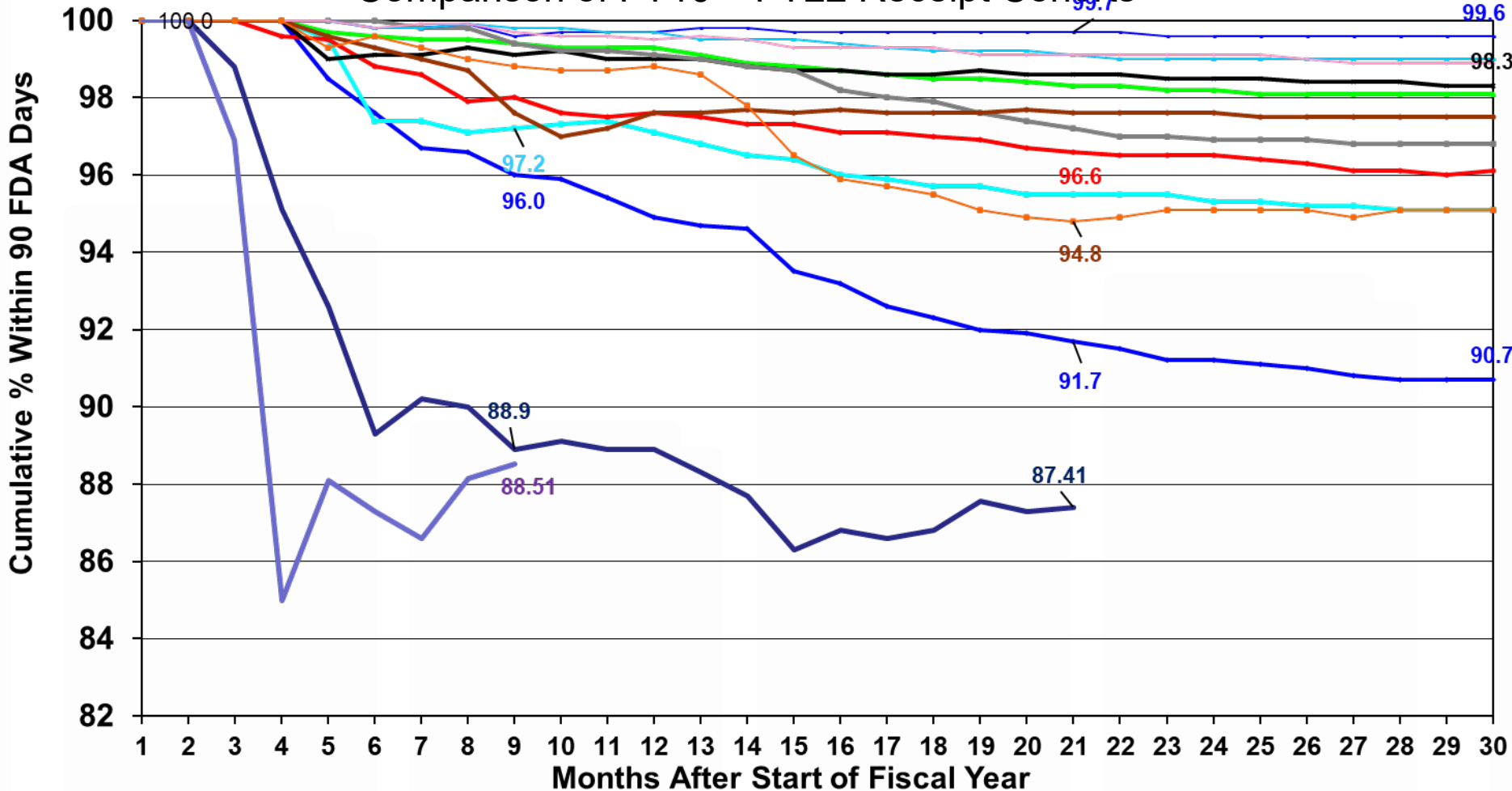


510(k) Average Days to MDUFA (SE/NSE) Decision at 85 % Cohort Closure by FY of Receipt



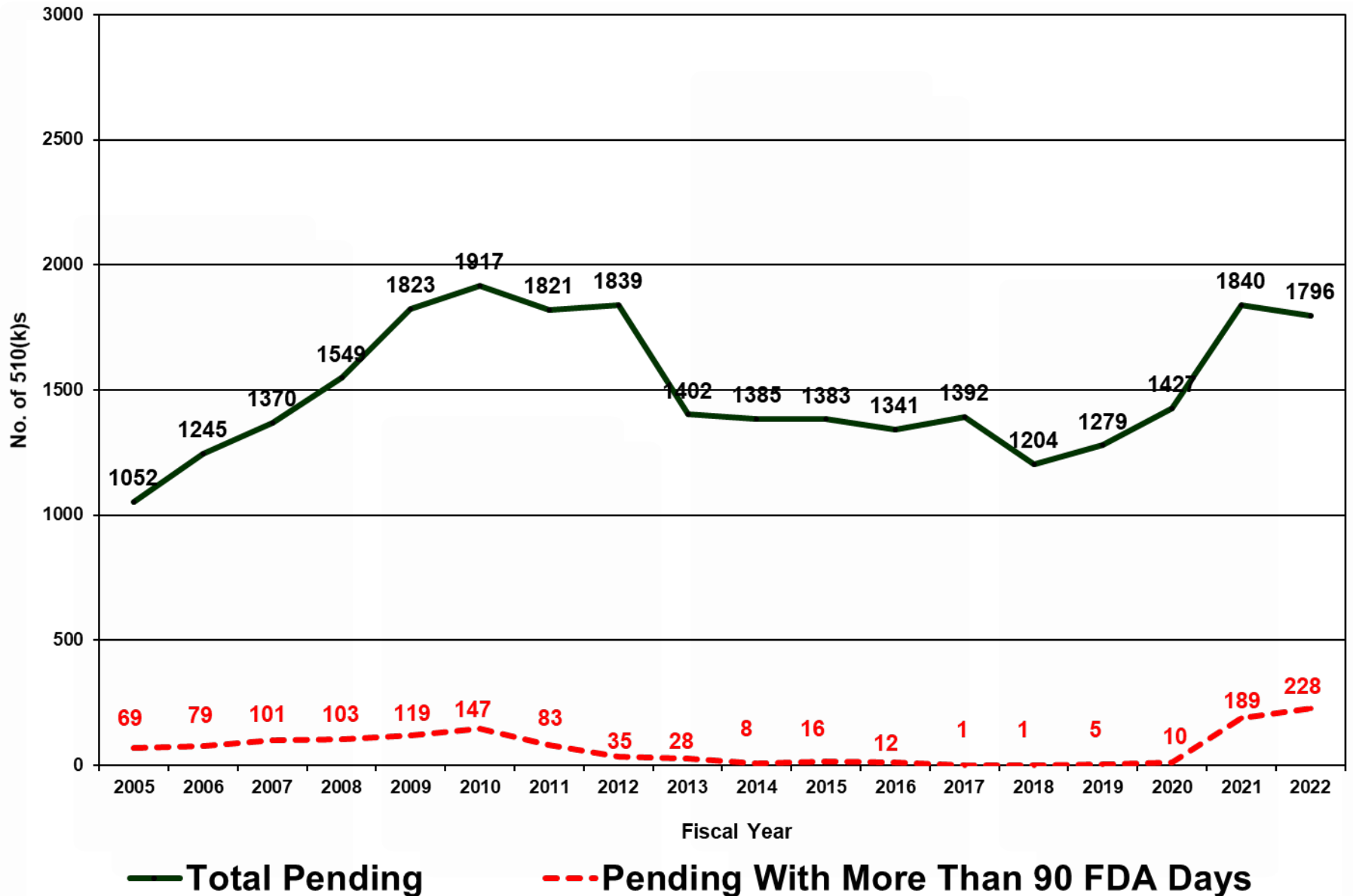
Trend in 510(k) MDUFA Decision Goal Performance

Comparison of FY10 – FY22 Receipt Cohorts



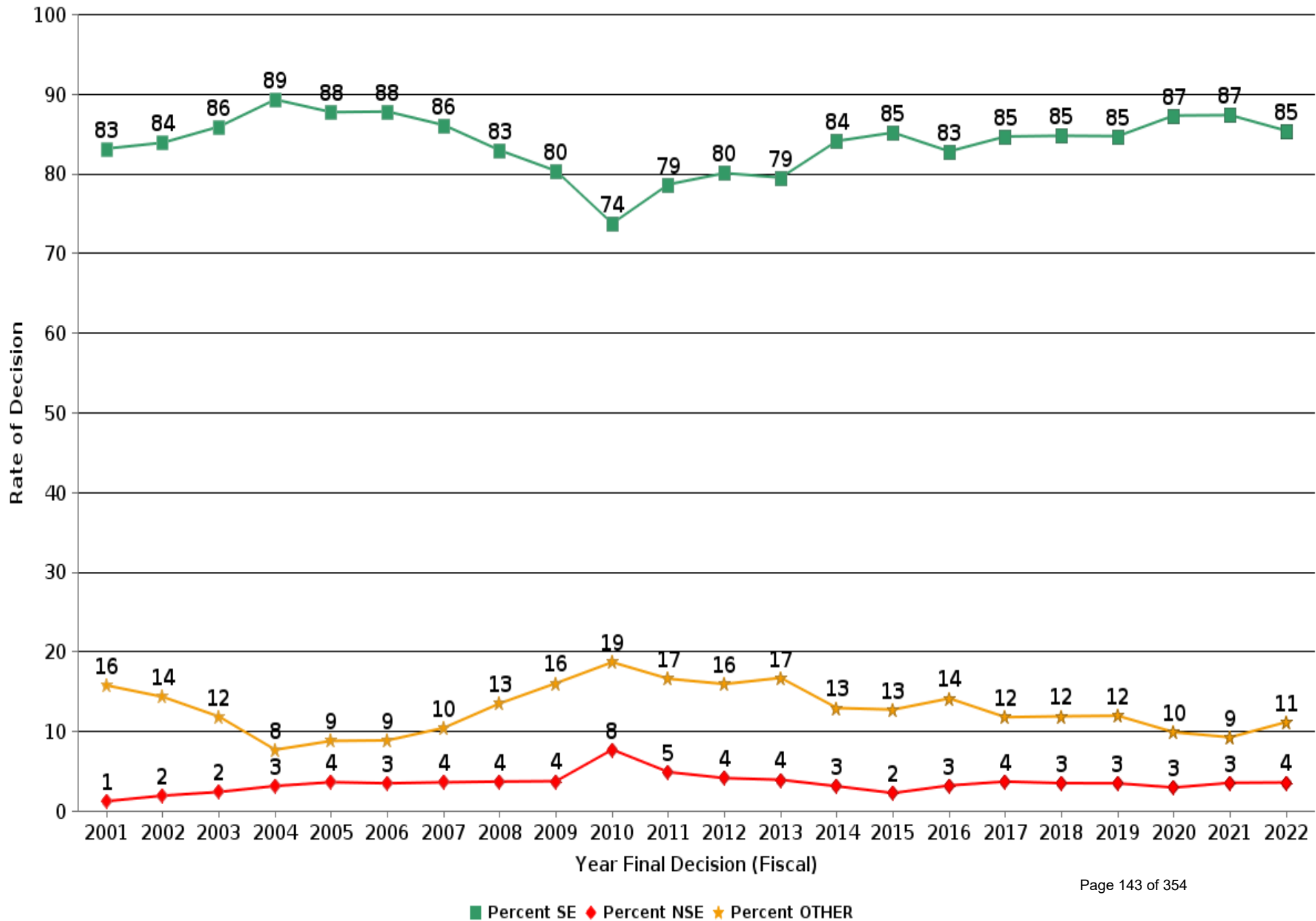
- FY10 Receipt Cohort
- FY11 Receipt Cohort
- FY12 Receipt Cohort
- FY13 Receipt Cohort
- FY14 Receipt Cohort
- FY15 Receipt Cohort
- FY16 Receipt Cohort
- FY17 Receipt Cohort
- FY18 Receipt Cohort
- FY19 Receipt Cohort
- FY20 Receipt Cohort
- FY21 Receipt Cohort
- FY22 Receipt Cohort

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



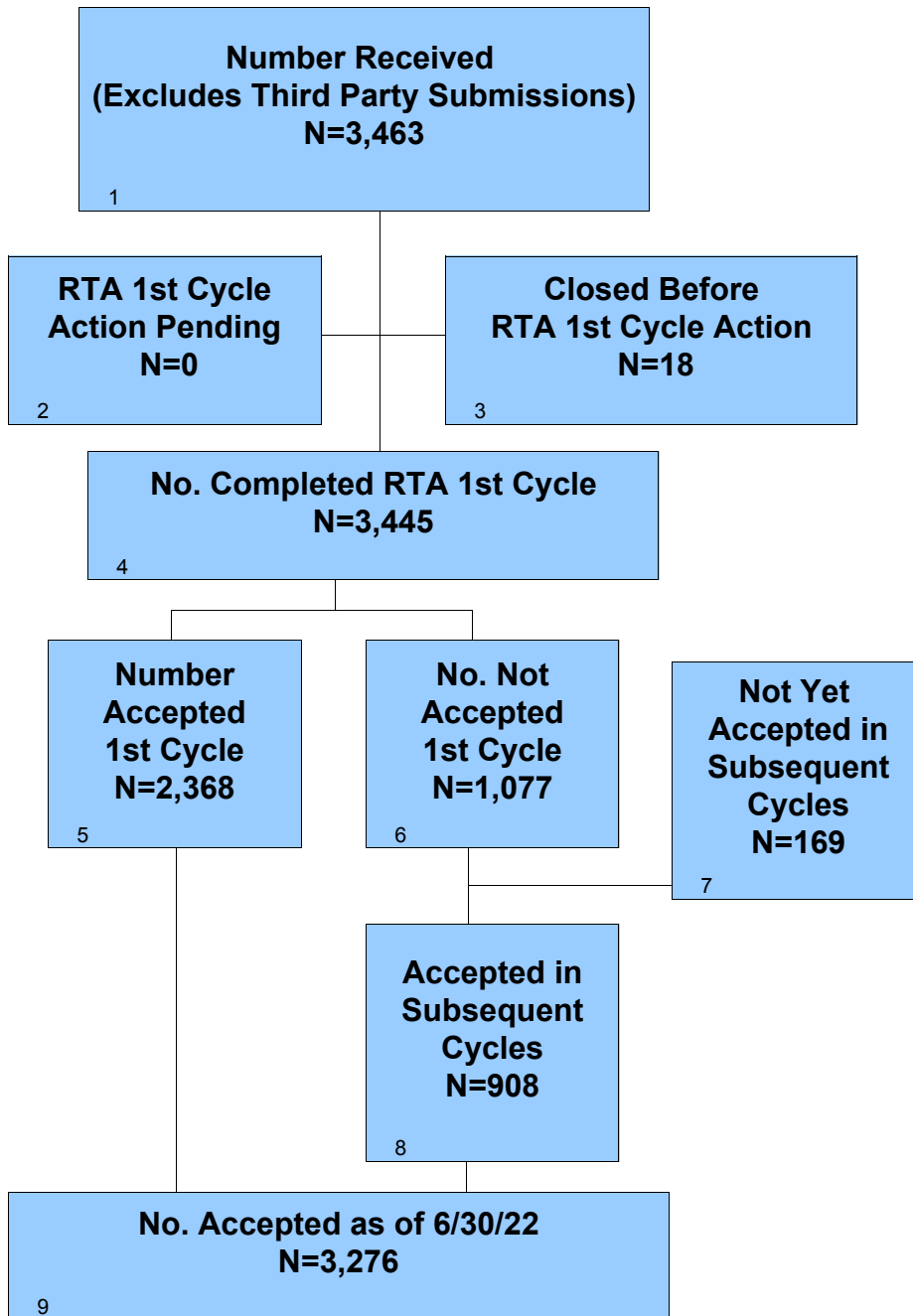
“Pending” means 510ks under review or on hold following a positive RTA decision (FY13 and later).

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

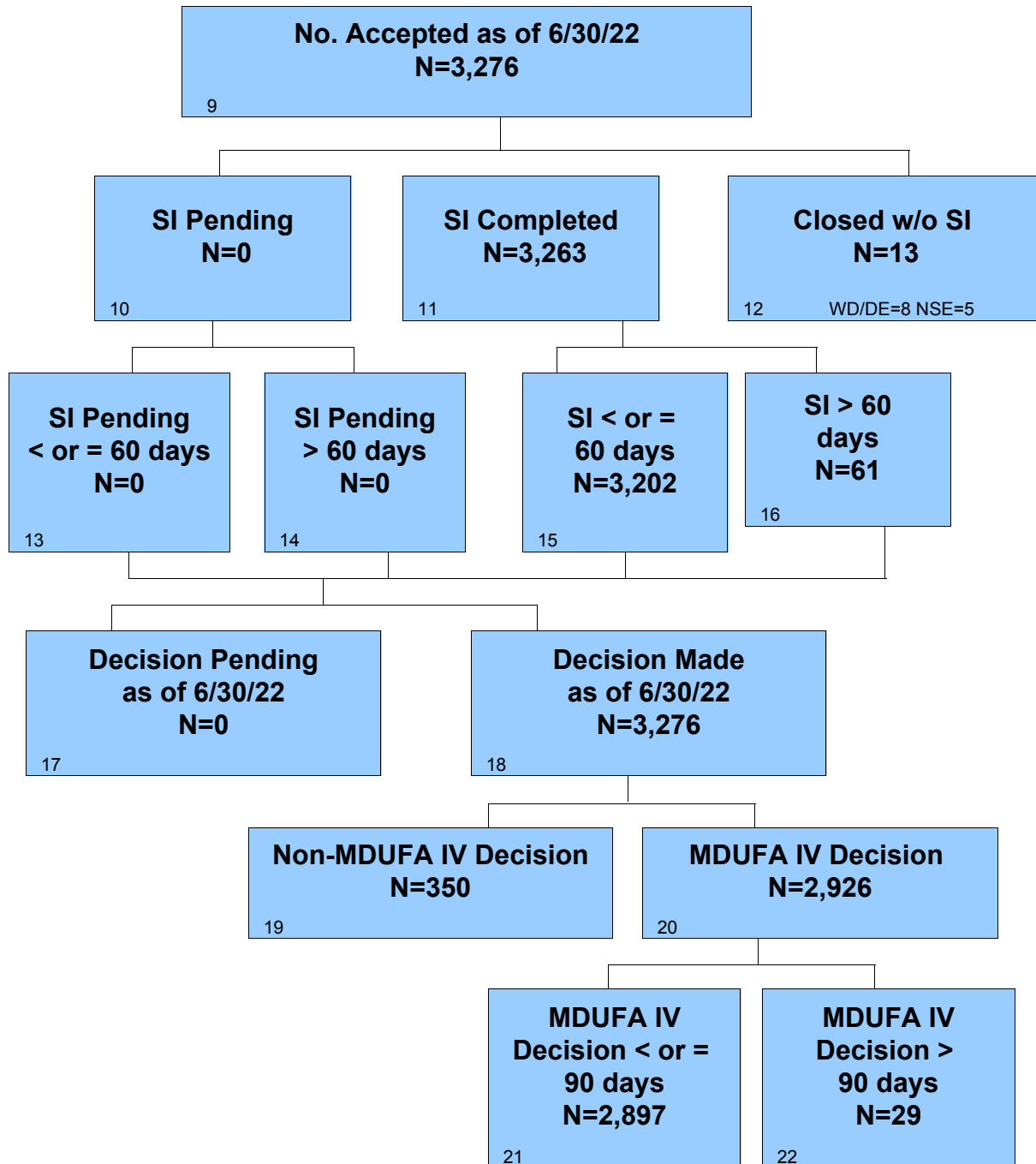


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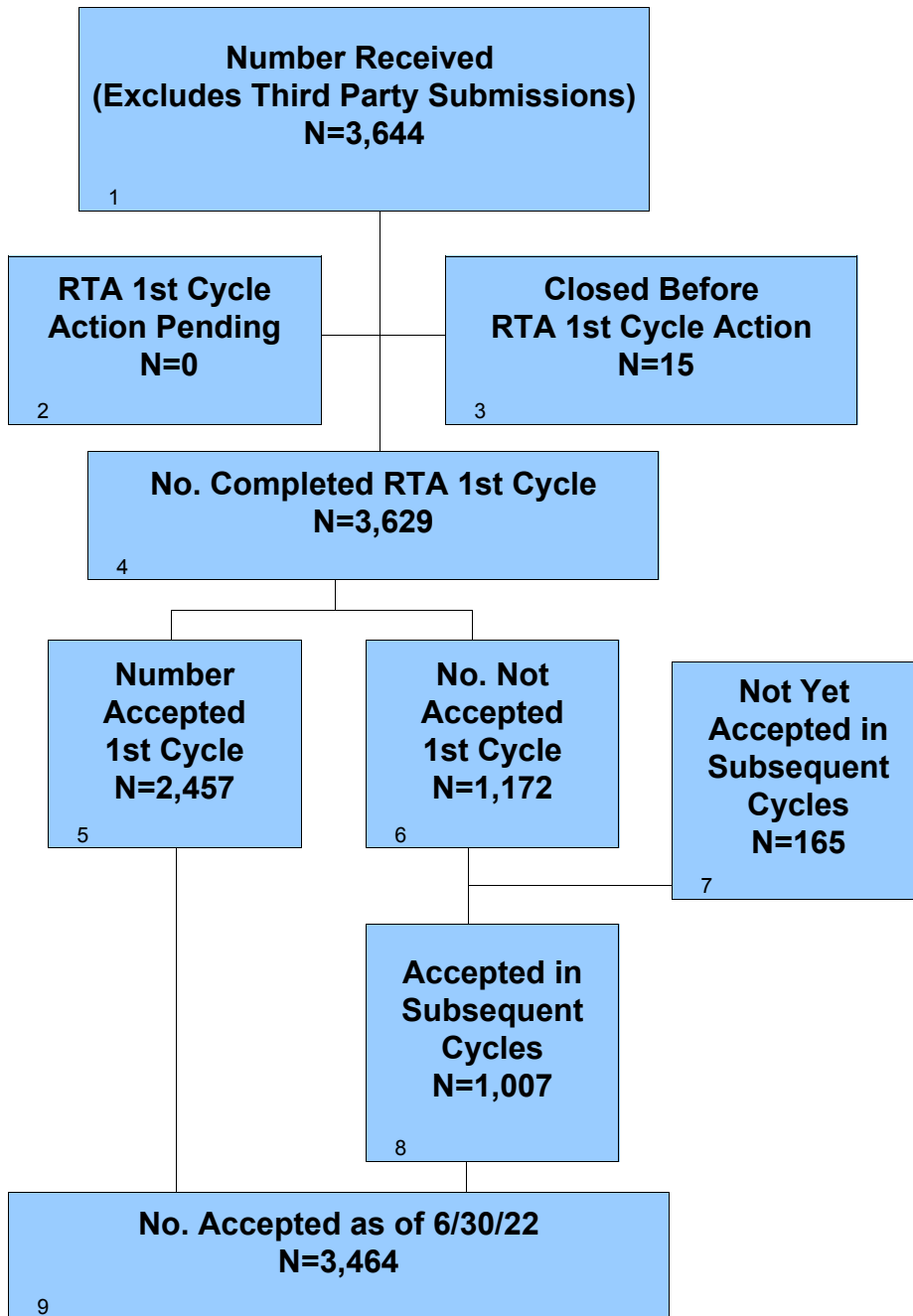
CDRH 510(k)s - FY 2018 as of 6/30/22



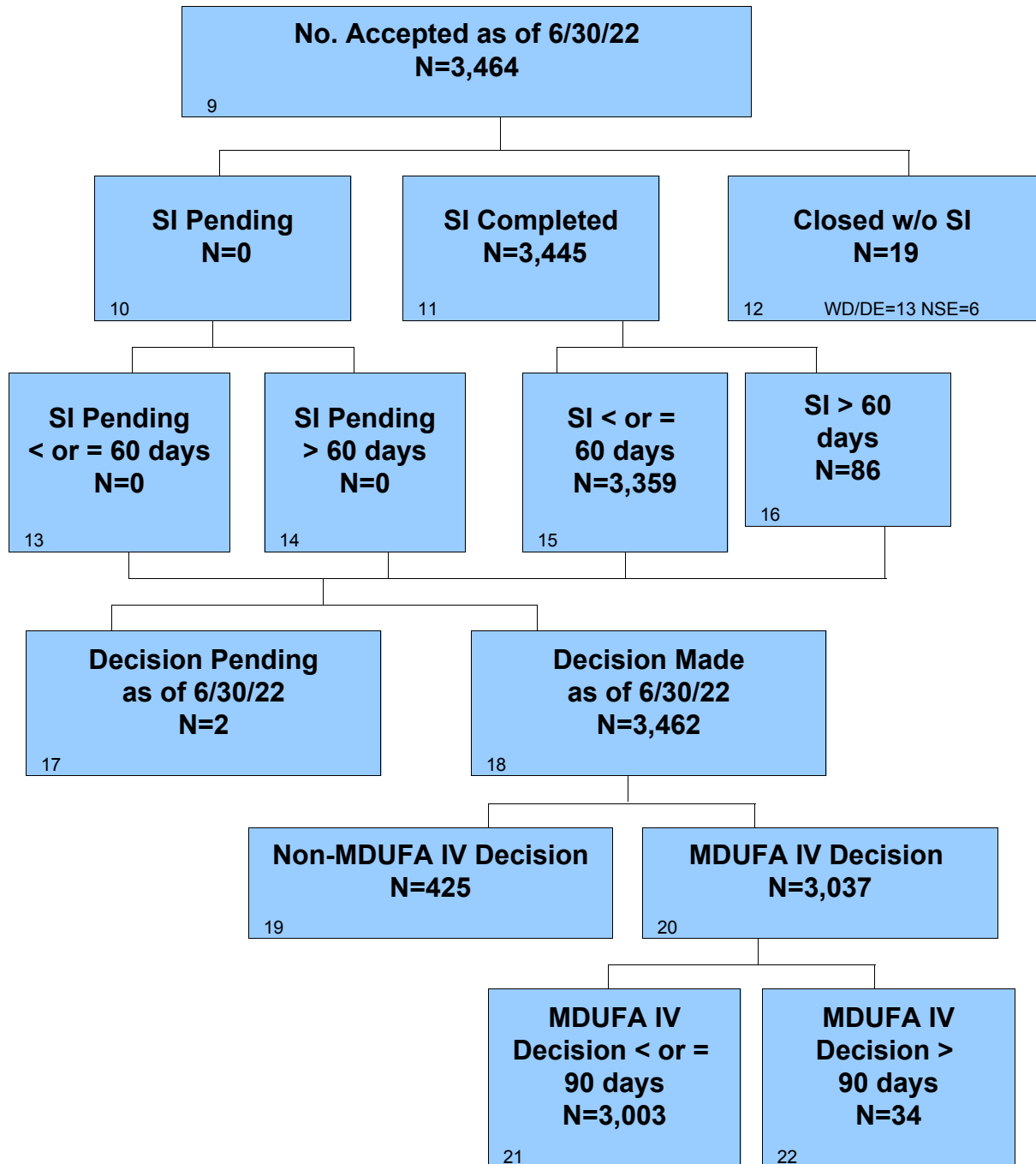
CDRH 510(k)s - FY 2018 as of 6/30/22 Continued



