

**Agenda for Quarterly Meeting on
MDUFA IV (FY 2018-2022) Performance
February 25, 2022, 10:30 – 11:30 pm
Zoom**

Welcome –

Guidance Development

FDA MDUFA Performance — Actions through December 31, 2021

- Report on decision goals for 1st Quarter FY 2022

Registration and Listing

Qualitative Update on Finances – 1st Quarter FY 2022

- User fee receipts through the 1st Quarter FY 2022

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Medical Devices

Guidance Documents

Pursuant to the MDUFA IV Commitment Letter,¹ the table below includes all FDA guidance documents issued in the specified quarter related to the devices program. Pursuant to section 738A(a)(1)(A)(iii) of the FD&C Act, guidance documents that are related to the process for the review of devices and whether they are required by statute or are being issued pursuant to the MDUFA IV Commitment Letter are indicated as such.² The table also indicates whether a guidance document is on the Center for Devices and Radiological Health's annual agenda of guidance documents (known as the A/B List).³

Table 1: Draft and Final Guidance Documents Related to the Devices Program for FY 2022

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
1	Q1	⁴ User Fees and Refunds for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/user-fees-and-refunds-de-novo-classification-requests	10/5/2021	Yes	No	N/A	No
2	Q1	⁴ De Novo Classification Process (Evaluation of Automatic Class III Designation) http://www.fda.gov/regulatory-information/search-fda-guidance-documents/de-novo-classification-process-evaluation-automatic-class-iii-designation	10/5/2021	Yes	No	N/A	No
3	Q1	⁴ FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals	10/5/2021	Yes	No	N/A	No
4	Q1	⁴ Acceptance Review for De Novo Classification Requests www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests	10/5/2021	Yes	No	N/A	No
5	Q1	Surgical Staplers and Staples for Internal Use - Labeling Recommendations www.fda.gov/regulatory-information/search-fda-guidance-	10/8/2021	Yes	No	N/A	A-List

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

² CDRH provides the annotation of "yes" for guidances that are substantially related to the process. CDRH provides the annotation of "no" for guidances that contain a minimal amount of guidance related to the process.

³ www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2022-fy2022.

⁴ This is a Level 2 guidance document as defined in 21 CFR 10.115(c)(2).

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
		documents/surgical-staplers-and-staples-internal-use-labeling-recommendations					
6	Q1	Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-unique-device-identification-policy-regarding-global-unique-device-identification	10/14/21	No	No	N/A	A-List
7	Q1	Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products	10/20/21	No	Yes	Section 709(c) of the FDA Reauthorization Act	No
8	Q1	Content of Premarket Submissions for Device Software Functions www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions	11/4/21	Yes	Yes	MDUFA IV Commitment Letter Section IV.I.3.c.	A-List
9	Q1	⁵ Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised	11/15/21	No	No	N/A	No
10	Q1	⁵ Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-viral-transport-media-during-coronavirus-disease-2019-covid-19-public-health	11/15/21	Yes	No	N/A	No
11	Q1	Referencing the Definition of “Device” in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents www.fda.gov/regulatory-information/search-fda-guidance-documents/referencing-definition-device-federal-food-drug-and-cosmetic-act-guidance-regulatory-documents	12/16/21	No	No	N/A	No
12	Q1	Digital Health Technologies for Remote Data Acquisition in Clinical Investigations	12/23/21	Yes	No	N/A	No

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

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
		www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations					
13	Q1	Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-fall-within-enforcement-policies-issued-during-coronavirus-disease	12/23/21	Yes	No	N/A	A-List
14	Q1	Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency www.fda.gov/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-during-coronavirus-disease	12/23/21	Yes	No	N/A	A-List
15	Q1	Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-medical-devices-physiologic-closed-loop-control-technology	12/23/21	Yes	No	N/A	No
16	Q1	Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions	12/23/21	Yes	No	N/A	No
17	Q1	Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use - Premarket Notification (510(k)) Submissions www.fda.gov/regulatory-information/search-fda-guidance-documents/arthroscopy-pump-tubing-sets-intended-multiple-patient-use-premarket-notification-510k-submissions	12/23/21	Yes	No	N/A	No
18	Q1	Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers www.fda.gov/regulatory-information/search-fda-guidance-documents/pathology-peer-review-nonclinical-toxicology-studies-questions-and-answers	12/27/21	Yes	No	N/A	No

#	Quarter Issued	Title & Website Link	Date Issued	Related to the Process for the Review of Devices	Required by Statute or Commitment Letter	Statutory or Commitment Letter Citation (if applicable)	A/B List
19	Q1	Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) www.fda.gov/regulatory-information/search-fda-guidance-documents/non-clinical-and-clinical-investigation-devices-used-treatment-benign-prostatic-hyperplasia-bph	12/27/21	Yes	No	N/A	No

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CDRH Performance Data ----
Actions through 31 December 2021**

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Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Amendments
IDE	Investigational Device Exemption
IVD	In Vitro Diagnostic
LDT	Laboratory Developed Test
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

Office Organizations

OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device

OHT2: Office of Cardiovascular Devices

OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics and Radiological Health

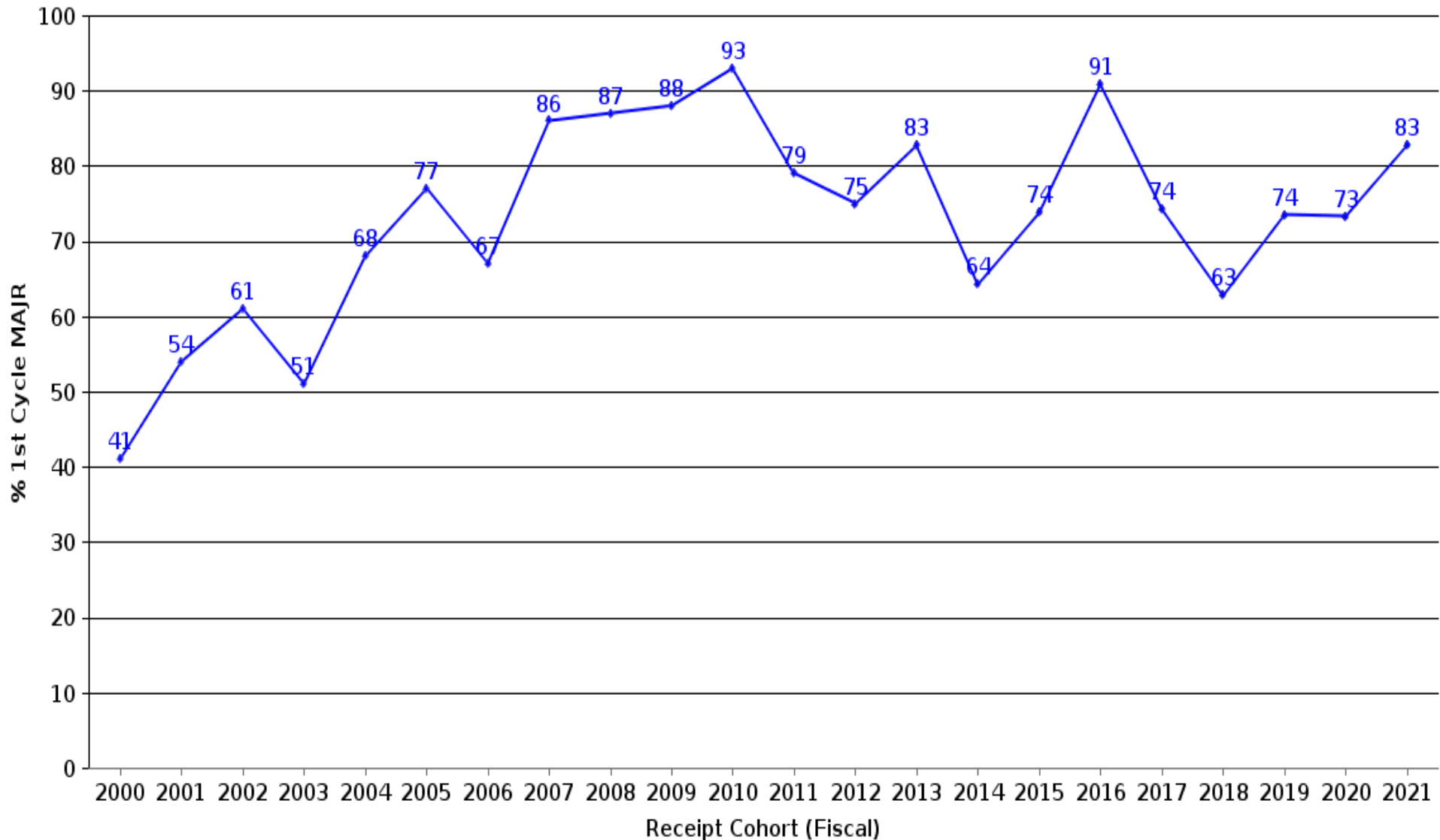
Note: Data may change in subsequent quarterly and annual reports.

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PMA's

Q1FY2022

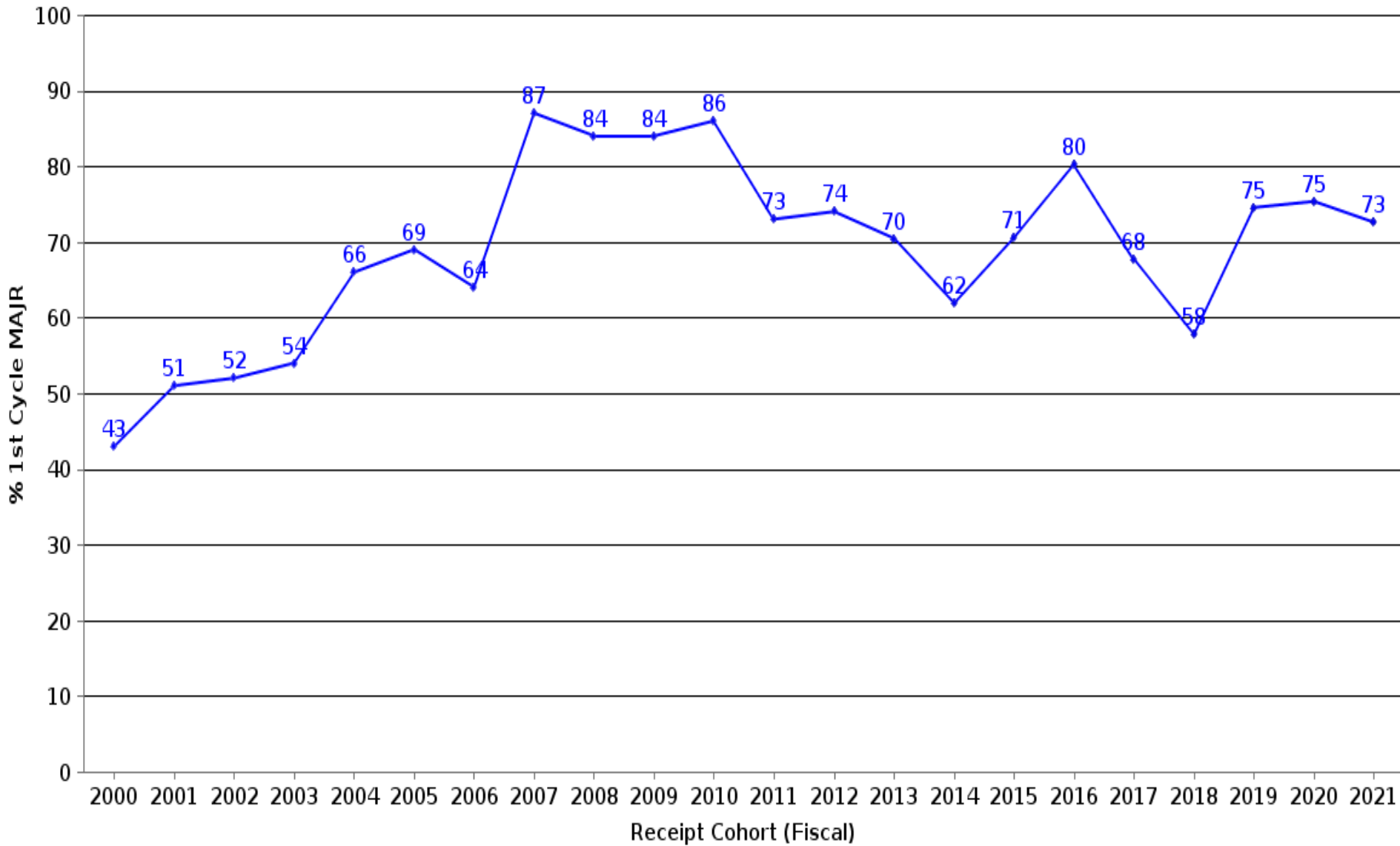
PMA Originals Filed As Of 9/30/21: 1st Cycle Major Deficiency Rate as of 12/31/21



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 9/30/21.

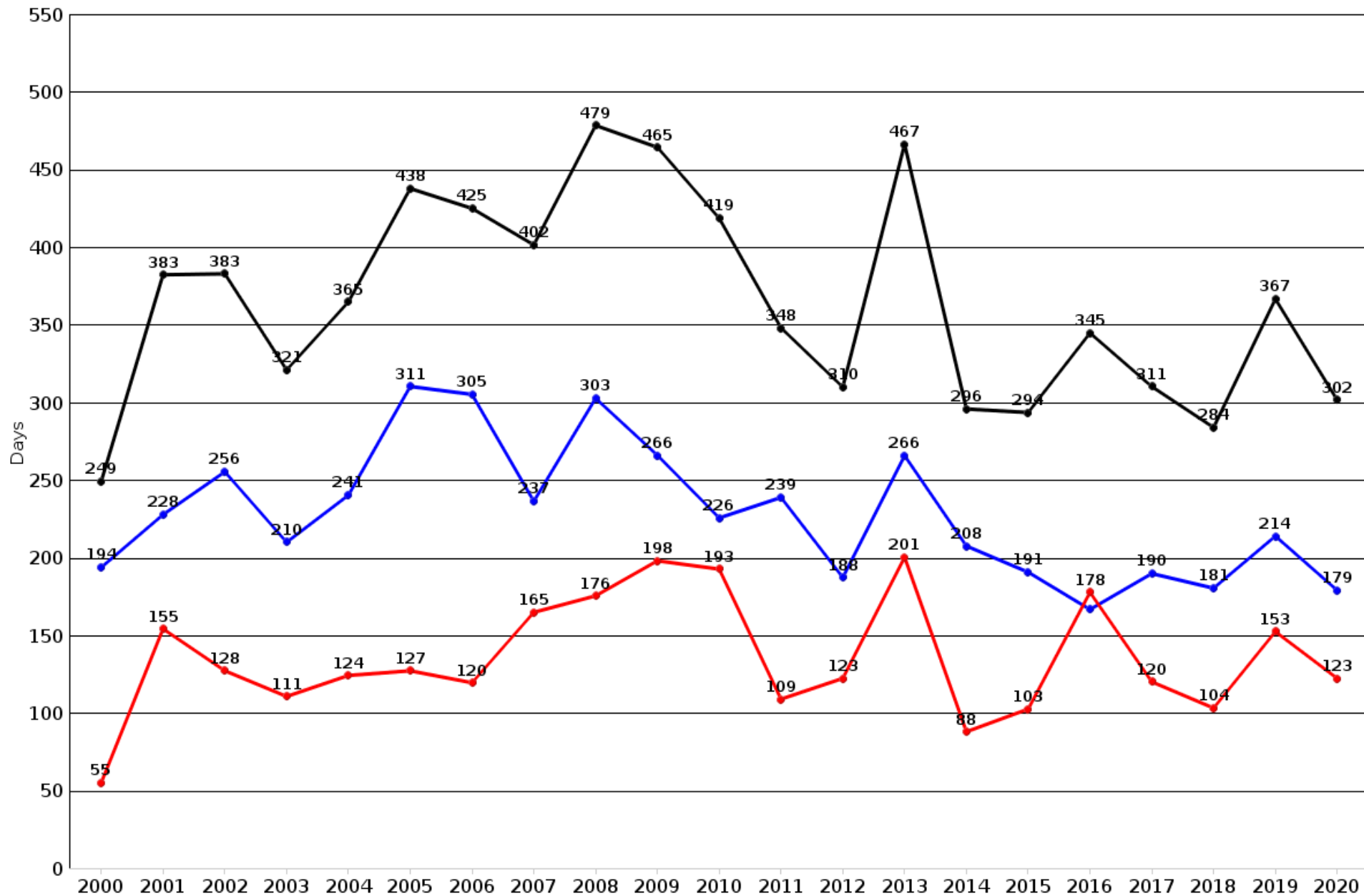
Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

PMA Originals and Panel Track Supplements Filed As Of 9/30/21: 1st Cycle Major Deficiency Rate as of 12/31/21



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 9/30/21. Note: For the current FY, a Proceed Interactively decision is considered a completed 1st cycle.

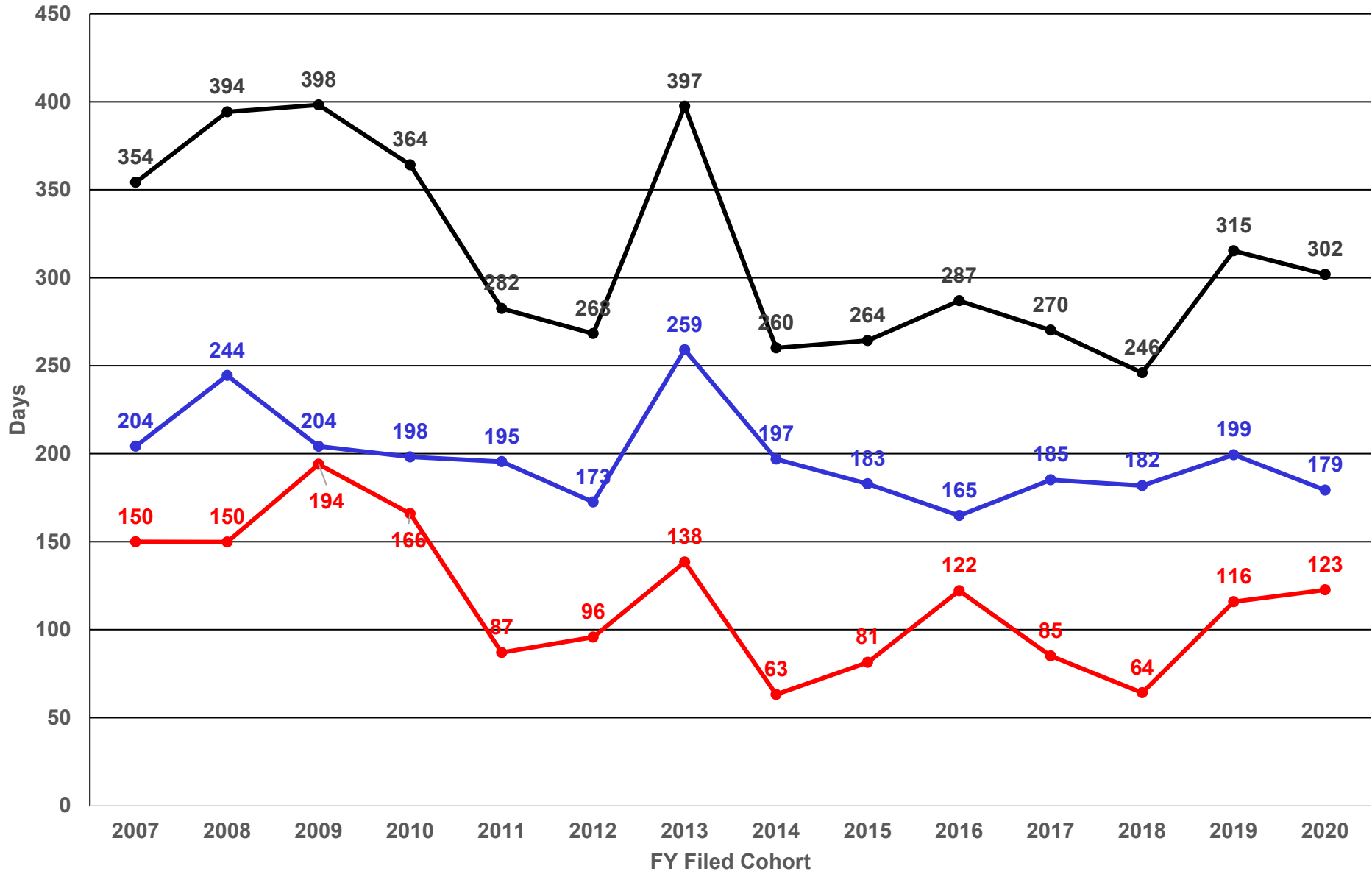
PMA Originals Filed As Of 12/31/2021: Average Time to MDUFA Decision



Cohorts not yet closed: 2020: 86.67%

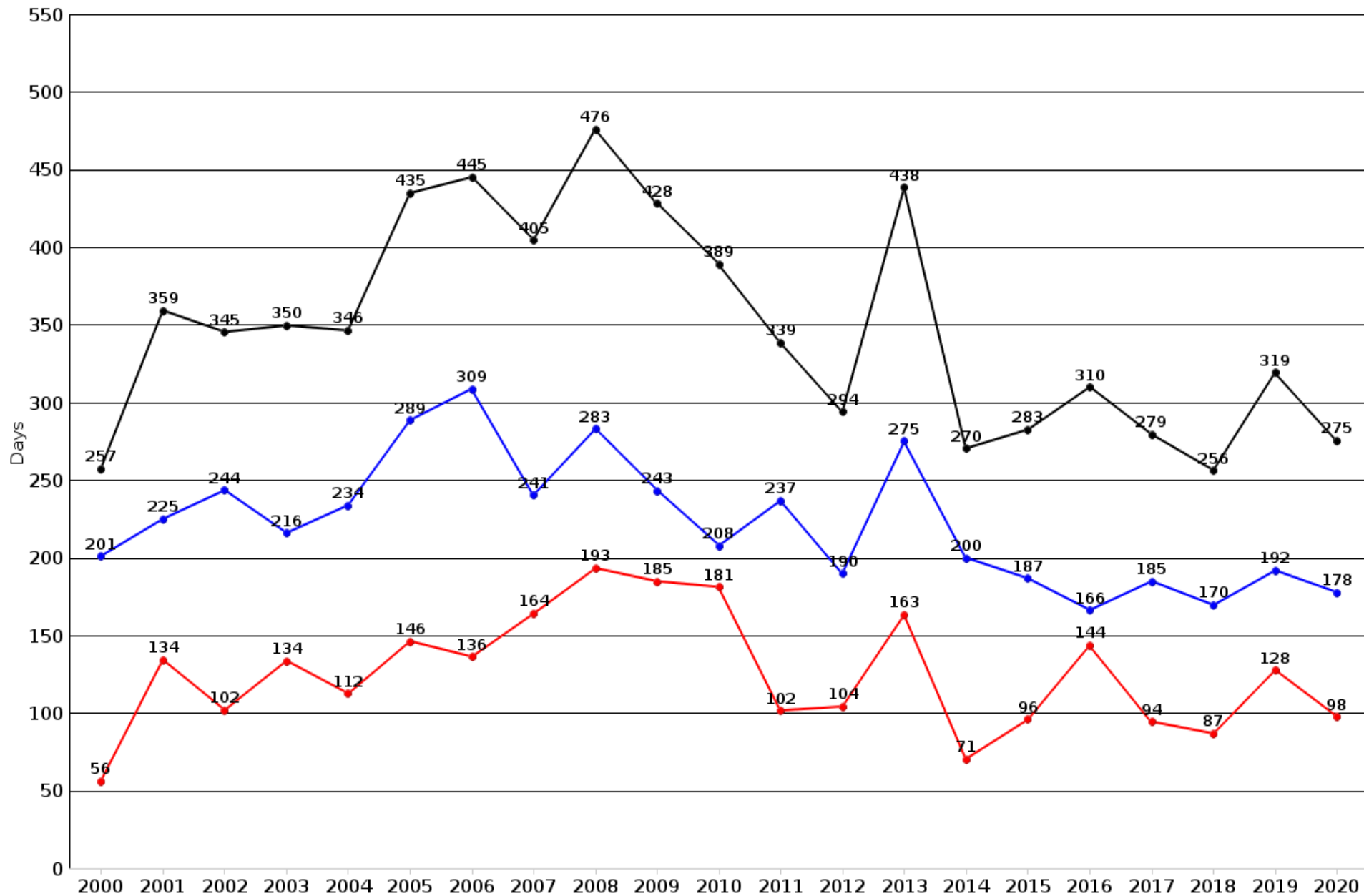
● Avg FDA Days to MDUFA PMAO ● Avg MFR Days to MDUFA PMAO ● Avg Total Days to MDUFA PMAO