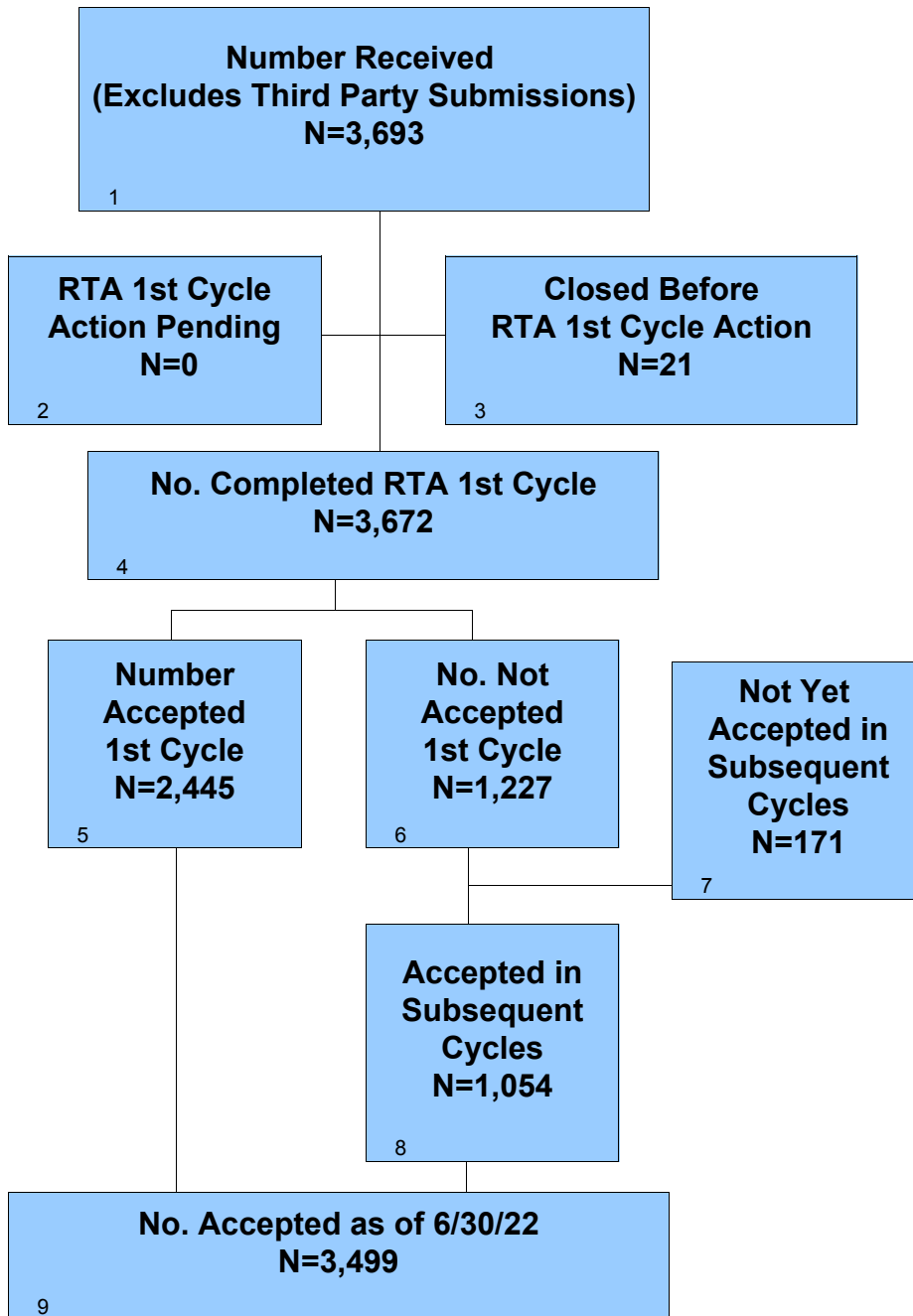
CDRH 510(k)s - FY 2019 as of 6/30/22



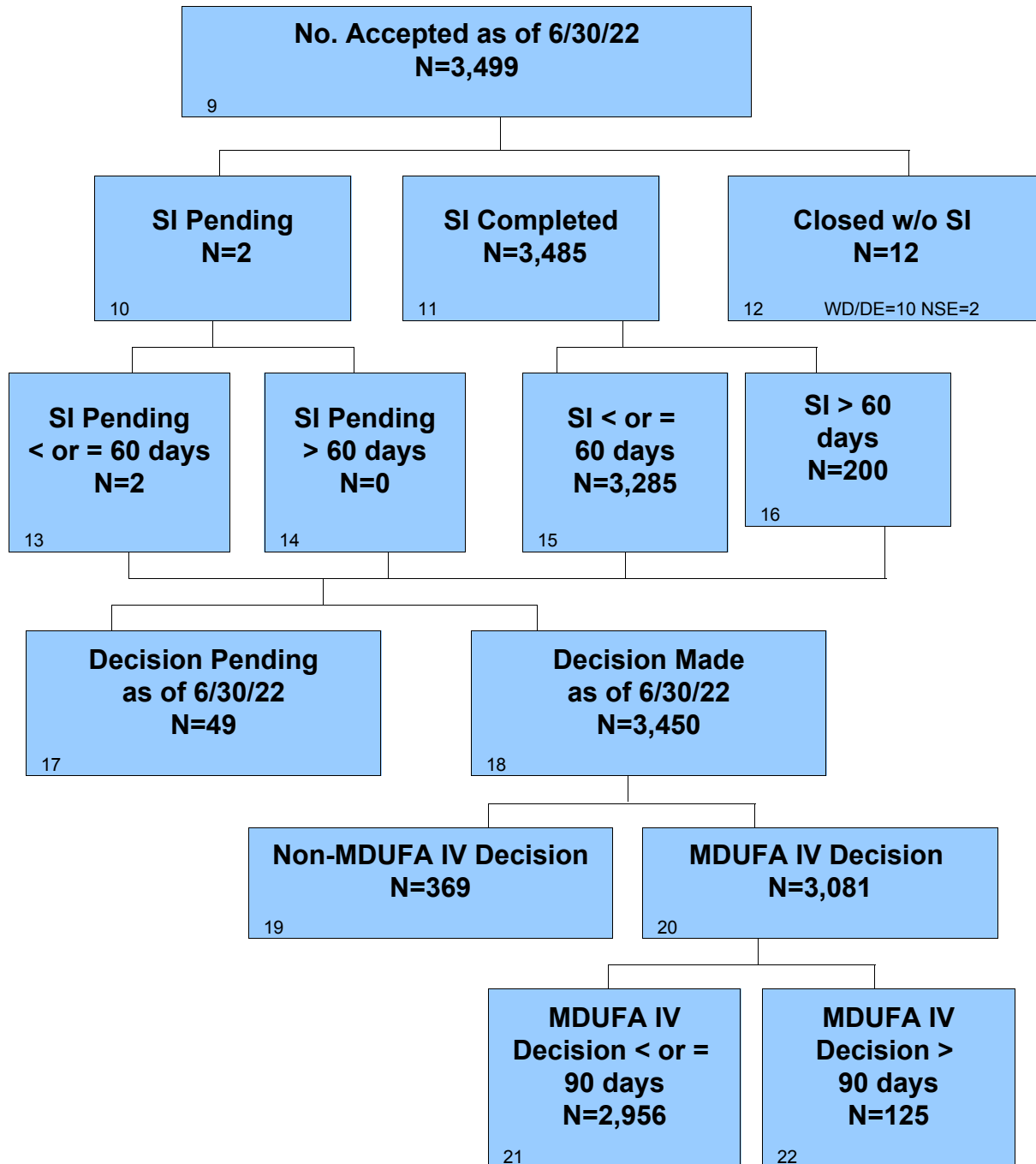
CDRH 510(k)s - FY 2019 as of 6/30/22 Continued



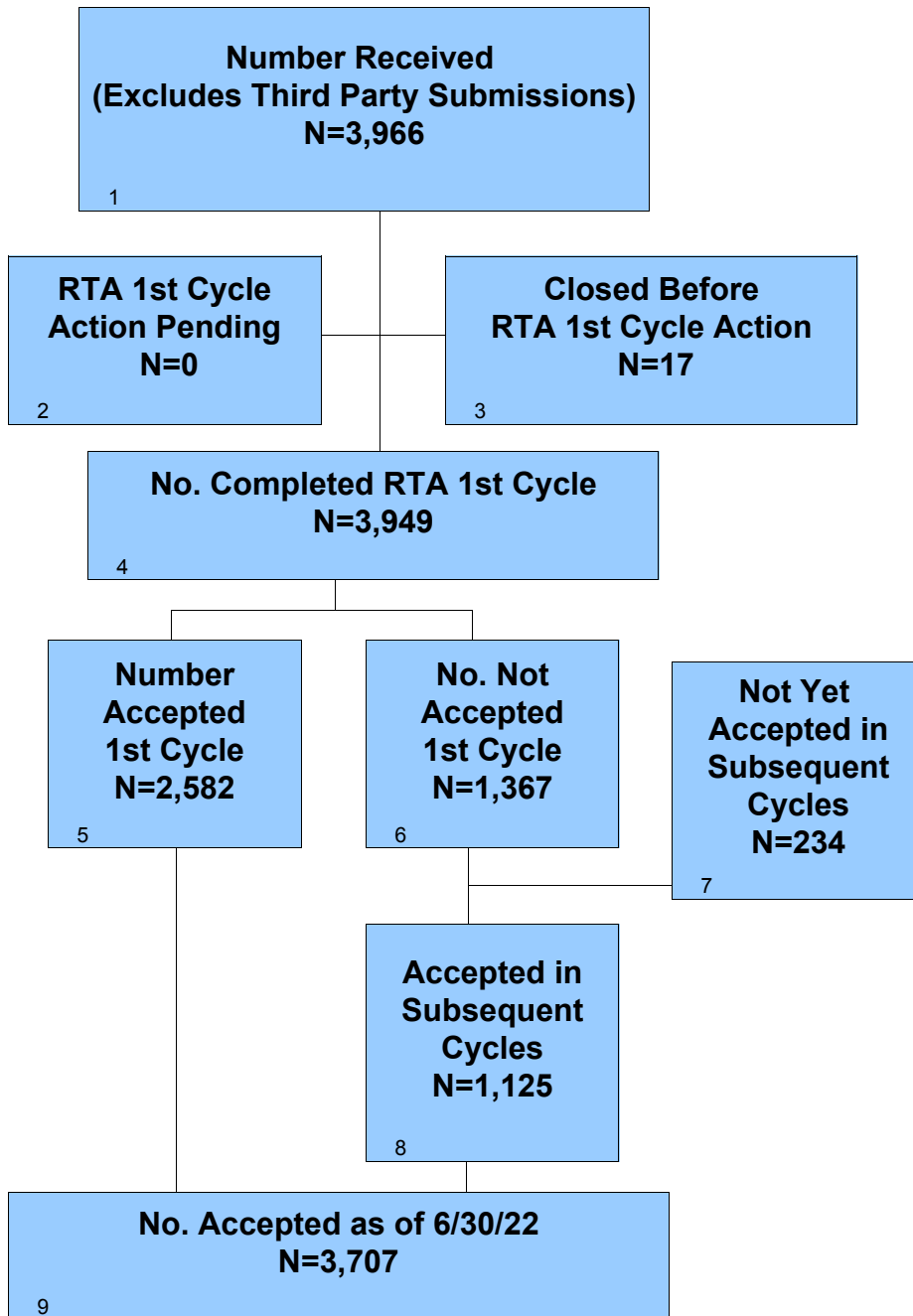
CDRH 510(k)s - FY 2020 as of 6/30/22



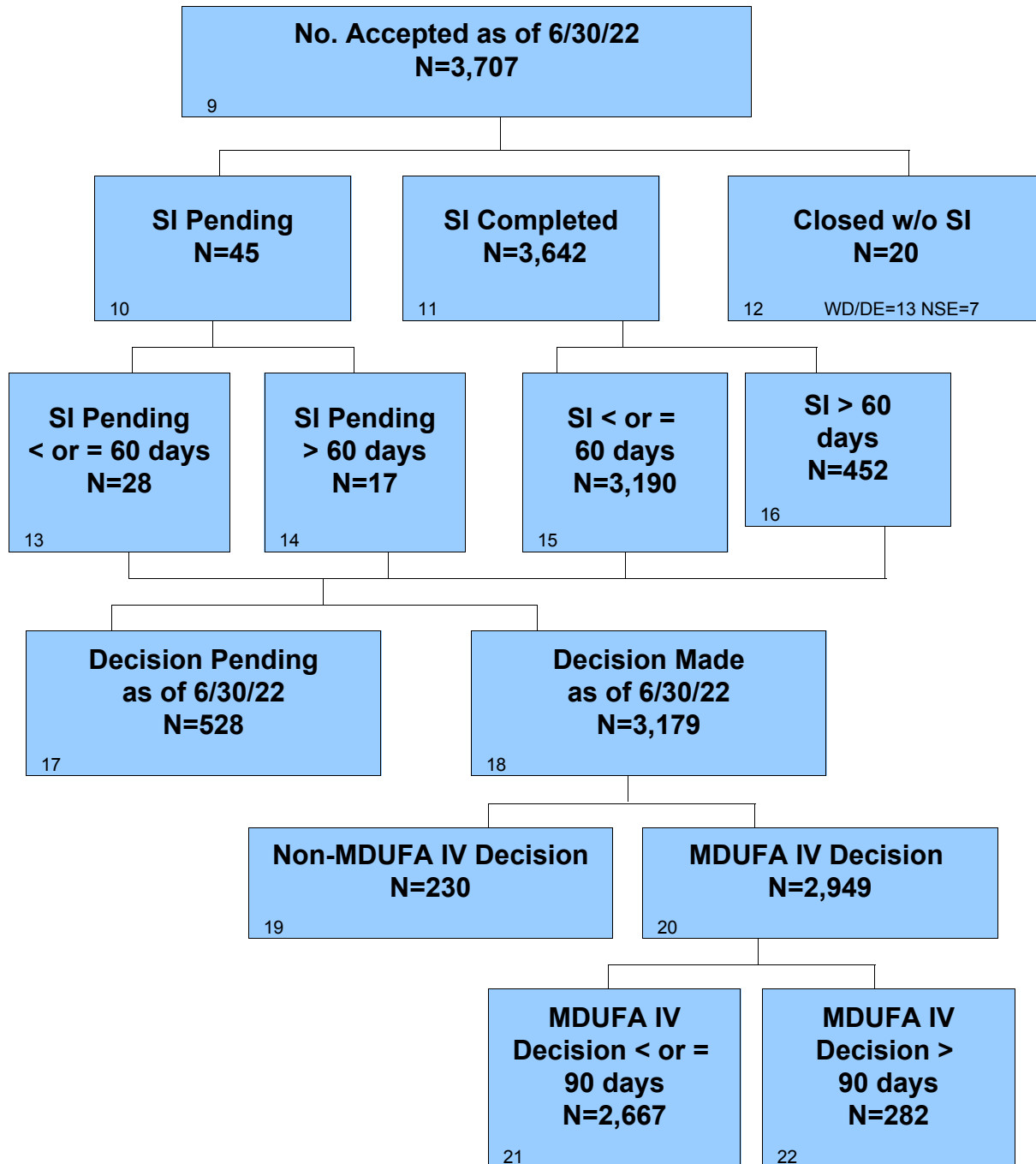
CDRH 510(k)s - FY 2020 as of 6/30/22 Continued



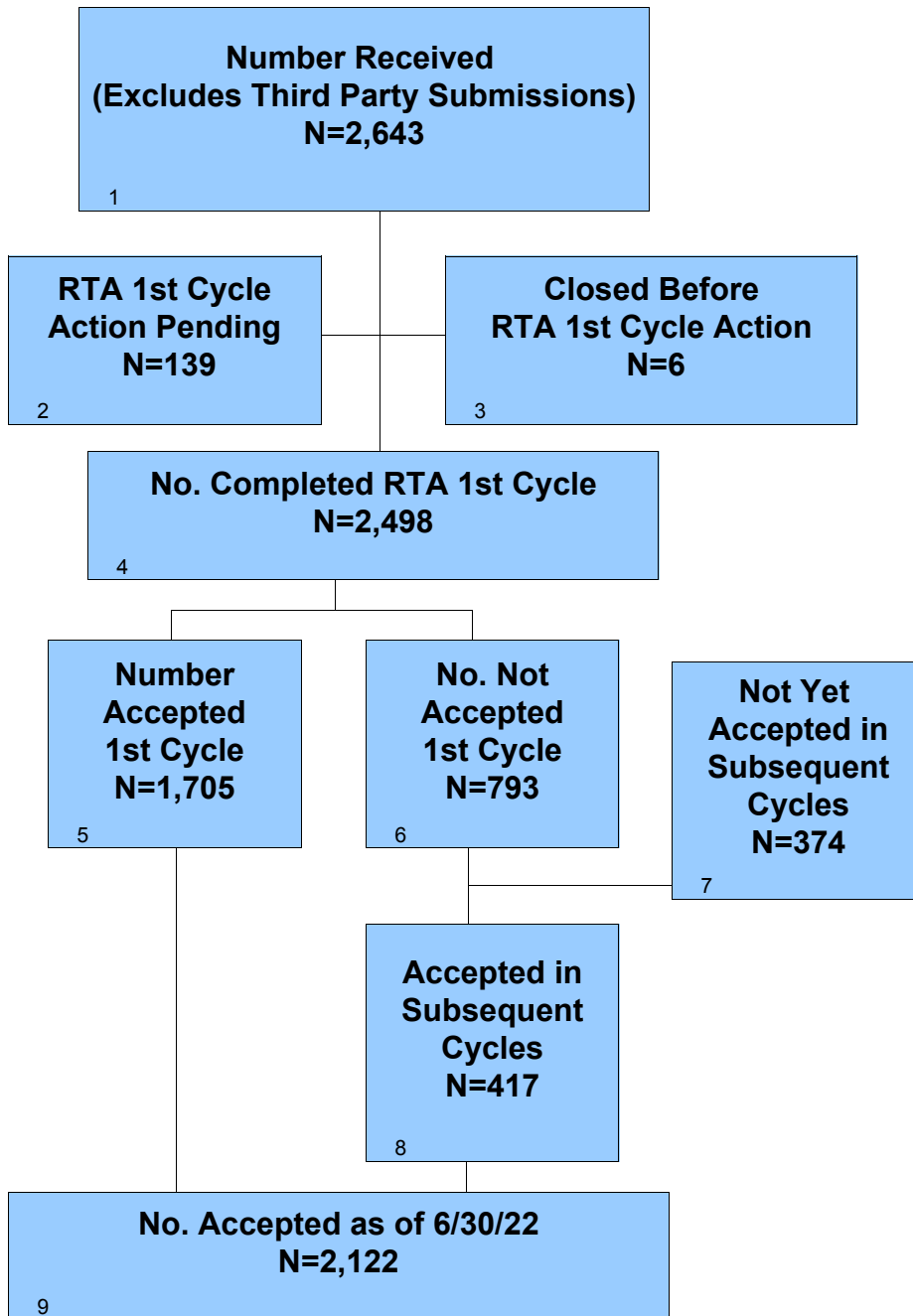
CDRH 510(k)s - FY 2021 as of 6/30/22



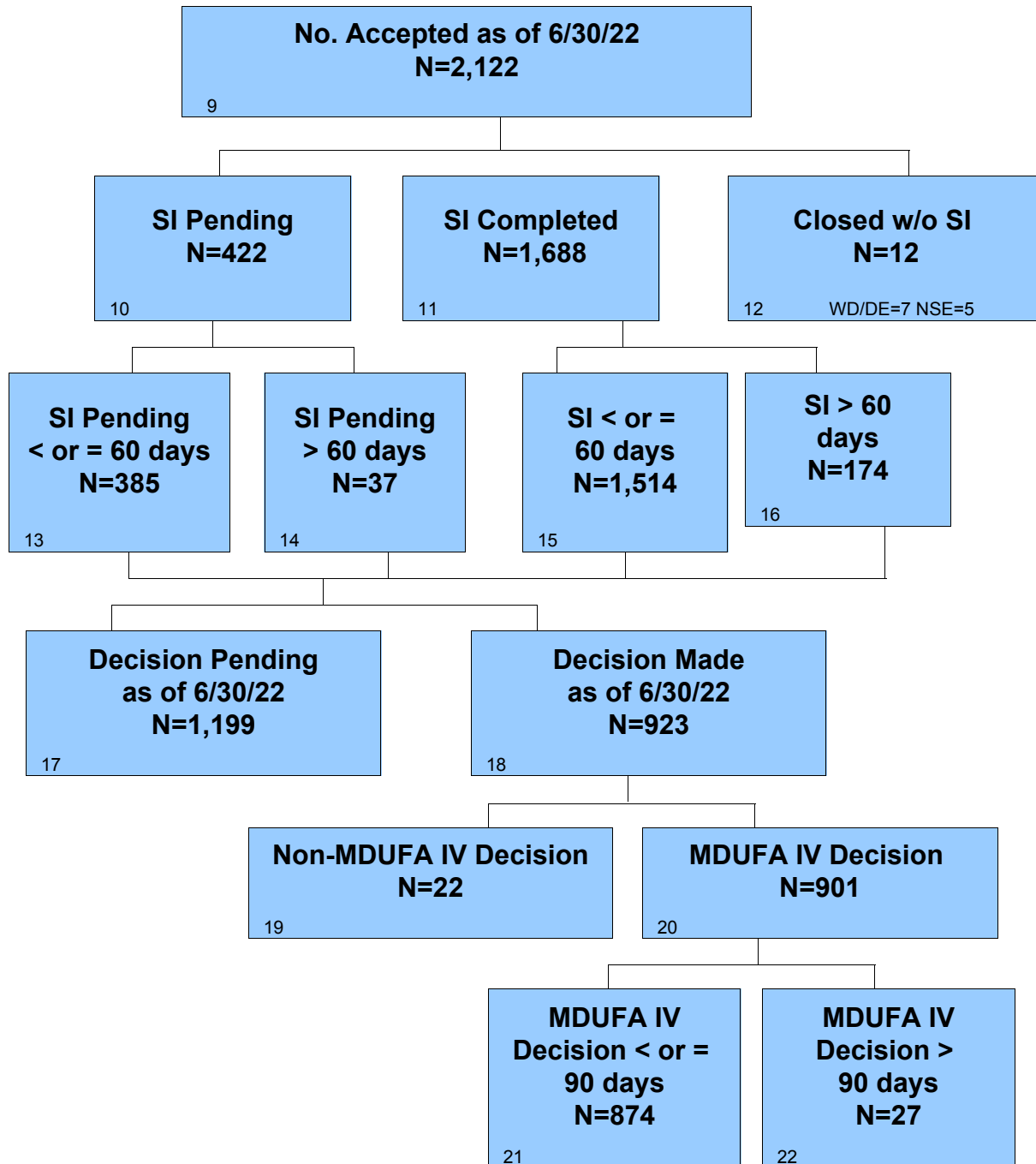
CDRH 510(k)s - FY 2021 as of 6/30/22 Continued



CDRH 510(k)s - FY 2022 as of 6/30/22



CDRH 510(k)s - FY 2022 as of 6/30/22 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	3,693	3,966	2,643
Closed Before RTA Action or TS	18	15	21	17	6
Number Accepted	2,353	2,403	2,396	2,362	1,463
Number Without a RTA Review and > 15 Days Since Date Received	15	54	49	220	242
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	139
Number Not Accepted	1,077	1,172	1,227	1,367	793
Rate of Submissions Not Accepted for Review	31.26%	32.30%	33.42%	34.62%	31.75%

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	3,464	3,499	3,707	2,122
Deleted or Withdrawn Prior to SI	8	13	10	13	7
SI Within 60 FDA Days	3,202	3,359	3,285	3,190	1,514
SI Over 60 FDA Days	61	86	200	452	174
SI Pending Within 60 FDA Days	0	0	2	28	385
SI Pending Over 60 FDA Days	0	0	0	17	37
510(k)s NSE Without SI	5	6	2	7	5
Current SI Performance Percent Within 60 FDA Days	97.98%	97.33%	94.21%	87.02%	87.51%

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	3,445	3,485	3,642	1,688
Average Number of FDA Days to Substantive Interaction	51.04	51.42	55.02	59.43	55.88
20th Percentile FDA Days to Substantive Interaction	43	43	46	50	48
40th Percentile FDA Days to Substantive Interaction	55	56	56	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	86	90	496	381	196

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	3,464	3,499	3,707	2,122					
Non-MDUFA IV Decision	350	425	369	230	22					
MDUFA IV Decision (SE/NSE)	2,926	3,037	3,081	2,949	901					
MDUFA IV Decision Within 90 FDA Days	2,897	3,003	2,956	2,667	874					
510(k)s Pending MDUFA IV Decision	0	2	49	528	1,199					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	26	108	92					
Current Performance Percent Within 90 FDA Days	99.01%	98.88%	95.14%	87.24%	88.02%					

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	3,081	2,949	901
Average Number of FDA Days to MDUFA IV Decision	72.62	73.53	78.43	80.24	65.84
20th Percentile FDA Days to MDUFA IV Decision	54	55	55	57	30
40th Percentile FDA Days to MDUFA IV Decision	79	82	84	84	59
60th Percentile FDA Days to MDUFA IV Decision	87	88	88	88	84
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	89
Maximum FDA Days to MDUFA IV Decision	220	655	673	389	210
Average Number of Industry Days to MDUFA IV Decision	54.69	60.21	68.29	59.47	17.76
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	5	0	4	3	0
60th Percentile Industry Days to MDUFA IV Decision	44	49	53	49	0
80th Percentile Industry Days to MDUFA IV Decision	127	139	143	124	34
Maximum Industry Days to MDUFA IV Decision	563	448	667	500	182
Average Number of Total Days to MDUFA IV Decision	127.31	133.74	146.72	139.71	83.61
20th Percentile Total Days to MDUFA IV Decision	57	57	56	58	36
40th Percentile Total Days to MDUFA IV Decision	89	90	90	91	60
60th Percentile Total Days to MDUFA IV Decision	128	133	139	141	90
80th Percentile Total Days to MDUFA IV Decision	212	224	237	219	120
Maximum Total Days to MDUFA IV Decision	783	871	775	590	264

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	3,464	3,499	3,707	2,122
Number With MDUFA IV Decision	2,926	3,037	3,081	2,949	901
Number of SE Decision	2,810	2,922	2,982	2,845	887
Number of NSE Decision	116	115	99	104	14
Number of Withdrawal	185	213	208	161	22
Number of Deleted	156	194	157	66	0
Rate of SE Decision	96.04%	96.21%	96.79%	96.47%	98.45%
Rate of NSE Decision	3.96%	3.79%	3.21%	3.53%	1.55%
Rate of Withdrawal	5.65%	6.15%	5.94%	4.34%	1.04%
Rate of Deleted	4.76%	5.60%	4.49%	1.78%	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	125	282	27
Mean FDA Days for Submissions that Missed the Goal	111.38	141.53	221.52	149.04	113.96
Mean Industry Days for Submissions that Missed the Goal	136.24	192.97	150.42	64.45	10.41

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	1	1
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	1	1
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	1	1
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		194		138
Non-MDUFA IV Decision		41		37		41		17		3
MDUFA IV Decision (SE/NSE)		231		241		191		105		17
MDUFA IV Decision Within 90 FDA Days		230		237		122		13		6
510(k)s Pending MDUFA IV Decision		0		0		21		72		118
510(k)s Pending MDUFA IV Decision Over 90 FDA Days		0		0		21		70		78
Current Performance Percent Within 90 FDA Days		99.57%		98.34%		57.55%		7.43%		6.32%

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	396
Closed Before RTA Action	1	1	0	0	1
Number Accepted	208	207	226	207	140
Number Without a RTA Review and > 15 Days Since Date Received	0	12	8	11	18
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	19
Number Not Accepted	343	373	302	315	218
Rate of Submissions Not Accepted for Review	62.25%	63.01%	56.34%	59.10%	57.98%