PMA Originals Filed as of 12/31/2021: Average Time to MDUFA Decision Comparison of Cohorts at 86.7% Closure



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

PMA Originals and Panel Track Supplements Filed As Of 12/31/2021: Average Time to MDUFA Decision

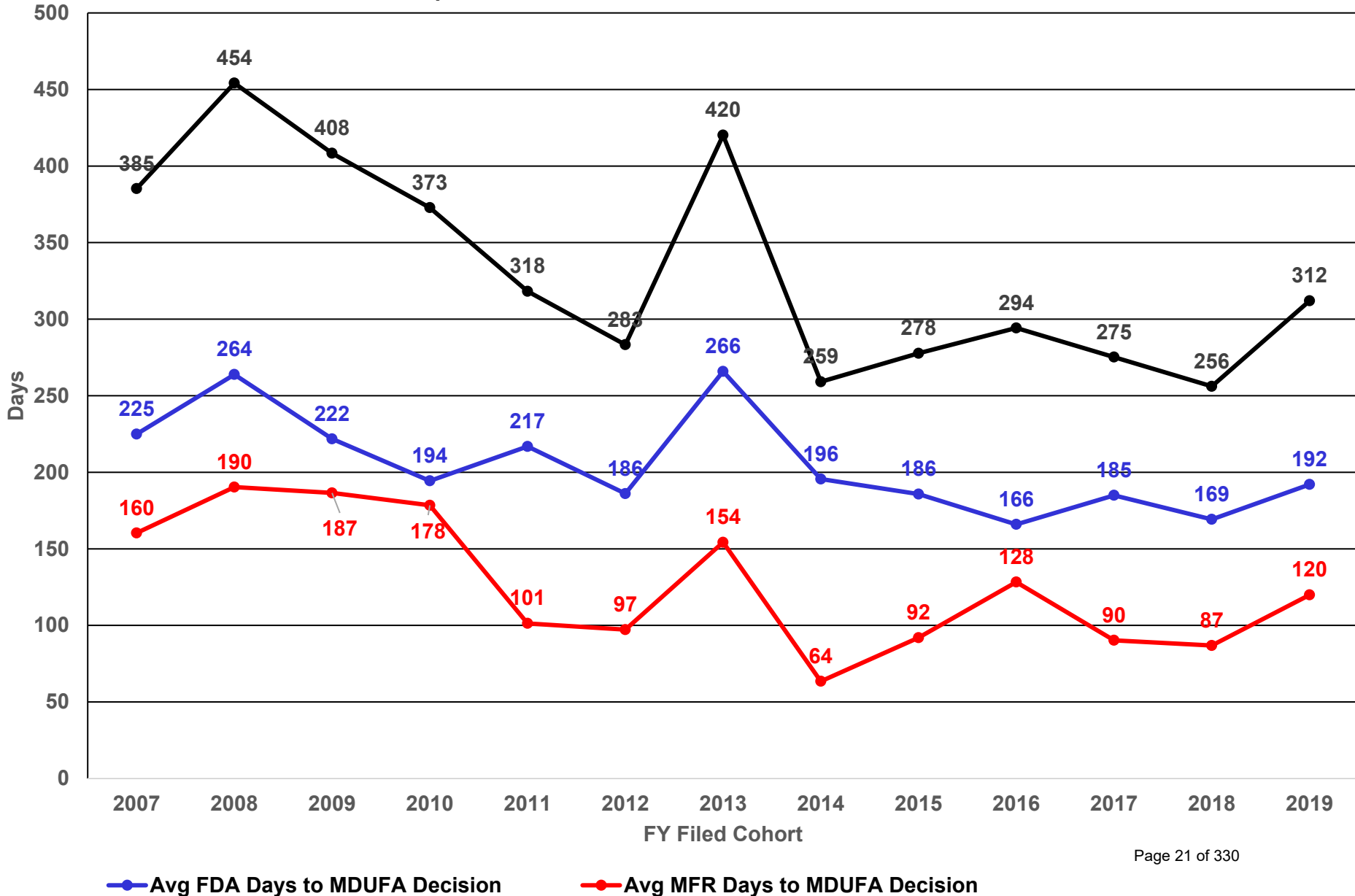


Cohorts not yet closed: 2018: 98.59%; 2020: 90.41%

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

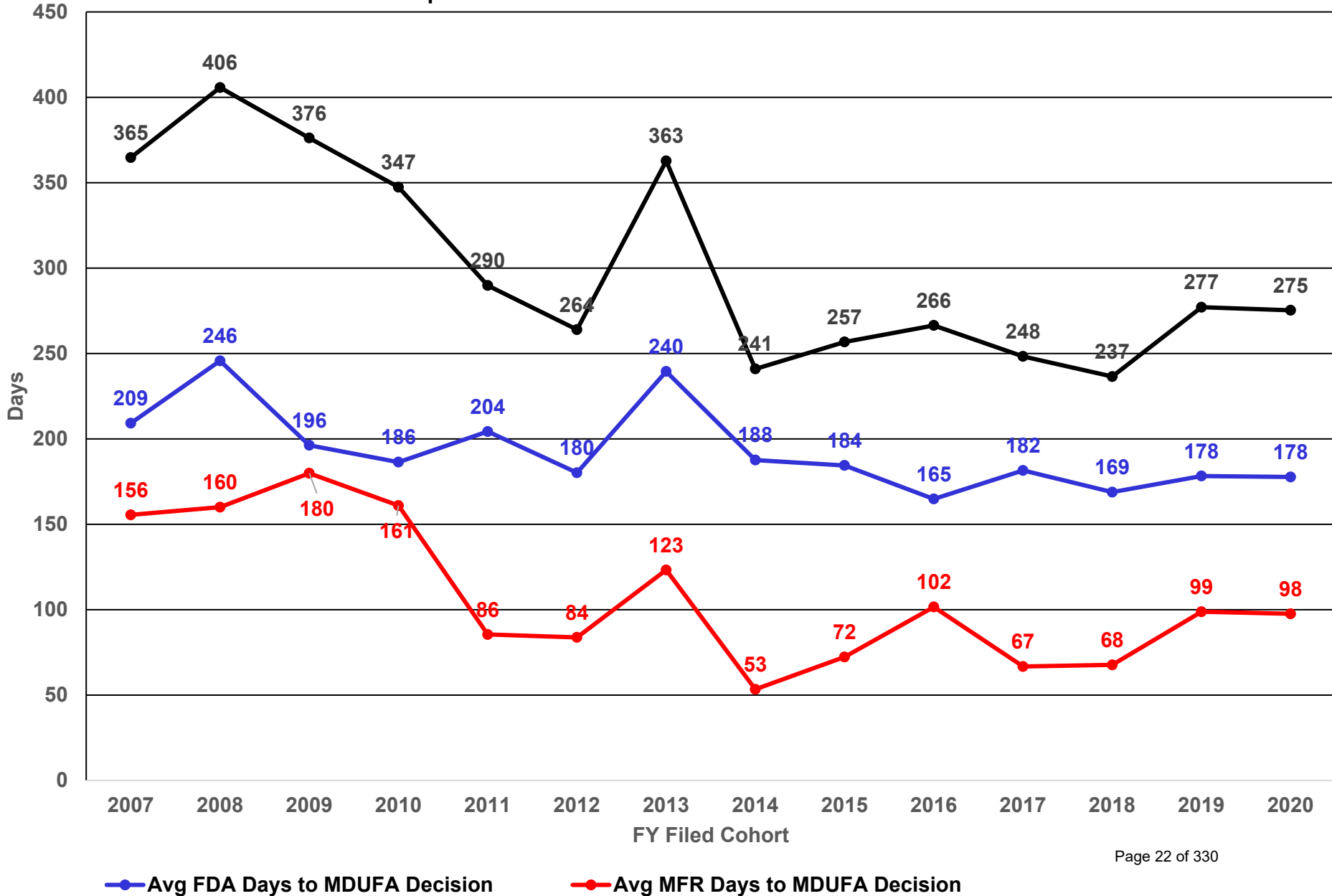
PMA Originals and Panel Track Supplements Filed as of 12/31/2021: Average Time to MDUFA Decision

Comparison of Cohorts at 98.6% Closure

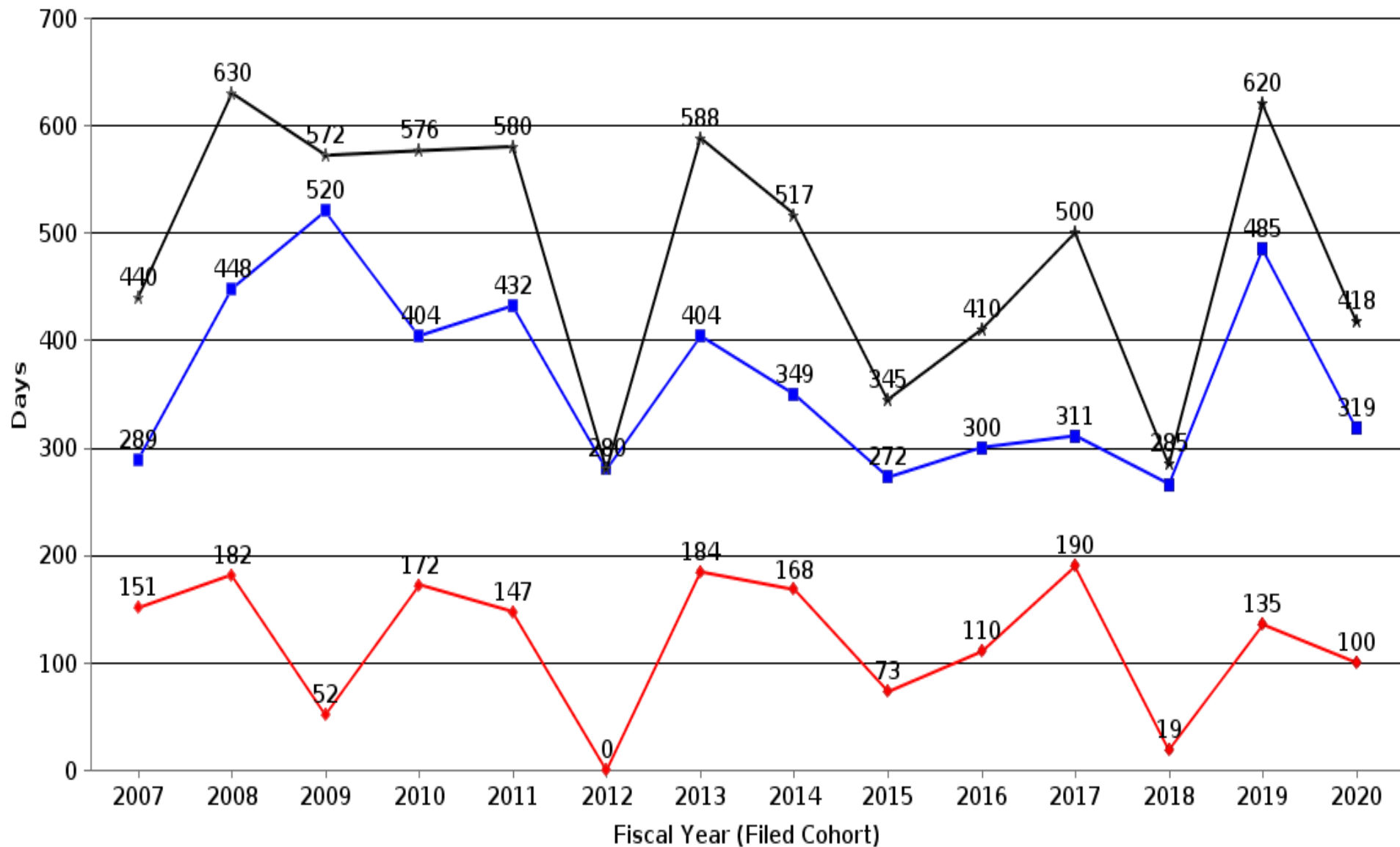


PMA Originals and Panel Track Supplements Filed as of 12/31/2021: Average Time to MDUFA Decision

Comparison of Cohorts at 90.4% Closure



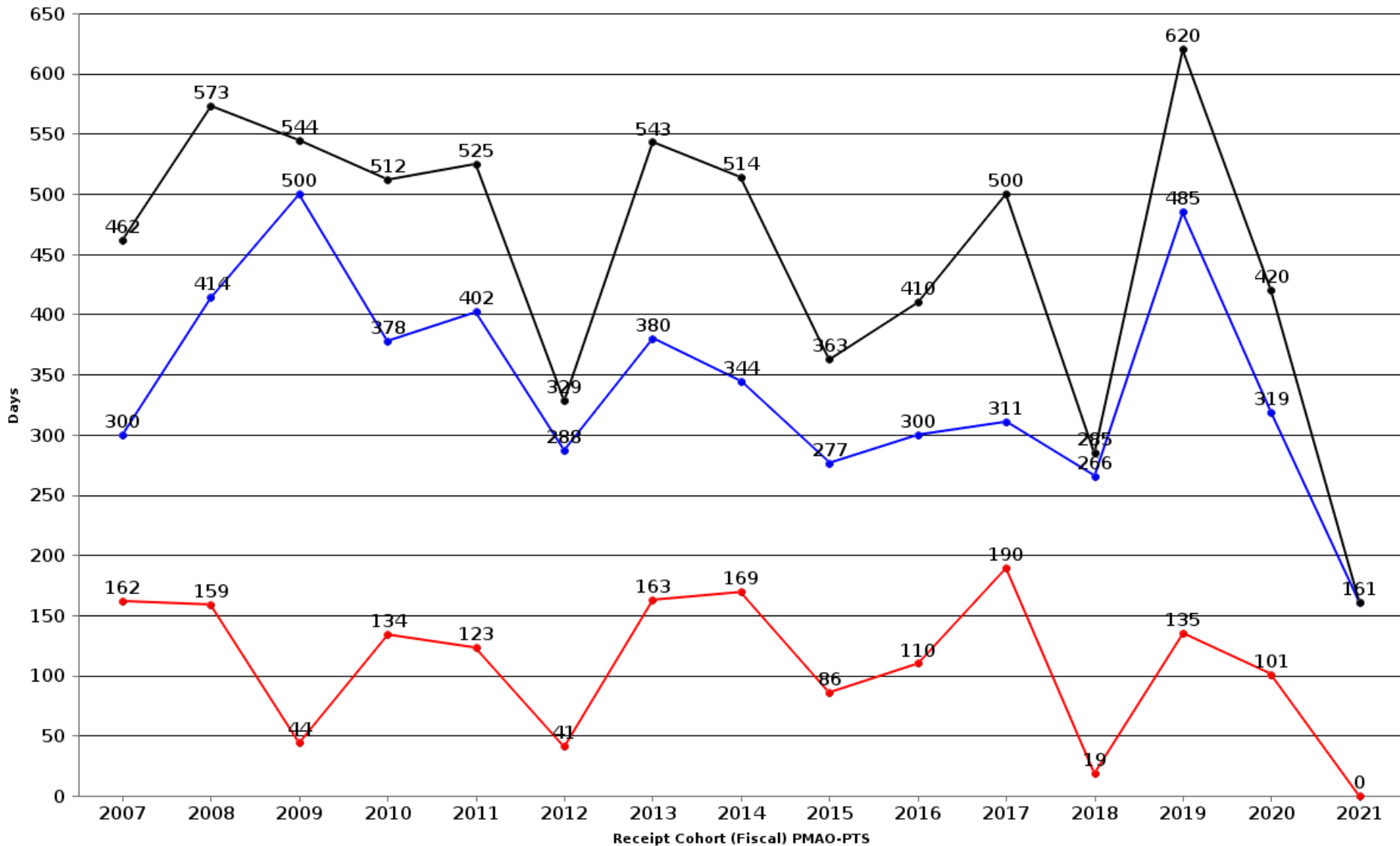
PMA Originals With Panel Review: Average Time to MDUFA Decision for Submissions Filed As Of: 2021/12/31



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

■ 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: 2021/12/31

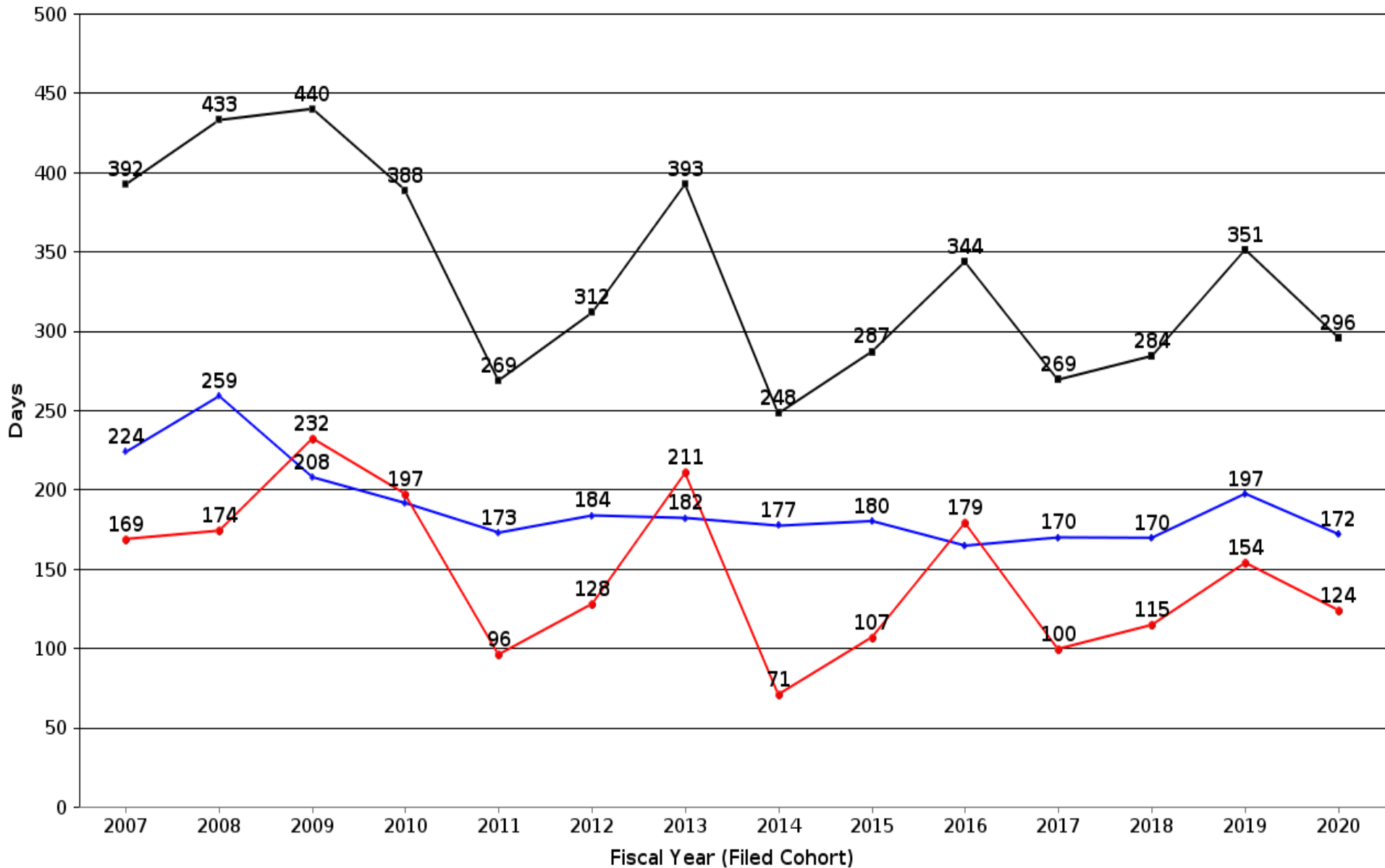


Numbers Filed/Closed: 2007 = 8/8; 2008 = 8/8; 2009 = 7/7; 2010 = 9/9; 2011 = 14/14; +2012 = 2/2; 2013 = 17/17; + 2014 = 6/6; 2015 = 6/6; 2016 = 1/1; 2017 = 5/5; 2018 = 5/5; 2019 = 2/2; 2020 = 4/3; 2021 = 2/1

● 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.