**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	551	504	483	271
Deleted or Withdrawn Prior to SI	2	6	0	0	0
SI Within 60 FDA Days	477	490	414	409	183
SI Over 60 FDA Days	14	54	90	67	24
SI Pending Within 60 FDA Days	0	0	0	7	64
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%	89.91%	82.14%	85.92%	88.41%

**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	544	504	476	207
Average Number of FDA Days to Substantive Interaction	55.63	56.04	55.38	55.86	54.59
20th Percentile FDA Days to Substantive Interaction	54	54	51	53	52
40th Percentile FDA Days to Substantive Interaction	58	58	57	58	57
60th Percentile FDA Days to Substantive Interaction	59	59	60	59	59
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	551	504	483	271					
Non-MDUFA IV Decision	74	85	60	46	1					
MDUFA IV Decision (SE/NSE)	420	465	436	351	79					
MDUFA IV Decision Within 90 FDA Days	417	463	432	350	79					
510(k)s Pending MDUFA IV Decision	0	1	8	86	191					
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%	99.08%	99.43%	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	1.67	1.42
Number With MDUFA IV Decision	420	465	436	351	79
Average Number of FDA Days to MDUFA IV Decision	81.05	82.39	79.86	79.07	67.51
20th Percentile FDA Days to MDUFA IV Decision	77	84	76	60	46
40th Percentile FDA Days to MDUFA IV Decision	87	88	87	86	60
60th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	87
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	89
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	71.28	69.15	17.97
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	18	20	17	18	0
60th Percentile Industry Days to MDUFA IV Decision	63	67	63	65	5
80th Percentile Industry Days to MDUFA IV Decision	152	153	152	143	33
Maximum Industry Days to MDUFA IV Decision	389	356	449	500	160
Average Number of Total Days to MDUFA IV Decision	146.51	151.03	151.14	148.22	85.48
20th Percentile Total Days to MDUFA IV Decision	79	88	84	74	51
40th Percentile Total Days to MDUFA IV Decision	103	106	99	99	62
60th Percentile Total Days to MDUFA IV Decision	148	153	149	153	89
80th Percentile Total Days to MDUFA IV Decision	241	242	241	231	119
Maximum Total Days to MDUFA IV Decision	479	446	539	590	250

**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	551	504	483	271
Number With MDUFA IV Decision	420	465	436	351	79
Number of SE Decision	402	442	421	339	79
Number of NSE Decision	18	23	15	12	0
Number of Withdrawal	35	48	34	40	1
Number of Deleted	39	34	26	4	0
Rate of SE Decision	95.71%	95.05%	96.56%	96.58%	100.00%
Rate of NSE Decision	4.29%	4.95%	3.44%	3.42%	0.00%
Rate of Withdrawal	7.09%	8.71%	6.75%	8.28%	0.37%
Rate of Deleted	7.89%	6.17%	5.16%	0.83%	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	0.00%	0.00%	0.00%	0.00%	0.00%

**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	0.00%		0.00%		0.00%		0.00%		0.00%	

**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	376	386	273
Closed Before RTA Action	4	2	1	2	0
Number Accepted	237	266	281	275	174
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4	17	28
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	22
Number Not Accepted	114	100	90	92	49
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.00%	23.96%	19.52%

**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	377	229
Deleted or Withdrawn Prior to SI	4	0	1	1	5
SI Within 60 FDA Days	324	358	353	352	171
SI Over 60 FDA Days	13	8	12	18	4
SI Pending Within 60 FDA Days	0	0	1	2	48
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%	96.45%	94.12%	97.16%

**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	365	370	175
Average Number of FDA Days to Substantive Interaction	49.74	50.76	51.61	51.32	50.36
20th Percentile FDA Days to Substantive Interaction	30	30	36	30	31
40th Percentile FDA Days to Substantive Interaction	53	56	57	57	55
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	377	229					
Non-MDUFA IV Decision	32	52	31	19	6					
MDUFA IV Decision (SE/NSE)	309	314	334	298	86					
MDUFA IV Decision Within 90 FDA Days	303	303	319	292	86					
510(k)s Pending MDUFA IV Decision	0	0	3	60	137					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	3	0					
Current Performance Percent Within 90 FDA Days	98.06%	96.50%	95.51%	97.01%	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	1.82	1.76	1.57
Number With MDUFA IV Decision	309	314	334	298	86
Average Number of FDA Days to MDUFA IV Decision	71.68	71.37	75.02	72.47	63.35
20th Percentile FDA Days to MDUFA IV Decision	50	49	55	51	30
40th Percentile FDA Days to MDUFA IV Decision	80	80	86	84	56
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	88	85
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	88.69	79.61	31.52
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	19	20	28	34	0
60th Percentile Industry Days to MDUFA IV Decision	65	68	80	78	27
80th Percentile Industry Days to MDUFA IV Decision	146	140	159	155	58
Maximum Industry Days to MDUFA IV Decision	292	359	607	386	182
Average Number of Total Days to MDUFA IV Decision	136.48	137.61	163.71	152.08	94.87
20th Percentile Total Days to MDUFA IV Decision	55	51	56	55	30
40th Percentile Total Days to MDUFA IV Decision	102	98	117	113	60
60th Percentile Total Days to MDUFA IV Decision	150	148	165	167	105
80th Percentile Total Days to MDUFA IV Decision	228	227	249	243	146
Maximum Total Days to MDUFA IV Decision	370	447	707	476	230

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	377	229
Number With MDUFA IV Decision	309	314	334	298	86
Number of SE Decision	291	289	308	265	82
Number of NSE Decision	18	25	26	33	4
Number of Withdrawal	20	31	21	14	6
Number of Deleted	10	20	10	5	0
Rate of SE Decision	94.17%	92.04%	92.22%	88.93%	95.35%
Rate of NSE Decision	5.83%	7.96%	7.78%	11.07%	4.65%
Rate of Withdrawal	5.87%	8.47%	5.71%	3.71%	2.62%
Rate of Deleted	2.93%	5.46%	2.72%	1.33%	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	15	6	0
Mean FDA Days for Submissions that Missed the Goal	107.17	99.82	110.13	131.83	0.00
Mean Industry Days for Submissions that Missed the Goal	131.50	159.09	261.60	174.17	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	
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 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	305
Closed Before RTA Action	3	4	4	6	0
Number Accepted	334	350	287	292	171
Number Without a RTA Review and > 15 Days Since Date Received	2	6	2	14	24
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	16
Number Not Accepted	116	117	147	199	94
Rate of Submissions Not Accepted for Review	25.66%	24.74%	33.72%	39.41%	32.53%

**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	418	467	249
Deleted or Withdrawn Prior to SI	0	1	1	2	0
SI Within 60 FDA Days	427	448	403	426	192
SI Over 60 FDA Days	6	4	13	24	14
SI Pending Within 60 FDA Days	0	0	1	6	43
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%	96.88%	92.81%	93.20%

**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	416	450	206
Average Number of FDA Days to Substantive Interaction	51.10	52.60	53.38	54.02	55.42
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	80

**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	418	467	249					
Non-MDUFA IV Decision	50	77	56	26	2					
MDUFA IV Decision (SE/NSE)	386	377	352	362	85					
MDUFA IV Decision Within 90 FDA Days	382	372	345	358	83					
510(k)s Pending MDUFA IV Decision	0	0	10	79	162					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	2	7	0					
Current Performance Percent Within 90 FDA Days	98.96%	98.67%	97.46%	97.02%	97.65%					

**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	1.79	1.56
Number With MDUFA IV Decision	386	377	352	362	85
Average Number of FDA Days to MDUFA IV Decision	75.68	78.18	78.49	79.92	73.05
20th Percentile FDA Days to MDUFA IV Decision	58	60	65	79	57
40th Percentile FDA Days to MDUFA IV Decision	84	87	87	87	82
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	89	89
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	118	150	135	199	95
Average Number of Industry Days to MDUFA IV Decision	74.93	95.65	101.71	87.91	29.59
20th Percentile Industry Days to MDUFA IV Decision	0	5	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	29	53	54	52	0
60th Percentile Industry Days to MDUFA IV Decision	94	118	123	96	23
80th Percentile Industry Days to MDUFA IV Decision	165	174	178	160	55
Maximum Industry Days to MDUFA IV Decision	214	444	490	361	174
Average Number of Total Days to MDUFA IV Decision	150.61	173.83	180.20	167.83	102.64
20th Percentile Total Days to MDUFA IV Decision	64	87	87	86	59
40th Percentile Total Days to MDUFA IV Decision	113	140	137	141	87
60th Percentile Total Days to MDUFA IV Decision	177	205	210	185	106
80th Percentile Total Days to MDUFA IV Decision	248	261	266	248	143
Maximum Total Days to MDUFA IV Decision	304	540	580	450	264

**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	418	467	249
Number With MDUFA IV Decision	386	377	352	362	85
Number of SE Decision	361	354	332	334	83
Number of NSE Decision	25	23	20	28	2
Number of Withdrawal	20	31	26	15	2
Number of Deleted	30	44	29	11	0
Rate of SE Decision	93.52%	93.90%	94.32%	92.27%	97.65%
Rate of NSE Decision	6.48%	6.10%	5.68%	7.73%	2.35%
Rate of Withdrawal	4.59%	6.83%	6.22%	3.21%	0.80%
Rate of Deleted	6.88%	9.69%	6.94%	2.36%	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	4	2
Mean FDA Days for Submissions that Missed the Goal	100.00	111.20	108.57	166.50	93.50
Mean Industry Days for Submissions that Missed the Goal	117.00	332.20	145.00	103.50	37.50

**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	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 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	719	1,026	533
Closed Before RTA Action	2	0	3	4	0
Number Accepted	368	392	447	601	294
Number Without a RTA Review and > 15 Days Since Date Received	6	7	5	36	53
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	31
Number Not Accepted	176	205	264	385	155
Rate of Submissions Not Accepted for Review	32.00%	33.94%	36.87%	37.67%	30.88%

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	933	425
Deleted or Withdrawn Prior to SI	0	3	2	3	0
SI Within 60 FDA Days	512	543	626	748	297
SI Over 60 FDA Days	4	12	25	170	52
SI Pending Within 60 FDA Days	0	0	0	4	69
SI Pending Over 60 FDA Days	0	0	0	8	6
510(k)s NSE Without SI	0	1	1	0	1
Current SI Performance Percent Within 60 FDA Days	99.22%	97.66%	96.01%	80.78%	83.43%

**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	651	918	349
Average Number of FDA Days to Substantive Interaction	52.60	52.19	53.97	58.13	55.90
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	58
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	69	90	91	332	148

**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	933	425					
Non-MDUFA IV Decision	68	74	83	54	3					
MDUFA IV Decision (SE/NSE)	448	484	565	750	212					
MDUFA IV Decision Within 90 FDA Days	440	480	537	573	198					
510(k)s Pending MDUFA IV Decision	0	1	6	129	210					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	3	26	13					
Current Performance Percent Within 90 FDA Days	98.21%	99.17%	94.54%	73.84%	88.00%					

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	1.64	1.42
Number With MDUFA IV Decision	448	484	565	750	212
Average Number of FDA Days to MDUFA IV Decision	73.88	73.11	76.78	83.91	70.67
20th Percentile FDA Days to MDUFA IV Decision	57	55	59	73	52
40th Percentile FDA Days to MDUFA IV Decision	79	81	84	87	69
60th Percentile FDA Days to MDUFA IV Decision	87	87	87	89	85
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	92	88
Maximum FDA Days to MDUFA IV Decision	220	207	212	283	129
Average Number of Industry Days to MDUFA IV Decision	48.98	54.82	65.97	53.19	16.69
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	11	6	0
60th Percentile Industry Days to MDUFA IV Decision	31	41	62	39	7
80th Percentile Industry Days to MDUFA IV Decision	110	128	138	104	34
Maximum Industry Days to MDUFA IV Decision	563	355	391	404	153
Average Number of Total Days to MDUFA IV Decision	122.86	127.93	142.75	137.09	87.36
20th Percentile Total Days to MDUFA IV Decision	59	57	60	81	54
40th Percentile Total Days to MDUFA IV Decision	88	87	91	94	83
60th Percentile Total Days to MDUFA IV Decision	110	125	145	130	90
80th Percentile Total Days to MDUFA IV Decision	193	210	227	202	121
Maximum Total Days to MDUFA IV Decision	783	511	497	493	240

**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	933	425
Number With MDUFA IV Decision	448	484	565	750	212
Number of SE Decision	437	470	552	741	210
Number of NSE Decision	11	14	13	9	2
Number of Withdrawal	36	37	37	25	3
Number of Deleted	31	35	45	28	0
Rate of SE Decision	97.54%	97.11%	97.70%	98.80%	99.06%
Rate of NSE Decision	2.46%	2.89%	2.30%	1.20%	0.94%
Rate of Withdrawal	6.98%	6.62%	5.66%	2.68%	0.71%
Rate of Deleted	6.01%	6.26%	6.88%	3.00%	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	28	177	14
Mean FDA Days for Submissions that Missed the Goal	119.50	121.00	107.79	108.02	102.64
Mean Industry Days for Submissions that Missed the Goal	168.63	132.50	138.00	65.68	13.86

**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	198
Closed Before RTA Action	3	0	3	1	0
Number Accepted	147	155	110	135	94
Number Without a RTA Review and > 15 Days Since Date Received	3	7	5	8	13
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	13
Number Not Accepted	107	112	143	132	78
Rate of Submissions Not Accepted for Review	41.63%	40.88%	55.43%	48.00%	42.16%

**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	238	255	148
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	232	257	229	250	118
SI Over 60 FDA Days	4	3	9	2	3
SI Pending Within 60 FDA Days	0	0	0	3	27
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%	96.22%	99.21%	97.52%

**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	238	252	121
Average Number of FDA Days to Substantive Interaction	53.91	54.53	53.51	53.68	54.06
20th Percentile FDA Days to Substantive Interaction	53	54	50	54	53
40th Percentile FDA Days to Substantive Interaction	58	58	58	58	58
60th Percentile FDA Days to Substantive Interaction	60	60	59	59	59
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	238	255	148					
Non-MDUFA IV Decision	30	31	17	20	1					
MDUFA IV Decision (SE/NSE)	206	229	220	201	66					
MDUFA IV Decision Within 90 FDA Days	201	222	220	200	66					
510(k)s Pending MDUFA IV Decision	0	0	1	34	81					
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%	99.50%	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	1.56	1.38
Number With MDUFA IV Decision	206	229	220	201	66
Average Number of FDA Days to MDUFA IV Decision	76.47	80.32	75.64	75.00	67.91
20th Percentile FDA Days to MDUFA IV Decision	60	69	60	56	55
40th Percentile FDA Days to MDUFA IV Decision	86	88	87	85	59
60th Percentile FDA Days to MDUFA IV Decision	89	90	89	88	86
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	89
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	59.79	58.98	20.76
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	25	45	0
80th Percentile Industry Days to MDUFA IV Decision	84	129	123	121	53
Maximum Industry Days to MDUFA IV Decision	187	391	360	360	142
Average Number of Total Days to MDUFA IV Decision	119.07	136.10	135.43	133.99	88.67
20th Percentile Total Days to MDUFA IV Decision	61	83	60	59	56
40th Percentile Total Days to MDUFA IV Decision	89	90	89	88	60
60th Percentile Total Days to MDUFA IV Decision	117	125	112	128	89
80th Percentile Total Days to MDUFA IV Decision	171	219	209	210	137
Maximum Total Days to MDUFA IV Decision	346	543	449	450	228

**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	238	255	148
Number With MDUFA IV Decision	206	229	220	201	66
Number of SE Decision	198	222	209	193	64
Number of NSE Decision	8	7	11	8	2
Number of Withdrawal	17	16	13	14	1
Number of Deleted	10	14	4	6	0
Rate of SE Decision	96.12%	96.94%	95.00%	96.02%	96.97%
Rate of NSE Decision	3.88%	3.06%	5.00%	3.98%	3.03%
Rate of Withdrawal	7.20%	6.15%	5.46%	5.49%	0.68%
Rate of Deleted	4.24%	5.38%	1.68%	2.35%	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	656	578	432
Closed Before RTA Action	2	4	5	2	1
Number Accepted	466	489	493	435	263
Number Without a RTA Review and > 15 Days Since Date Received	0	5	6	6	26
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	17
Number Not Accepted	138	136	152	135	125
Rate of Submissions Not Accepted for Review	22.85%	21.59%	23.35%	23.44%	30.19%

**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	559	353
Deleted or Withdrawn Prior to SI	0	2	3	1	1
SI Within 60 FDA Days	575	617	634	553	290
SI Over 60 FDA Days	19	3	1	1	0
SI Pending Within 60 FDA Days	0	0	0	4	60
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	0	2
Current SI Performance Percent Within 60 FDA Days	96.80%	99.52%	99.84%	99.82%	99.32%

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	554	290
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.83	50.26	51.19
20th Percentile FDA Days to Substantive Interaction	39	30	30	33	41
40th Percentile FDA Days to Substantive Interaction	55	56	56	55	56
60th Percentile FDA Days to Substantive Interaction	57	58	58	58	58
80th Percentile FDA Days to Substantive Interaction	59	60	60	59	60
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	559	353					
Non-MDUFA IV Decision	40	47	61	32	5					
MDUFA IV Decision (SE/NSE)	554	575	577	484	182					
MDUFA IV Decision Within 90 FDA Days	552	574	577	483	182					
510(k)s Pending MDUFA IV Decision	0	0	0	43	166					
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%	99.79%	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	1.50	1.29
Number With MDUFA IV Decision	554	575	577	484	182
Average Number of FDA Days to MDUFA IV Decision	71.36	70.57	66.97	65.26	60.01
20th Percentile FDA Days to MDUFA IV Decision	52	51	37	39	30
40th Percentile FDA Days to MDUFA IV Decision	74	76	60	59	57
60th Percentile FDA Days to MDUFA IV Decision	86	87	86	84	67
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	87
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	54.44	43.02	10.85
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	23	0
80th Percentile Industry Days to MDUFA IV Decision	103	103	98	84	24
Maximum Industry Days to MDUFA IV Decision	340	444	667	381	128
Average Number of Total Days to MDUFA IV Decision	120.19	121.55	121.41	108.27	70.86
20th Percentile Total Days to MDUFA IV Decision	57	56	38	45	30
40th Percentile Total Days to MDUFA IV Decision	86	87	67	60	58
60th Percentile Total Days to MDUFA IV Decision	115	111	103	98	80
80th Percentile Total Days to MDUFA IV Decision	189	185	184	164	103
Maximum Total Days to MDUFA IV Decision	430	533	756	469	185

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	559	353
Number With MDUFA IV Decision	554	575	577	484	182
Number of SE Decision	540	563	573	481	180
Number of NSE Decision	14	12	4	3	2
Number of Withdrawal	24	28	38	26	5
Number of Deleted	16	19	23	6	0
Rate of SE Decision	97.47%	97.91%	99.31%	99.38%	98.90%
Rate of NSE Decision	2.53%	2.09%	0.69%	0.62%	1.10%
Rate of Withdrawal	4.04%	4.50%	5.96%	4.65%	1.42%
Rate of Deleted	2.69%	3.05%	3.61%	1.07%	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	117.50	91.00	0.00	151.00	0.00
Mean Industry Days for Submissions that Missed the Goal	208.50	260.00	0.00	109.00	0.00

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

510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	290	300	271	205	171
Closed Before RTA Action	3	3	3	1	2
Number Accepted	245	237	191	56	74
Number Without a RTA Review and > 15 Days Since Date Received	1	4	18	116	59
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	13
Number Not Accepted	41	56	59	32	23
Rate of Submissions Not Accepted for Review	14.29%	18.86%	22.01%	15.69%	14.74%

Table 6.2 OHT7 - Office of In Vitro Diagnostics

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	274	279	257	195	139
Deleted or Withdrawn Prior to SI	1	1	3	6	1
SI Within 60 FDA Days	271	273	204	19	8
SI Over 60 FDA Days	1	2	50	170	77
SI Pending Within 60 FDA Days	0	0	0	0	22
SI Pending Over 60 FDA Days	0	0	0	0	31
510(k)s NSE Without SI	1	3	0	0	0
Current SI Performance Percent Within 60 FDA Days	99.27%	98.20%	80.31%	10.05%	6.90%

Table 6.3 OHT7 - Office of In Vitro Diagnostics

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	272	275	254	189	85
Average Number of FDA Days to Substantive Interaction	50.56	49.13	93.22	162.53	113.36
20th Percentile FDA Days to Substantive Interaction	44	30	45	116	111
40th Percentile FDA Days to Substantive Interaction	54	53	58	128	119
60th Percentile FDA Days to Substantive Interaction	58	58	60	173	120
80th Percentile FDA Days to Substantive Interaction	59	60	60	238	123
Maximum FDA Days to Substantive Interaction	61	61	496	381	196

Table 6.4 OHT7 - Office of In Vitro Diagnostics

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	274	279	257	195	139					
Non-MDUFA IV Decision	42	37	41	17	3					
MDUFA IV Decision (SE/NSE)	232	242	195	105	17					
MDUFA IV Decision Within 90 FDA Days	231	238	124	13	6					
510(k)s Pending MDUFA IV Decision	0	0	21	73	119					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	21	71	79					
Current Performance Percent Within 90 FDA Days	99.57%	98.35%	57.41%	7.39%	6.25%					

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.51	1.36	1.55	1.41	1.06
Number With MDUFA IV Decision	232	242	195	105	17
Average Number of FDA Days to MDUFA IV Decision	72.98	71.48	153.45	207.35	97.12
20th Percentile FDA Days to MDUFA IV Decision	53	31	56	127	49
40th Percentile FDA Days to MDUFA IV Decision	84	60	87	196	101
60th Percentile FDA Days to MDUFA IV Decision	88	87	90	224	120
80th Percentile FDA Days to MDUFA IV Decision	90	90	290	290	130
Maximum FDA Days to MDUFA IV Decision	93	655	673	389	210
Average Number of Industry Days to MDUFA IV Decision	58.27	46.80	71.94	43.45	0.71
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	52	0	64	3	0
80th Percentile Industry Days to MDUFA IV Decision	145	129	151	119	0
Maximum Industry Days to MDUFA IV Decision	231	448	360	190	12
Average Number of Total Days to MDUFA IV Decision	131.25	118.28	225.39	250.80	97.82
20th Percentile Total Days to MDUFA IV Decision	55	31	56	132	49
40th Percentile Total Days to MDUFA IV Decision	88	67	90	207	101
60th Percentile Total Days to MDUFA IV Decision	134	90	212	267	120
80th Percentile Total Days to MDUFA IV Decision	235	194	424	385	130
Maximum Total Days to MDUFA IV Decision	321	871	775	575	210

Table 6.6 OHT7 - Office of In Vitro Diagnostics

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	274	279	257	195	139
Number With MDUFA IV Decision	232	242	195	105	17
Number of SE Decision	221	234	190	104	17
Number of NSE Decision	11	8	5	1	0
Number of Withdrawal	26	14	26	17	3
Number of Deleted	15	23	14	0	0
Rate of SE Decision	95.26%	96.69%	97.44%	99.05%	100.00%
Rate of NSE Decision	4.74%	3.31%	2.56%	0.95%	0.00%
Rate of Withdrawal	9.49%	5.02%	10.12%	8.72%	2.16%
Rate of Deleted	5.47%	8.24%	5.45%	0.00%	0.00%

Table 6.7 OHT7 - Office of In Vitro Diagnostics

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	71	92	11
Mean FDA Days for Submissions that Missed the Goal	93.00	370.00	307.82	228.73	132.09
Mean Industry Days for Submissions that Missed the Goal	202.00	268.00	131.39	48.58	1.09

Table 6.8 OHT7 - Office of In Vitro Diagnostics

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	1	1
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	1	1
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	1	1
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
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric**

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95% FDA Days	Within 90 FDA Days	95% FDA Days	Within 90 FDA Days	95% FDA Days	Within 90 FDA Days	95% FDA Days	Within 90 FDA Days	95% FDA Days	Within 90 FDA Days
510(k)s Accepted	272		278		253		194		138	
Non-MDUFA IV Decision	41		37		41		17		3	
MDUFA IV Decision (SE/NSE)	231		241		191		105		17	
MDUFA IV Decision Within 90 FDA Days	230		237		122		13		6	
510(k)s Pending MDUFA IV Decision	0		0		21		72		118	
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0		0		21		70		78	
Current Performance Percent Within 90 FDA Days	99.57%		98.34%		57.55%		7.43%		6.32%	

Table 6.1 OHT8 - Office of Radiological Health

510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	391	384	434	451	335
Closed Before RTA Action	0	1	2	1	2
Number Accepted	348	307	361	361	253
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1	12	21
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	8
Number Not Accepted	42	73	70	77	51
Rate of Submissions Not Accepted for Review	10.74%	19.06%	16.20%	17.11%	15.69%

Table 6.2 OHT8 - Office of 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	385	373	422	438	308
Deleted or Withdrawn Prior to SI	1	0	0	0	0
SI Within 60 FDA Days	384	373	422	433	255
SI Over 60 FDA Days	0	0	0	0	0
SI Pending Within 60 FDA Days	0	0	0	2	52
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	3	1
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	100.00%	99.31%	99.61%

Table 6.3 OHT8 - Office of 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	384	373	422	433	255
Average Number of FDA Days to Substantive Interaction	43.70	44.96	46.49	48.73	48.06
20th Percentile FDA Days to Substantive Interaction	29	28	29	36	29
40th Percentile FDA Days to Substantive Interaction	42	47	49	51	51
60th Percentile FDA Days to Substantive Interaction	52	54	55	56	57
80th Percentile FDA Days to Substantive Interaction	57	58	58	59	59
Maximum FDA Days to Substantive Interaction	60	60	60	60	60

Table 6.4 OHT8 - Office of 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
510(k)s Accepted	385	373	422	438	308
Non-MDUFA IV Decision	14	22	20	16	1
MDUFA IV Decision (SE/NSE)	371	351	402	398	174
MDUFA IV Decision Within 90 FDA Days	371	351	402	398	174
510(k)s Pending MDUFA IV Decision	0	0	0	24	133
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 OHT8 - Office of Radiological Health
510(k) Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.50	1.54	1.54	1.32
Number With MDUFA IV Decision	371	351	402	398	174
Average Number of FDA Days to MDUFA IV Decision	58.72	61.13	63.56	67.81	59.19
20th Percentile FDA Days to MDUFA IV Decision	30	28	29	46	29
40th Percentile FDA Days to MDUFA IV Decision	55	58	60	67	55
60th Percentile FDA Days to MDUFA IV Decision	73	77	82	85	72
80th Percentile FDA Days to MDUFA IV Decision	84	86	87	88	87
Maximum FDA Days to MDUFA IV Decision	90	90	90	90	90
Average Number of Industry Days to MDUFA IV Decision	33.09	40.27	44.85	46.28	14.16
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	19	23	32	30	0
80th Percentile Industry Days to MDUFA IV Decision	56	81	87	93	28
Maximum Industry Days to MDUFA IV Decision	181	329	357	360	137
Average Number of Total Days to MDUFA IV Decision	91.81	101.40	108.41	114.09	73.35
20th Percentile Total Days to MDUFA IV Decision	30	28	29	47	29
40th Percentile Total Days to MDUFA IV Decision	58	59	63	77	55
60th Percentile Total Days to MDUFA IV Decision	93	103	114	115	84
80th Percentile Total Days to MDUFA IV Decision	138	165	167	179	113
Maximum Total Days to MDUFA IV Decision	270	416	447	449	227