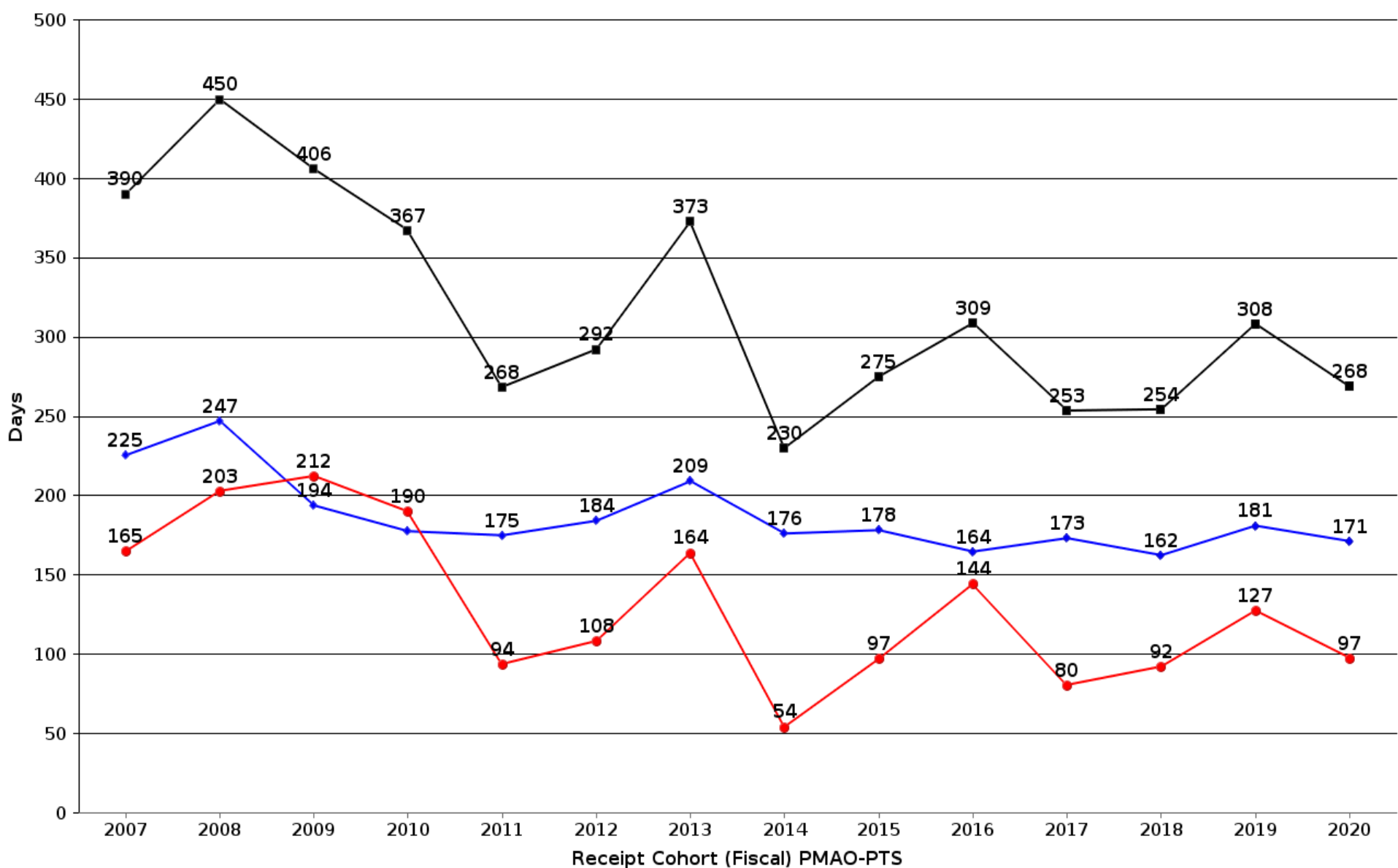
PMA Originals: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2021/12/31



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

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

PMA Originals and Panel Track Supplements: Average Time to MDUFA Decision for Submissions Without Panel Review Filed as of 2021/12/31

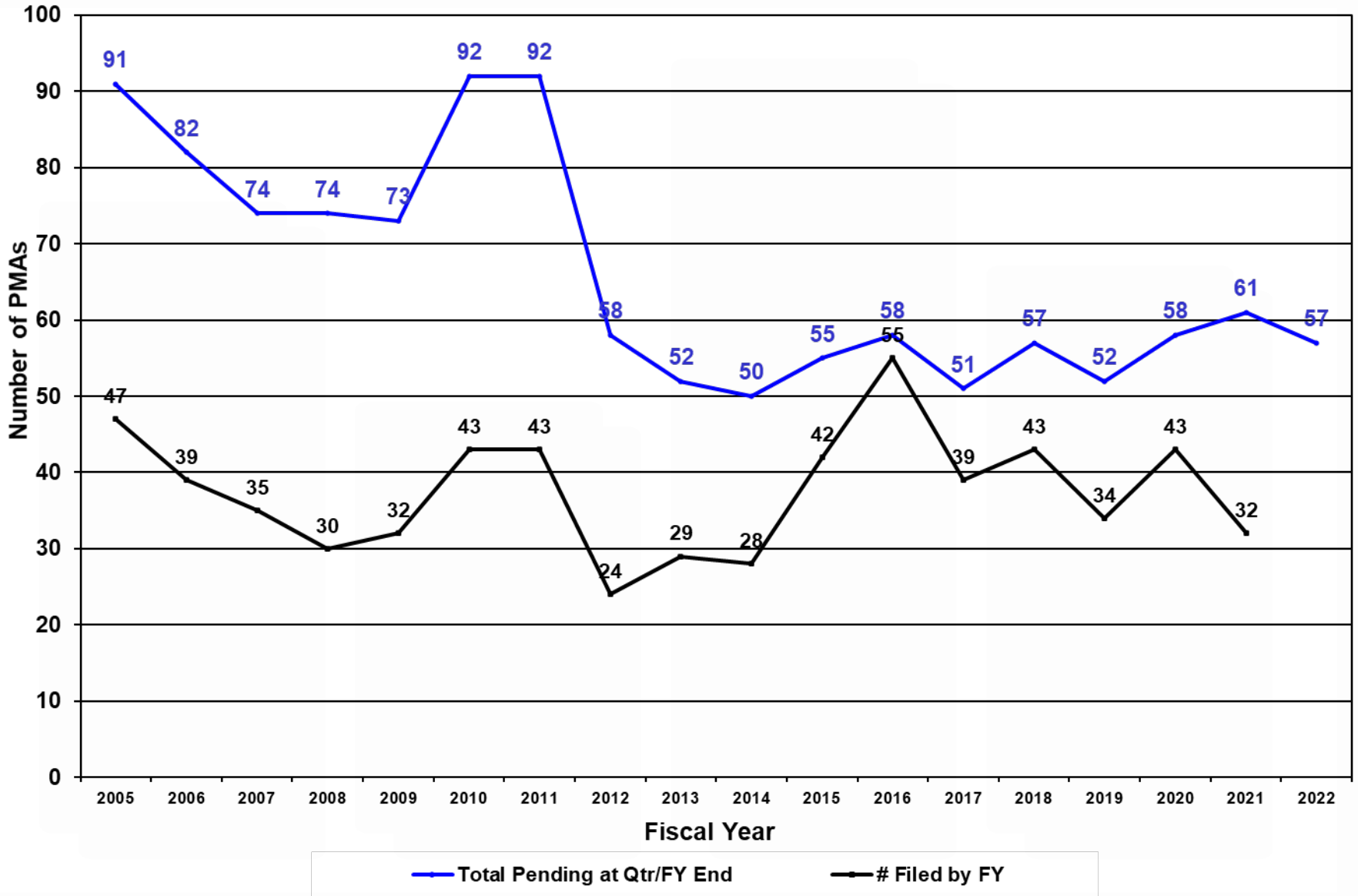


Numbers Filed/Closed: 2007 = 31/31; 2008 = 29/29; 2009 = 36/36; 2010 = 50/50; 2011 = 37/37; 2012 = 32/32; 2013 = 27/27; 2014 = 36/36; 2015 = 62/62; 2016 = 70/70; 2017 = 60/60; 2018 = 66/65; 2019 = 53/53; 2020 = 69/63

◆ Avg FDA Days to MDUFA Decision PMAO-PTS ● Avg MFR Days to MDUFA Decision PMAO-PTS ■ Avg Total Days to MDUFA Decision PMAO-PTS
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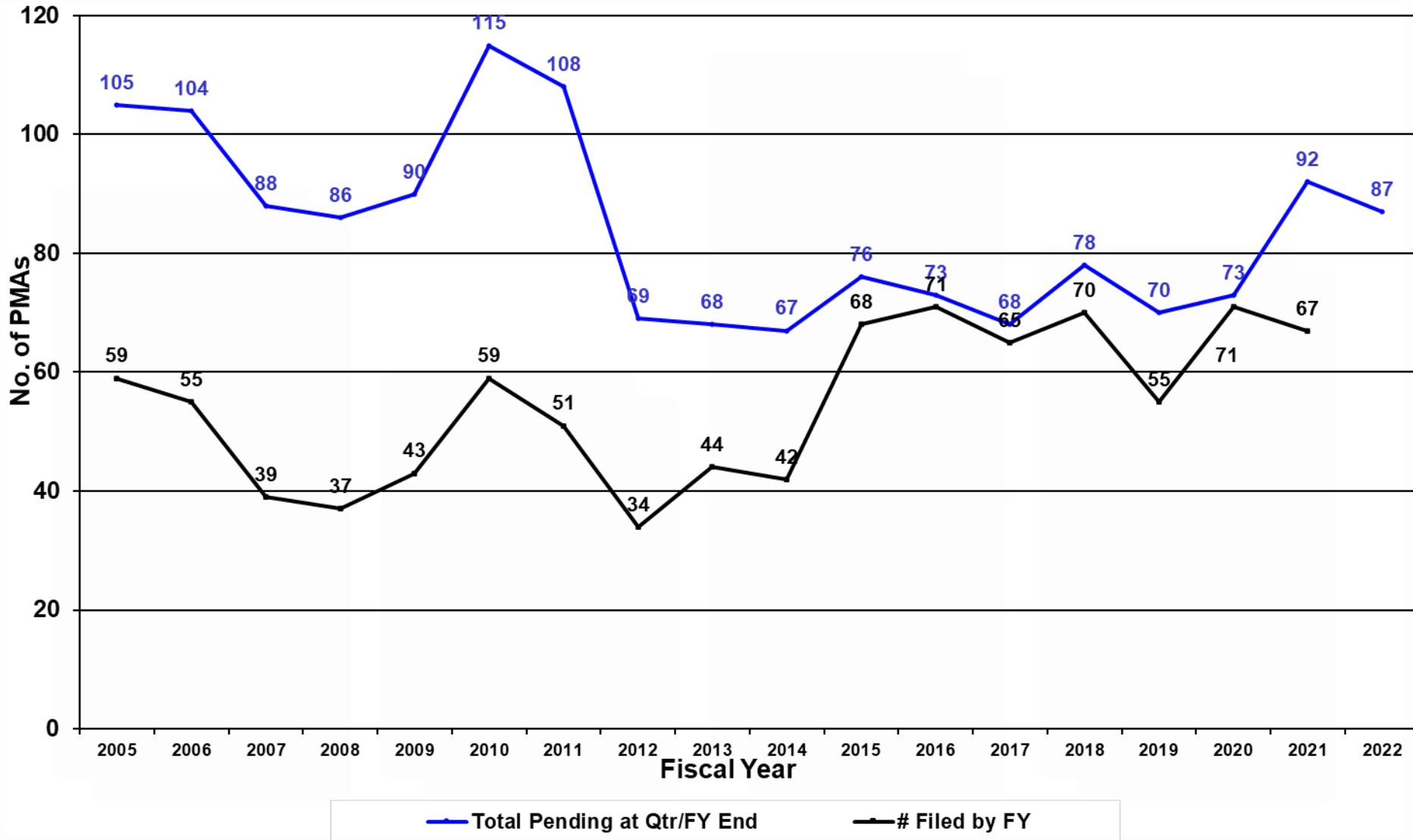
Performance data from FY13 onward map to Table 1.7. Numbers filed map to table 1.5.

PMA Originals Pending* at End of Quarter/Year



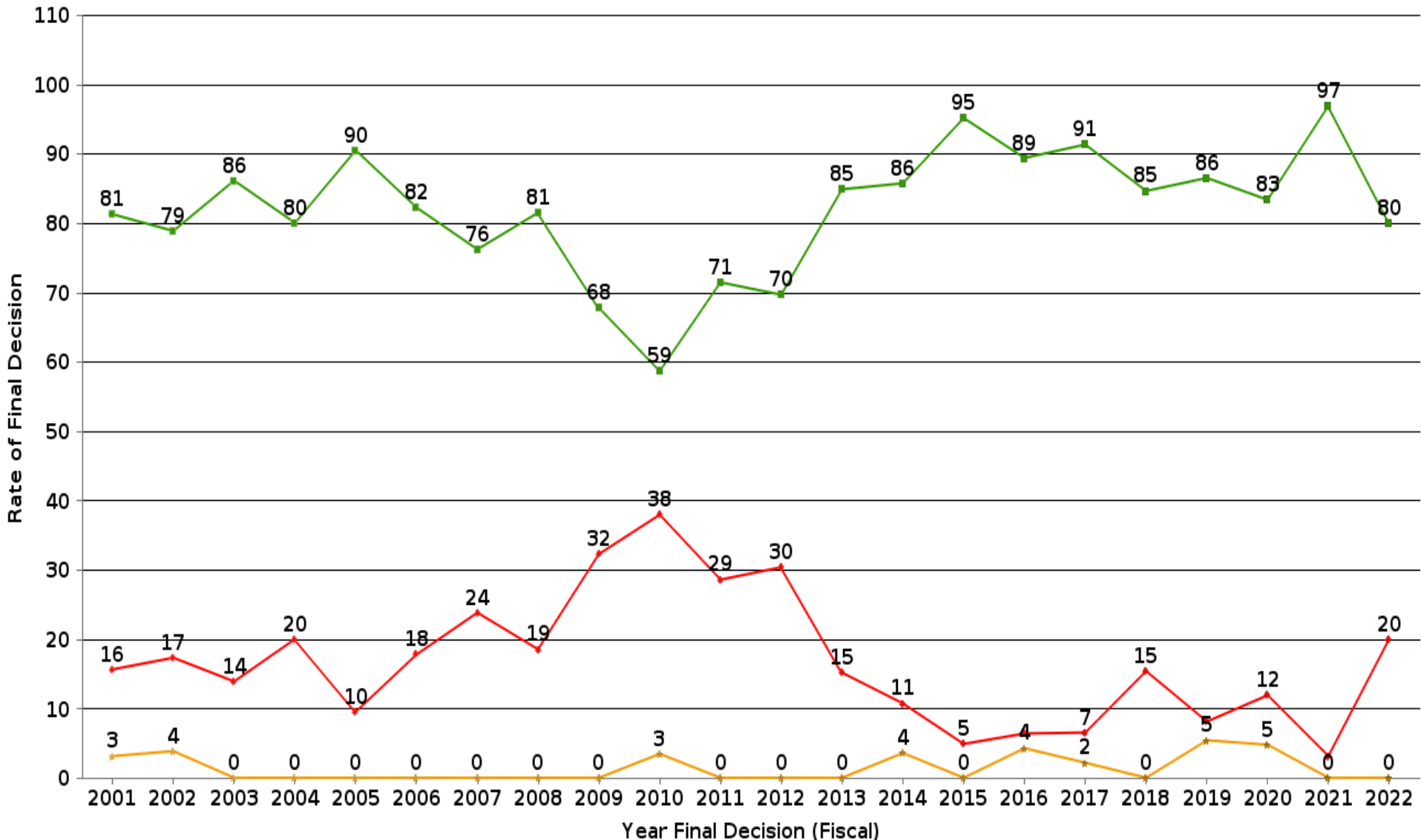
*Original PMAs awaiting filing, MDUFA or final decision under review or on hold. Numbers filed and pending from FY13 onward include only receipts that were accepted for review as of end of quarter/year. For the current FY, numbers filed are updated starting in Q2.

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



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

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

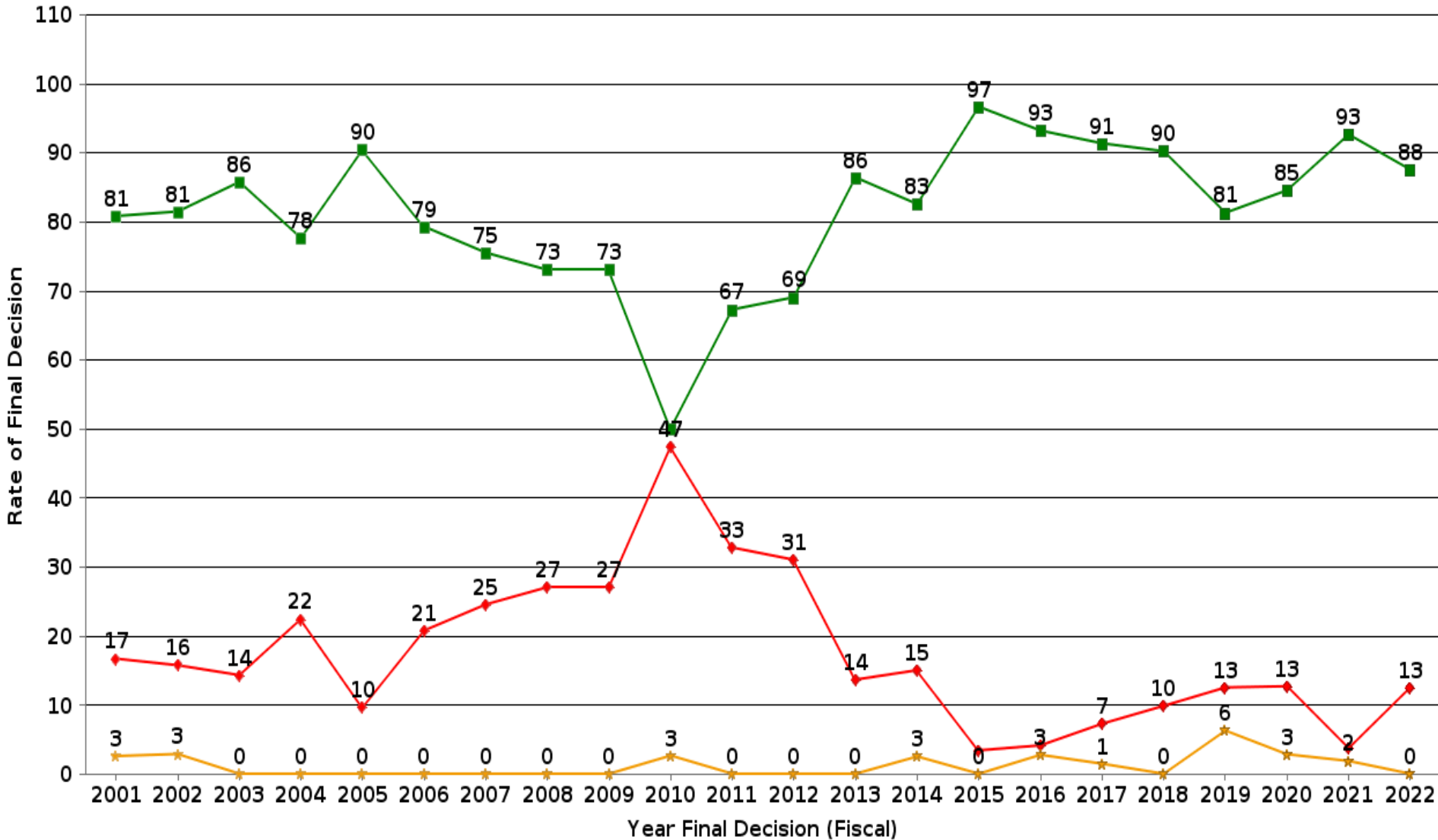


Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

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

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

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

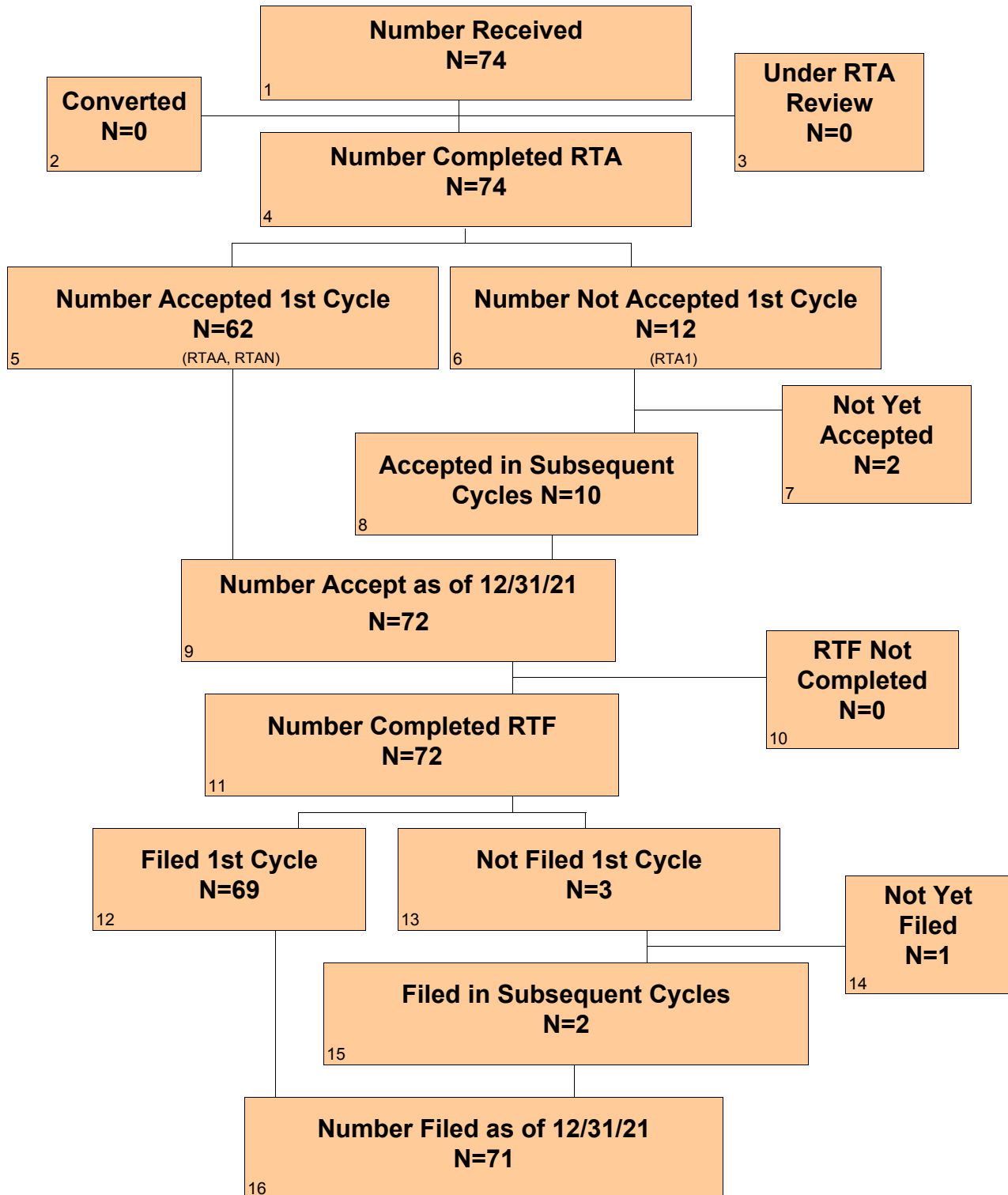


Current FY data represents a partial year in 1st, 2nd and 3rd quarter reporting.