Table 6.6 OHT8 - Office of 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	385	373	422	438	308
Number With MDUFA IV Decision	371	351	402	398	174
Number of SE Decision	360	348	397	388	172
Number of NSE Decision	11	3	5	10	2
Number of Withdrawal	7	8	13	10	1
Number of Deleted	5	5	6	6	0
Rate of SE Decision	97.04%	99.15%	98.76%	97.49%	98.85%
Rate of NSE Decision	2.96%	0.85%	1.24%	2.51%	1.15%
Rate of Withdrawal	1.82%	2.14%	3.08%	2.28%	0.32%
Rate of Deleted	1.30%	1.34%	1.42%	1.37%	0.00%

Table 6.7 OHT8 - Office of 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	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 6.8 OHT8 - Office of 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	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%	0.00%	0.00%	0.00%	0.00%	0.00%

Table 6.9 OHT8 - Office of 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	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%	0.00%	0.00%	0.00%	0.00%	0.00%

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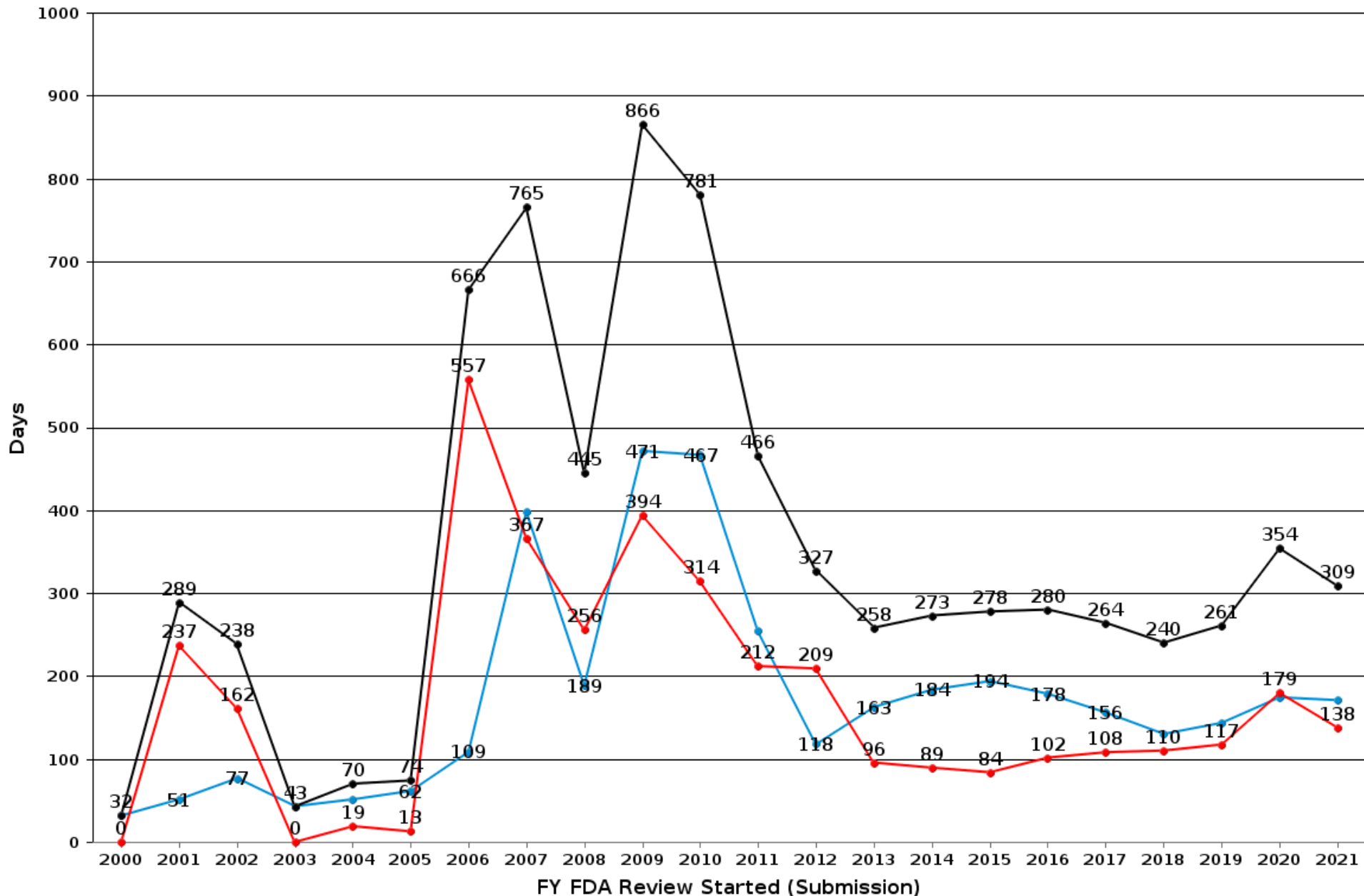
Section 7 510(k) Annual General Metrics - Annual Metrics and Goals will be reported in the Annual Report.

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De Novos

Q3FY2022

De Novo Average Days to MDUFA Decision as of: 6/30/22

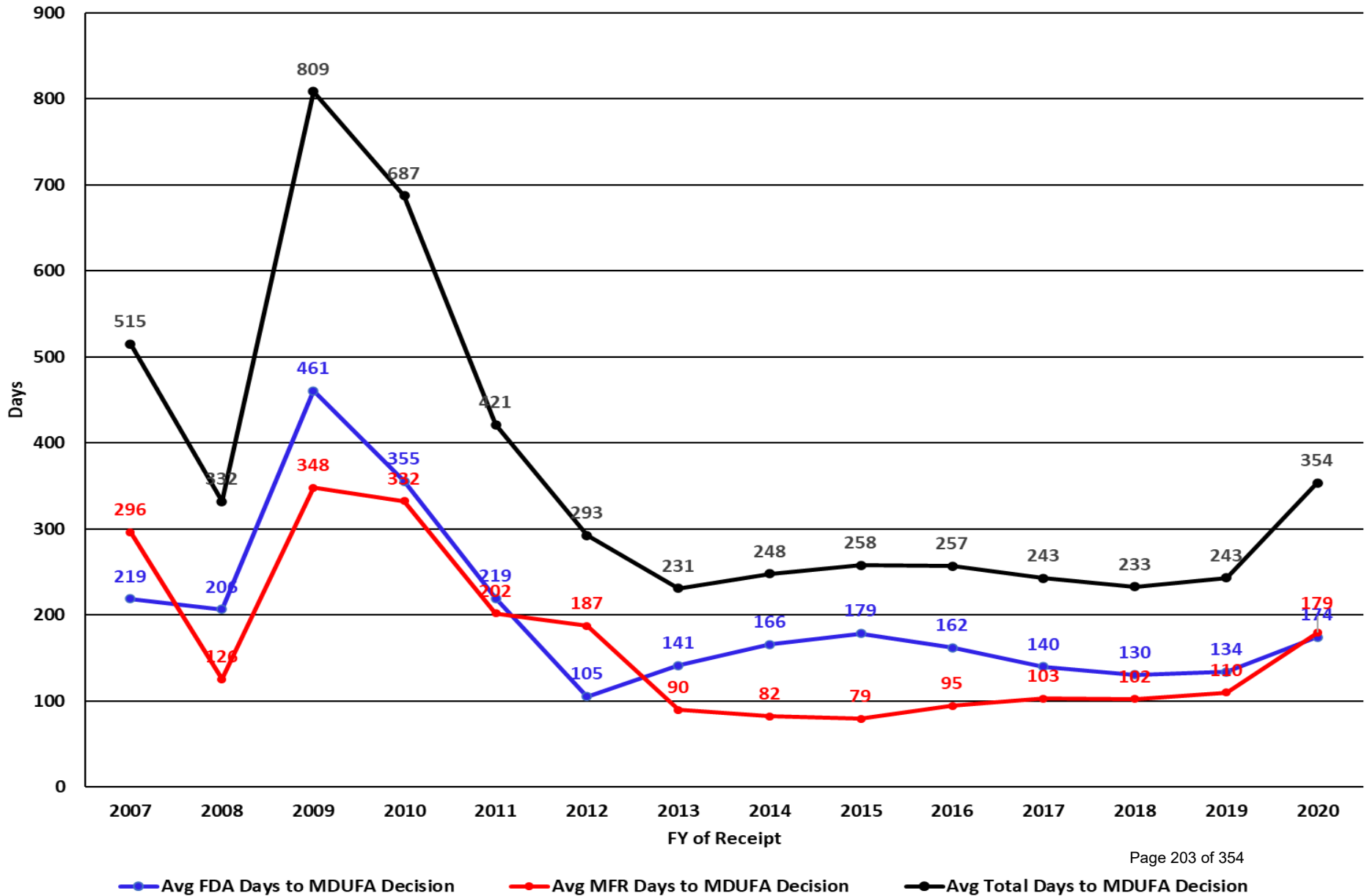


Cohorts not yet closed: 2020: 95.31%; 2021: 52.73%

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

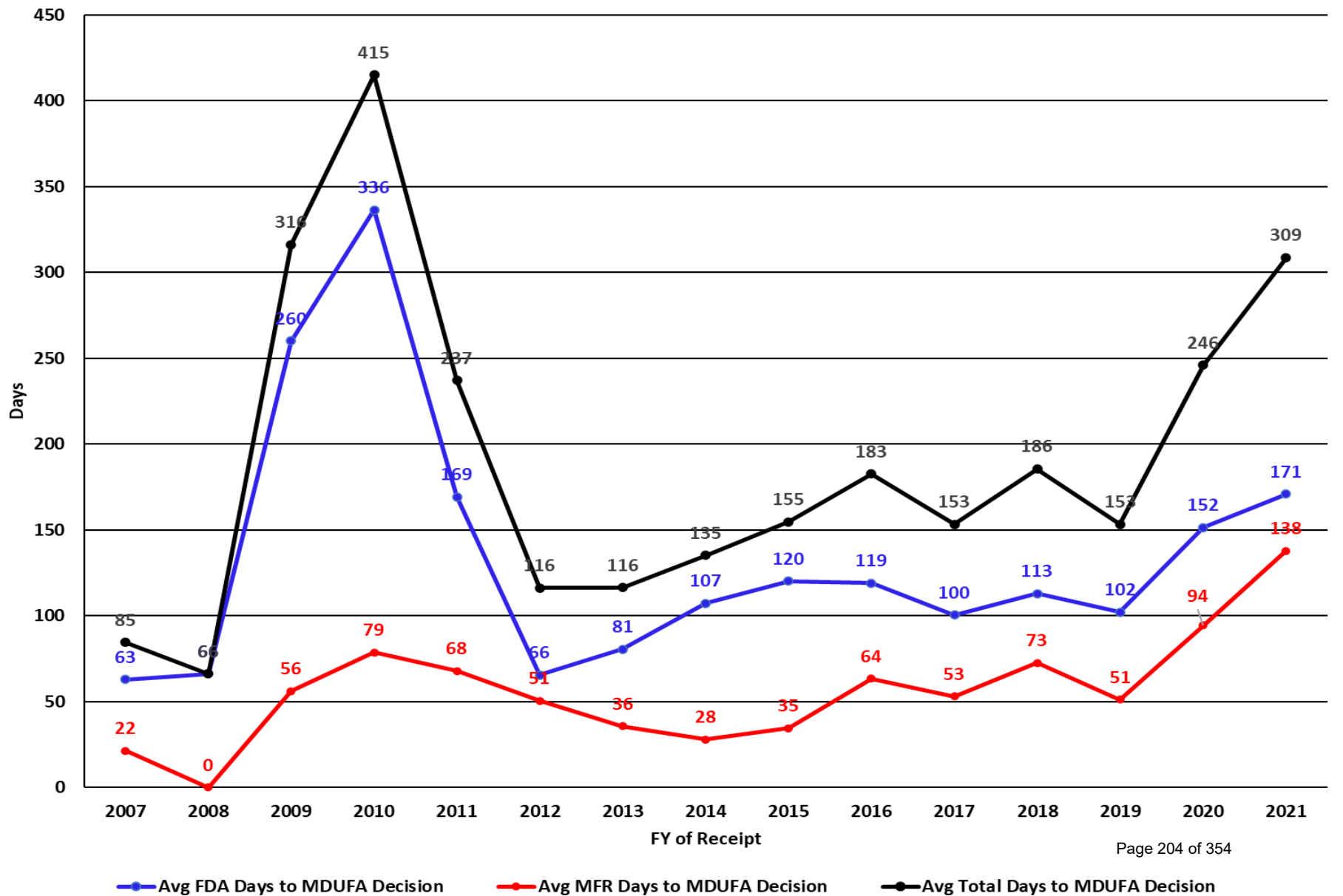
Average Time to MDUFA Decision: De Novos

(95.3% closure comparison)

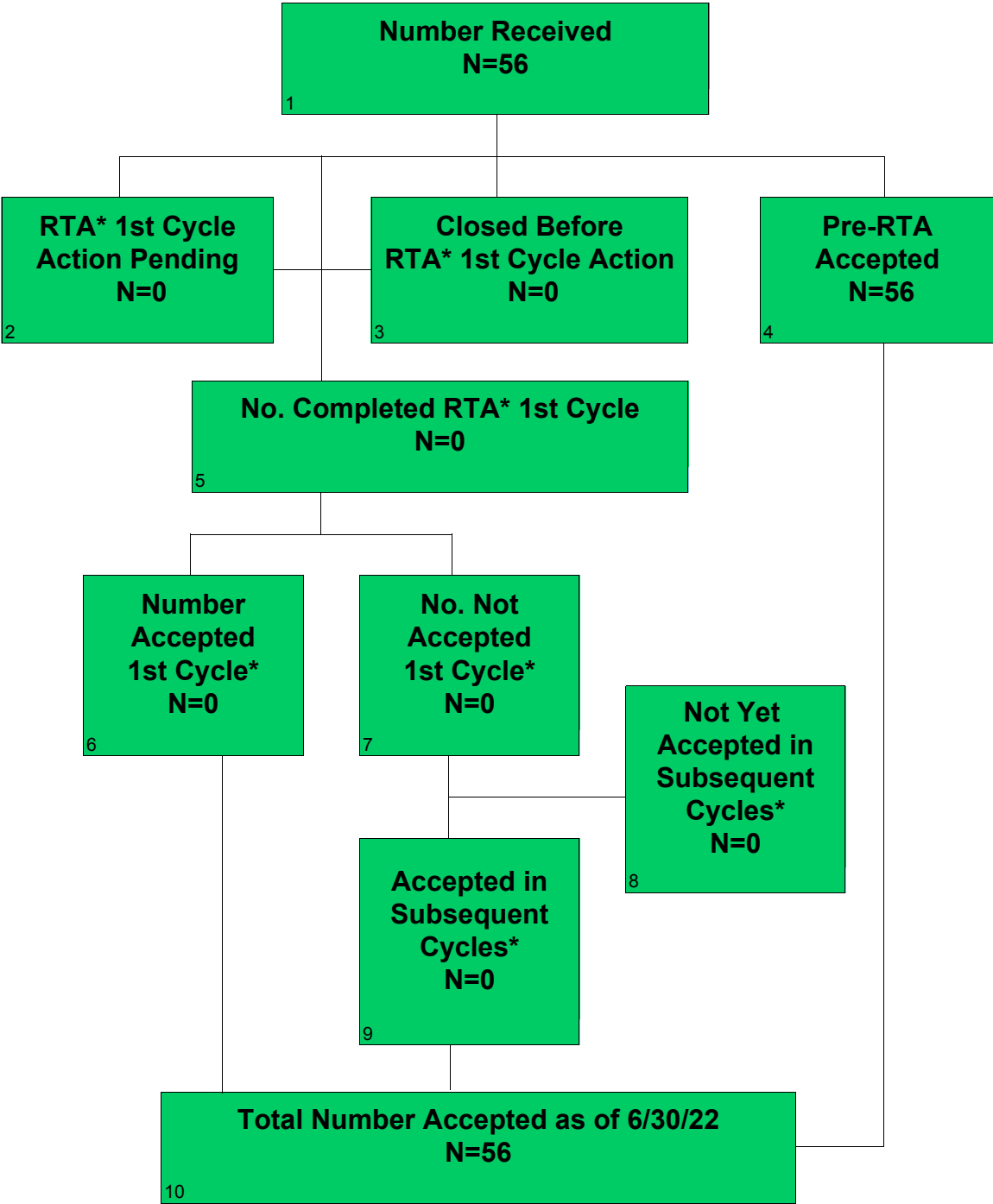


Average Time to MDUFA Decision: De Novos

(52.7% closure comparison)

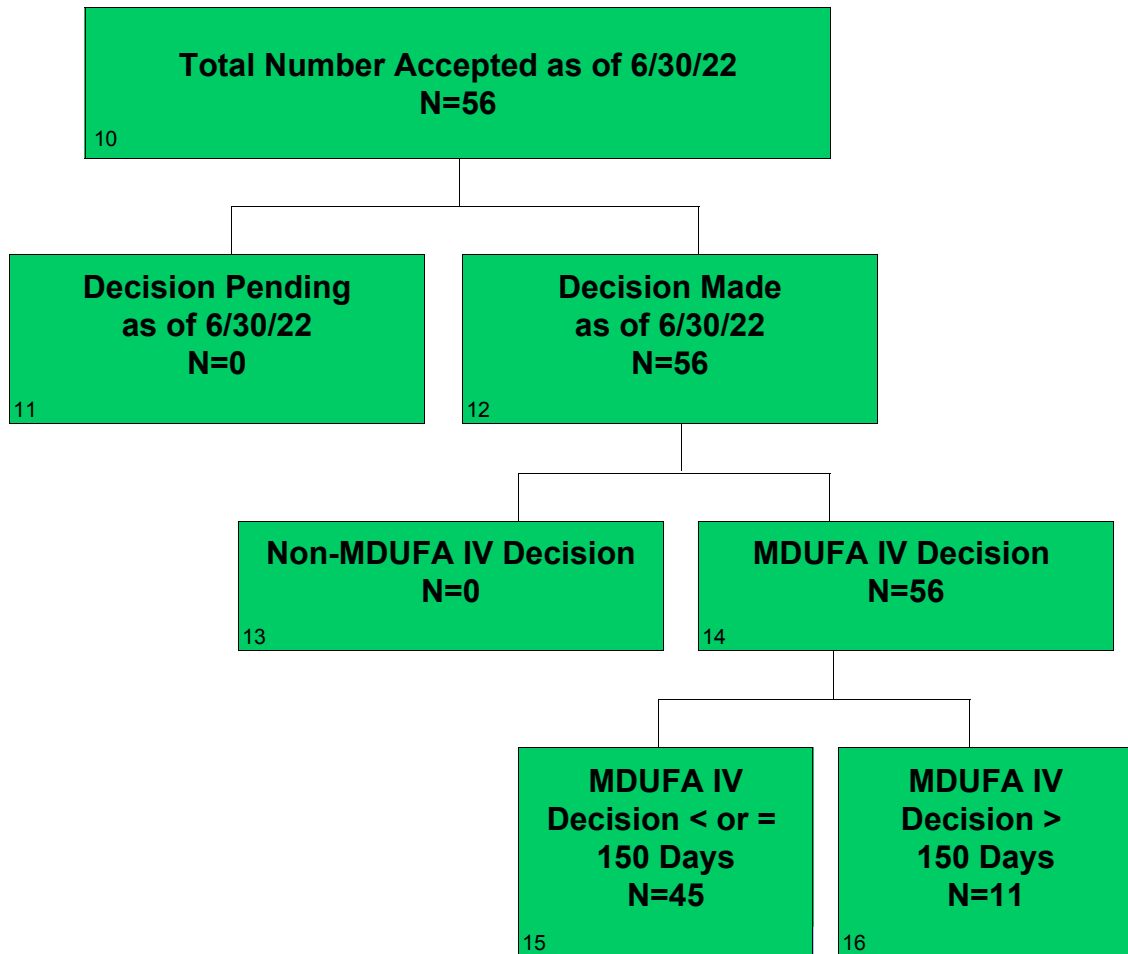


CDRH De Novo - FY 2018 as of 6/30/22

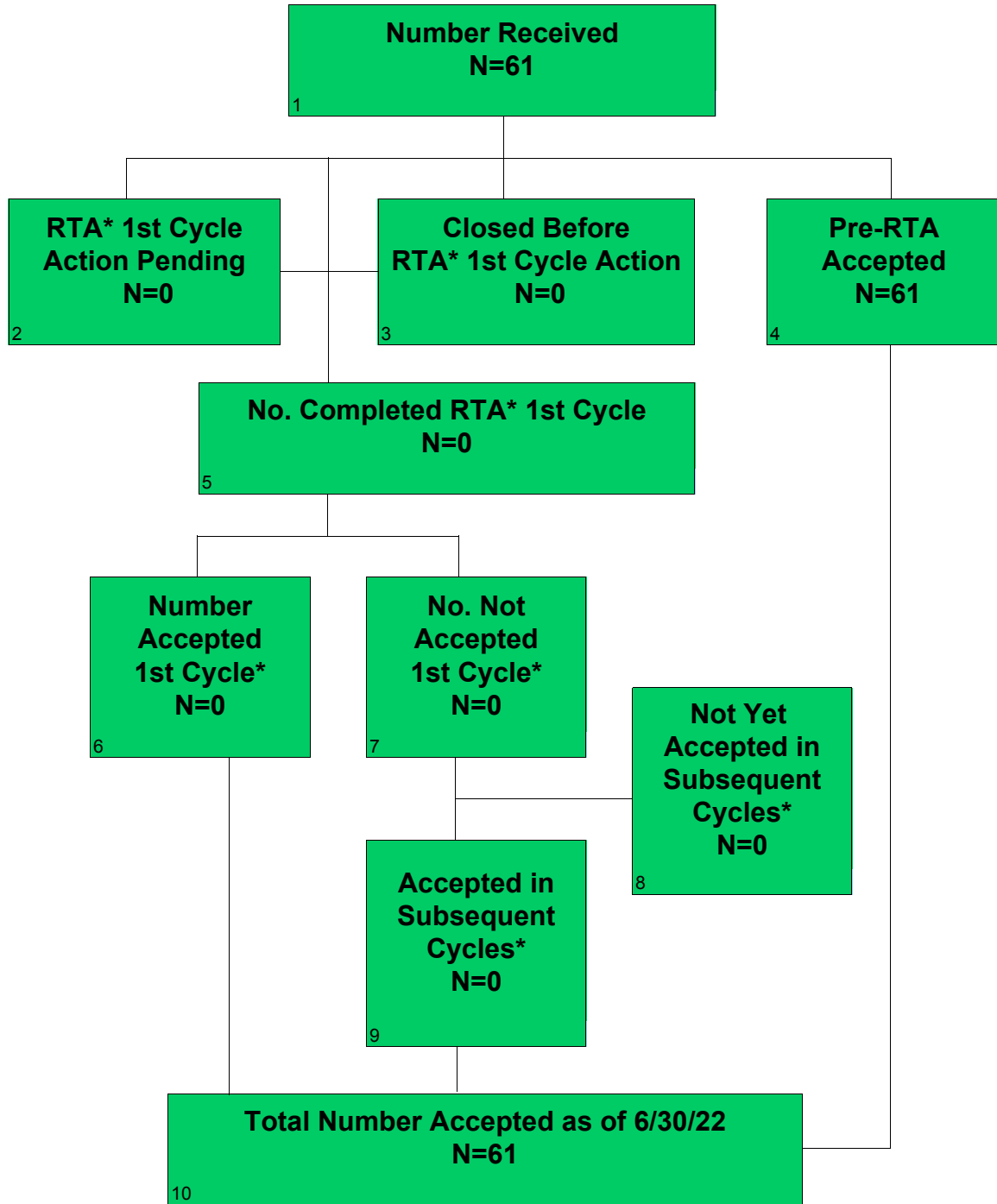


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018 as of 6/30/22 Continued

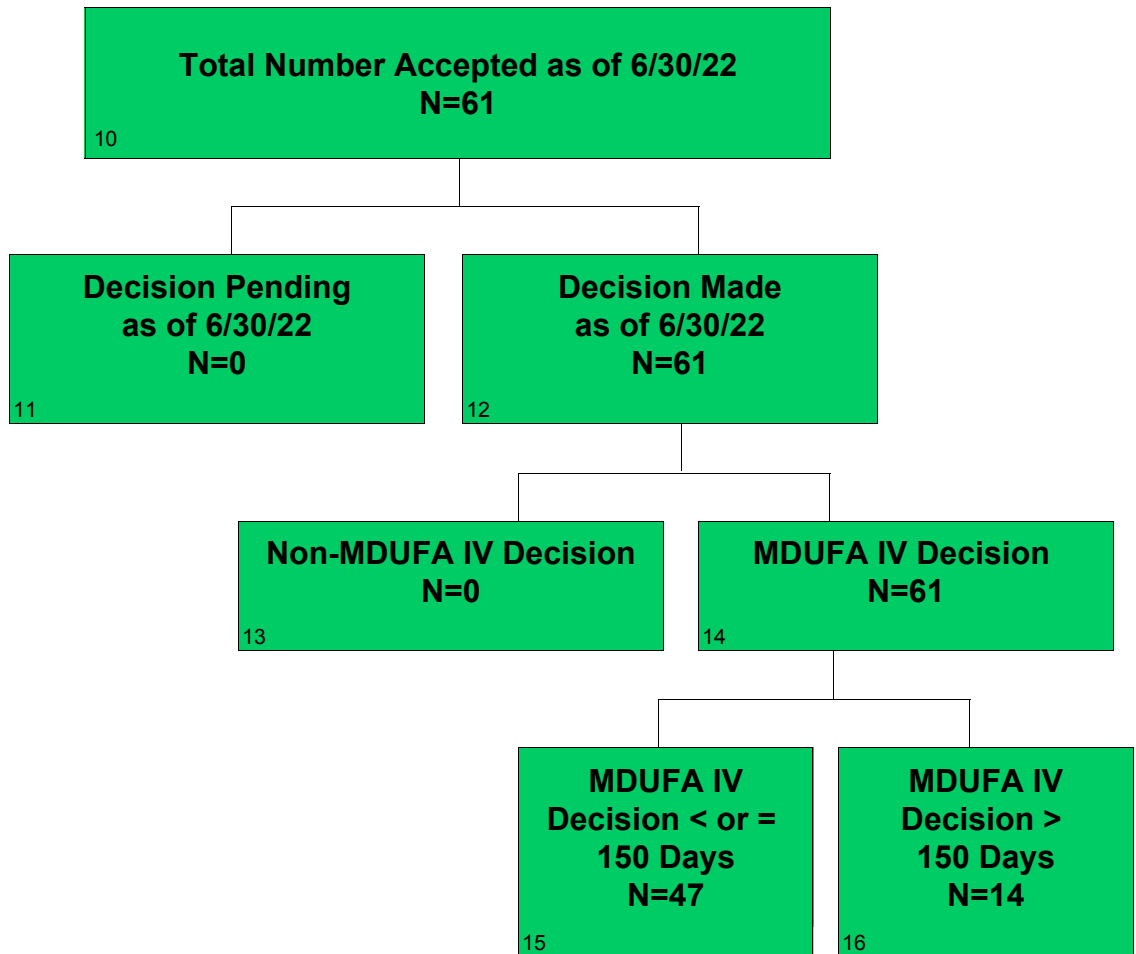


CDRH De Novo - FY 2019 as of 6/30/22

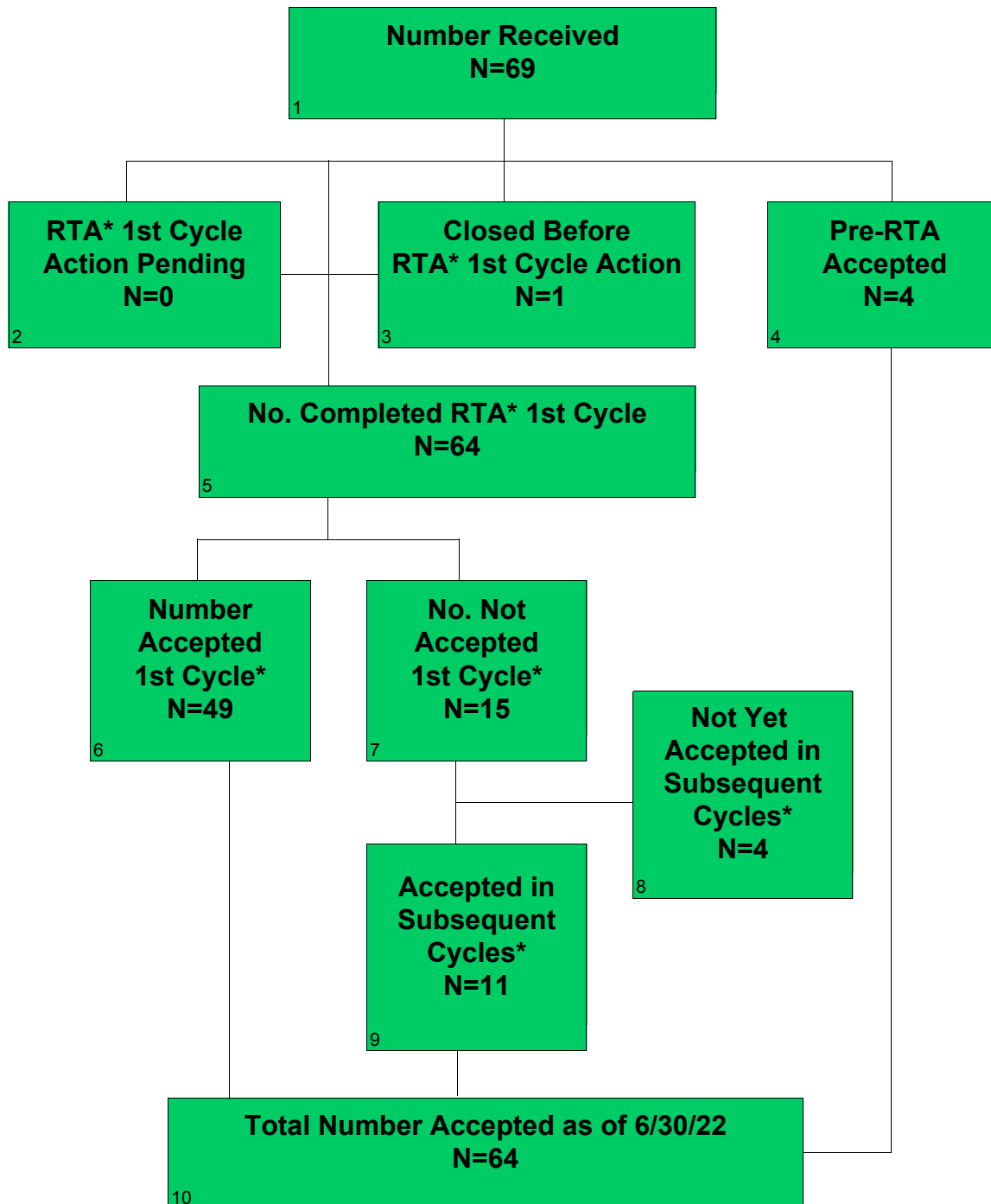


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019 as of 6/30/22 Continued

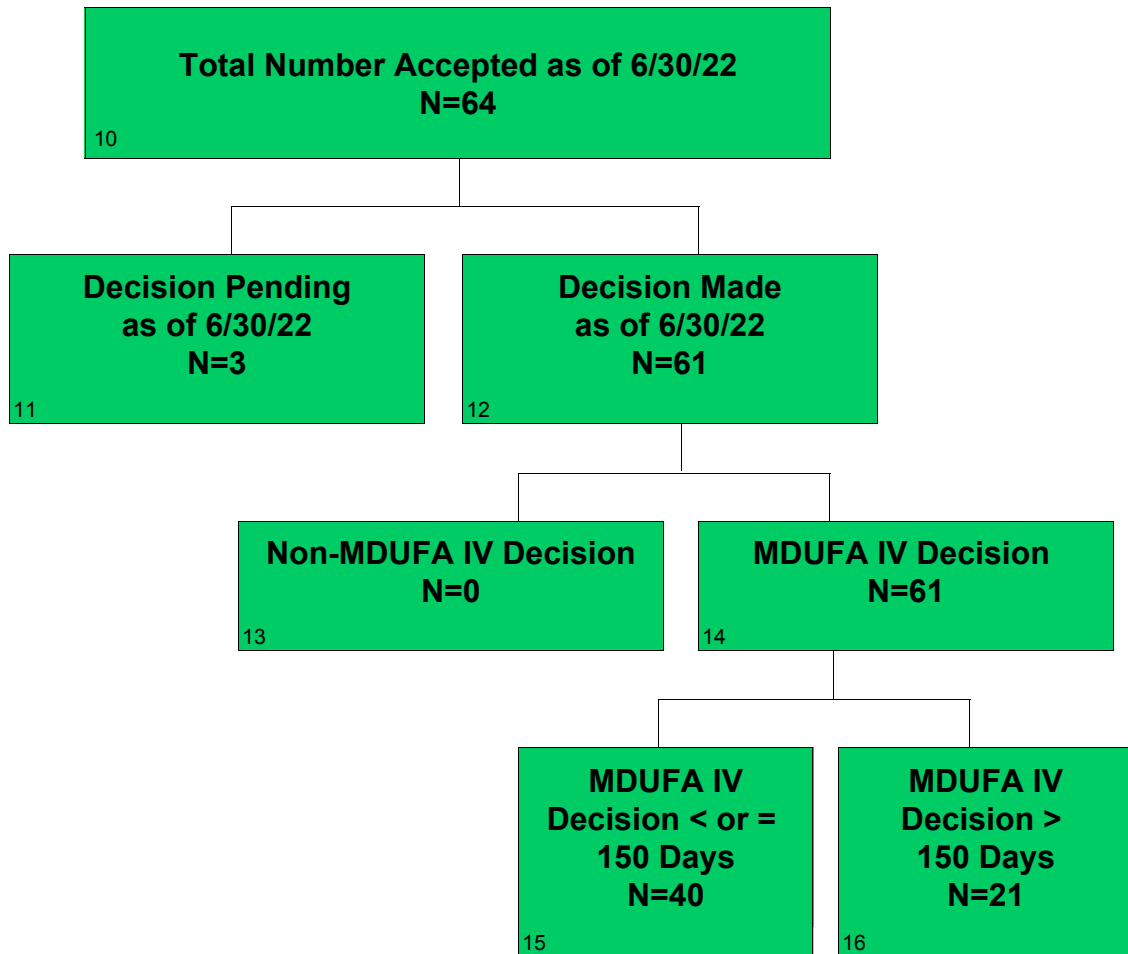


CDRH De Novo - FY 2020 as of 6/30/22

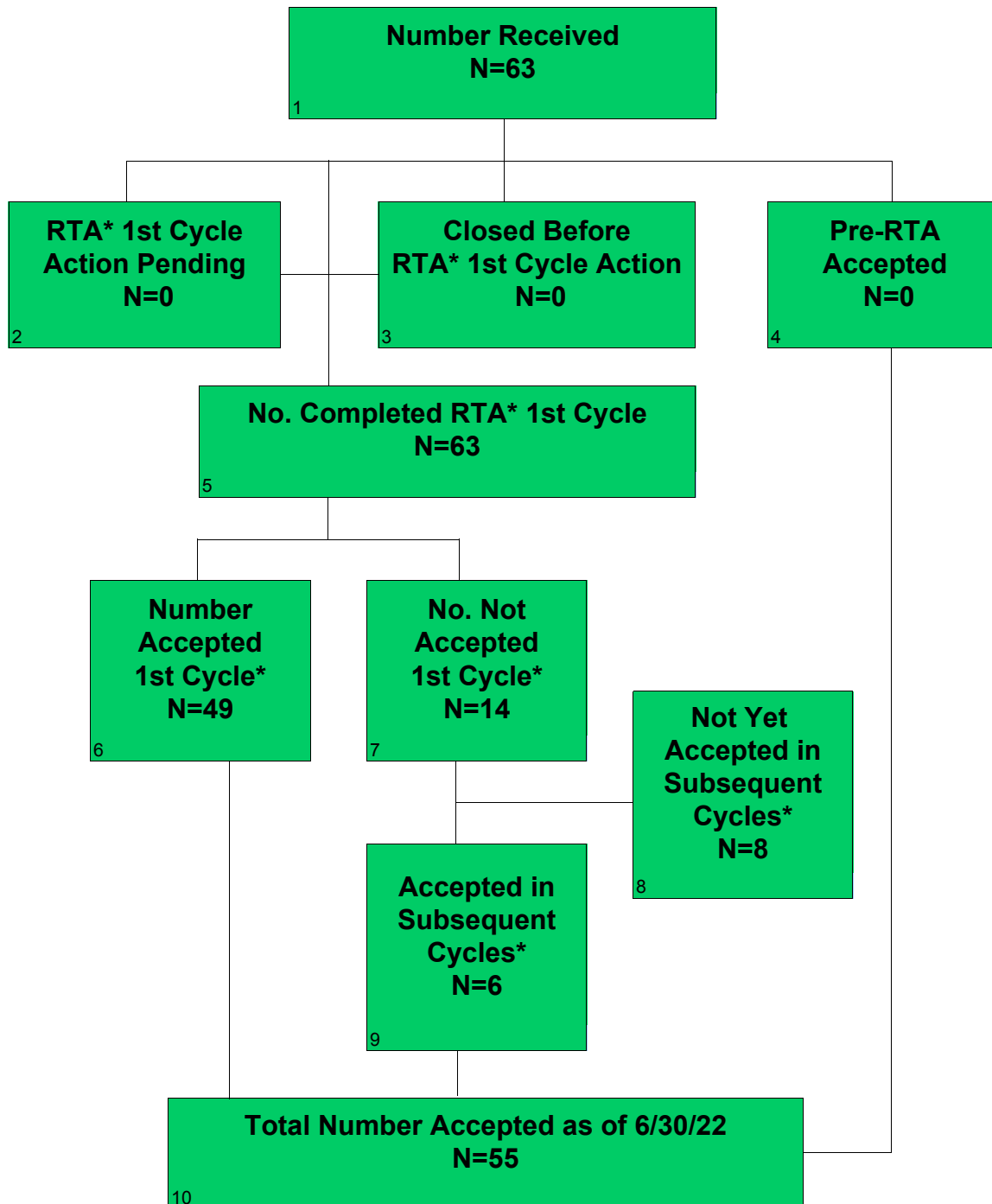


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020 as of 6/30/22 Continued

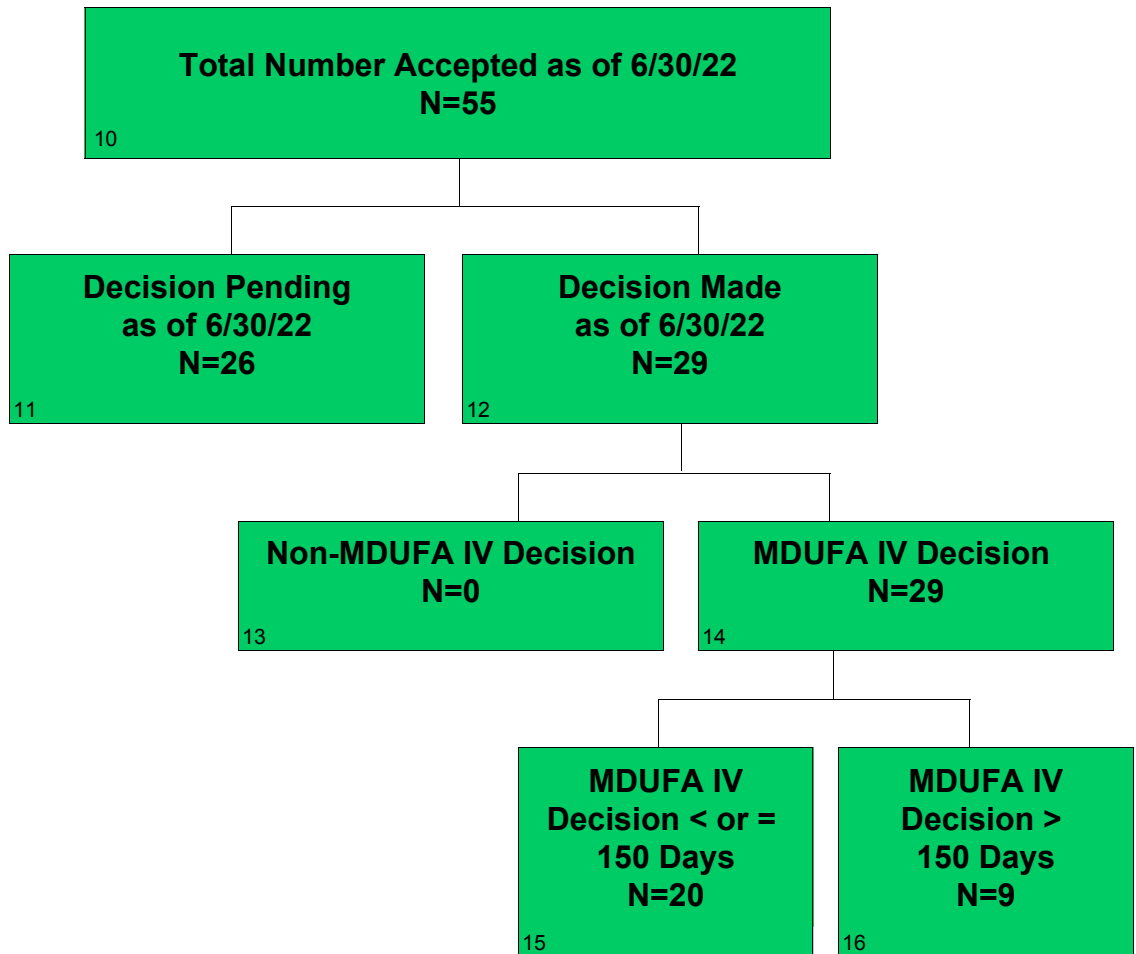


CDRH De Novo - FY 2021 as of 6/30/22

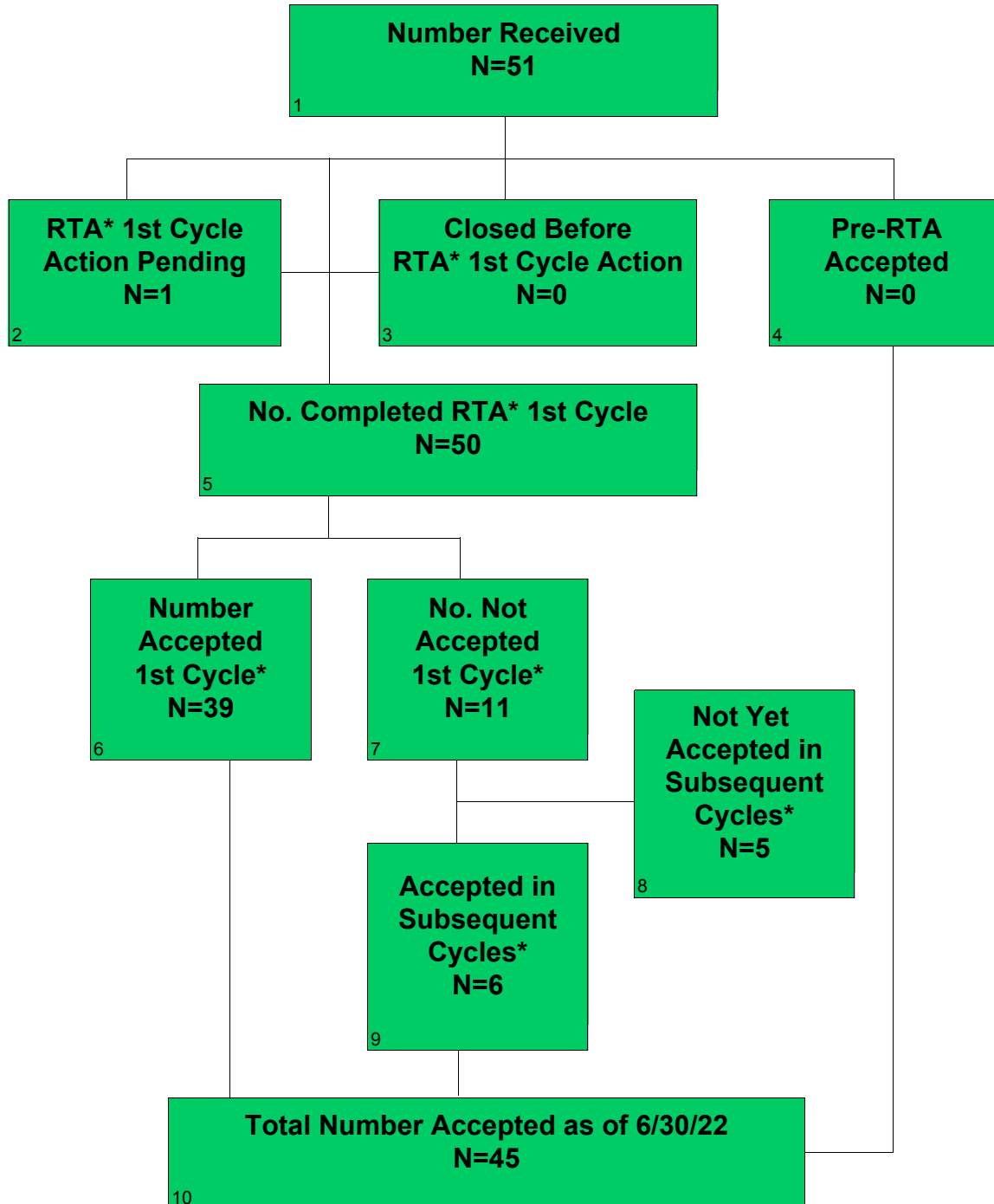


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2021 as of 6/30/22 Continued

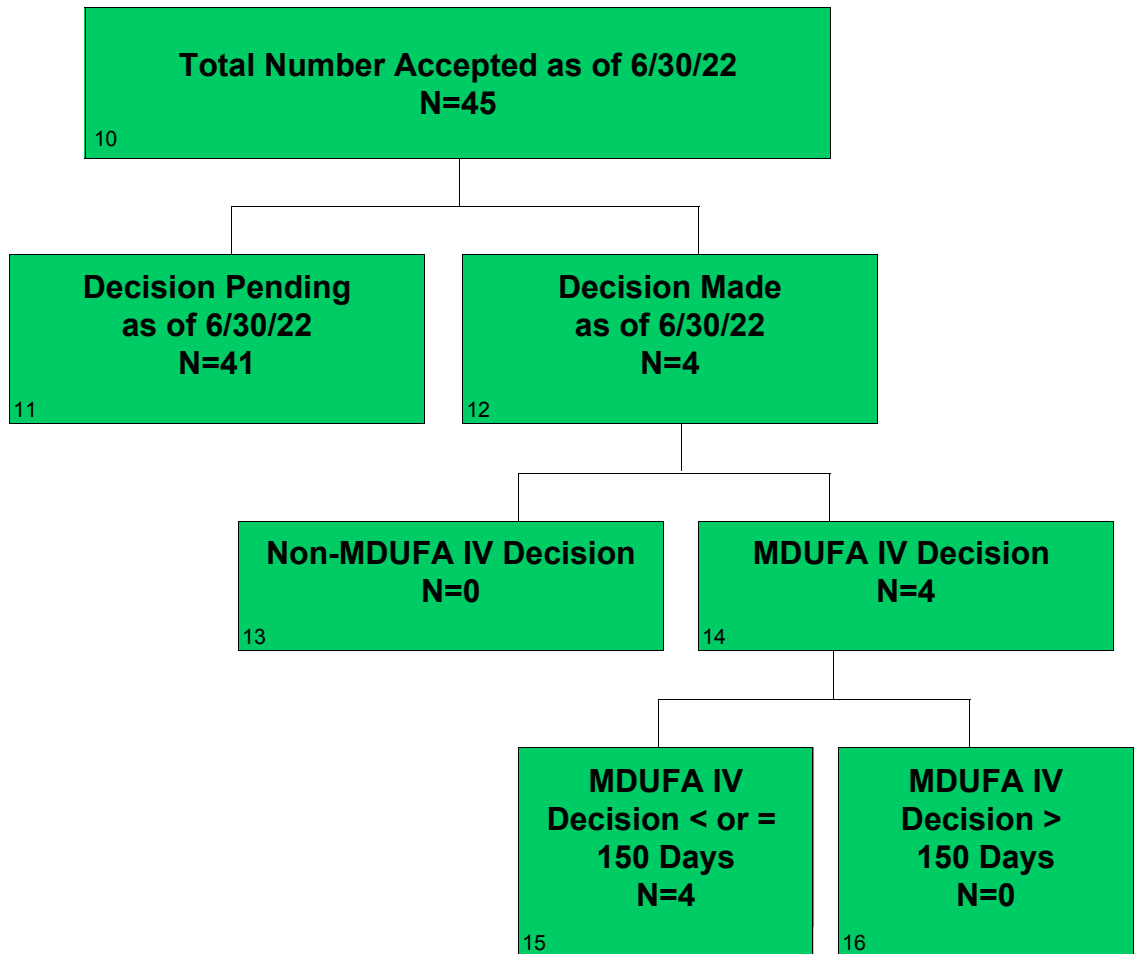


CDRH De Novo - FY 2022 as of 6/30/22



*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 6/30/22 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	51
Closed Before RTA Action	N/A	N/A	1	0	0
Number Accepted First RTA Cycle	N/A	N/A	46	41	34
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	3	8	5
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	15	14	11
Rate of Submissions Not Accepted for Review	N/A	N/A	23.44%	22.22%	22.00%

*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 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	55	45
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	56	61	61	29	4
MDUFA IV Decisions Within 150 FDA Days	45	47	40	20	4
De Novos Pending MDUFA IV Decision	0	0	3	26	41
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	3	6	1
Current Performance Percent Within 150 FDA Days	80.36%	77.05%	62.50%	57.14%	80.00%

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	1.79	1.25
Number With MDUFA IV Decision	56	61	61	29	4
Average FDA Days to MDUFA IV Decision	130.13	143.57	174.31	170.86	88.25
20th Percentile FDA Days to MDUFA IV Decision	75	76	115	144	29
40th Percentile FDA Days to MDUFA IV Decision	145	130	149	149	60
60th Percentile FDA Days to MDUFA IV Decision	150	148	150	150	128
80th Percentile FDA Days to MDUFA IV Decision	150	180	212	209	150
Maximum FDA Days to MDUFA IV Decision	254	485	497	425	150
Average Industry Days to MDUFA IV Decision	110.13	117.44	179.49	137.72	18.50
20th Percentile Industry Days to MDUFA IV Decision	0	0	24	39	0
40th Percentile Industry Days to MDUFA IV Decision	89	29	136	81	0
60th Percentile Industry Days to MDUFA IV Decision	166	177	222	139	0
80th Percentile Industry Days to MDUFA IV Decision	180	204	326	216	30
Maximum Industry Days to MDUFA IV Decision	389	373	431	388	74
Average Total Days to MDUFA IV Decision	240.25	261.02	353.80	308.59	106.75
20th Percentile Total Days to MDUFA IV Decision	145	107	210	207	29
40th Percentile Total Days to MDUFA IV Decision	251	179	312	234	60
60th Percentile Total Days to MDUFA IV Decision	292	304	395	287	128
80th Percentile Total Days to MDUFA IV Decision	324	388	474	493	180
Maximum Total Days to MDUFA IV Decision	463	680	928	599	224

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	55	45
Number With MDUFA IV Decisions	56	61	61	29	4
Number With Granted Decisions	25	28	31	18	2
Number With Declined Decisions	15	15	16	5	0
Number of Withdrawals	10	13	9	5	2
Number Deleted	6	5	5	1	0
Rate of Granted Decisions	44.64%	45.90%	50.82%	62.07%	50.00%
Rate of Declined Decisions	26.79%	24.59%	26.23%	17.24%	0.00%
Rate of Withdrawals	17.86%	21.31%	14.75%	17.24%	50.00%
Rate of Deleted	10.71%	8.20%	8.20%	3.45%	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	21	9	0
Mean FDA Days for Submissions that Missed the Goal	192.45	248.29	270.29	242.67	0.00
Mean Industry Days for Submissions that Missed the Goal	127.27	218.64	196.76	195.00	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	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	5	2	0	0
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	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	8
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	14	5	0
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	2	8	8
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	2	6	1
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	9.09%	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	9
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	10	8	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	3	5
Rate of Submissions Not Accepted for Review	N/A	N/A	16.67%	27.27%	55.56%

*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	8
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	8	5	12	5	0
MDUFA IV Decisions Within 150 FDA Days	5	4	10	5	0
De Novos Pending MDUFA IV Decision	0	0	1	5	8
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	5	0
Average FDA Days to MDUFA IV Decision	141.25	124.80	138.17	148.60	0.00
20th Percentile FDA Days to MDUFA IV Decision	110	75	74	148	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	171.40	0.00
20th Percentile Industry Days to MDUFA IV Decision	9	185	108	81	0
40th Percentile Industry Days to MDUFA IV Decision	45	192	152	112	0
60th Percentile Industry Days to MDUFA IV Decision	75	199	259	151	0
80th Percentile Industry Days to MDUFA IV Decision	167	206	312	222	0
Maximum Industry Days to MDUFA IV Decision	389	212	366	388	0
Average Total Days to MDUFA IV Decision	247.38	320.00	335.67	320.00	0.00
20th Percentile Total Days to MDUFA IV Decision	157	268	262	231	0
40th Percentile Total Days to MDUFA IV Decision	199	304	313	261	0
60th Percentile Total Days to MDUFA IV Decision	260	336	370	298	0
80th Percentile Total Days to MDUFA IV Decision	332	360	435	368	0
Maximum Total Days to MDUFA IV Decision	463	392	653	538	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	8
Number With MDUFA IV Decisions	8	5	12	5	0
Number With Granted Decisions	5	2	5	3	0
Number With Declined Decisions	2	1	4	1	0
Number of Withdrawals	0	0	2	1	0
Number Deleted	1	2	1	0	0
Rate of Granted Decisions	62.50%	40.00%	41.67%	60.00%	0.00%
Rate of Declined Decisions	25.00%	20.00%	33.33%	20.00%	0.00%
Rate of Withdrawals	0.00%	0.00%	16.67%	20.00%	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	5
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	6	4	3
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	5
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	5
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	5
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	5
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	11	6	2	2
MDUFA IV Decisions Within 150 FDA Days	3	5	4	2	2
De Novos Pending MDUFA IV Decision	0	0	0	4	3
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%	100.00%

**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	1.00
Number With MDUFA IV Decision	4	11	6	2	2
Average FDA Days to MDUFA IV Decision	100.00	186.55	161.50	148.50	94.00
20th Percentile FDA Days to MDUFA IV Decision	57	148	148	148	60
40th Percentile FDA Days to MDUFA IV Decision	97	150	150	148	83
60th Percentile FDA Days to MDUFA IV Decision	135	191	150	149	105
80th Percentile FDA Days to MDUFA IV Decision	149	211	203	149	128
Maximum FDA Days to MDUFA IV Decision	151	327	243	150	150
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	94.00
20th Percentile Total Days to MDUFA IV Decision	179	283	209	192	60
40th Percentile Total Days to MDUFA IV Decision	293	347	213	204	83
60th Percentile Total Days to MDUFA IV Decision	312	368	267	215	105
80th Percentile Total Days to MDUFA IV Decision	321	416	372	227	128
Maximum Total Days to MDUFA IV Decision	325	617	438	238	150