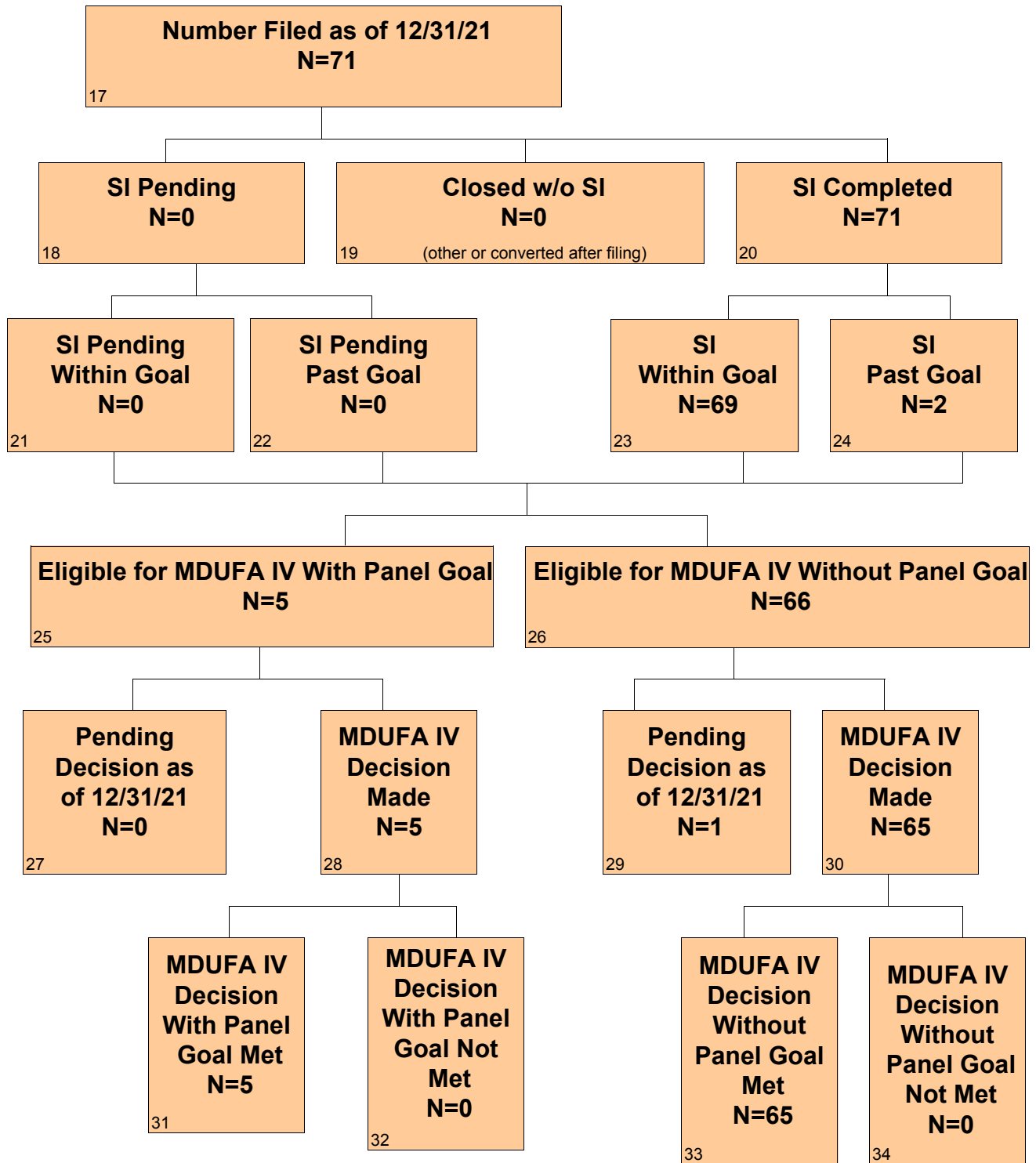
■ % Approved PMAO-PTS ♦ % WTDR PMAO-PTS ★ % All Other PMAO-PTS

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

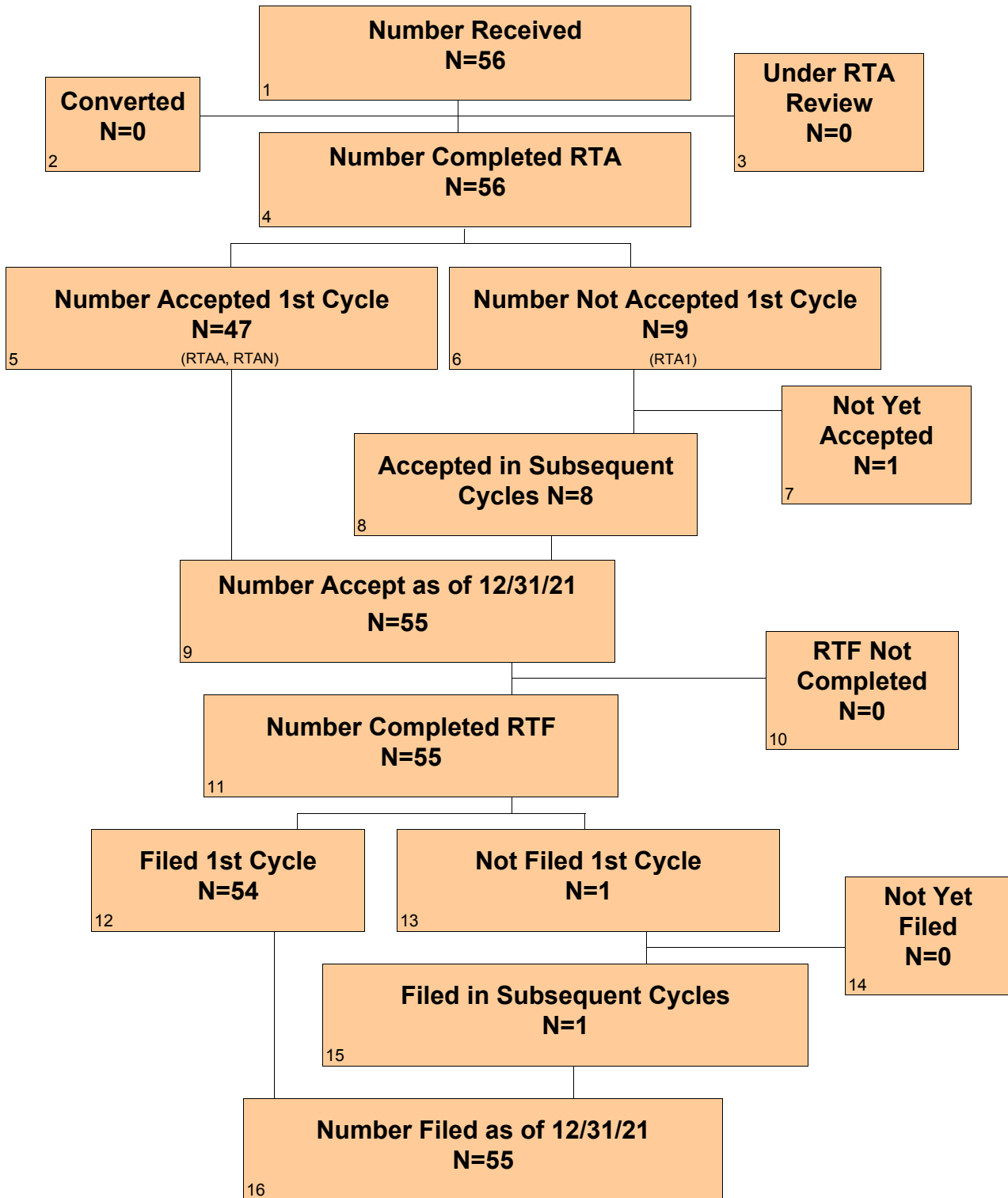
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 12/31/21



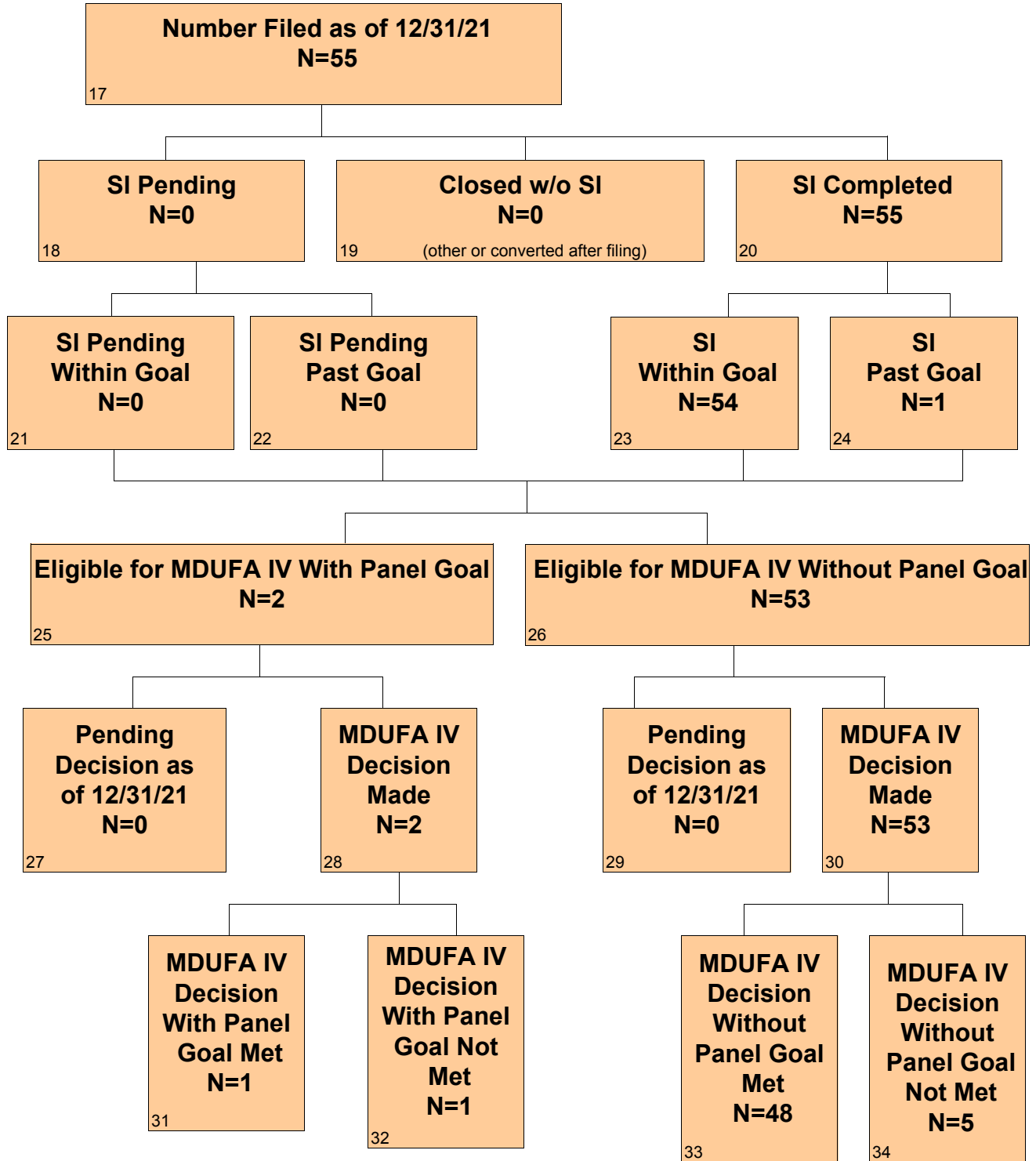
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 12/31/21 Continued



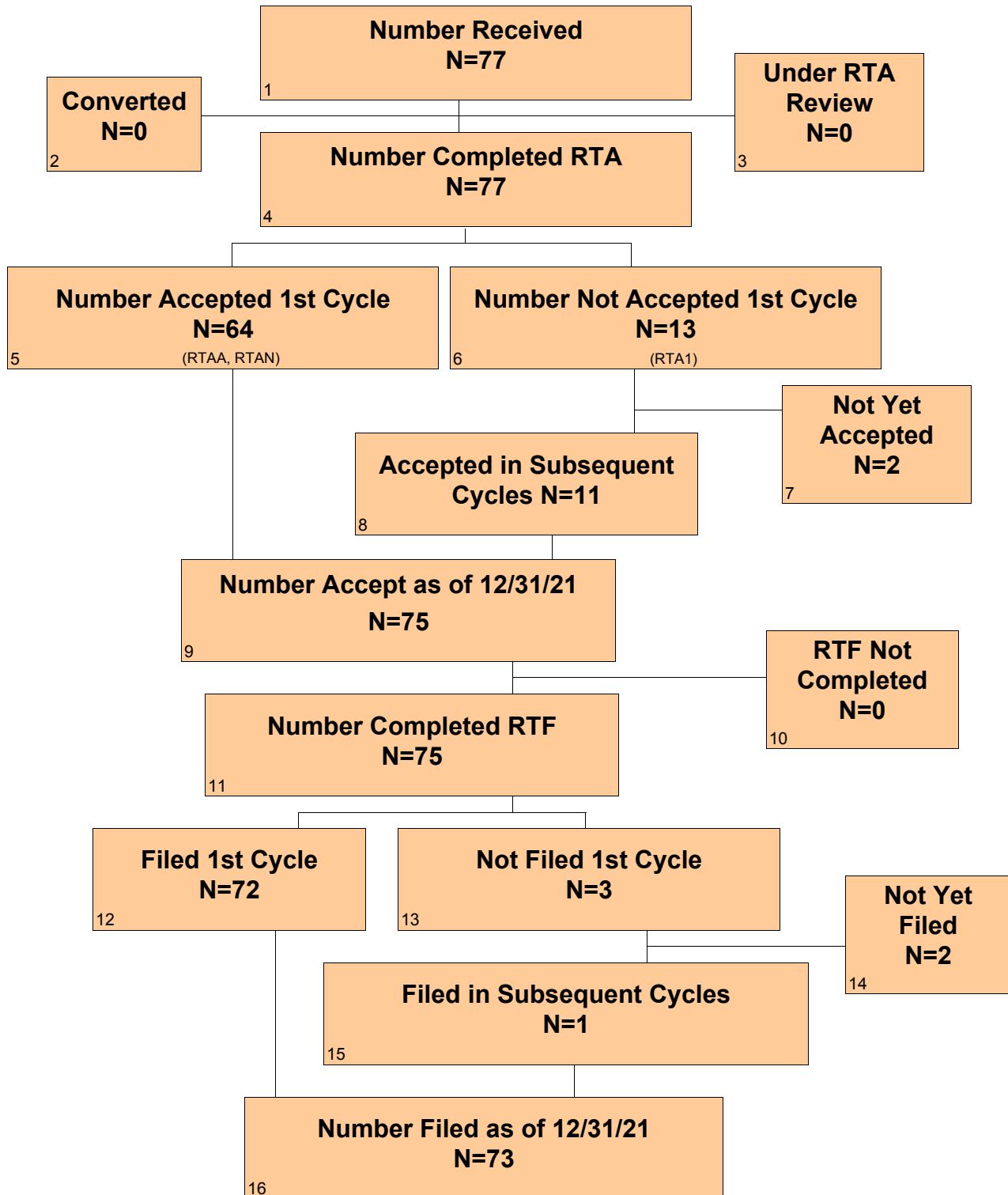
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 12/31/21



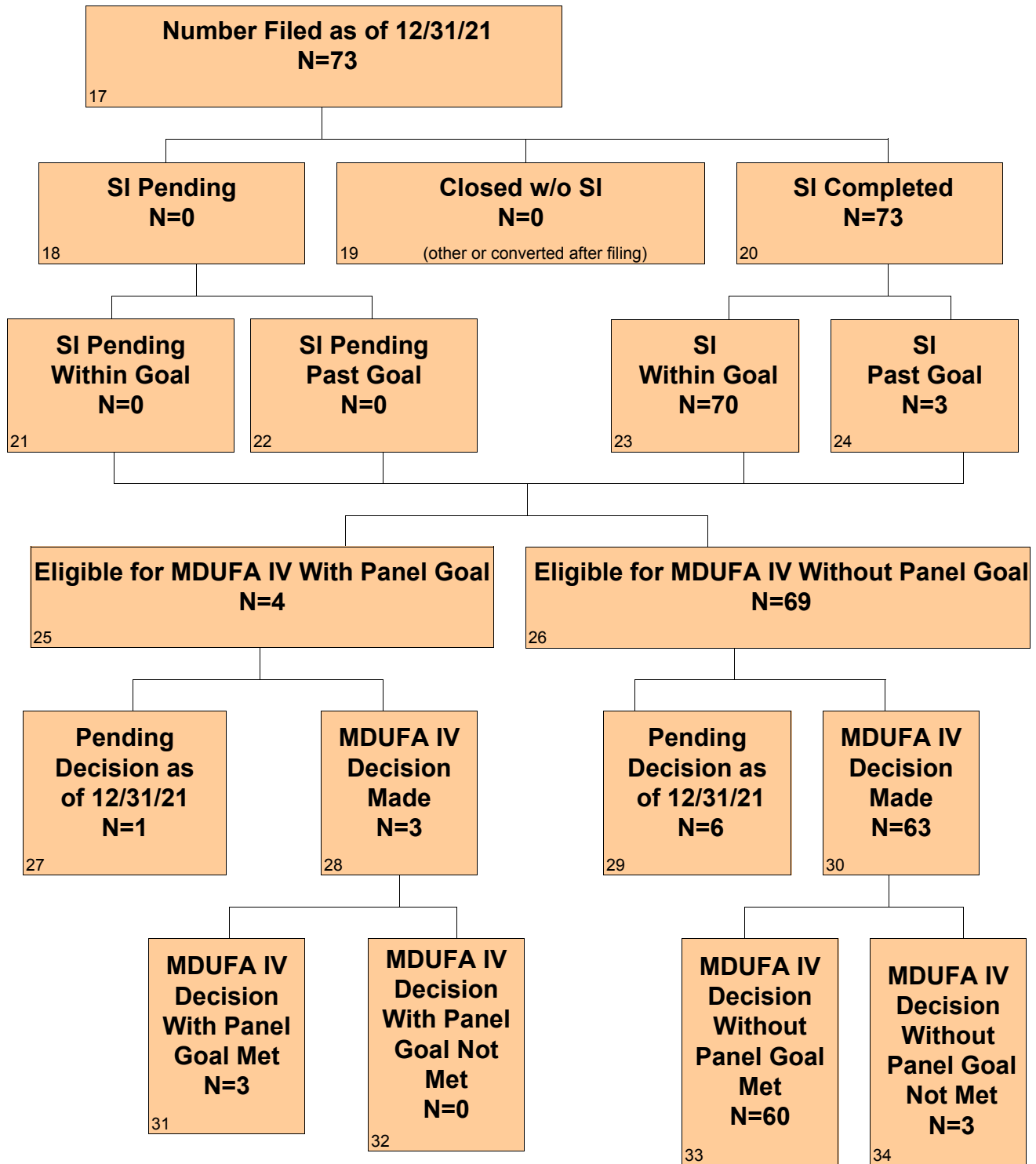
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 12/31/21 Continued



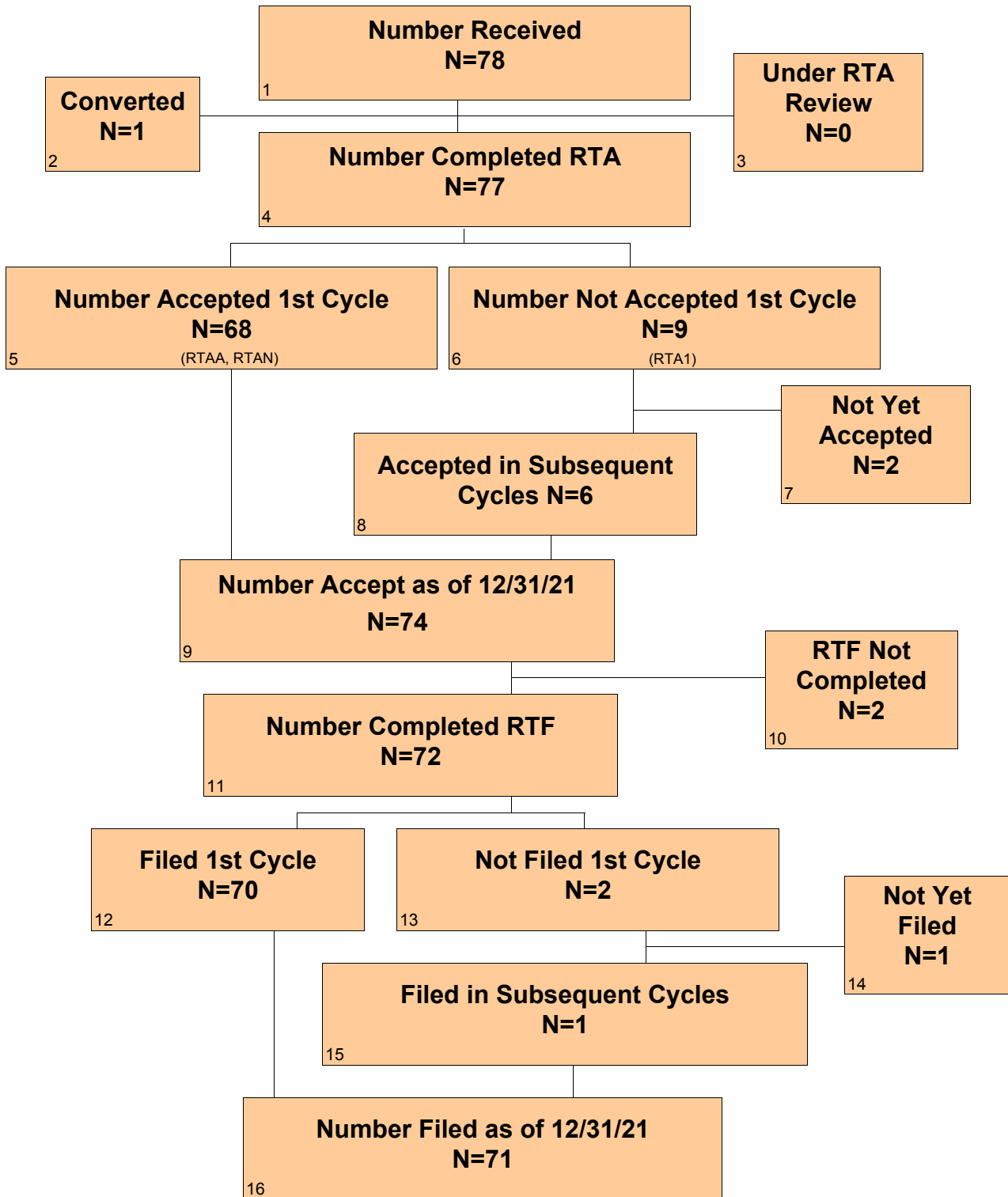
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 12/31/21



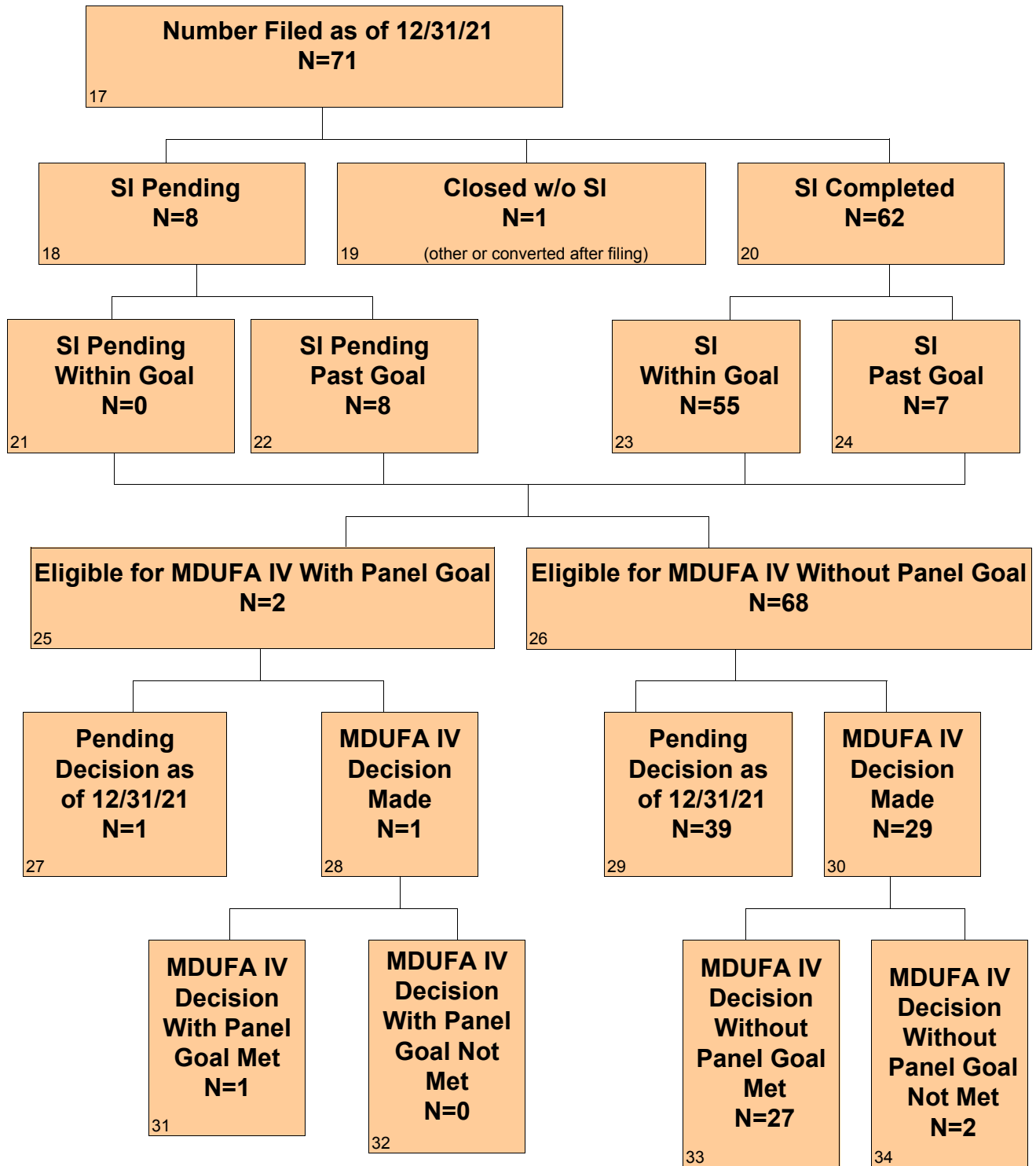
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 12/31/21 Continued