**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	5
Number With MDUFA IV Decisions	4	11	6	2	2
Number With Granted Decisions	0	8	3	2	1
Number With Declined Decisions	3	3	2	0	0
Number of Withdrawals	0	0	0	0	1
Number Deleted	1	0	1	0	0
Rate of Granted Decisions	0.00%	72.73%	50.00%	100.00%	50.00%
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%	50.00%
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	6	3
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	5	6	7	2	0
MDUFA IV Decisions Within 150 FDA Days	3	4	3	0	0
De Novos Pending MDUFA IV Decision	0	0	0	4	3
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	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	1.50	0.00
Number With MDUFA IV Decision	5	6	7	2	0
Average FDA Days to MDUFA IV Decision	147.40	182.50	165.14	206.50	0.00
20th Percentile FDA Days to MDUFA IV Decision	133	93	113	201	0
40th Percentile FDA Days to MDUFA IV Decision	150	98	146	205	0
60th Percentile FDA Days to MDUFA IV Decision	151	107	174	208	0
80th Percentile FDA Days to MDUFA IV Decision	167	236	189	212	0
Maximum FDA Days to MDUFA IV Decision	221	485	323	215	0
Average Industry Days to MDUFA IV Decision	90.80	125.83	231.86	317.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	12	0	161	289	0
40th Percentile Industry Days to MDUFA IV Decision	65	0	248	308	0
60th Percentile Industry Days to MDUFA IV Decision	124	187	267	326	0
80th Percentile Industry Days to MDUFA IV Decision	165	195	331	345	0
Maximum Industry Days to MDUFA IV Decision	179	373	365	363	0
Average Total Days to MDUFA IV Decision	238.20	308.33	397.00	523.50	0.00
20th Percentile Total Days to MDUFA IV Decision	145	93	331	501	0
40th Percentile Total Days to MDUFA IV Decision	215	107	408	516	0
60th Percentile Total Days to MDUFA IV Decision	275	285	436	531	0
80th Percentile Total Days to MDUFA IV Decision	332	609	469	546	0
Maximum Total Days to MDUFA IV Decision	400	680	668	561	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	6	3
Number With MDUFA IV Decisions	5	6	7	2	0
Number With Granted Decisions	3	1	1	1	0
Number With Declined Decisions	1	3	3	0	0
Number of Withdrawals	1	1	2	0	0
Number Deleted	0	1	1	1	0
Rate of Granted Decisions	60.00%	16.67%	14.29%	50.00%	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%	50.00%	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	2	0
Mean FDA Days for Submissions that Missed the Goal	187.00	360.50	215.50	206.50	0.00
Mean Industry Days for Submissions that Missed the Goal	170.50	284.00	246.25	317.00	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	5
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	5	7	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	2	1
Rate of Submissions Not Accepted for Review	N/A	N/A	28.57%	22.22%	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 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	4
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	13	6	6	6	1
MDUFA IV Decisions Within 150 FDA Days	9	6	5	5	1
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%	100.00%

**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	2.00
Number With MDUFA IV Decision	13	6	6	6	1
Average FDA Days to MDUFA IV Decision	153.00	113.33	138.67	156.33	150.00
20th Percentile FDA Days to MDUFA IV Decision	104	76	149	148	150
40th Percentile FDA Days to MDUFA IV Decision	148	127	149	149	150
60th Percentile FDA Days to MDUFA IV Decision	150	136	150	150	150
80th Percentile FDA Days to MDUFA IV Decision	219	149	150	150	150
Maximum FDA Days to MDUFA IV Decision	254	150	175	270	150
Average Industry Days to MDUFA IV Decision	106.08	20.17	134.67	83.33	74.00
20th Percentile Industry Days to MDUFA IV Decision	39	0	14	51	74
40th Percentile Industry Days to MDUFA IV Decision	82	0	84	62	74
60th Percentile Industry Days to MDUFA IV Decision	164	0	125	80	74
80th Percentile Industry Days to MDUFA IV Decision	174	45	169	141	74
Maximum Industry Days to MDUFA IV Decision	183	76	416	166	74
Average Total Days to MDUFA IV Decision	259.08	133.50	273.33	239.67	224.00
20th Percentile Total Days to MDUFA IV Decision	226	76	163	201	224
40th Percentile Total Days to MDUFA IV Decision	266	127	234	211	224
60th Percentile Total Days to MDUFA IV Decision	316	136	274	230	224
80th Percentile Total Days to MDUFA IV Decision	323	195	344	289	224
Maximum Total Days to MDUFA IV Decision	371	225	566	436	224

**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	4
Number With MDUFA IV Decisions	13	6	6	6	1
Number With Granted Decisions	3	2	6	3	1
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%	100.00%
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	7
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	5	5	6
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	7
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	4	5	5	0
MDUFA IV Decisions Within 150 FDA Days	3	3	5	3	0
De Novos Pending MDUFA IV Decision	0	0	0	1	7
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	75.00%	75.00%	100.00%	60.00%	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	1.60	0.00
Number With MDUFA IV Decision	4	4	5	5	0
Average FDA Days to MDUFA IV Decision	133.25	144.75	147.40	172.40	0.00
20th Percentile FDA Days to MDUFA IV Decision	122	116	147	141	0
40th Percentile FDA Days to MDUFA IV Decision	148	143	150	145	0
60th Percentile FDA Days to MDUFA IV Decision	150	144	150	170	0
80th Percentile FDA Days to MDUFA IV Decision	150	173	150	209	0
Maximum FDA Days to MDUFA IV Decision	151	217	150	231	0
Average Industry Days to MDUFA IV Decision	161.00	178.50	132.60	105.80	0.00
20th Percentile Industry Days to MDUFA IV Decision	149	104	62	0	0
40th Percentile Industry Days to MDUFA IV Decision	179	175	107	44	0
60th Percentile Industry Days to MDUFA IV Decision	180	177	146	84	0
80th Percentile Industry Days to MDUFA IV Decision	180	252	179	150	0
Maximum Industry Days to MDUFA IV Decision	181	362	245	357	0
Average Total Days to MDUFA IV Decision	294.25	323.25	280.00	278.20	0.00
20th Percentile Total Days to MDUFA IV Decision	260	221	209	199	0
40th Percentile Total Days to MDUFA IV Decision	278	333	256	224	0
60th Percentile Total Days to MDUFA IV Decision	316	380	296	259	0
80th Percentile Total Days to MDUFA IV Decision	330	439	329	342	0
Maximum Total Days to MDUFA IV Decision	331	505	395	504	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	7
Number With MDUFA IV Decisions	4	4	5	5	0
Number With Granted Decisions	1	1	3	3	0
Number With Declined Decisions	1	3	2	1	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%	60.00%	0.00%
Rate of Declined Decisions	25.00%	75.00%	40.00%	20.00%	0.00%
Rate of Withdrawals	25.00%	0.00%	0.00%	20.00%	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	2	0
Mean FDA Days for Submissions that Missed the Goal	151.00	217.00	0.00	217.50	0.00
Mean Industry Days for Submissions that Missed the Goal	180.00	178.00	0.00	49.00	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
De Novo Acceptance Review Decision***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	19	21	15	13
Closed Before RTA Action	N/A	N/A	1	0	0
Number Accepted First RTA Cycle	N/A	N/A	12	6	9
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	0
Number Not Accepted	N/A	N/A	5	2	3
Rate of Submissions Not Accepted for Review	N/A	N/A	26.32%	13.33%	23.08%

*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
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	16	19	18	13	10
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	16	19	16	5	0
MDUFA IV Decisions Within 150 FDA Days	16	16	9	1	0
De Novos Pending MDUFA IV Decision	0	0	2	8	10
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	2	6	1
Current Performance Percent Within 150 FDA Days	100.00%	84.21%	50.00%	9.09%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.58	1.63	1.80	0.00
Number With MDUFA IV Decision	16	19	16	5	0
Average FDA Days to MDUFA IV Decision	126.25	120.16	220.56	237.20	0.00
20th Percentile FDA Days to MDUFA IV Decision	109	71	115	190	0
40th Percentile FDA Days to MDUFA IV Decision	132	118	147	209	0
60th Percentile FDA Days to MDUFA IV Decision	147	148	211	215	0
80th Percentile FDA Days to MDUFA IV Decision	150	150	364	263	0
Maximum FDA Days to MDUFA IV Decision	150	243	497	425	0
Average Industry Days to MDUFA IV Decision	108.25	110.00	195.63	171.40	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	71	33	0
40th Percentile Industry Days to MDUFA IV Decision	121	0	171	121	0
60th Percentile Industry Days to MDUFA IV Decision	175	176	232	231	0
80th Percentile Industry Days to MDUFA IV Decision	180	222	326	319	0
Maximum Industry Days to MDUFA IV Decision	189	276	431	325	0
Average Total Days to MDUFA IV Decision	234.50	230.16	416.19	408.60	0.00
20th Percentile Total Days to MDUFA IV Decision	145	90	210	235	0
40th Percentile Total Days to MDUFA IV Decision	236	150	402	422	0
60th Percentile Total Days to MDUFA IV Decision	281	295	441	529	0
80th Percentile Total Days to MDUFA IV Decision	313	340	502	546	0
Maximum Total Days to MDUFA IV Decision	327	509	928	599	0

Table 8.4 OHT7 - Office of In Vitro Diagnostics

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	16	19	18	13	10
Number With MDUFA IV Decisions	16	19	16	5	0
Number With Granted Decisions	9	11	7	4	0
Number With Declined Decisions	1	0	3	0	0
Number of Withdrawals	5	7	4	1	0
Number Deleted	1	1	2	0	0
Rate of Granted Decisions	56.25%	57.89%	43.75%	80.00%	0.00%
Rate of Declined Decisions	6.25%	0.00%	18.75%	0.00%	0.00%
Rate of Withdrawals	31.25%	36.84%	25.00%	20.00%	0.00%
Rate of Deleted	6.25%	5.26%	12.50%	0.00%	0.00%

Table 8.5 OHT7 - Office of In Vitro Diagnostics

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	7	4	0
Mean FDA Days for Submissions that Missed the Goal	0.00	209.33	353.71	266.50	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	217.67	229.86	214.25	0.00

Table 8.6 OHT7 - Office of In Vitro Diagnostics

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	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	5	2	0	0
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	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

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	8
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	14	5	0
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	2	8	8
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	2	6	1
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	9.09%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	1	1	2	4
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	1	2	2
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	1
Number Not Accepted	N/A	N/A	0	0	0
Rate of Submissions Not Accepted for Review	N/A	N/A	0.00%	0.00%	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 OHT8 - Office of 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	1	1	1	2	3
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	1	1	1	1
MDUFA IV Decisions Within 150 FDA Days	1	1	1	1	1
De Novos Pending MDUFA IV Decision	0	0	0	1	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.00	2.00	2.00	2.00	1.00
Number With MDUFA IV Decision	1	1	1	1	1
Average FDA Days to MDUFA IV Decision	108.00	149.00	148.00	149.00	15.00
20th Percentile FDA Days to MDUFA IV Decision	108	149	148	149	15
40th Percentile FDA Days to MDUFA IV Decision	108	149	148	149	15
60th Percentile FDA Days to MDUFA IV Decision	108	149	148	149	15
80th Percentile FDA Days to MDUFA IV Decision	108	149	148	149	15
Maximum FDA Days to MDUFA IV Decision	108	149	148	149	15
Average Industry Days to MDUFA IV Decision	0.00	15.00	360.00	177.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	15	360	177	0
40th Percentile Industry Days to MDUFA IV Decision	0	15	360	177	0
60th Percentile Industry Days to MDUFA IV Decision	0	15	360	177	0
80th Percentile Industry Days to MDUFA IV Decision	0	15	360	177	0
Maximum Industry Days to MDUFA IV Decision	0	15	360	177	0
Average Total Days to MDUFA IV Decision	108.00	164.00	508.00	326.00	15.00
20th Percentile Total Days to MDUFA IV Decision	108	164	508	326	15
40th Percentile Total Days to MDUFA IV Decision	108	164	508	326	15
60th Percentile Total Days to MDUFA IV Decision	108	164	508	326	15
80th Percentile Total Days to MDUFA IV Decision	108	164	508	326	15
Maximum Total Days to MDUFA IV Decision	108	164	508	326	15

Table 8.4 OHT8 - Office of 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	1	1	1	2	3
Number With MDUFA IV Decisions	1	1	1	1	1
Number With Granted Decisions	1	1	1	0	0
Number With Declined Decisions	0	0	0	1	0
Number of Withdrawals	0	0	0	0	1
Number Deleted	0	0	0	0	0
Rate of Granted Decisions	100.00%	100.00%	100.00%	0.00%	0.00%
Rate of Declined Decisions	0.00%	0.00%	0.00%	100.00%	0.00%
Rate of Withdrawals	0.00%	0.00%	0.00%	0.00%	100.00%
Rate of Deleted	0.00%	0.00%	0.00%	0.00%	0.00%

Table 8.5 OHT8 - Office of 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	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 OHT8 - Office of Radiological Health

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%

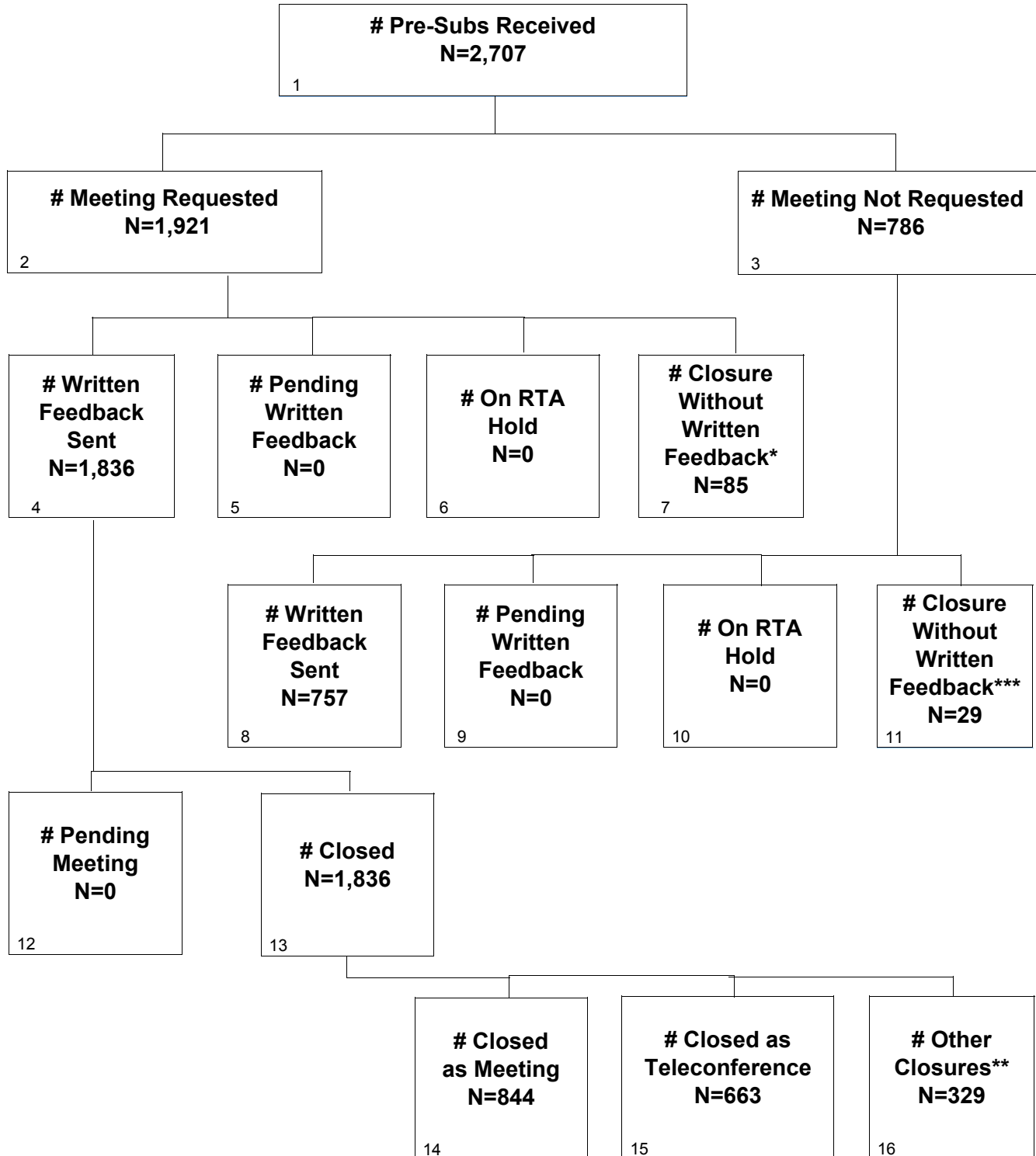
Table 8.7 OHT8 - Office of Radiological Health

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	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%

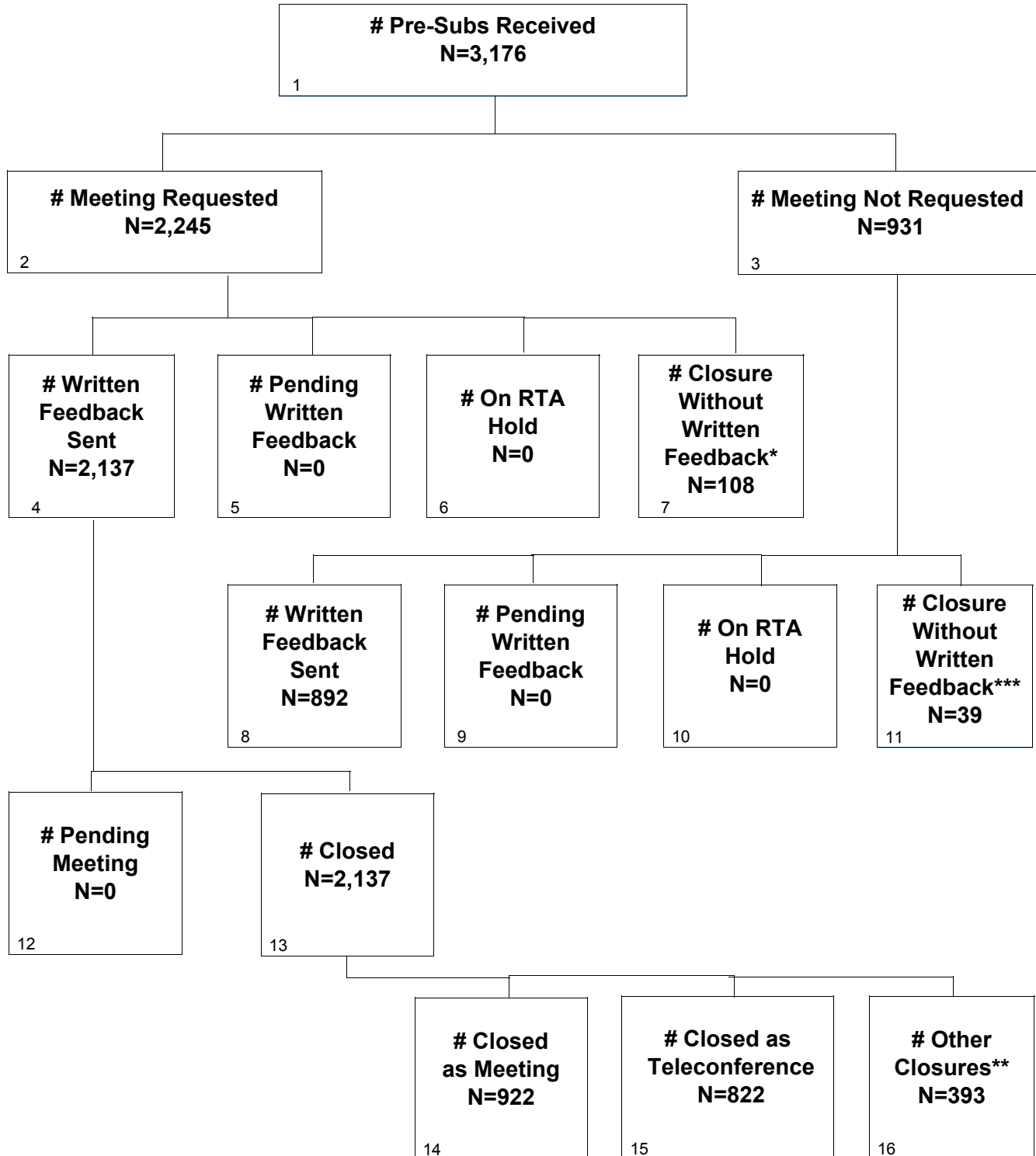
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CDRH Pre-Sub - FY 2018 as of 6/30/22



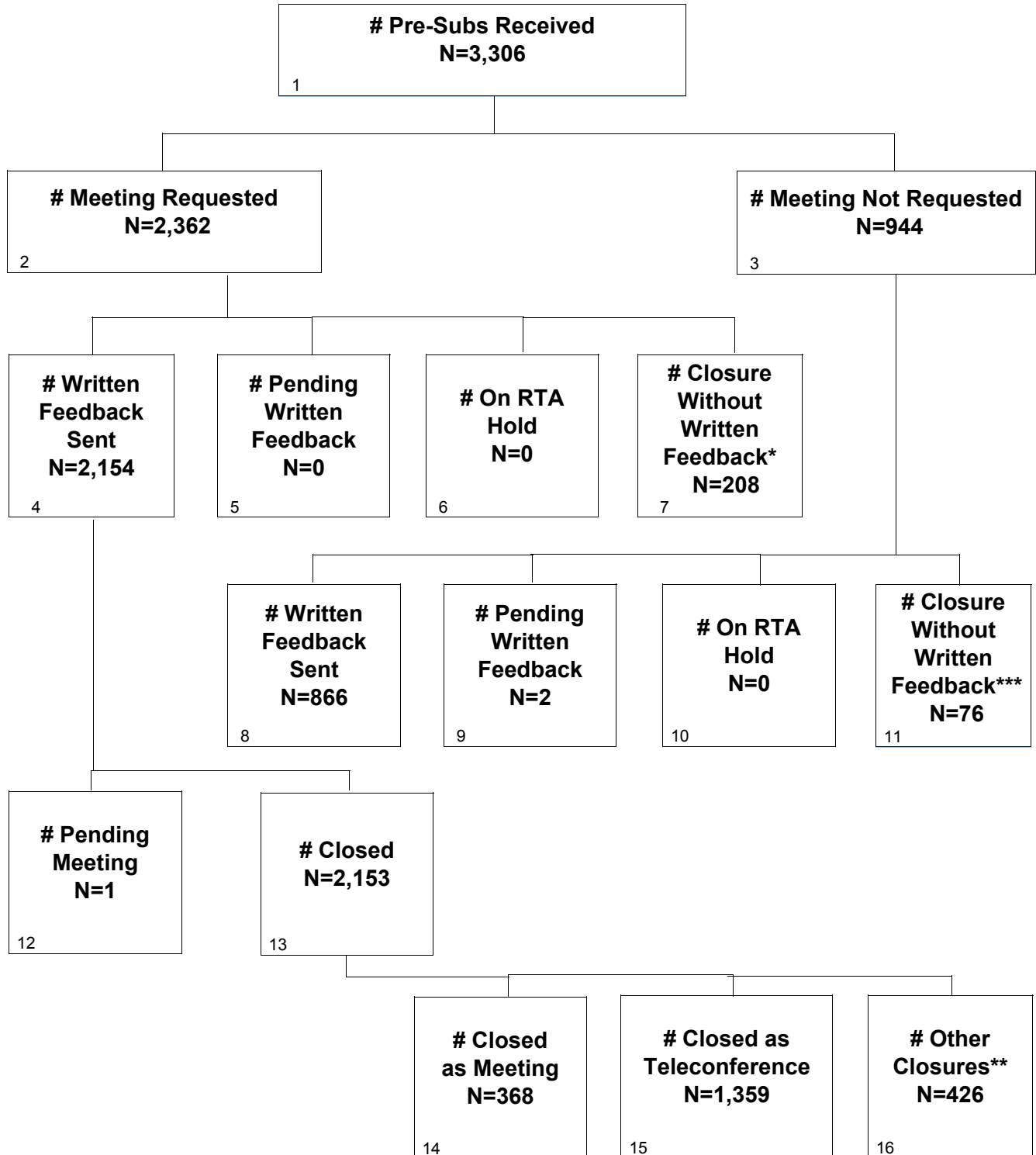
* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR
 ** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR
 *** Closures include JTRX, JPND, DELE & WTDR

CDRH Pre-Sub - FY 2019 as of 6/30/22



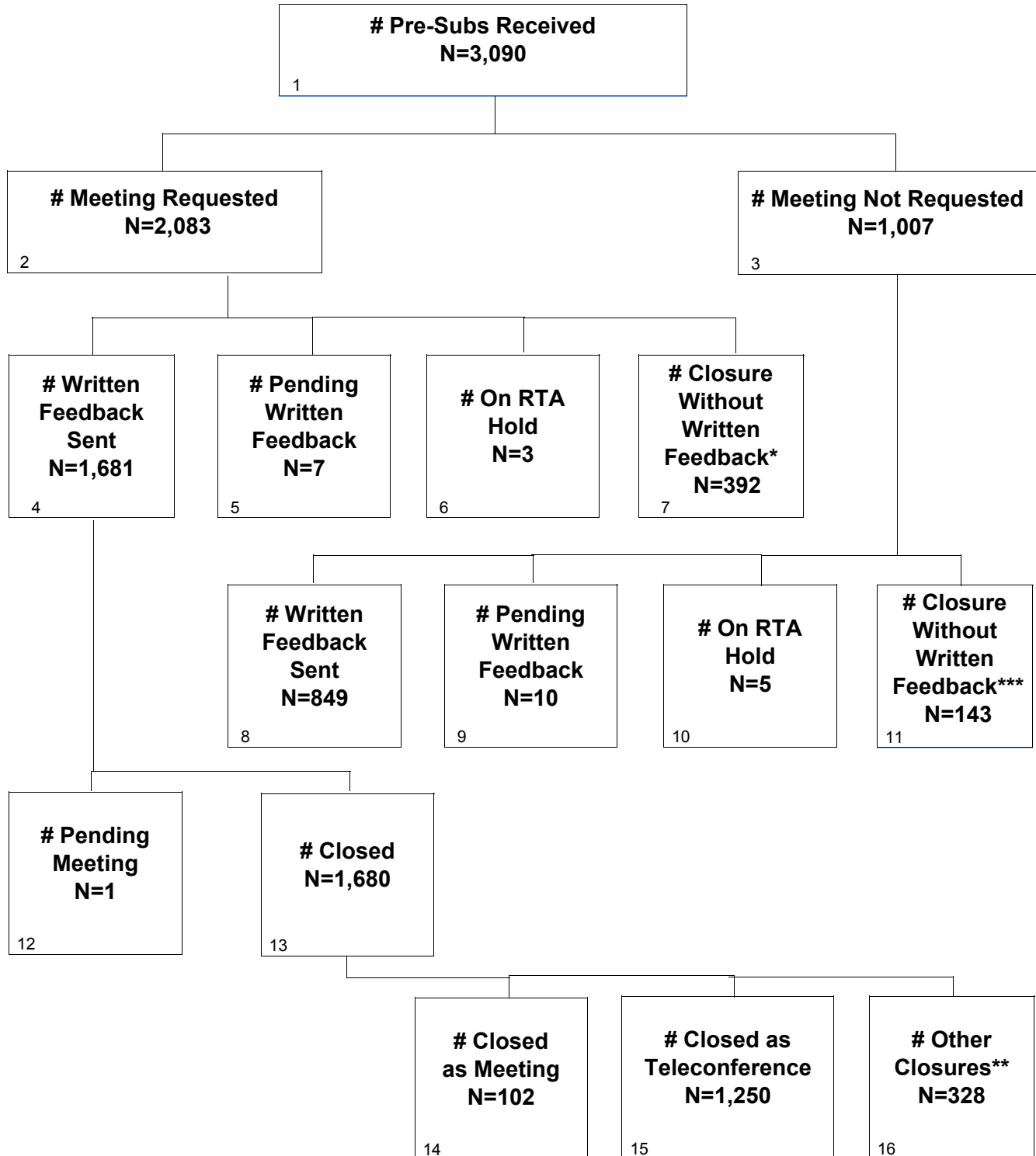
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 *** Closures include JTRX, JPND, DELE & WTDR

CDRH Pre-Sub - FY 2020 as of 6/30/22



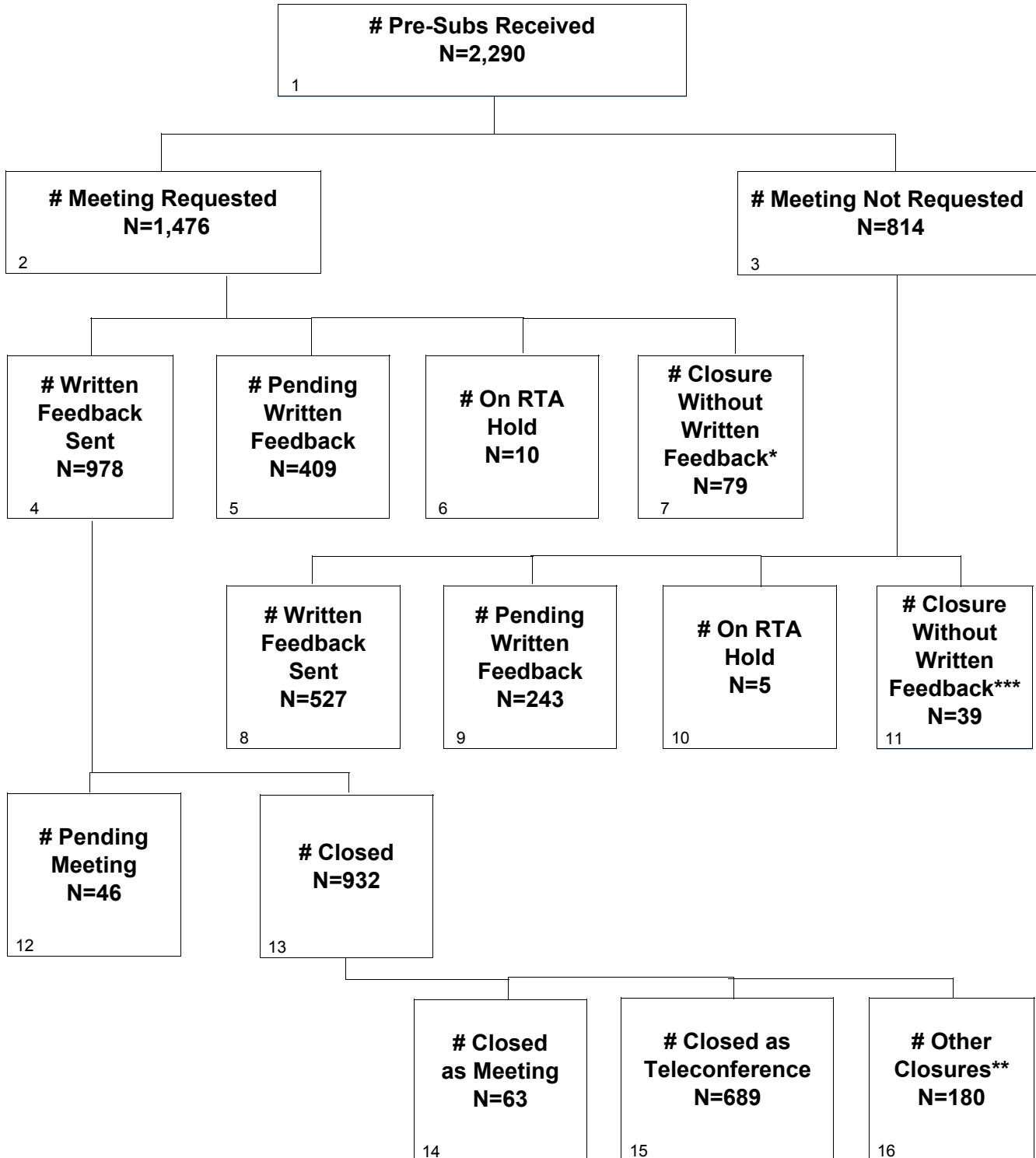
* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR
 ** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR
 *** Closures include JTRX, JPND, DELE & WTDR

CDRH Pre-Sub - FY 2021 as of 6/30/22



* 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 2022 as of 6/30/22



* 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

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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	2,290
Closed Before RTA Action**	27	41	109	388	58
Number Accepted First RTA Cycle**	2,565	3,004	3,035	2,449	1,904
Number Without a RTA Review and > 15 Days Since Date Received**	49	71	121	224	191
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	108
Number Not Accepted	66	60	41	29	29
Rate of Submissions Not Accepted for Review	2.46%	1.91%	1.28%	1.07%	1.37%

*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	3,029	3,020	2,530	1,505
Written Feedback Provided Within MDUFA IV Goal	2,439	2,848	2,652	2,022	1,206

*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	3,029	3,020	2,530	1,505
Average FDA Days to Written Feedback	58.86	60.22	63.26	67.24	64.39
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	950	389	377	254

*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	83
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.62	43.33	48.15	48.87

*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	1,352	752
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,113	1,110	890	465
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	44
Meeting Minutes Past 15 Days of Meeting	483	560	539	418	203
Meeting Minutes Not Submitted and >15 Days Since Meeting	53	71	78	44	40
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.43%	63.82%	64.27%	65.83%	65.68%

*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	430	401	297
Closed Before RTA Action**	0	6	5	8	1
Number Accepted First RTA Cycle**	284	359	407	376	267
Number Without a RTA Review and > 15 Days Since Date Received**	8	9	10	13	10
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	13
Number Not Accepted	27	15	8	4	6
Rate of Submissions Not Accepted for Review	8.46%	3.92%	1.88%	1.02%	2.12%

*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	402	378	200
Written Feedback Provided Within MDUFA IV Goal	256	314	280	225	120

*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	402	378	200
Average FDA Days to Written Feedback	64.18	64.05	73.3	73.35	72.43
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	81
Maximum FDA Days to Written Feedback	168	119	389	219	190

*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	18
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75	34.00	42.40	60.50	46.61

*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	243	222	107
Meeting Minutes Submitted Within 15 Days of Meeting	126	151	152	143	63
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	5
Meeting Minutes Past 15 Days of Meeting	50	68	80	75	32
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	11	4	7
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.85%	67.41%	62.55%	64.41%	61.76%

*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	674	773	512
Closed Before RTA Action**	6	7	4	7	0
Number Accepted First RTA Cycle**	506	555	648	738	473
Number Without a RTA Review and > 15 Days Since Date Received**	12	14	13	24	17
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	19
Number Not Accepted	6	6	9	4	3
Rate of Submissions Not Accepted for Review	1.15%	1.04%	1.34%	0.52%	0.61%

*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	746	376
Written Feedback Provided Within MDUFA IV Goal	482	535	610	676	355

*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	746	376
Average FDA Days to Written Feedback	53.02	55.51	56.20	58.80	57.71
20th Percentile FDA Days to Written Feedback	39	44	45	45	45
40th Percentile FDA Days to Written Feedback	50	53	55	57	58
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	190
Meeting Minutes Submitted Within 15 Days of Meeting	183	199	212	248	113
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	17
Meeting Minutes Past 15 Days of Meeting	119	105	123	125	50
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	20	22	12	10
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	58.47%	61.42%	59.38%	64.42%	65.32%

*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	400	377	289
Closed Before RTA Action**	5	7	11	30	1
Number Accepted First RTA Cycle**	307	359	376	326	244
Number Without a RTA Review and > 15 Days Since Date Received**	11	7	4	16	19
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	19
Number Not Accepted	11	9	9	5	6
Rate of Submissions Not Accepted for Review	3.34%	2.40%	2.31%	1.44%	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 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	355	372	336	198
Written Feedback Provided Within MDUFA IV Goal	300	344	352	294	180

*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	355	372	336	198
Average FDA Days to Written Feedback	60.53	63.35	61.36	65.67	63.52
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	950	168	204	114

*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	9
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	36.88	36.00	52.11	45.22

*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	106
Meeting Minutes Submitted Within 15 Days of Meeting	112	125	156	141	73
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	8
Meeting Minutes Past 15 Days of Meeting	64	73	61	52	22
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3	4	3
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.92%	61.27%	70.91%	71.57%	74.49%

*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	335	314	222
Closed Before RTA Action**	4	5	21	118	1
Number Accepted First RTA Cycle**	234	250	302	164	196
Number Without a RTA Review and > 15 Days Since Date Received**	6	11	7	29	12
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	9
Number Not Accepted	7	9	5	3	4
Rate of Submissions Not Accepted for Review	2.83%	3.33%	1.59%	1.53%	1.89%

*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	298	178	164
Written Feedback Provided Within MDUFA IV Goal	215	221	262	118	106

*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	298	178	164
Average FDA Days to Written Feedback	60.70	62.60	63.10	70.48	68.33
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	69
80th Percentile FDA Days to Written Feedback	69	70	70	80	77
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	14
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25	34.25	42.80	42.84	52.07

*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	178	96	88
Meeting Minutes Submitted Within 15 Days of Meeting	92	95	117	69	48
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	8
Meeting Minutes Past 15 Days of Meeting	26	41	49	23	24
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	5	12	4	8
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.19%	67.38%	65.73%	71.88%	60.00%

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

**Table 9.1 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	309	342	250
Closed Before RTA Action**	3	2	2	2	2
Number Accepted First RTA Cycle**	232	253	286	317	220
Number Without a RTA Review and > 15 Days Since Date Received**	7	10	16	15	13
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	8
Number Not Accepted	7	12	5	8	7
Rate of Submissions Not Accepted for Review	2.85%	4.36%	1.63%	2.35%	2.92%

*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	298	325	162
Written Feedback Provided Within MDUFA IV Goal	202	219	185	216	113

*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	298	325	162
Average FDA Days to Written Feedback	64.73	72.86	80.68	81.96	70.80
20th Percentile FDA Days to Written Feedback	58	63	65	64	63
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	377	194

*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	19
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	33.00	37.50	38.50	41.68

*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	177	174	84
Meeting Minutes Submitted Within 15 Days of Meeting	99	103	107	107	48
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	4
Meeting Minutes Past 15 Days of Meeting	50	59	63	57	29
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%	60.45%	61.49%	60.00%

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

**Table 9.1 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	184
Closed Before RTA Action**	1	3	1	2	1
Number Accepted First RTA Cycle**	127	162	168	230	171
Number Without a RTA Review and > 15 Days Since Date Received**	5	6	7	6	4
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	7
Number Not Accepted	0	2	3	3	1
Rate of Submissions Not Accepted for Review	0.0%	1.18%	1.69%	1.26%	0.57%

*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	134
Written Feedback Provided Within MDUFA IV Goal	115	154	169	224	132

*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	134
Average FDA Days to Written Feedback	61.91	61.18	62.34	58.92	55.32
20th Percentile FDA Days to Written Feedback	52	55	57	45	44
40th Percentile FDA Days to Written Feedback	62	62	63	60	55
60th Percentile FDA Days to Written Feedback	67	66	69	65	61
80th Percentile FDA Days to Written Feedback	70	70	70	70	67
Maximum FDA Days to Written Feedback	106	92	105	78	71

*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	3
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	43.75	0.00	31.00	35.67

*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	58
Meeting Minutes Submitted Within 15 Days of Meeting	55	53	61	63	43
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	19	29	15	35	11
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5	3	2	4
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	60.92%	77.22%	63.00%	74.14%

*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
Pre-Sub Acceptance Review Decision***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	759	906	766	434	360
Closed Before RTA Action**	7	7	61	221	48
Number Accepted First RTA Cycle**	749	885	645	99	169
Number Without a RTA Review and > 15 Days Since Date Received**	0	12	60	113	113
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	30
Number Not Accepted	3	2	0	1	0
Rate of Submissions Not Accepted for Review	0.40%	0.22%	0.00%	0.47%	0.00%

*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
MDUFA IV Pre-Sub Performance Goals***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	746	891	610	135	139
Written Feedback Provided Within MDUFA IV Goal	743	881	590	64	69

*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
Pre-Sub Time to MDUFA IV Decision***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	746	891	610	135	139
Average FDA Days to Written Feedback	58.34	57.48	59.87	91.19	74.65
20th Percentile FDA Days to Written Feedback	49	46	51	51	57
40th Percentile FDA Days to Written Feedback	59	58	60	69	67
60th Percentile FDA Days to Written Feedback	64	64	65	88	72
80th Percentile FDA Days to Written Feedback	69	69	69	127	94
Maximum FDA Days to Written Feedback	85	307	142	295	254

*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
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	4	6	4	12
Average Days to Scheduling for Meetings Scheduled After Day 30	34.40	35.50	53.50	95.25	66.42

*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
MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	390	475	334	27	29
Meeting Minutes Submitted Within 15 Days of Meeting	239	310	213	18	17
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	134	150	108	6	11
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	15	13	3	1
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	61.28%	65.26%	63.77%	66.67%	58.62%

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

**Table 9.1 OHT8 - Office of Radiological Health
Pre-Sub Acceptance Review Decision***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	132	192	213	208	176
Closed Before RTA Action**	1	4	4	0	4
Number Accepted First RTA Cycle**	126	181	203	199	164
Number Without a RTA Review and > 15 Days Since Date Received**	0	2	4	8	3
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	3
Number Not Accepted	5	5	2	1	2
Rate of Submissions Not Accepted for Review	3.82%	2.66%	0.96%	0.48%	1.18%

*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 OHT8 - Office of Radiological Health
MDUFA IV Pre-Sub Performance Goals***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	181	207	205	132
Written Feedback Provided Within MDUFA IV Goal	126	180	204	205	131

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

**Table 9.3 OHT8 - Office of Radiological Health
Pre-Sub Time to MDUFA IV Decision***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	181	207	205	132
Average FDA Days to Written Feedback	51.53	52.29	55.62	56.54	58.14
20th Percentile FDA Days to Written Feedback	43	39	48	49	50
40th Percentile FDA Days to Written Feedback	49	52	55	56	57
60th Percentile FDA Days to Written Feedback	56	57	59	61	63
80th Percentile FDA Days to Written Feedback	61	65	65	65	66
Maximum FDA Days to Written Feedback	70	70	190	70	72

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

**Table 9.4 OHT8 - Office of 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	1	1	0	1	2
Average Days to Scheduling for Meetings Scheduled After Day 30	31.00	36.00	0.00	34.00	43.00

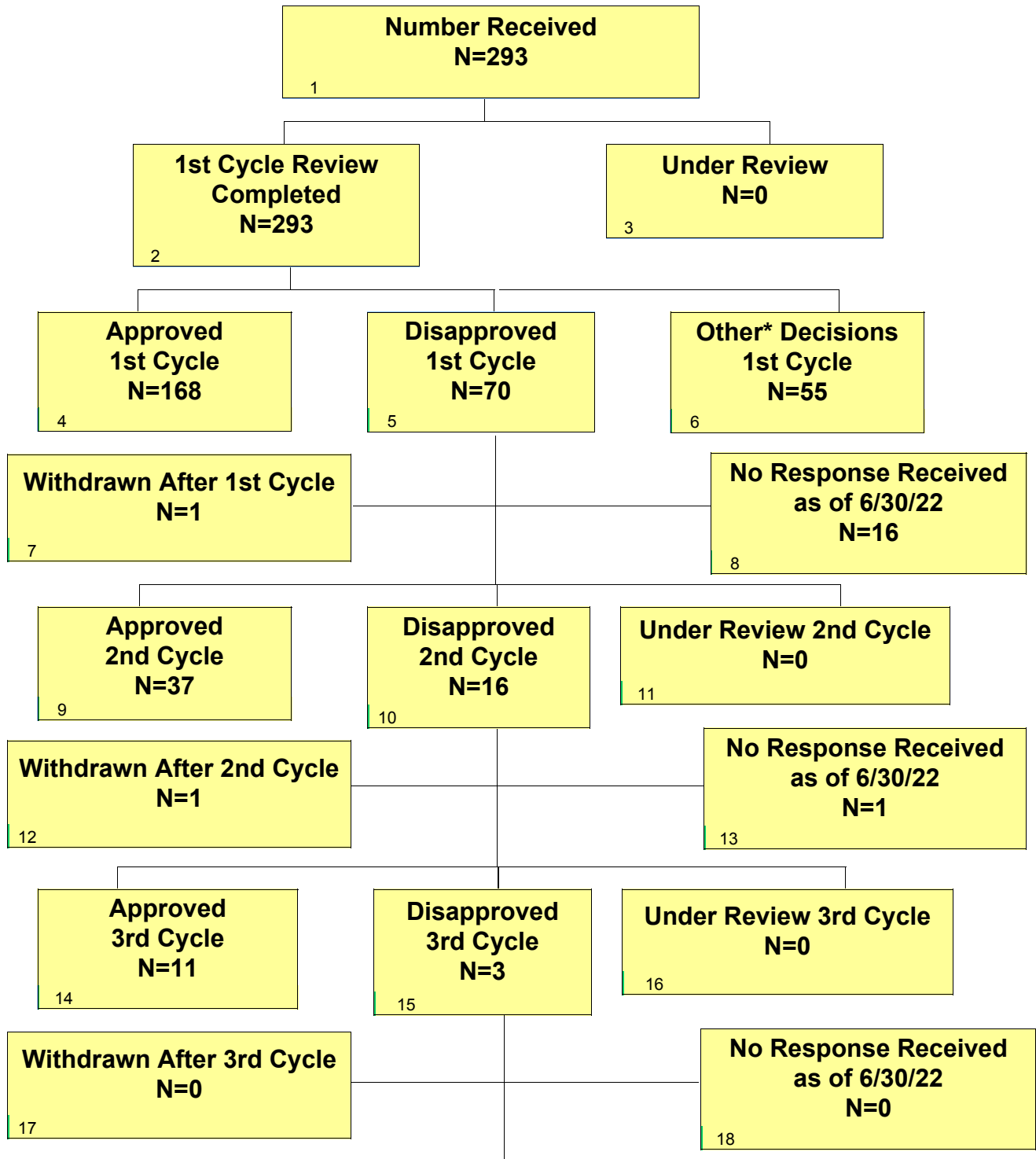
*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

Table 9.5 OHT8 - Office of Radiological Health

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	86	115	139	151	90
Meeting Minutes Submitted Within 15 Days of Meeting	65	77	92	101	60
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	2
Meeting Minutes Past 15 Days of Meeting	21	35	40	45	24
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	3	7	5	4
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.58%	66.96%	66.19%	66.89%	68.18%

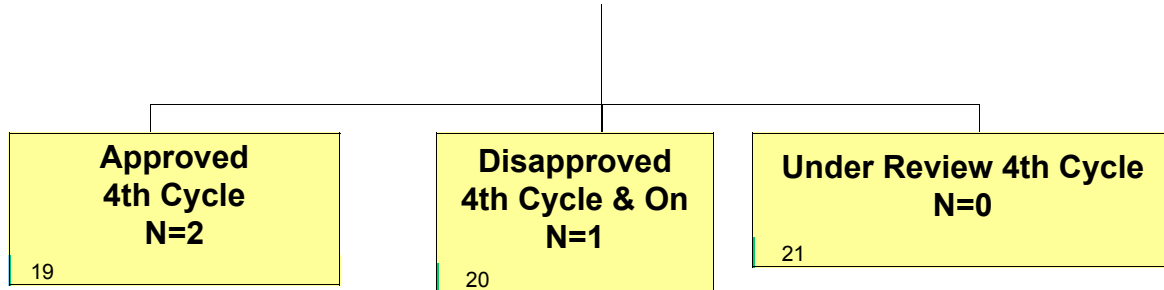
*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

CDRH IDEs - FY 2018 as of 6/30/22

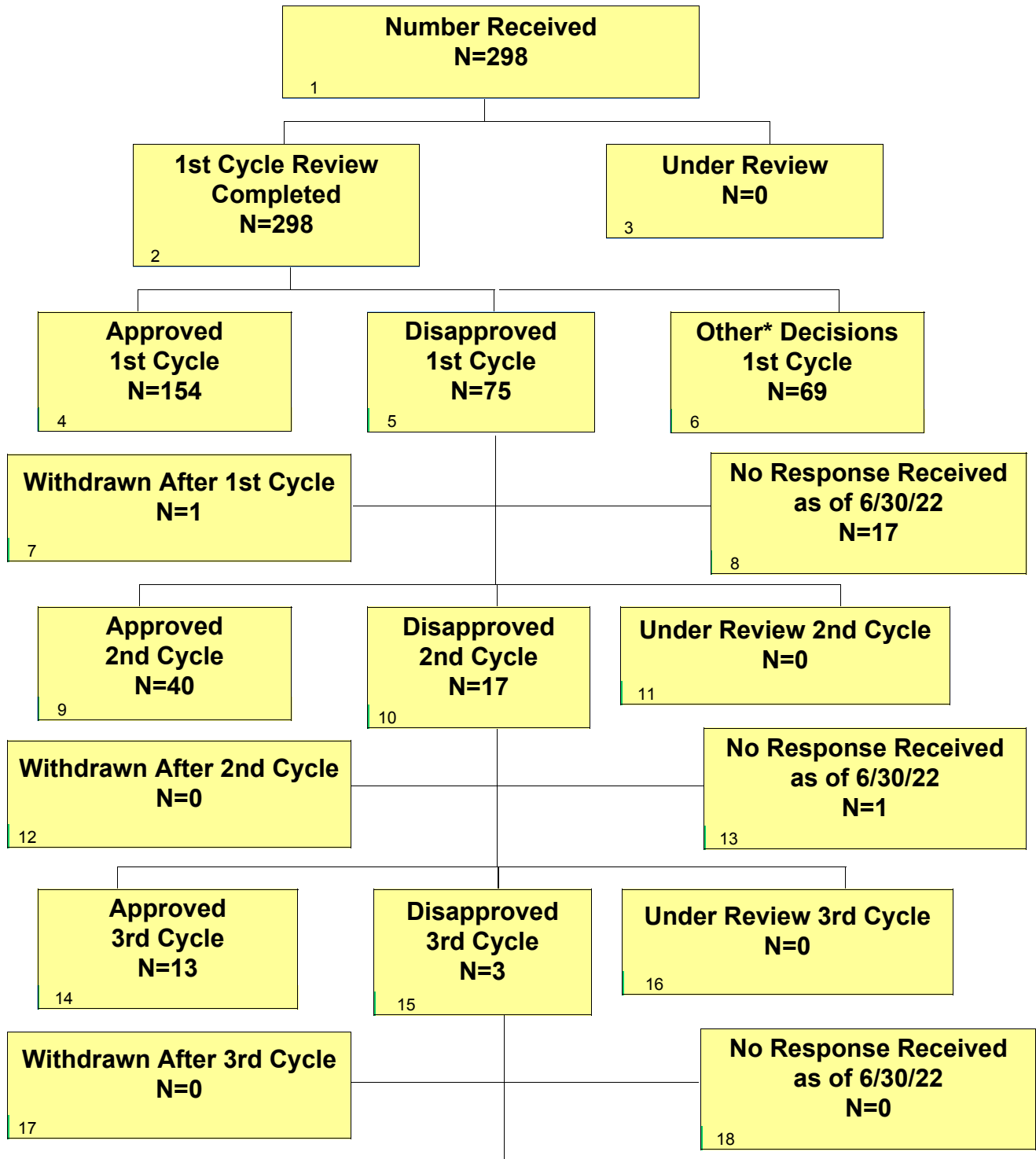


* Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

CDRH IDEs - FY 2018 as of 6/30/22

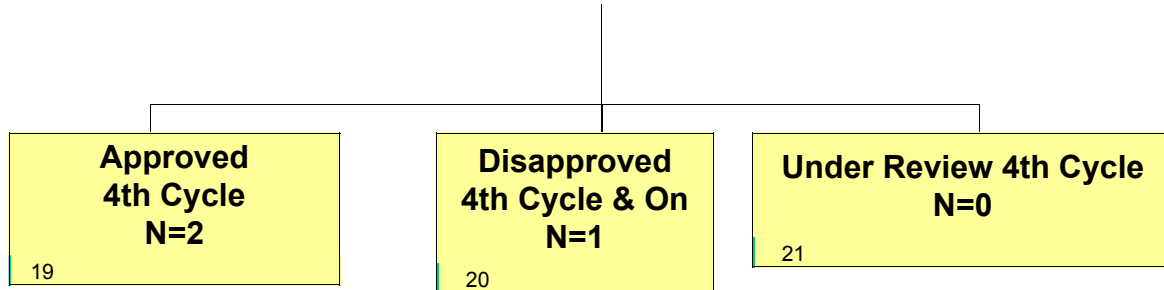


CDRH IDEs - FY 2019 as of 6/30/22

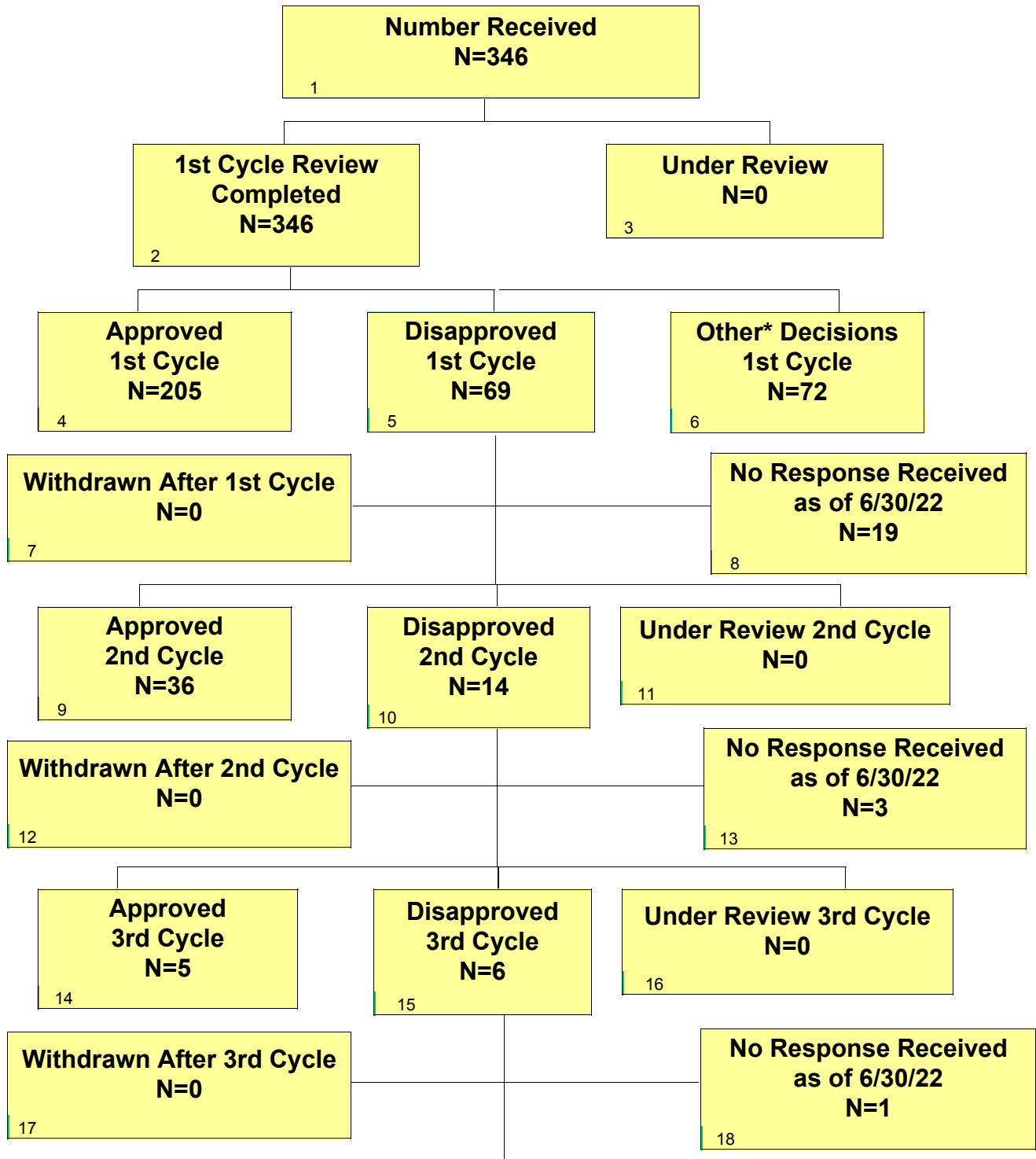


* Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).