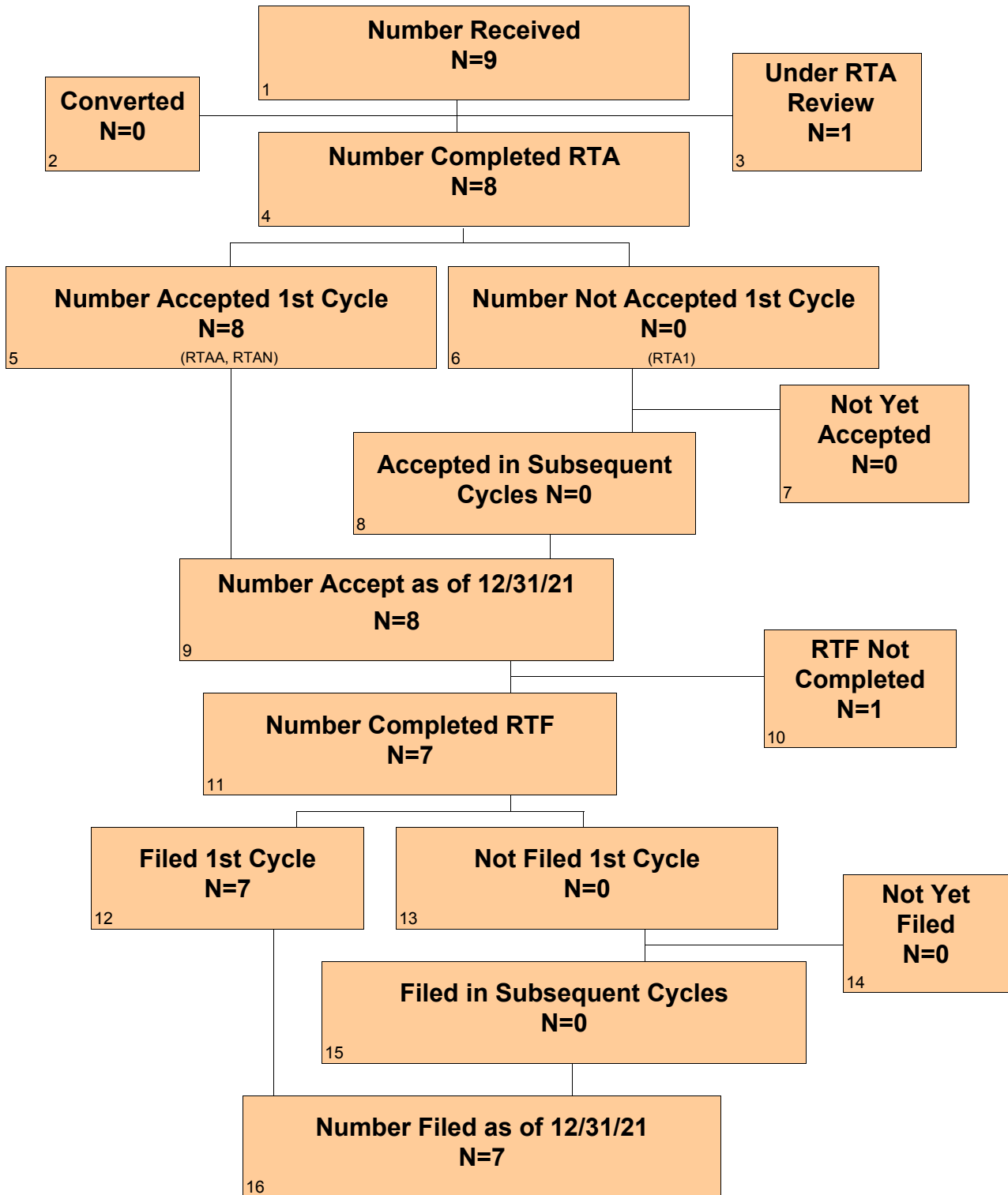
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 12/31/21



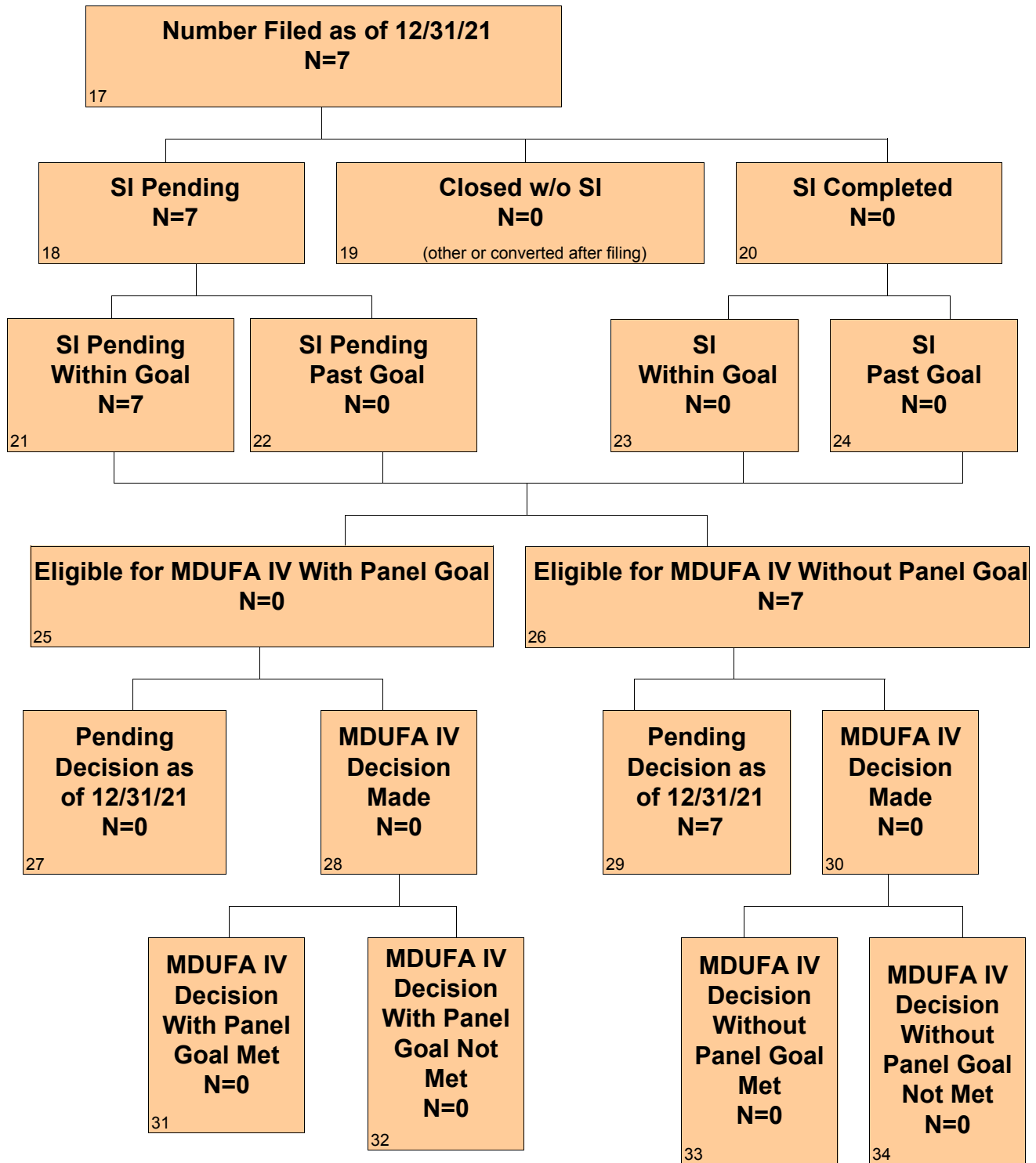
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 12/31/21 Continued



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 12/31/21



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 12/31/21 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	9
Closed Before RTA Action	0	0	0	1	0
Number with Accepted RTA Review	62	46	63	59	8
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	0
Rate of Submissions Not Accepted for Filing Review	16.22%	16.07%	16.88%	11.69%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	74	56	77	78	9
Number Accepted	62	47	64	68	8
Completed RTF	72	55	75	72	7
Number Not Filed	3	1	3	2	0
Rate of Submissions Not Filed	4.17%	1.82%	4.00%	2.78%	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	71	7
SI Goal Met	69	54	70	55	0
SI Goal Not Met	2	1	3	7	0
SI Pending Within Goal	0	0	0	0	7
SI Pending Past Goal	0	0	0	8	0
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	97.18%	98.18%	95.89%	78.57%	N/A

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	62	0
Average Number of FDA Days to Substantive Interaction	87.03	89.95	91.74	96.65	0.00
20th Percentile FDA Days to Substantive Interaction	84	87	88	87	0
40th Percentile FDA Days to Substantive Interaction	88	88	88	88	0
60th Percentile FDA Days to Substantive Interaction	90	89	90	90	0
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	0
Maximum FDA Days to Substantive Interaction	178	246	325	250	0

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	69	7
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	65	53	63	29	0
MDUFA IV Decision Goal Met	65	48	60	27	0
PMAs Pending MDUFA IV Decision	1	0	6	39	7
PMAs Pending MDUFA IV Decision Past Goal	0	0	2	8	0
Current Performance Percent Goal Met	100.00%	90.57%	92.31%	72.97%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	5	2	4	2	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	5	2	3	1	0
MDUFA IV Decision Goal Met	5	1	3	1	0
PMAs Pending MDUFA IV Decision	0	0	1	1	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	50.00%	100.00%	100.00%	N/A

Table 1.7 CDRH - PMA Original and Panel-Track Supplements (Without Panel Review)					
Performance Metric - Time to MDUFA IV Decision					
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	65	53	63	29	0
Average FDA Days to MDUFA IV Decision	162.15	180.74	171.00	159.03	0.00
20th Percentile FDA Days to MDUFA IV Decision	144	147	175	126	0
40th Percentile FDA Days to MDUFA IV Decision	177	178	179	176	0
60th Percentile FDA Days to MDUFA IV Decision	178	180	180	178	0
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	0
Maximum FDA Days to MDUFA IV Decision	279	338	406	226	0
Average Industry Days to MDUFA IV Decision	93.18	127.28	97.44	44.17	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	18	31	32	23	0
60th Percentile Industry Days to MDUFA IV Decision	88	130	69	33	0
80th Percentile Industry Days to MDUFA IV Decision	162	192	168	77	0
Maximum Industry Days to MDUFA IV Decision	360	540	521	318	0
Average Total Days to MDUFA IV Decision	255.34	308.02	268.44	203.21	0.00
20th Percentile Total Days to MDUFA IV Decision	167	175	177	168	0
40th Percentile Total Days to MDUFA IV Decision	180	204	207	180	0
60th Percentile Total Days to MDUFA IV Decision	257	310	260	207	0
80th Percentile Total Days to MDUFA IV Decision	342	440	353	239	0
Maximum Total Days to MDUFA IV Decision	540	718	609	406	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	5	2	3	1	0
Average FDA Days to MDUFA IV Decision	265.80	485.00	319.00	161.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	193	299	318	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	319	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	101.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	104	79	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	125	96	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	145	110	0	0
80th Percentile Industry Days to MDUFA IV Decision	19	166	123	0	0
Maximum Industry Days to MDUFA IV Decision	95	187	136	0	0
Average Total Days to MDUFA IV Decision	284.80	620.00	420.00	161.00	0.00
20th Percentile Total Days to MDUFA IV Decision	256	403	398	161	0
40th Percentile Total Days to MDUFA IV Decision	297	548	415	161	0
60th Percentile Total Days to MDUFA IV Decision	316	692	430	161	0
80th Percentile Total Days to MDUFA IV Decision	320	837	443	161	0
Maximum Total Days to MDUFA IV Decision	322	982	455	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	69	7
Number with MDUFA IV Decision	65	53	63	29	0
Number of Withdrawal	6	3	4	1	0
Number of Not Approvable	8	7	5	1	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	9.23%	5.66%	6.35%	3.45%	N/A
Rate of Not Approvable	12.31%	13.21%	7.94%	3.45%	N/A

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

Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	5	2	4	2	0
Number With MDUFA IV Decision	5	2	3	1	0
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	4	1	1	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%	33.33%	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	10	0
Mean FDA Days for Submissions that Missed the Goal	0.00	266.60	232.60	279.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	235.00	112.40	31.30	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	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	11	2	0
MDUFA IV Decision Goal Met	1	4	11	2	0
PMAs Pending MDUFA IV Decision	0	0	0	3	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	1	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	66.67%	N/A

*Includes submission that went to panel

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	17	15	20	2
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	13	7	0
MDUFA IV Decision Goal Met	15	13	12	7	0
PMAs Pending MDUFA IV Decision	0	0	2	12	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	7	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	50.00%	N/A

*Includes submission that went to panel

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

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

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

**Table 1.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
PMA Original and Panel-Track Supplements - Filing Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	7	6	8	0
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	2	0
MDUFA IV Decision Goal Met	15	7	6	2	0
PMAs Pending MDUFA IV Decision	0	0	0	5	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	N/A

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	15	7	6	2	0
Average FDA Days to MDUFA IV Decision	177.33	179.14	180.00	179.00	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	179	0
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	179	0
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	0
Maximum FDA Days to MDUFA IV Decision	180	180	180	180	0
Average Industry Days to MDUFA IV Decision	130.93	65.43	160.17	59.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	4	68	40	0
40th Percentile Industry Days to MDUFA IV Decision	52	20	81	53	0
60th Percentile Industry Days to MDUFA IV Decision	141	50	108	65	0
80th Percentile Industry Days to MDUFA IV Decision	278	148	277	78	0
Maximum Industry Days to MDUFA IV Decision	360	180	400	90	0
Average Total Days to MDUFA IV Decision	308.27	244.57	340.17	238.00	0.00
20th Percentile Total Days to MDUFA IV Decision	178	184	248	220	0
40th Percentile Total Days to MDUFA IV Decision	232	200	261	232	0
60th Percentile Total Days to MDUFA IV Decision	321	230	288	244	0
80th Percentile Total Days to MDUFA IV Decision	450	328	457	256	0
Maximum Total Days to MDUFA IV Decision	528	359	580	268	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	2	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	26.67%	14.29%	33.33%	0.00%	N/A

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	14	23	19	3
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	20	11	21	18	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	1
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	3
Number Accepted	20	11	21	18	2
Completed RTF	22	14	23	19	1
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	1
SI Goal Met	22	14	23	19	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	100.00%	100.00%	100.00%	100.00%	N/A

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	0
Average Number of FDA Days to Substantive Interaction	83.36	85.21	88.26	88.74	0.00
20th Percentile FDA Days to Substantive Interaction	84	85	87	88	0
40th Percentile FDA Days to Substantive Interaction	87	88	88	89	0
60th Percentile FDA Days to Substantive Interaction	89	89	90	90	0
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	0
Maximum FDA Days to Substantive Interaction	90	90	90	90	0

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	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	21	12	19	11	0
MDUFA IV Decision Goal Met	21	12	19	11	0
PMAs Pending MDUFA IV Decision	0	0	3	8	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 OHT2 - Office of Cardiovascular Devices

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	21	12	19	11	0
Average FDA Days to MDUFA IV Decision	174.00	178.92	178.05	173.82	0.00
20th Percentile FDA Days to MDUFA IV Decision	161	159	176	176	0
40th Percentile FDA Days to MDUFA IV Decision	178	178	179	178	0
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	179	0
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	0
Maximum FDA Days to MDUFA IV Decision	279	295	180	180	0
Average Industry Days to MDUFA IV Decision	51.48	107.00	82.16	33.27	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	10	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	67	15	28	0
60th Percentile Industry Days to MDUFA IV Decision	45	122	59	47	0
80th Percentile Industry Days to MDUFA IV Decision	91	171	113	53	0
Maximum Industry Days to MDUFA IV Decision	162	322	424	78	0
Average Total Days to MDUFA IV Decision	225.48	285.92	260.21	207.09	0.00
20th Percentile Total Days to MDUFA IV Decision	168	170	177	178	0
40th Percentile Total Days to MDUFA IV Decision	180	245	194	204	0
60th Percentile Total Days to MDUFA IV Decision	229	302	236	225	0
80th Percentile Total Days to MDUFA IV Decision	324	363	293	231	0
Maximum Total Days to MDUFA IV Decision	340	501	604	258	0

Table 1.8 OHT2 - Office of Cardiovascular Devices

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	21	12	22	19	1
Number with MDUFA IV Decision	21	12	19	11	0
Number of Withdrawal	0	0	1	0	0
Number of Not Approvable	1	1	1	1	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	5.26%	0.00%	N/A
Rate of Not Approvable	4.76%	8.33%	5.26%	9.09%	N/A

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	5	3	5	4	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	5	3	4	1	0
MDUFA IV Decision Goal Met	5	3	4	1	0
PMAs Pending MDUFA IV Decision	0	0	1	3	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	1	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	26.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	77	2	269	26	0
40th Percentile Industry Days to MDUFA IV Decision	97	5	332	26	0
60th Percentile Industry Days to MDUFA IV Decision	108	76	338	26	0
80th Percentile Industry Days to MDUFA IV Decision	122	217	412	26	0
Maximum Industry Days to MDUFA IV Decision	163	357	521	26	0
Average Total Days to MDUFA IV Decision	280.20	349.33	498.75	206.00	0.00
20th Percentile Total Days to MDUFA IV Decision	248	247	449	206	0
40th Percentile Total Days to MDUFA IV Decision	270	308	512	206	0
60th Percentile Total Days to MDUFA IV Decision	285	375	517	206	0
80th Percentile Total Days to MDUFA IV Decision	302	450	555	206	0
Maximum Total Days to MDUFA IV Decision	350	524	609	206	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	1	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	239.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	323.00	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	1
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	1	1	3	3	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	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	1
Number Accepted	1	1	3	3	1
Completed RTF	2	2	4	6	1
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	1
SI Goal Met	1	2	4	4	0
SI Goal Not Met	1	0	0	0	0
SI Pending Within Goal	0	0	0	0	1
SI Pending Past Goal	0	0	0	1	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%	80.00%	N/A

**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	4	0
Average Number of FDA Days to Substantive Interaction	93.50	90.00	89.25	88.00	0.00
20th Percentile FDA Days to Substantive Interaction	90	90	89	86	0
40th Percentile FDA Days to Substantive Interaction	92	90	89	87	0
60th Percentile FDA Days to Substantive Interaction	95	90	90	89	0
80th Percentile FDA Days to Substantive Interaction	97	90	90	90	0
Maximum FDA Days to Substantive Interaction	99	90	90	90	0

**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	1
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	1
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	50.00%	33.33%	0.00%	N/A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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

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

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

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

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	4	5	3	8	1
SI Goal Met	3	5	3	8	0
SI Goal Not Met	1	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	75.00%	100.00%	100.00%	100.00%	N/A

**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	0
Average Number of FDA Days to Substantive Interaction	90.50	84.80	90.00	87.50	0.00
20th Percentile FDA Days to Substantive Interaction	90	84	90	85	0
40th Percentile FDA Days to Substantive Interaction	90	90	90	87	0
60th Percentile FDA Days to Substantive Interaction	90	90	90	89	0
80th Percentile FDA Days to Substantive Interaction	91	90	90	90	0
Maximum FDA Days to Substantive Interaction	92	90	90	90	0

**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	4	0
MDUFA IV Decision Goal Met	4	5	2	4	0
PMAs Pending MDUFA IV Decision	0	0	0	4	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	0	0	0
MDUFA IV Decision Goal Met	0	0	0	0	0
PMAs Pending MDUFA IV Decision	0	0	1	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 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	4	0
Average FDA Days to MDUFA IV Decision	180.00	188.00	132.50	176.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	180	162	107	174	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	179	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	13.75	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	4	0
60th Percentile Industry Days to MDUFA IV Decision	253	184	38	18	0
80th Percentile Industry Days to MDUFA IV Decision	320	224	51	26	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	189.75	0.00
20th Percentile Total Days to MDUFA IV Decision	236	256	158	179	0
40th Percentile Total Days to MDUFA IV Decision	314	282	162	183	0
60th Percentile Total Days to MDUFA IV Decision	433	325	167	196	0
80th Percentile Total Days to MDUFA IV Decision	500	430	171	201	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	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 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	4	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	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 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	1
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	2	2	2	3	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	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	1
Number Accepted	2	2	2	3	1
Completed RTF	2	3	2	3	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 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	3	1
SI Goal Met	2	3	2	3	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	100.00%	100.00%	100.00%	100.00%	N/A

Table 1.4 OHT6 - Office of Orthopedic Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	3	2	3	0
Average Number of FDA Days to Substantive Interaction	86.50	88.67	88.50	84.00	0.00
20th Percentile FDA Days to Substantive Interaction	84	88	88	81	0
40th Percentile FDA Days to Substantive Interaction	86	89	88	82	0
60th Percentile FDA Days to Substantive Interaction	87	89	89	84	0
80th Percentile FDA Days to Substantive Interaction	89	90	89	87	0
Maximum FDA Days to Substantive Interaction	90	90	89	90	0

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	3	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	2	3	2	1	0
MDUFA IV Decision Goal Met	2	3	2	1	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 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	1	0
Average FDA Days to MDUFA IV Decision	180.00	146.33	178.50	156.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	180	121	178	156	0
40th Percentile FDA Days to MDUFA IV Decision	180	156	178	156	0
60th Percentile FDA Days to MDUFA IV Decision	180	174	179	156	0
80th Percentile FDA Days to MDUFA IV Decision	180	177	179	156	0
Maximum FDA Days to MDUFA IV Decision	180	179	180	156	0
Average Industry Days to MDUFA IV Decision	141.50	203.67	103.50	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	57	67	41	0	0
40th Percentile Industry Days to MDUFA IV Decision	113	122	83	0	0
60th Percentile Industry Days to MDUFA IV Decision	170	209	124	0	0
80th Percentile Industry Days to MDUFA IV Decision	226	330	166	0	0
Maximum Industry Days to MDUFA IV Decision	283	450	207	0	0
Average Total Days to MDUFA IV Decision	321.50	350.00	282.00	156.00	0.00
20th Percentile Total Days to MDUFA IV Decision	237	191	219	156	0
40th Percentile Total Days to MDUFA IV Decision	293	282	261	156	0
60th Percentile Total Days to MDUFA IV Decision	350	387	303	156	0
80th Percentile Total Days to MDUFA IV Decision	406	505	345	156	0
Maximum Total Days to MDUFA IV Decision	463	623	387	156	0