CDRH IDEs - FY 2019 as of 6/30/22

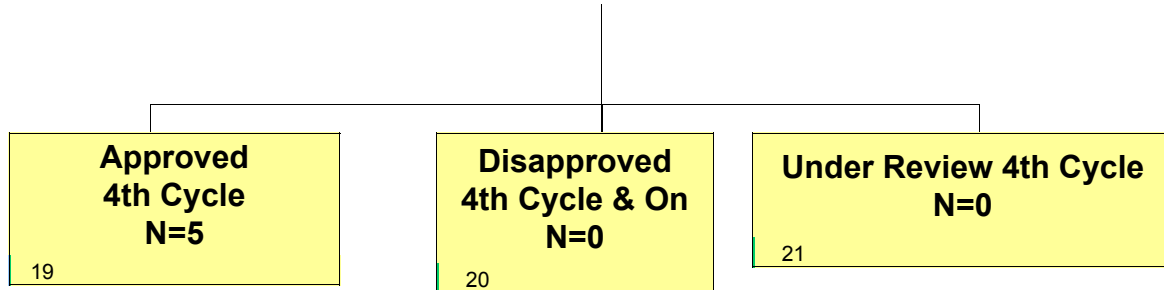


CDRH IDEs - FY 2020 as of 6/30/22

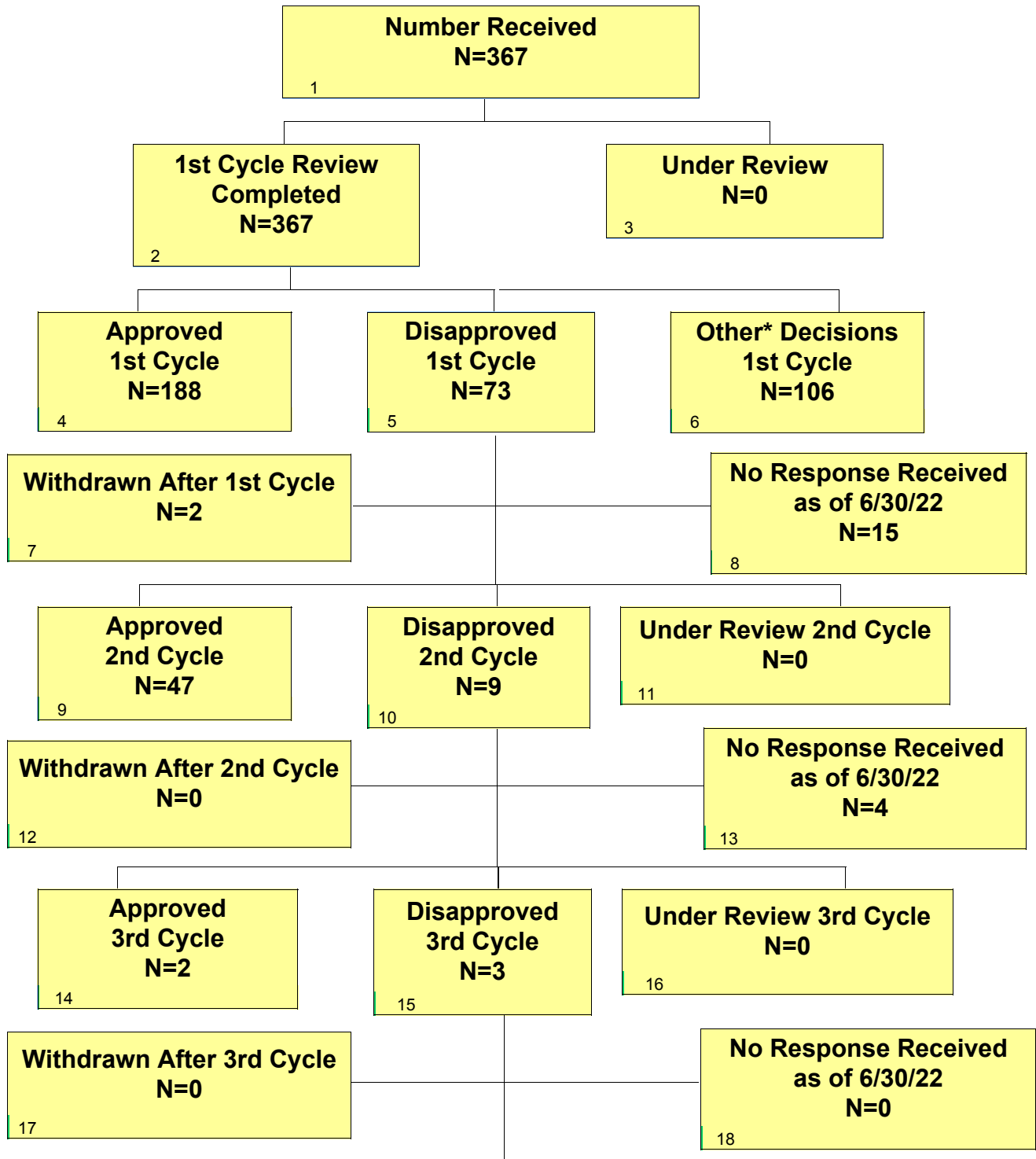


* Other decisions include withdrawn (N=12), withdrawn and converted (N=37), RTA (N=0), nonsignificant risk device (N=15), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).

CDRH IDEs - FY 2020 as of 6/30/22

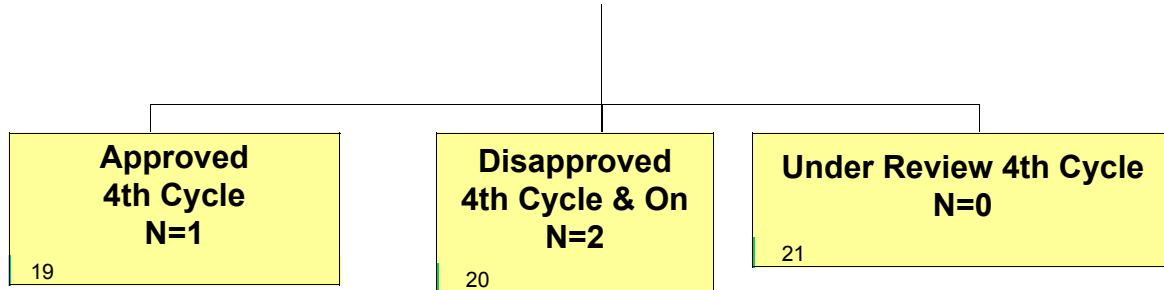


CDRH IDEs - FY 2021 as of 6/30/22

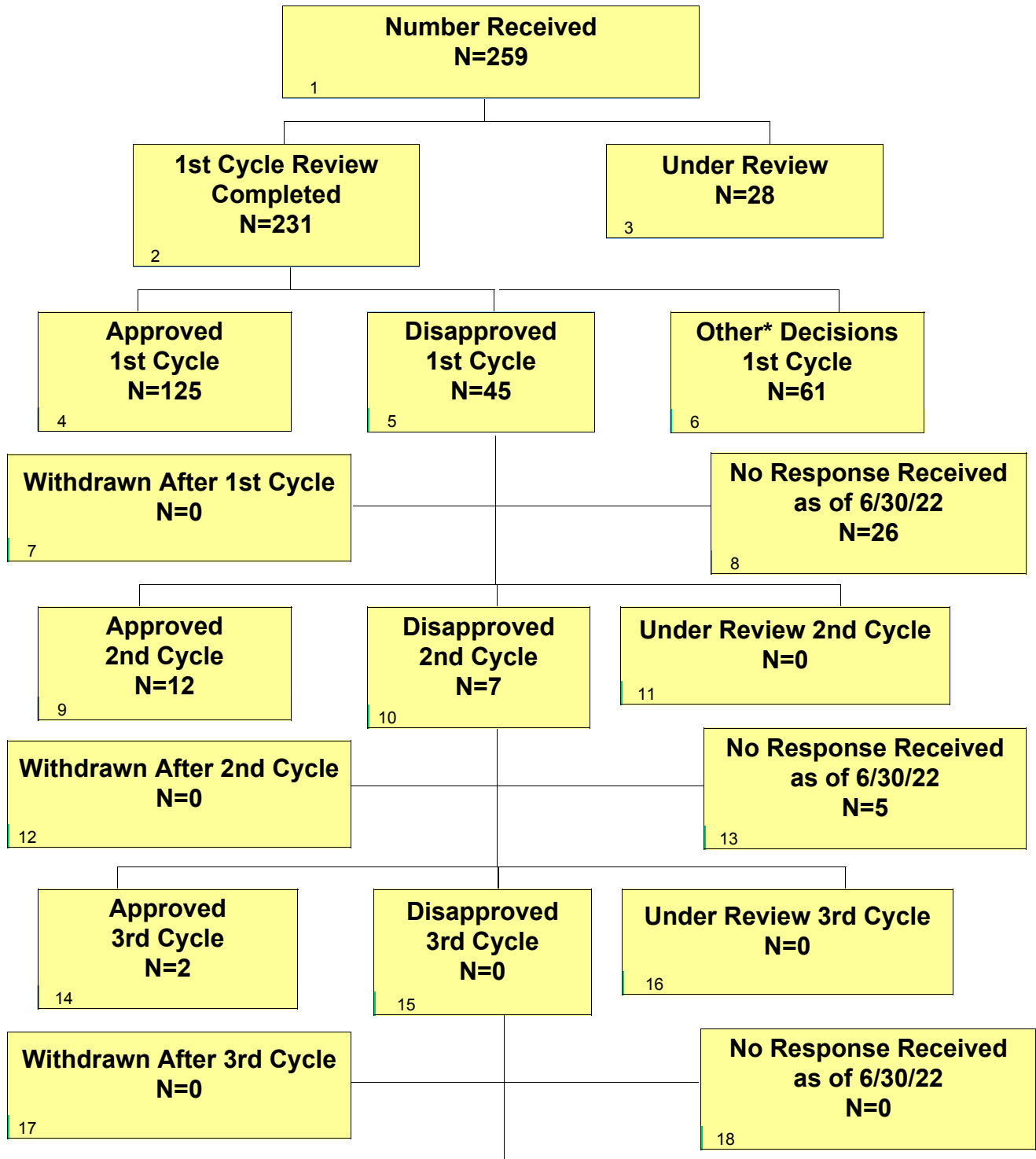


* Other decisions include withdrawn (N=26), withdrawn and converted (N=56), RTA (N=0), nonsignificant risk device (N=17), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=3), Basic Physiological Research (N=0).

CDRH IDEs - FY 2021 as of 6/30/22



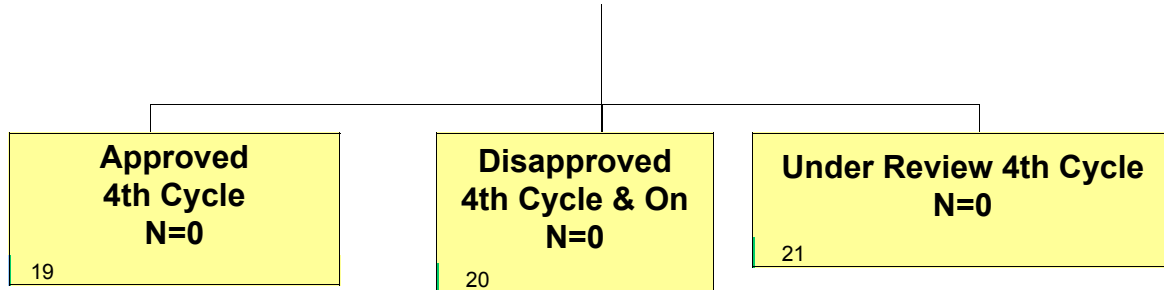
CDRH IDEs - FY 2022 as of 6/30/22



* Other decisions include withdrawn (N=10), withdrawn and converted (N=38), RTA (N=0), nonsignificant risk device (N=8), 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 6/30/22



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	259
Average Number of Cycles to IDE Approval or Conditional Approval	1.32	1.34	1.24	1.23	1.12
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.34	0.24	0.23	0.12

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	23
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.36	1.32	1.45	1.20
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.36	0.32	0.45	0.20

**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	63
Average Number of Cycles to IDE Approval or Conditional Approval	1.58	1.43	1.45	1.39	1.33
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.43	0.45	0.39	0.33

**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	34
Average Number of Cycles to IDE Approval or Conditional Approval	1.60	1.50	1.45	1.41	1.05
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.60	0.50	0.45	0.41	0.05

**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	29
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.11	1.15	1.11
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.11	0.15	0.11

**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	48
Average Number of Cycles to IDE Approval or Conditional Approval	1.16	1.47	1.17	1.12	1.11
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.17	0.12	0.11

**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	9
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
IDE MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	44	43	53	76	44
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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	8	7	10	10	9
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.00	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.00	0.00	0.00	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 30 Jun 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	67%	33%	0%	0%	0%

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	50.00	82.00	81.00	86.00	85.00
40th Percentile FDA Days to Substantive Interaction	50.00	84.00	89.00	86.00	85.00
60th Percentile FDA Days to Substantive Interaction	88.00	84.00	89.00	86.00	85.00
80th Percentile FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	85.00
Maximum FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	85.00

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	156.00	140.00	150.00	177.00	0.00
40th Percentile FDA Days to MDUFA IV Decision	156.00	171.00	169.00	177.00	0.00
60th Percentile FDA Days to MDUFA IV Decision	173.00	171.00	169.00	177.00	0.00
80th Percentile FDA Days to MDUFA IV Decision	173.00	176.00	175.00	177.00	0.00
Maximum FDA Days to MDUFA IV Decision	173.00	176.00	175.00	177.00	0.00
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	105.00	56.00	166.00	0.00	0.00
40th Percentile Industry Days to MDUFA IV Decision	105.00	177.00	166.00	0.00	0.00
60th Percentile Industry Days to MDUFA IV Decision	534.00	177.00	166.00	0.00	0.00
80th Percentile Industry Days to MDUFA IV Decision	534.00	250.00	166.00	0.00	0.00
Maximum Industry Days to MDUFA IV Decision	534.00	250.00	166.00	0.00	0.00
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	261.00	196.00	150.00	177.00	0.00
40th Percentile Total Days to MDUFA IV Decision	261.00	348.00	169.00	177.00	0.00
60th Percentile Total Days to MDUFA IV Decision	707.00	348.00	169.00	177.00	0.00
80th Percentile Total Days to MDUFA IV Decision	707.00	426.00	341.00	177.00	0.00
Maximum Total Days to MDUFA IV Decision	707.00	426.00	341.00	177.00	0.00

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%	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	7
SI Goal Met	8	5	8	4	5
SI Goal Not Met	0	0	0	0	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	3	0
Current SI Performance Percent Goal Met	100%	100%	100%	100%	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	7
Non-MDUFA IV Decision	0	0	0	4	0
MDUFA IV Decision	8	5	8	3	0
MDUFA IV Decision Goal Met	8	5	8	3	0
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%	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	7
Number with MDUFA IV Decision	8	5	8	3	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	7
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	3	2	5	9	6
MDUFA IV Decision Goal Met	3	2	5	9	6
Supplements Pending MDUFA IV Decision	0	0	0	0	1
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	100%

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	7
Number With MDUFA IV Decision	3	2	5	9	6
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0%	0%	0%	0%	0%

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	23
Closed Before RTA Action	0	0	1	1	0
Number Accepted	40	38	34	36	16
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	2
Number Not Accepted	11	15	14	5	5
Rate of Submissions Not Accepted for Review	20.75%	27.78%	28.57%	11.36%	23.81%

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	20
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	49	51	43	40	18
SI Over 60 FDA Days	0	0	1	0	0
SI Pending Within 60 FDA Days	0	0	0	0	2
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%	100%	98%	100%	100%

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	18
Average Number of FDA Days to Substantive Interaction	50.60	45.27	48.98	53.63	55.94
20th Percentile FDA Days to Substantive Interaction	43	21	21	56	57
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	20
Non-MDUFA IV Decision	6	5	7	0	1
MDUFA IV Decision (SE/NSE)	43	46	37	31	7
MDUFA IV Decision Within 90 FDA Days	43	46	37	31	7
510(k)s Pending MDUFA IV Decision	0	0	0	9	12
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	100%	100%	100%	100%	100%

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	1.34	1.14
Number With MDUFA IV Decision	43	46	37	32	7
Average Number of FDA Days to MDUFA IV Decision	75.58	67.48	64.08	74.88	67.14
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	73
60th Percentile FDA Days to MDUFA IV Decision	88	87	82	87	84
80th Percentile FDA Days to MDUFA IV Decision	90	89	88	90	87
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	43.53	14.71
20th Percentile Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
40th Percentile Industry Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00
60th Percentile Industry Days to MDUFA IV Decision	0.00	78.00	0.00	0.00	0.00
80th Percentile Industry Days to MDUFA IV Decision	59.00	179.00	29.00	100.00	0.00
Maximum Industry Days to MDUFA IV Decision	178.00	389.00	199.00	360.00	103.00
Average Number of Total Days to MDUFA IV Decision	100.84	143.24	81.05	118.41	81.86
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	72
60th Percentile Total Days to MDUFA IV Decision	90	141	82	90	84
80th Percentile Total Days to MDUFA IV Decision	147	269	105	189	88
Maximum Total Days to MDUFA IV Decision	268	463	287	450	190

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	20
Number With MDUFA IV Decision	43	46	37	32	7
Number of SE Decision	43	43	35	32	7
Number of NSE Decision	0	3	2	0	0
Number of Withdrawal	2	4	4	0	1
Number of Deleted	3	1	3	0	0
Rate of SE Decision	100%	93%	95%	100%	100%
Rate of NSE Decision	0%	7%	5%	0%	0%
Rate of Withdrawal	4%	8%	9%	0%	5%
Rate of Deleted	6%	2%	7%	0%	0%

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	6
Non-MDUFA IV Decision	0	1	0	0	0
MDUFA IV Decision (SE/NSE)	15	16	7	14	4
MDUFA IV Decision Within 90 FDA Days	15	16	7	14	4
510(k)s Pending MDUFA IV Decision	0	0	0	5	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	3
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	1
Number Not Accepted	N/A	N/A	0	0	1
Rate of Submissions Not Accepted for Review	N/A	N/A	0	0	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%	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	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	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	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	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	1	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%	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	35
Closed Before RTA Action	5	3	10	7	1
Number Accepted First RTA Cycle	69	70	65	67	29
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	1
Number Not Accepted	1	1	1	0	1
Rate of Submissions Not Accepted for Review	1.41%	1.35%	1.49%	0.00%	3.03%

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	25
Written Feedback Provided Within MDUFA IV Goal	68	71	63	67	22

*Due to resource limitations related to COVID-19 activities, some Pre-Subs were reviewed with a delayed timeline which may have res

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	25
Average FDA Days to Written Feedback	57.86	61.00	56.70	62.28	60.12
20th Percentile FDA Days to Written Feedback	47	55	48	54	49
40th Percentile FDA Days to Written Feedback	58	60	58	62	60
60th Percentile FDA Days to Written Feedback	64	63	64	64	66
80th Percentile FDA Days to Written Feedback	67	68	68	66	69
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 res

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	10
Meeting Minutes Submitted Within 15 Days of Meeting	33	30	26	33	7
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%	70.00%

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

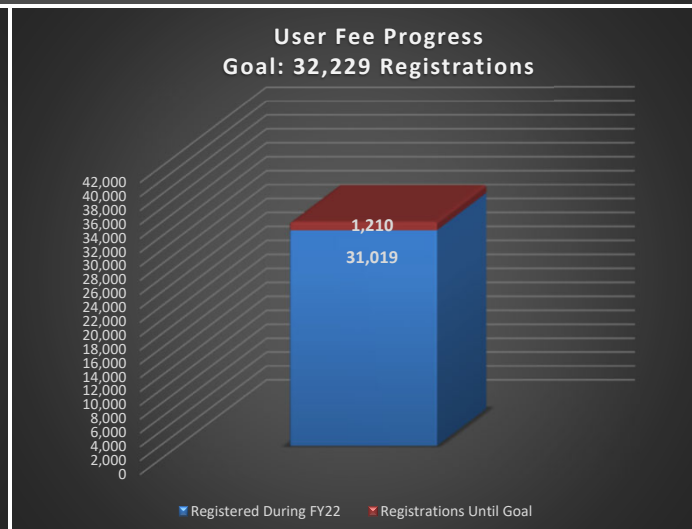
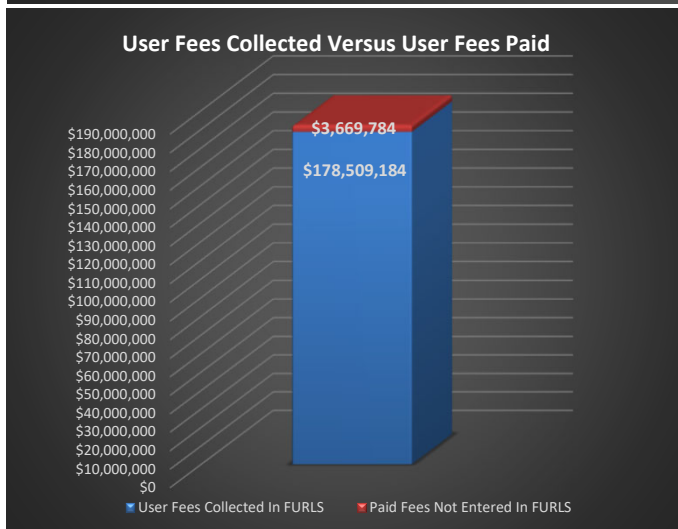
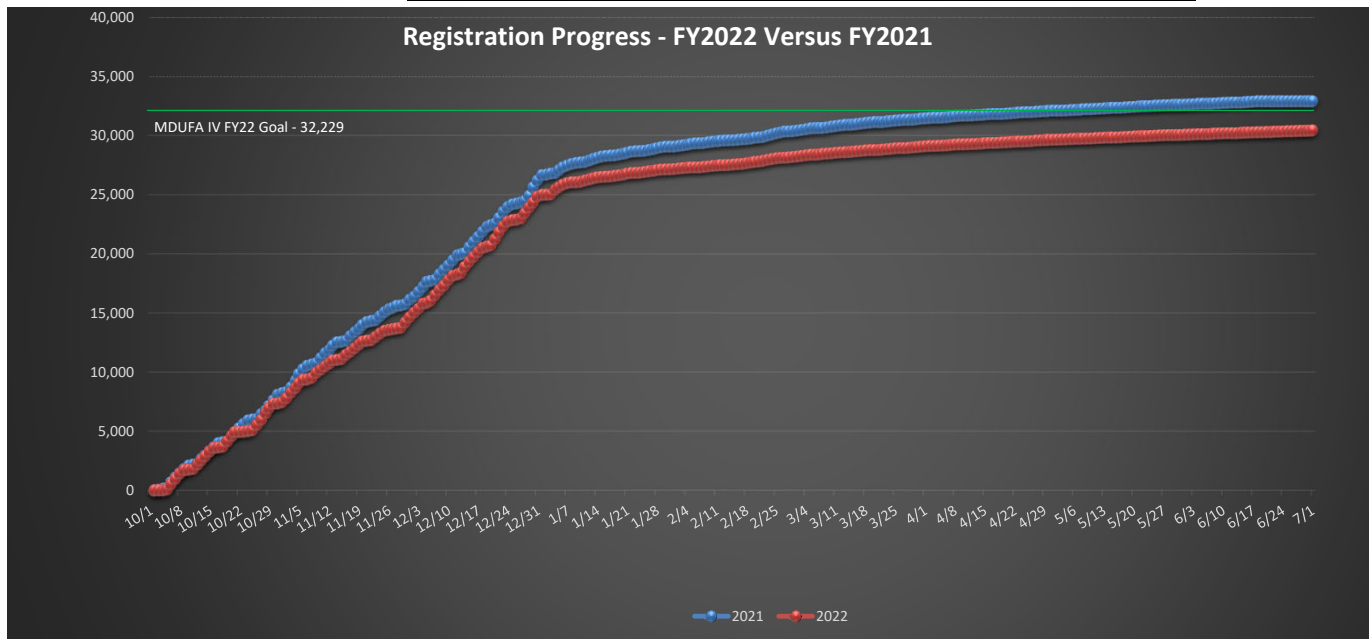
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	15	15	21	20	14
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.63	1.07	1.25	1.13
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.63	0.07	0.25	0.13

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MDUFA IV Registrations - 3rd Quarter Summary FY2022*

Current Active Registrations by Type	FY22 Q3			FY21 Year End Active Totals			FY22 vs End
	Domestic	Foreign	Total	Domestic	Foreign	Total	FY21
Manufacturer/ Complaint File Handler	6,747	12,653	19,398	6,899	14,017	20,916	92.74%
Contract Manufacturer	1,218	1,771	2,989	1,213	1,745	2,958	101.05%
Contract Sterilizer	66	160	226	70	156	226	100.00%
Specification Developer	1,733	575	2,308	1,785	594	2,379	97.02%
Reprocessor of Single Use Devices	25	5	30	30	8	38	78.95%
U.S. Manufacturer of Export Only Devices	137	0	137	133	0	133	103.01%
Repackager/Relabeler	1,140	204	1,344	1,186	230	1,416	94.92%
Remanufacturer	15	11	26	17	11	28	92.86%
Foreign Exporter/Private Label Distributor		1,132	1,132		1,179	1,179	96.01%
Initial Importer	3,601		3,601	4,125		4,125	87.30%
Unknown	5	12	17	4	5	9	188.89%
Total:	14,687	16,523	31,210	15,462	17,945	33,407	93.42%

*Note: This data is current as of 7/1/2022



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**FY 2022 Medical Device User Fee Collections
as of June 30, 2022
Excludes Unearned Fees**

	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$178,612,425	-\$431,201	\$178,181,224		
Application Fees	\$50,939,734	-\$1,290,797	\$49,648,937		
Total	\$229,552,158	-\$1,721,998	\$227,830,161	\$243,473,000	94%

**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	\$136,096,316	\$147,149,475	\$137,778,305
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
MD IV	\$193,456,432	\$202,326,017	\$290,515,625	\$275,978,172	\$227,830,161

MDUFA IV Commitment Letter - VI. Performance Reports**2.12. Number of discretionary fee waivers or reductions granted by type of submission^{1/}**

CDRH Data 3rd Quarter FY 2022 by Submission type	# Waived	# Reduced
Full Fee applications^{2/}		
PMA	1	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	0
De Novo Classification	3	30
180-Day Supplements	0	15
Real-Time Supplements	0	24
510(k)s	37	1135
30-day Notices	7	42
513(g)s	0	37
PMA Annual Report	0	50
Total	47	1,333

^{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.