Table 1.8 OHT6 - Office of Orthopedic Devices

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

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

Table 1.9 OHT6 - Office of Orthopedic Devices

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

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

Table 1.10 OHT6 - Office of Orthopedic Devices

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

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

Table 1.11 OHT6 - Office of Orthopedic Devices

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

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

Table 1.12 OHT6 - Office of Orthopedic Devices

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

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

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

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

*Includes submission that went to panel

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

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

*Includes submission that went to panel

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	21	30	28	3
Closed Before RTA Action	0	0	0	1	0
Number with Accepted RTA Review	17	19	26	17	3
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	9	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	2	4	1	0
Rate of Submissions Not Accepted for Filing Review	0.00%	9.52%	13.33%	3.70%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	21	30	28	3
Number Accepted	17	19	26	26	3
Completed RTF	17	21	30	25	3
Number Not Filed	0	0	2	1	0
Rate of Submissions Not Filed	0.00%	0.00%	6.67%	4.00%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	17	21	29	25	3
SI Goal Met	17	20	26	11	0
SI Goal Not Met	0	1	3	6	0
SI Pending Within Goal	0	0	0	0	3
SI Pending Past Goal	0	0	0	7	0
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	100.00%	95.24%	89.66%	45.83%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	17	21	29	17	0
Average Number of FDA Days to Substantive Interaction	84.29	87.76	96.55	115.18	0.00
20th Percentile FDA Days to Substantive Interaction	84	87	87	88	0
40th Percentile FDA Days to Substantive Interaction	87	88	88	89	0
60th Percentile FDA Days to Substantive Interaction	89	89	90	90	0
80th Percentile FDA Days to Substantive Interaction	90	90	90	153	0
Maximum FDA Days to Substantive Interaction	90	91	325	250	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	17	21	29	24	3
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	17	21	27	8	0
MDUFA IV Decision Goal Met	17	17	26	8	0
PMAs Pending MDUFA IV Decision	0	0	2	15	3
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	8	0
Current Performance Percent Goal Met	100.00%	80.95%	92.86%	50.00%	N/A

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	17	21	27	8	0
Average FDA Days to MDUFA IV Decision	123.35	178.67	165.37	111.63	0.00
20th Percentile FDA Days to MDUFA IV Decision	90	134	135	93	0
40th Percentile FDA Days to MDUFA IV Decision	99	173	179	103	0
60th Percentile FDA Days to MDUFA IV Decision	141	177	180	110	0
80th Percentile FDA Days to MDUFA IV Decision	174	180	180	130	0
Maximum FDA Days to MDUFA IV Decision	180	299	406	149	0
Average Industry Days to MDUFA IV Decision	86.18	142.38	68.63	68.25	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	16	24	0	0
60th Percentile Industry Days to MDUFA IV Decision	75	81	63	43	0
80th Percentile Industry Days to MDUFA IV Decision	149	325	138	100	0
Maximum Industry Days to MDUFA IV Decision	336	540	257	318	0
Average Total Days to MDUFA IV Decision	209.53	321.05	234.00	179.88	0.00
20th Percentile Total Days to MDUFA IV Decision	90	155	159	113	0
40th Percentile Total Days to MDUFA IV Decision	139	179	191	132	0
60th Percentile Total Days to MDUFA IV Decision	213	257	253	177	0
80th Percentile Total Days to MDUFA IV Decision	266	619	318	197	0
Maximum Total Days to MDUFA IV Decision	511	718	458	406	0

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	17	21	29	24	3
Number with MDUFA IV Decision	17	21	27	8	0
Number of Withdrawal	5	1	1	1	0
Number of Not Approvable	2	1	1	0	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	29.41%	4.76%	3.70%	12.50%	N/A
Rate of Not Approvable	11.76%	4.76%	3.70%	0.00%	N/A

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	2	8	0
Mean FDA Days for Submissions that Missed the Goal	0.00	287.25	254.00	297.63	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	288.50	73.50	16.13	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00
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 and Radiological Health
LDT PMA Original and Panel-Track Supplements Metric***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Number of PMAs Filed	1	4	11	5	0
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	11	2	0
MDUFA IV Decision Goal Met	1	4	11	2	0
PMAs Pending MDUFA IV Decision	0	0	0	3	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	1	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	66.67%	N/A

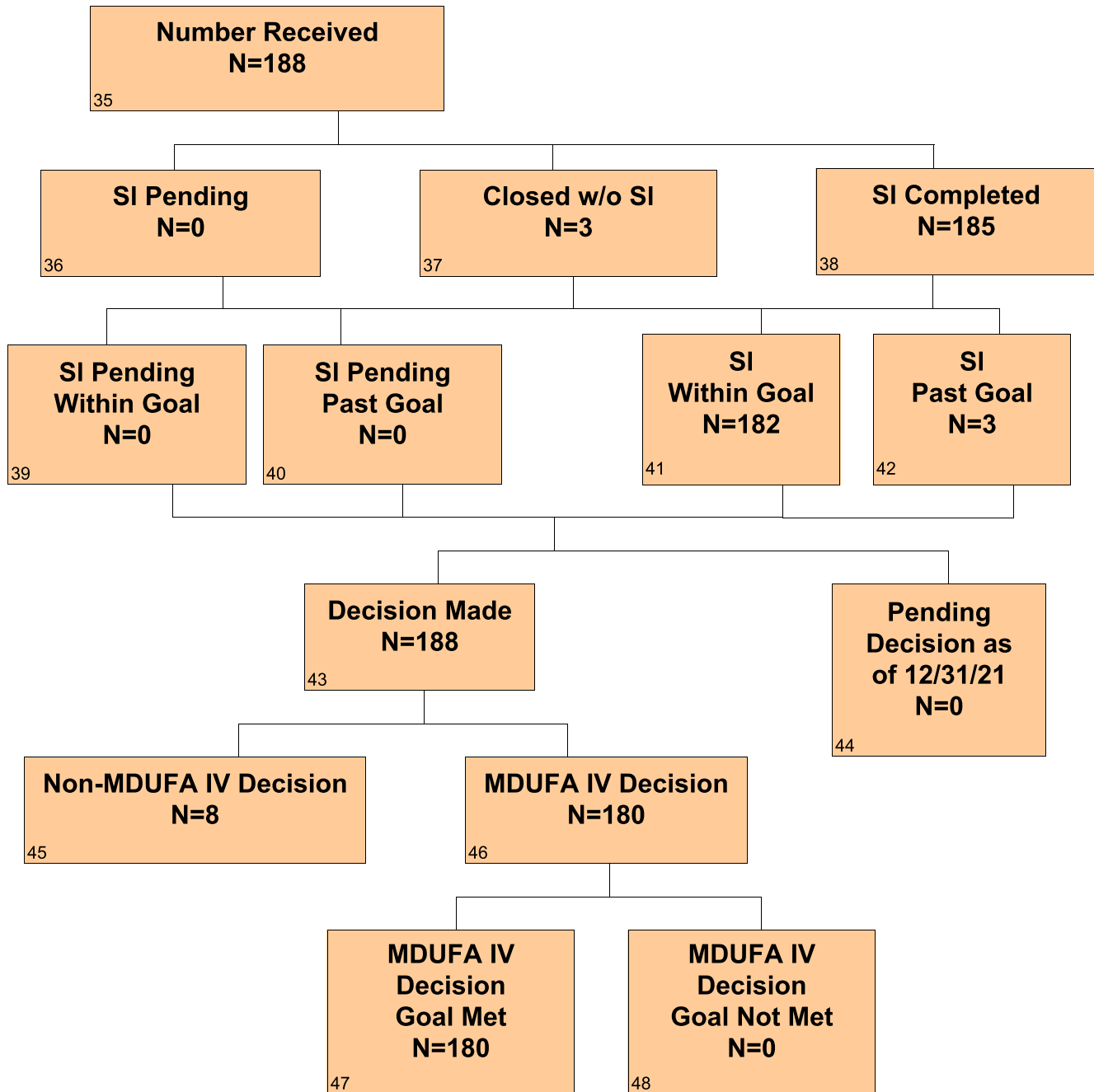
*Includes submission that went to panel

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

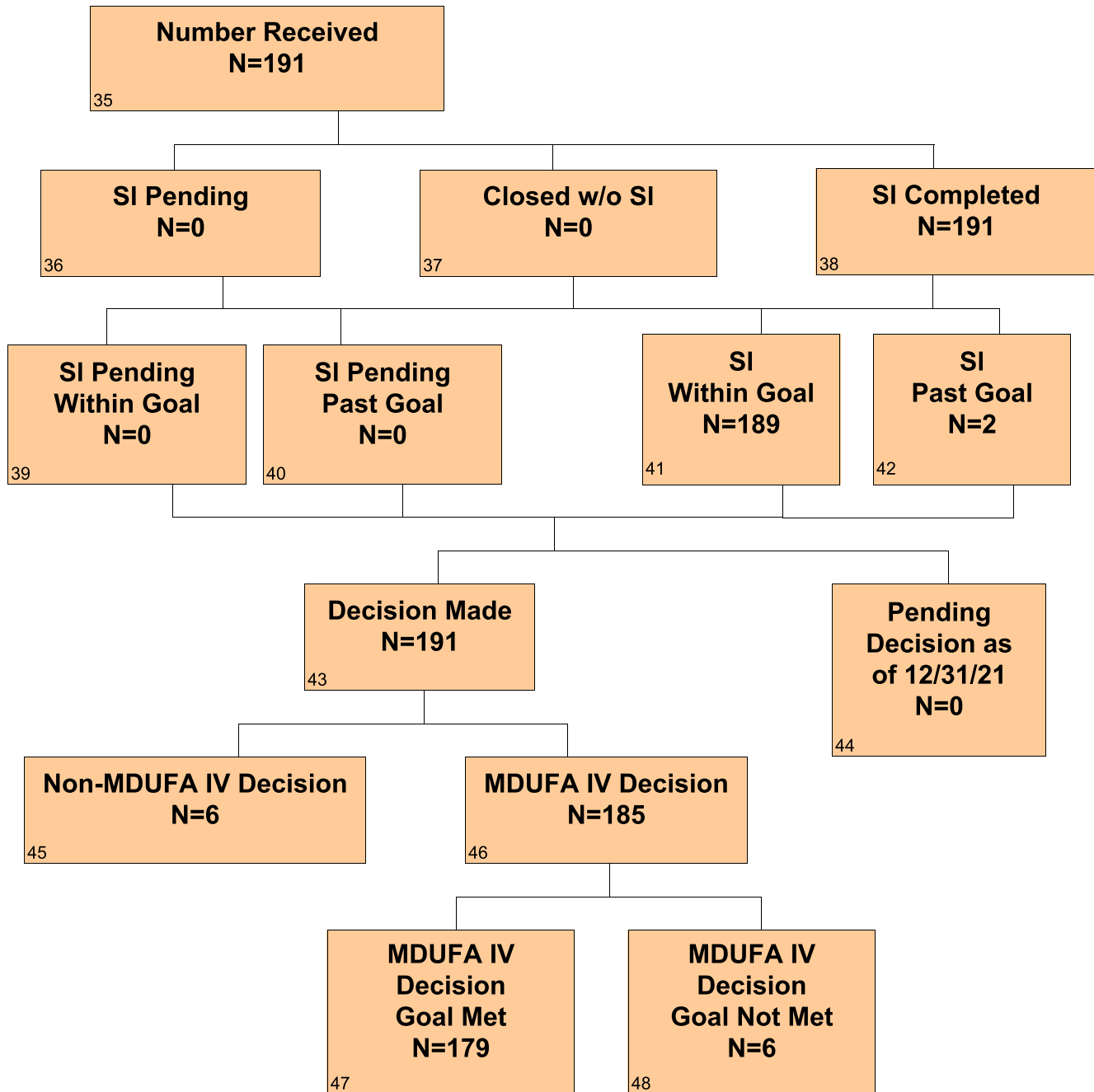
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Number of PMAs Filed	15	17	15	20	2
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	13	7	0
MDUFA IV Decision Goal Met	15	13	12	7	0
PMAs Pending MDUFA IV Decision	0	0	2	12	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	1	7	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	50.00%	N/A

*Includes submission that went to panel

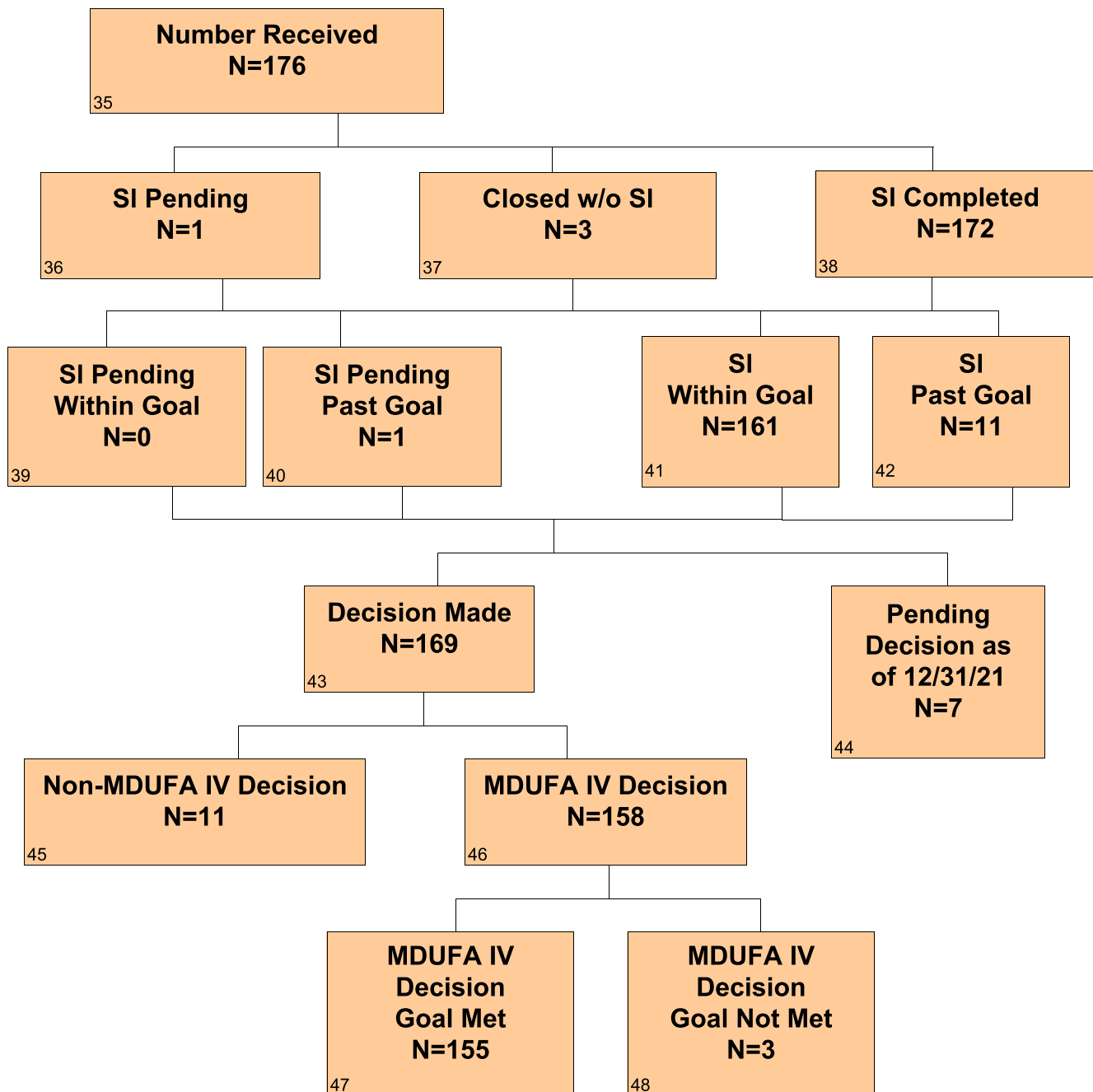
CDRH PMA 180 Day Supplements - FY 2018 as of 12/31/21



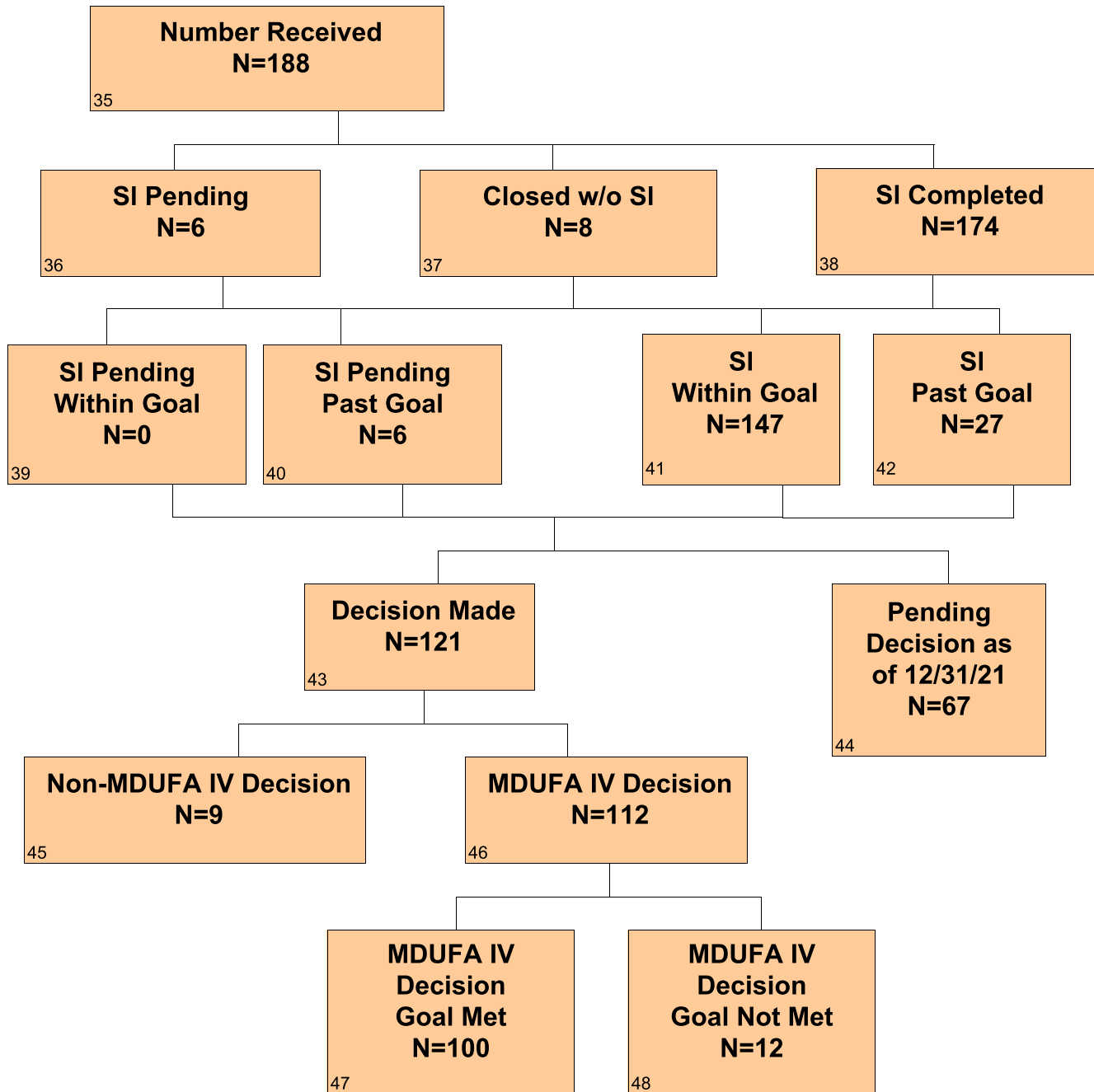
CDRH PMA 180 Day Supplements - FY 2019 as of 12/31/21



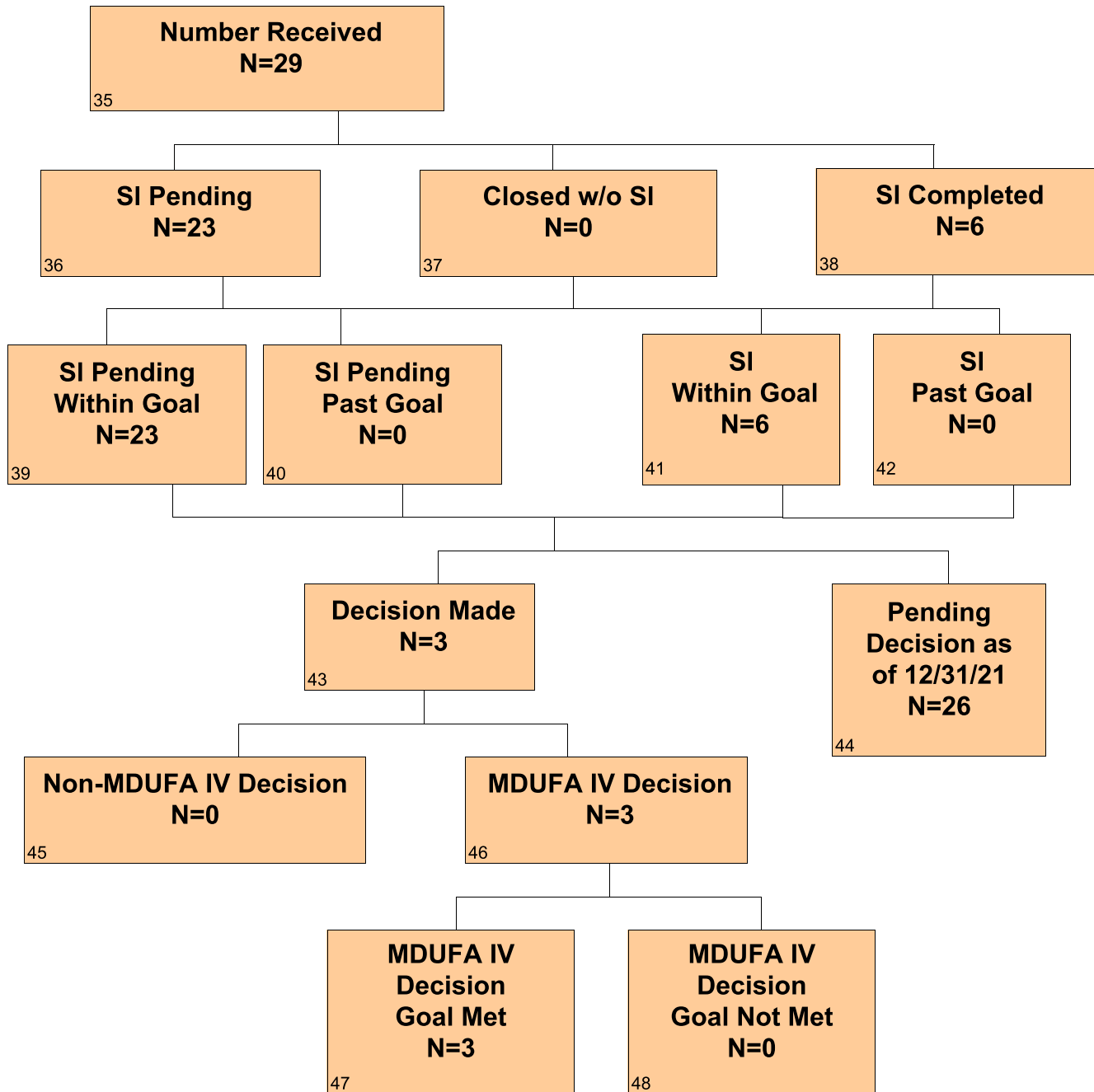
CDRH PMA 180 Day Supplements - FY 2020 as of 12/31/21



CDRH PMA 180 Day Supplements - FY 2021 as of 12/31/21



CDRH PMA 180 Day Supplements - FY 2022 as of 12/31/21



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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	29
SI Goal Met	182	189	161	147	6
SI Goal Not Met	3	2	11	27	0
SI Pending Within Goal	0	0	0	0	23
SI Pending Past Goal	0	0	1	6	0
Closed Without SI	3	0	3	8	0
Current SI Performance Percent Goal Met	98.38%	98.95%	93.06%	81.67%	100.00%

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	29
Non-MDUFA IV Decision	8	6	11	9	0
MDUFA IV Decision	180	185	158	112	3
MDUFA IV Decision Goal Met	180	179	155	100	3
Supplements Pending MDUFA IV Decision	0	0	7	67	26
Supplements Pending MDUFA IV Decision Past Goal	0	0	2	3	0
Current Performance Percent Goal Met	100.00%	96.76%	96.88%	86.96%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	188	191	176	188	29
Number with MDUFA IV Decision	180	185	158	112	3
Number of Not Approvable	13	10	8	2	0
Rate of Not Approvable	7.22%	5.41%	5.06%	1.79%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	6	5	15	0
Mean FDA Days for Submissions that Missed the Goal	0.00	263.33	338.80	230.73	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	69.67	69.60	25.27	0.00

Section 2 PMA 180-Day Supplements - Office Level Metric

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	20	36	28	15	4
SI Goal Met	20	36	28	14	0
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	4
SI Pending Past Goal	0	0	0	1	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	93.33%	N/A

**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	4
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	20	36	28	7	0
MDUFA IV Decision Goal Met	20	35	28	7	0
Supplements Pending MDUFA IV Decision	0	0	0	8	4
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%	N/A

**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	4
Number with MDUFA IV Decision	20	36	28	7	0
Number of Not Approvable	1	1	1	0	0
Rate of Not Approvable	5.00%	2.78%	3.57%	0.00%	N/A

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

Performance Metric	FY 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	9
SI Goal Met	91	81	66	79	3
SI Goal Not Met	1	0	4	7	0
SI Pending Within Goal	0	0	0	0	6
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%	100.00%

**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	9
Non-MDUFA IV Decision	2	3	1	8	0
MDUFA IV Decision	92	78	65	61	2
MDUFA IV Decision Goal Met	92	78	65	61	2
Supplements Pending MDUFA IV Decision	0	0	4	25	7
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

**Table 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	9
Number with MDUFA IV Decision	92	78	65	61	2
Number of Not Approvable	6	6	4	2	0
Rate of Not Approvable	6.52%	7.69%	6.15%	3.28%	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	2
SI Goal Met	14	15	16	18	0
SI Goal Not Met	1	1	0	1	0
SI Pending Within Goal	0	0	0	0	2
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	3	0	0
Current SI Performance Percent Goal Met	93.33%	93.75%	100.00%	94.74%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	15	16	19	19	2
Non-MDUFA IV Decision	0	2	7	1	0
MDUFA IV Decision	15	14	11	7	0
MDUFA IV Decision Goal Met	15	14	11	6	0
Supplements Pending MDUFA IV Decision	0	0	1	11	2
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	85.71%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	15	16	19	19	2
Number with MDUFA IV Decision	15	14	11	7	0
Number of Not Approvable	0	2	2	0	0
Rate of Not Approvable	0%	14%	18%	0%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	233.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	49.00	0.00

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	9	10	7	15	2
SI Goal Met	9	9	6	5	2
SI Goal Not Met	0	1	1	9	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	1	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	90.00%	85.71%	33.33%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	9	10	7	15	2
Non-MDUFA IV Decision	1	1	0	0	0
MDUFA IV Decision	8	9	6	12	0
MDUFA IV Decision Goal Met	8	5	6	8	0
Supplements Pending MDUFA IV Decision	0	0	1	3	2
Supplements Pending MDUFA IV Decision Past Goal	0	0	1	1	0
Current Performance Percent Goal Met	100.00%	55.56%	85.71%	61.54%	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	2
Number with MDUFA IV Decision	8	9	6	12	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	5	0
Mean FDA Days for Submissions that Missed the Goal	0.00	258.50	236.00	213.60	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	91.00	223.00	14.40	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	2
SI Goal Met	12	16	23	19	0
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	1	0
Closed Without SI	1	0	0		0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	95.00%	N/A

**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	2
Non-MDUFA IV Decision	2	0	2	0	0
MDUFA IV Decision	11	16	21	12	0
MDUFA IV Decision Goal Met	11	15	21	12	0
Supplements Pending MDUFA IV Decision	0	0	0	8	2
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	93.75%	100.00%	100.00%	N/A

**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	2
Number with MDUFA IV Decision	11	16	21	12	0
Number of Not Approvable	2	0	1	0	0
Rate of Not Approvable	18.18%	0.00%	4.76%	0.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0	0	0
Mean FDA Days for Submissions that Missed the Goal	0.00	244.00	0.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	13.00	0.00	0.00	0.00

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	0	6	2	4	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	1	0
MDUFA IV Decision Goal Met	0	6	1	1	0
Supplements Pending MDUFA IV Decision	0	0	0	3	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	1	0
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	N/A	0.00%	0.00%	0.00%	N/A

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

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

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	37	26	27	21	9
SI Goal Met	36	26	20	8	1
SI Goal Not Met	1	0	6	10	0
SI Pending Within Goal	0	0	0	0	8
SI Pending Past Goal	0	0	1	3	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	97.30%	100.00%	74.07%	38.10%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	37	26	27	21	9
Non-MDUFA IV Decision	3	0	0	0	0
MDUFA IV Decision	34	26	26	12	1
MDUFA IV Decision Goal Met	34	26	23	5	1
Supplements Pending MDUFA IV Decision	0	0	1	9	8
Supplements Pending MDUFA IV Decision Past Goal	0	0	1	2	0
Current Performance Percent Goal Met	100.00%	100.00%	85.19%	35.71%	100.00%

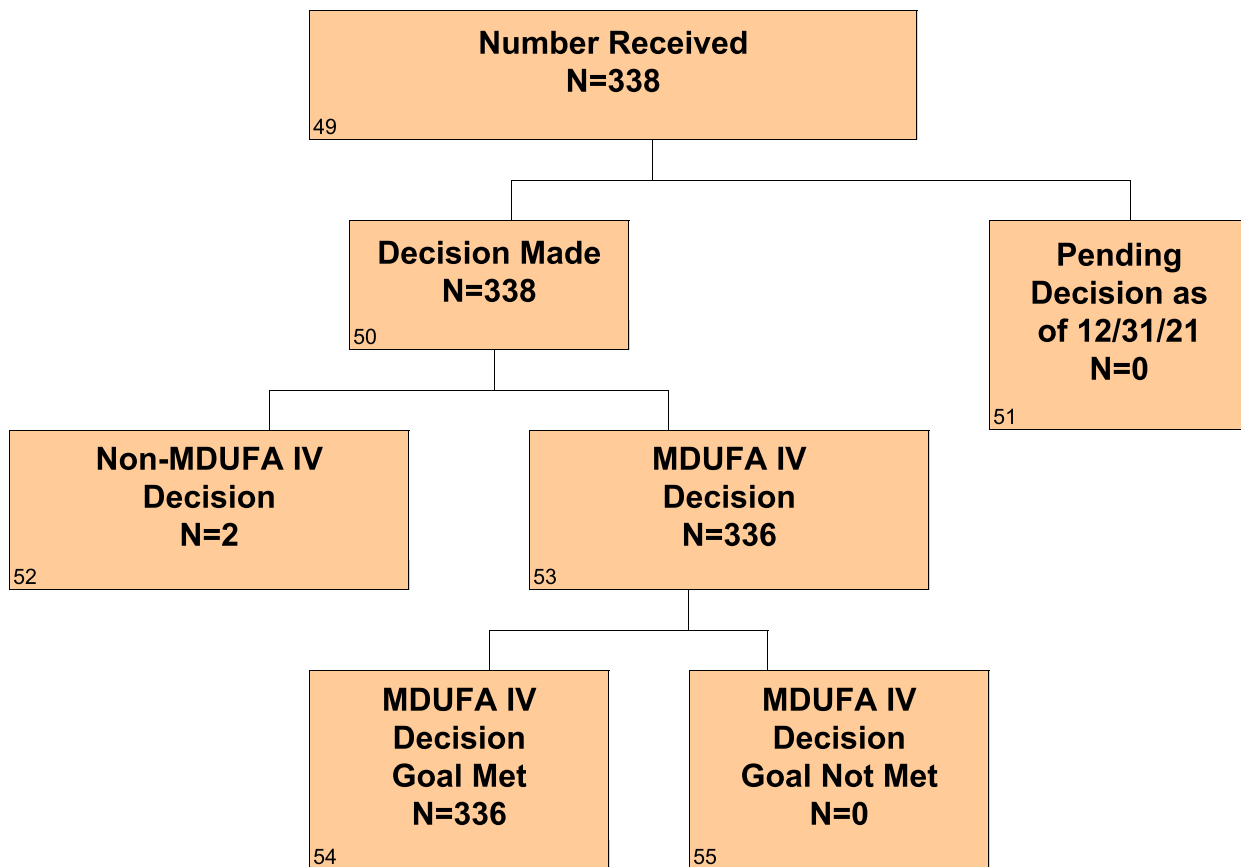
**Table 2.3 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	37	26	27	21	9
Number with MDUFA IV Decision	34	26	26	12	1
Number of Not Approvable	4	1	0	0	0
Rate of Not Approvable	11.76%	3.85%	0.00%	0.00%	0.00%

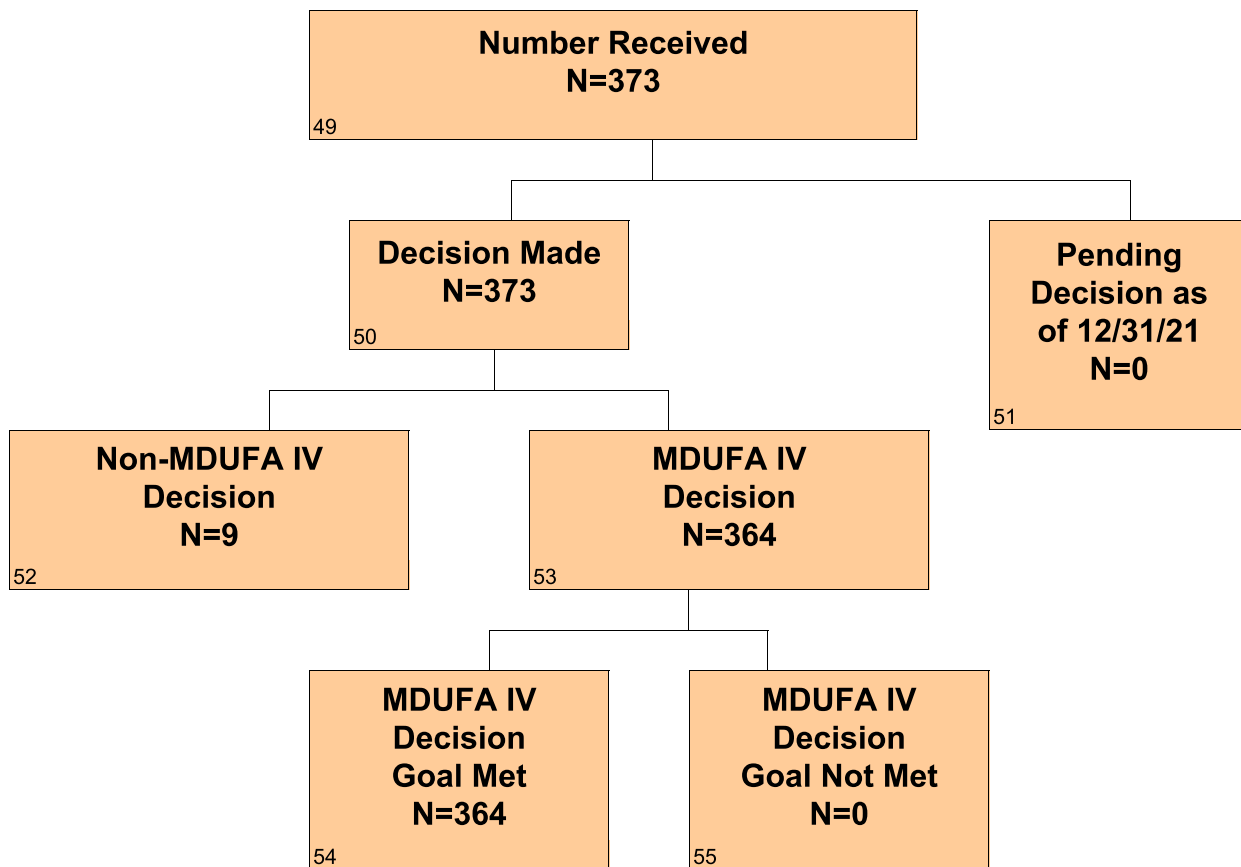
**Table 2.4 OHT7 - Office of In Vitro Diagnostics and Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	4	9	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	364.50	240.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	31.25	28.67	0.00

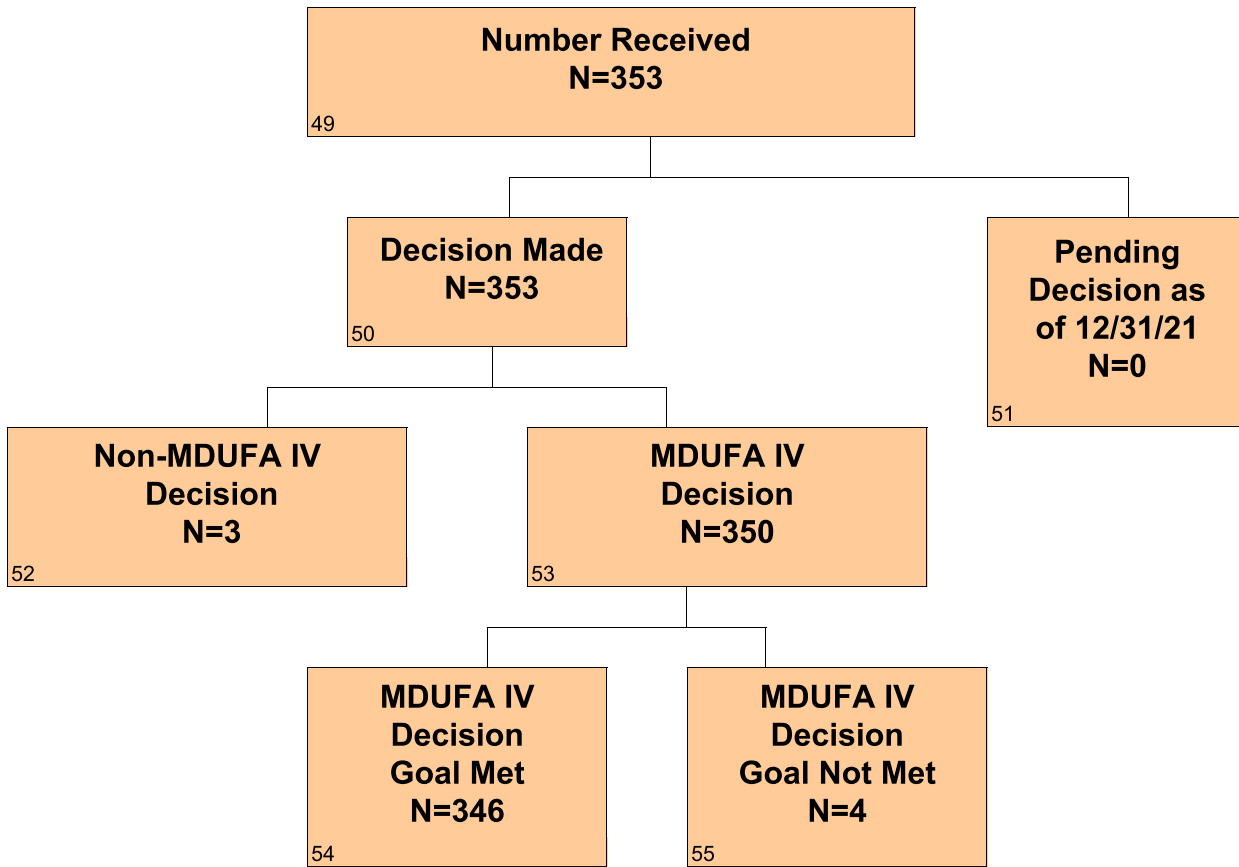
CDRH PMA Real Time Supplements - FY 2018 as of 12/31/21



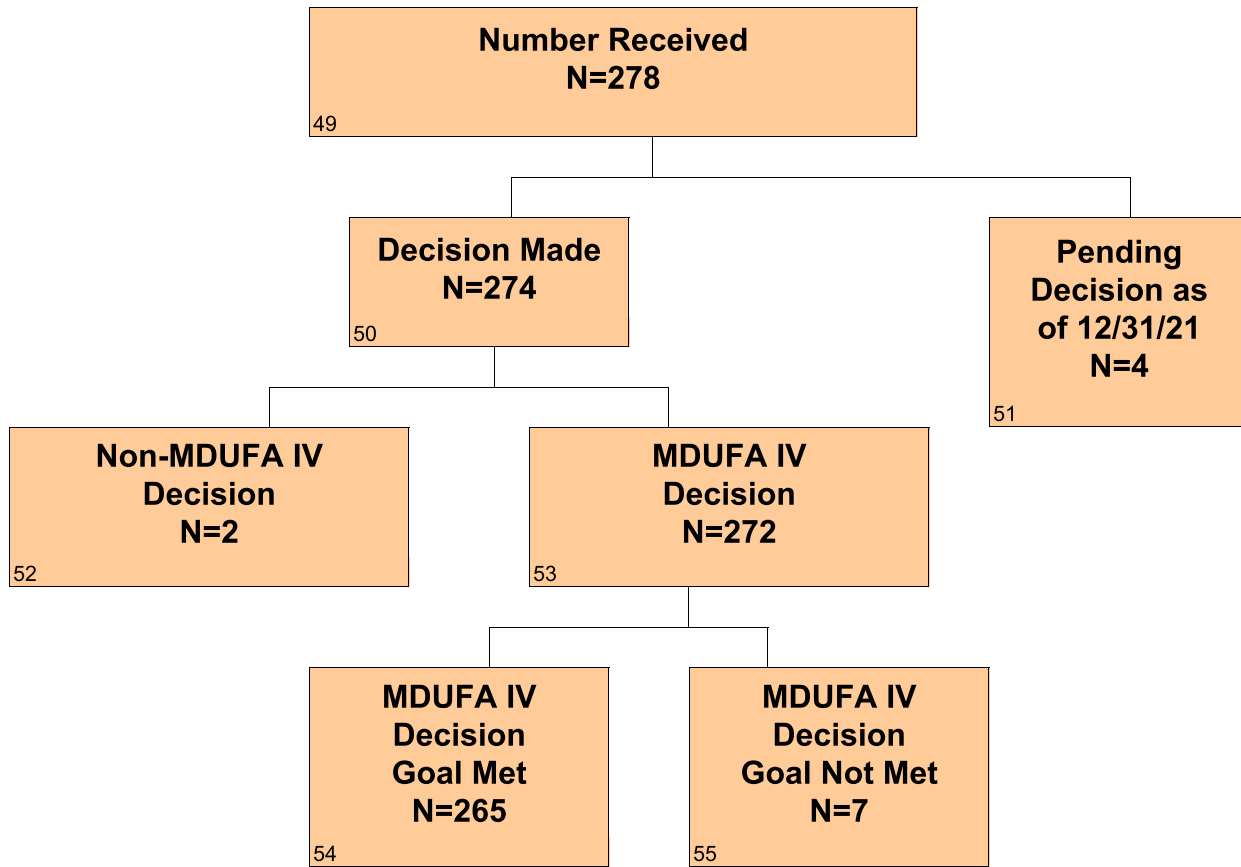
CDRH PMA Real Time Supplements - FY 2019 as of 12/31/21



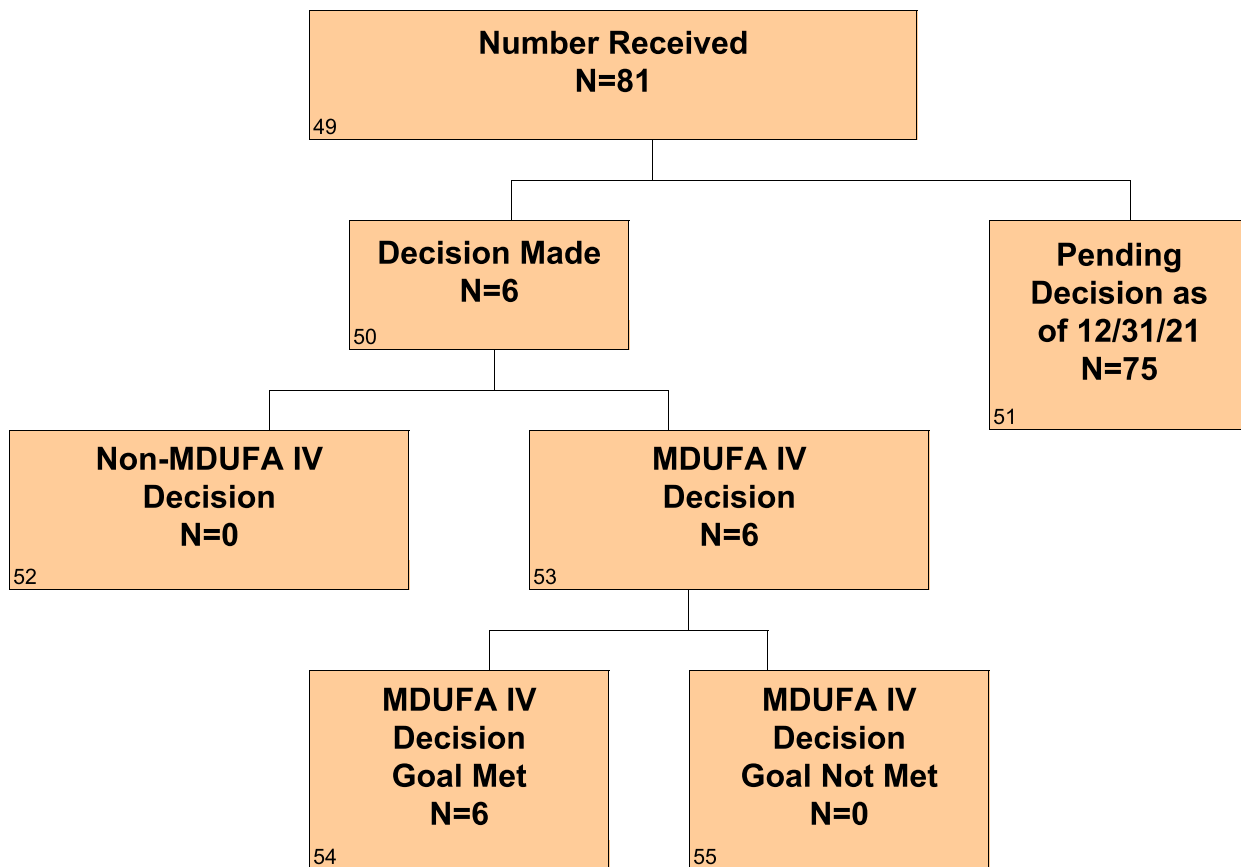
CDRH PMA Real Time Supplements - FY 2020 as of 12/31/21



CDRH PMA Real Time Supplements - FY 2021 as of 12/31/21



CDRH PMA Real Time Supplements - FY 2022 as of 12/31/21



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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	81
Non-MDUFA IV Decision	2	9	.	2	0
MDUFA IV Decision	336	364	350	272	6
MDUFA IV Decision Goal Met	336	364	346	265	6
Supplements Pending MDUFA IV Decision	0	0	0	4	75
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	4	0
Current Performance Percent Goal Met	100.00%	100.00%	98.86%	96.01%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	338	373	353	278	81
Number With MDUFA IV Decision	336	364	350	272	6
Number of Not Approvable	20	29	6	10	0
Rate of Not Approvable	5.95%	7.97%	1.71%	3.68%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	4	11	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.25	145.45	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Section 3 PMA Real-Time Supplements - Office Level Metric

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	23	40	16	21	3
Non-MDUFA IV Decision	0	2	1	0	0
MDUFA IV Decision	23	38	15	21	2
MDUFA IV Decision Goal Met	23	38	15	21	2
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	100.00%	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	3
Number With MDUFA IV Decision	23	38	15	21	2
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	45
Non-MDUFA IV Decision	0	3	2	0	0
MDUFA IV Decision	154	170	191	146	1
MDUFA IV Decision Goal Met	154	170	190	146	1
Supplements Pending MDUFA IV Decision	0	0	0	1	44
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	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	45
Number With MDUFA IV Decision	154	170	191	146	1
Number of Not Approvable	12	15	1	2	0
Rate of Not Approvable	7.79%	8.82%	0.52%	1.37%	0.00%

**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	92.00	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	9
Non-MDUFA IV Decision	0	1	0	2	0
MDUFA IV Decision	20	38	36	14	0
MDUFA IV Decision Goal Met	20	38	36	14	0
Supplements Pending MDUFA IV Decision	0	0	0	0	9
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 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	9
Number with MDUFA IV Decision	20	38	36	14	0
Number of Not Approvable	1	8	1	0	0
Rate of Not Approvable	5.00%	21.05%	2.78%	0.00%	N/A

**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	0
Non-MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision	12	18	13	11	0
MDUFA IV Decision Goal Met	12	18	13	10	0
Supplements Pending MDUFA IV Decision	0	0	0	2	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	2	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	76.92%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	18	13	13	0
Number with MDUFA IV Decision	12	18	13	11	0
Number of Not Approvable	4	0	0	1	0
Rate of Not Approvable	33.33%	0.00%	0.00%	9.09%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	3	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	113.67	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	16	32	24	22	9
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	16	32	24	22	3
MDUFA IV Decision Goal Met	16	32	24	22	3
Supplements Pending MDUFA IV Decision	0	0	0	0	6
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	9
Number with MDUFA IV Decision	16	32	24	22	3
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	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	17	22	9	3	0
MDUFA IV Decision Goal Met	17	22	9	3	0
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	100.00%	100.00%	100.00%	100.00%	N/A

**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	1
Number with MDUFA IV Decision	17	22	9	3	0
Number of Not Approvable	2	2	1	1	0
Rate of Not Approvable	11.76%	9.09%	11.11%	33.33%	N/A

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	95	49	62	56	14
Non-MDUFA IV Decision	1	3	0	0	0
MDUFA IV Decision	94	46	62	55	0
MDUFA IV Decision Goal Met	94	46	59	49	0
Supplements Pending MDUFA IV Decision	0	0	0	1	14
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	0
Current Performance Percent Goal Met	100.00%	100.00%	95.16%	87.50%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	95	49	62	56	14
Number with MDUFA IV Decision	94	46	62	55	0
Number of Not Approvable	0	1	0	5	0
Rate of Not Approvable	0.00%	2.17%	0.00%	9.09%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	3	7	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.00	166.71	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Section 4 Pre-Market Report Submissions

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

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Section 5 PMA Annual Metrics and Goals

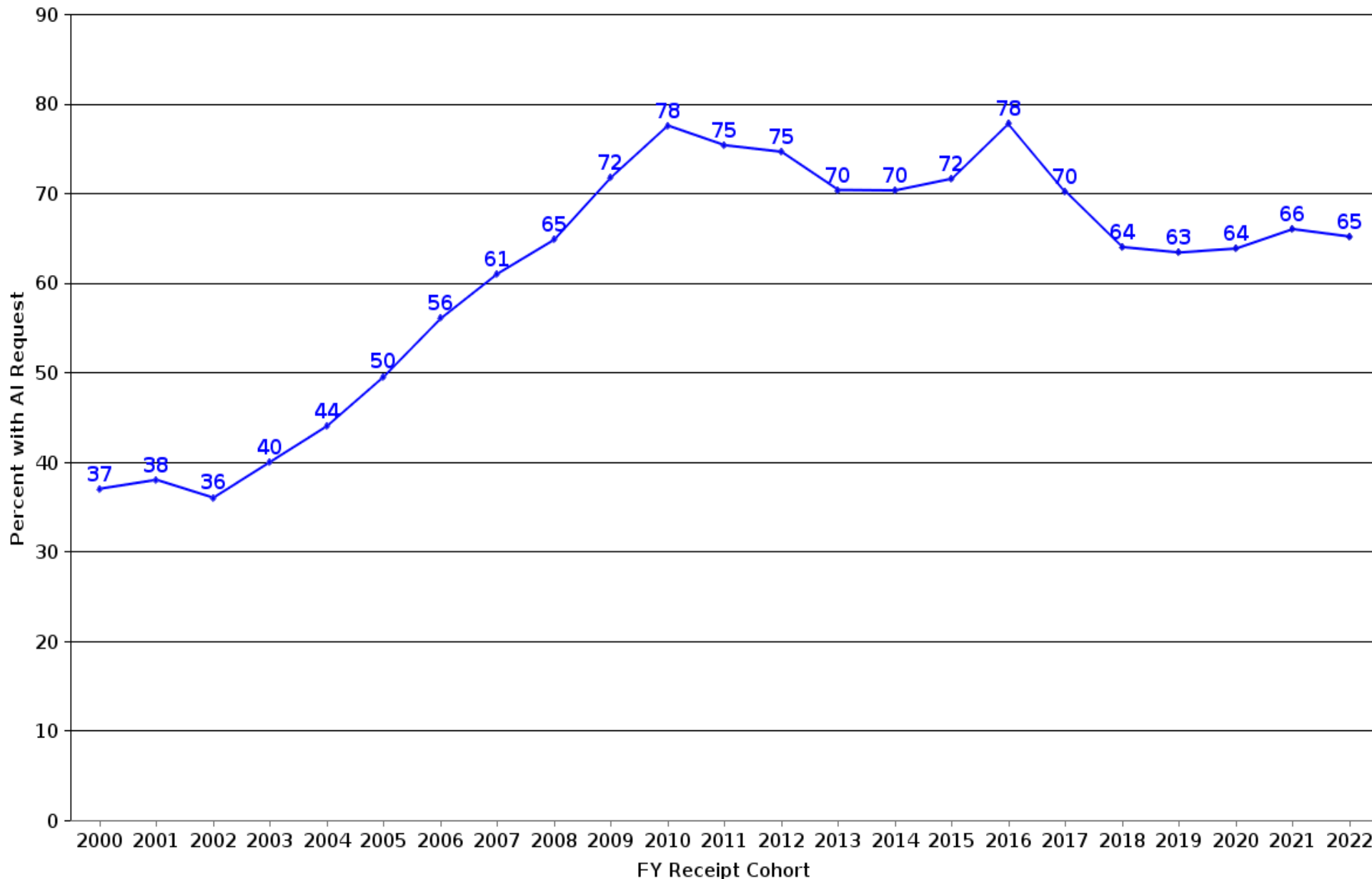
PMA Annual Metrics and Goals will be reported in the Annual Report.

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510(k)s

Q1FY2022

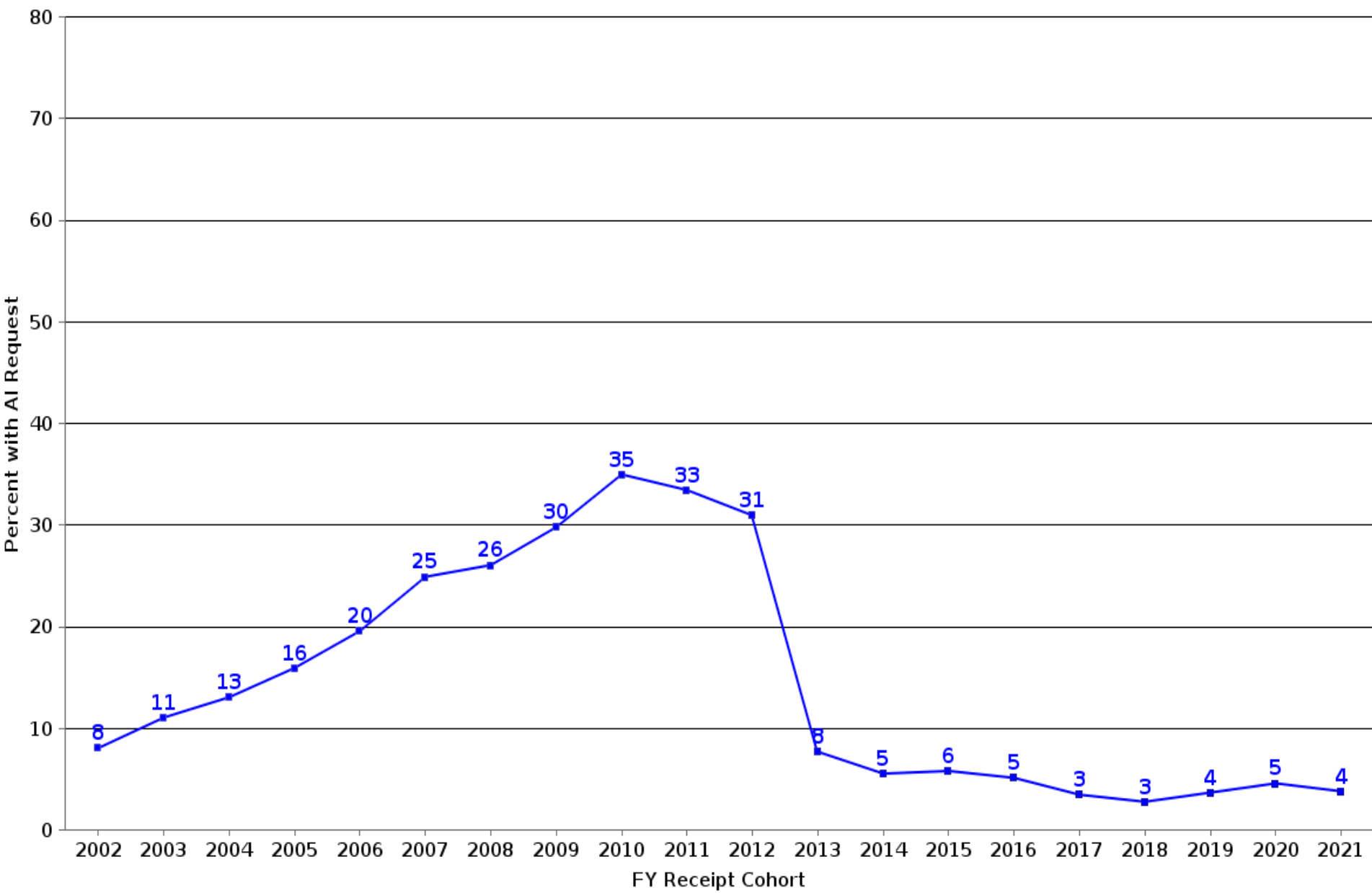
Percent of 510(k)s With Additional Information (AI) Request on 1st FDA Review Cycle



AI rates after FY13 are based on the 1st substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 10/31/21

◆ % with 1st Cycle AI Request

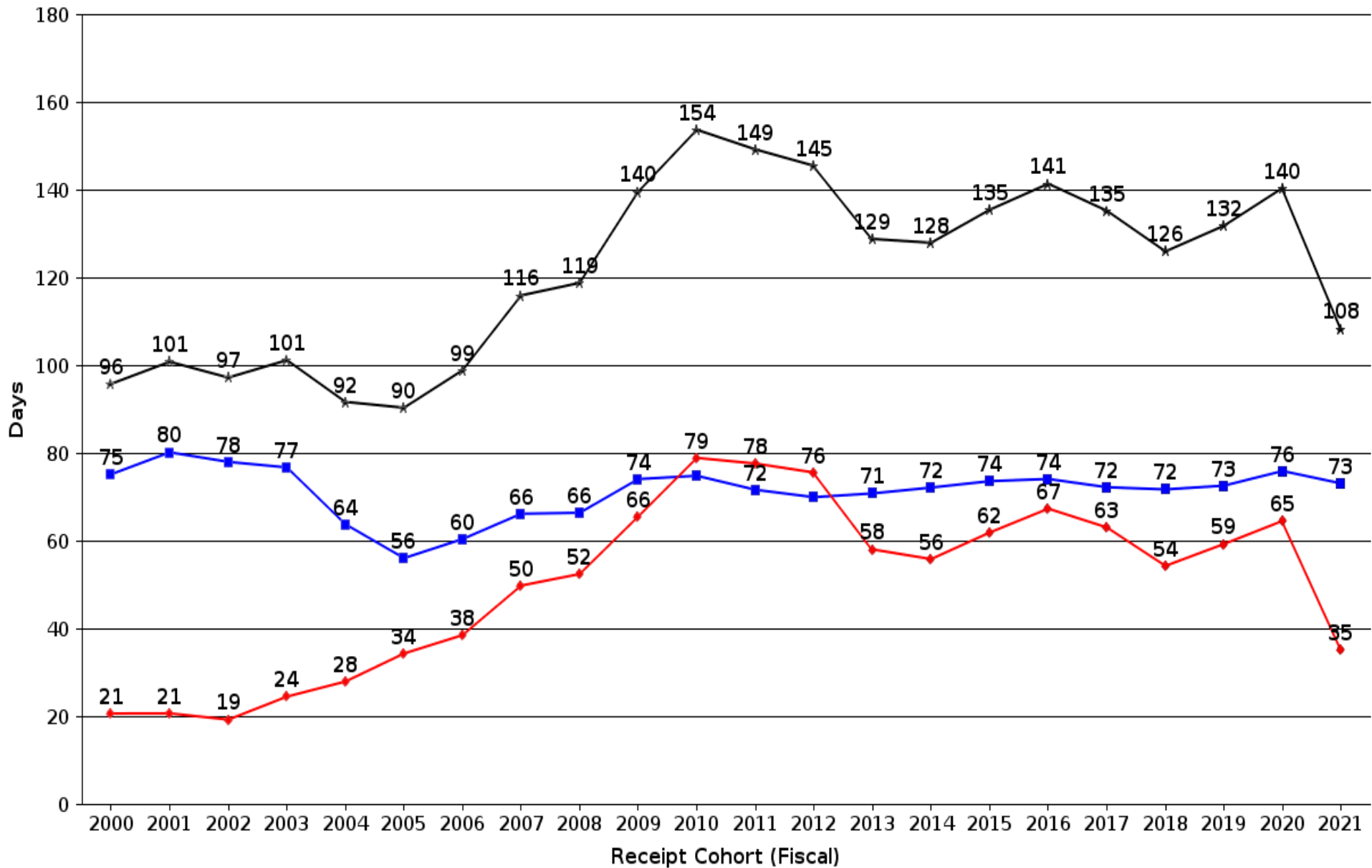
Percent of 510(k)s With Additional Information (AI) Request on 2nd FDA Review Cycle



AI rates after FY13 are based on the 2nd substantive review cycle (i.e., excluding RTA cycles) for 510ks accepted as of 5/31/21

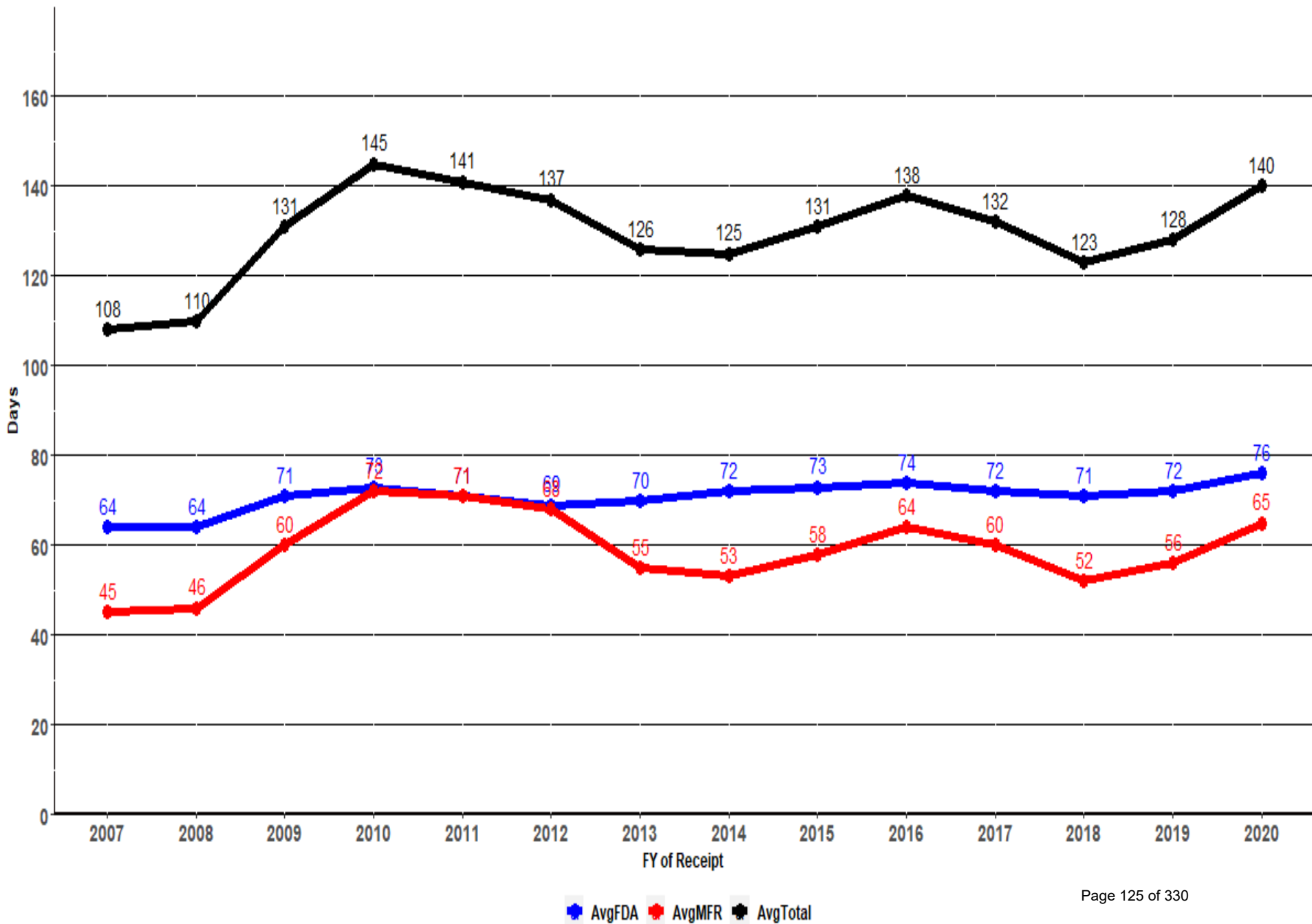
■ % with 2nd Cycle AI Request

510(k) Average Days to MDUFA (SE/NSE) Decision as of: 12/31/21

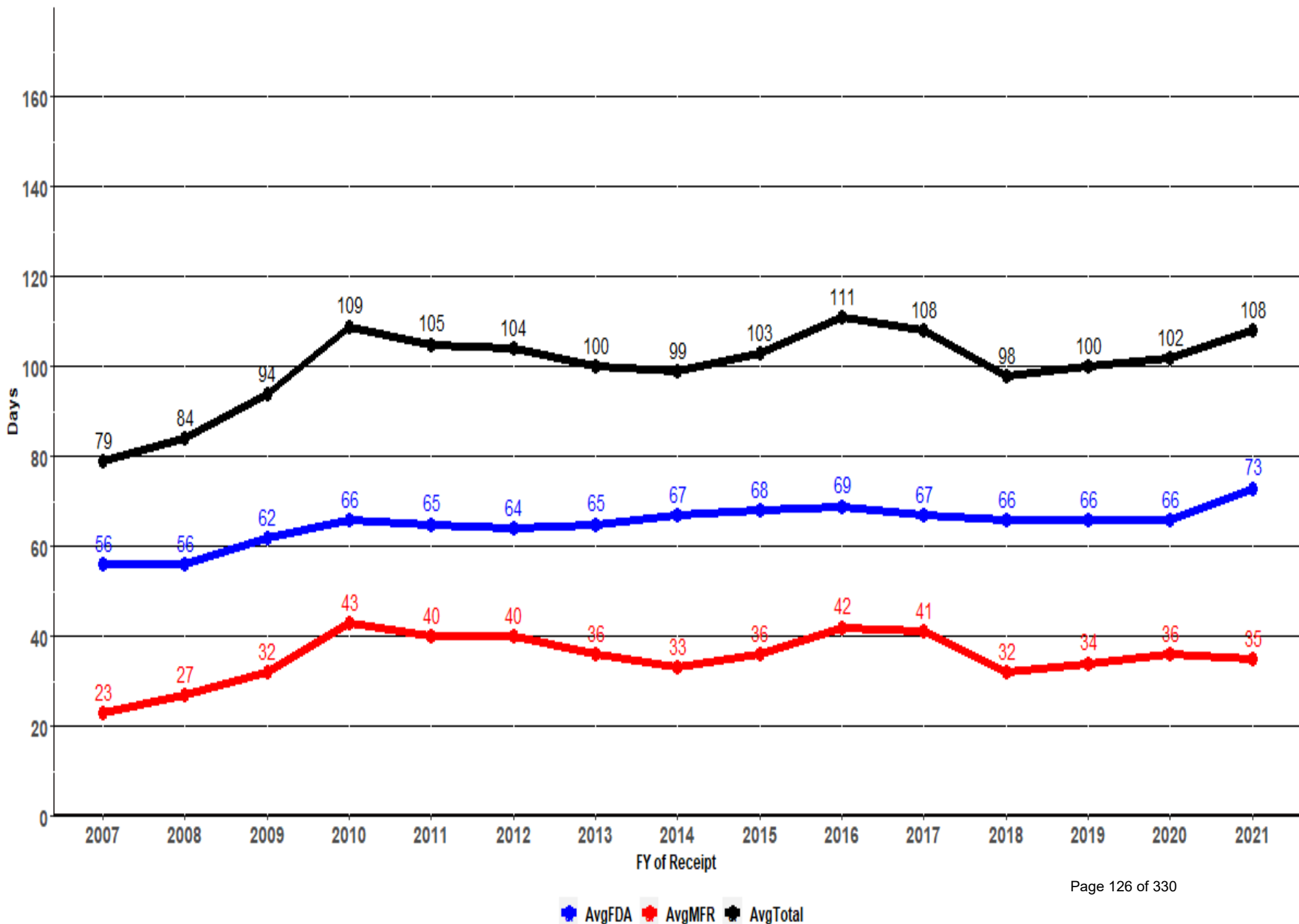


Cohorts not yet closed: 2019: 99.84%; 2020: 95.87%; 2021: 65.76%

510(k) Average Days to MDUFA (SE/NSE) Decision at 95.8 % Cohort Closure by FY of Receipt

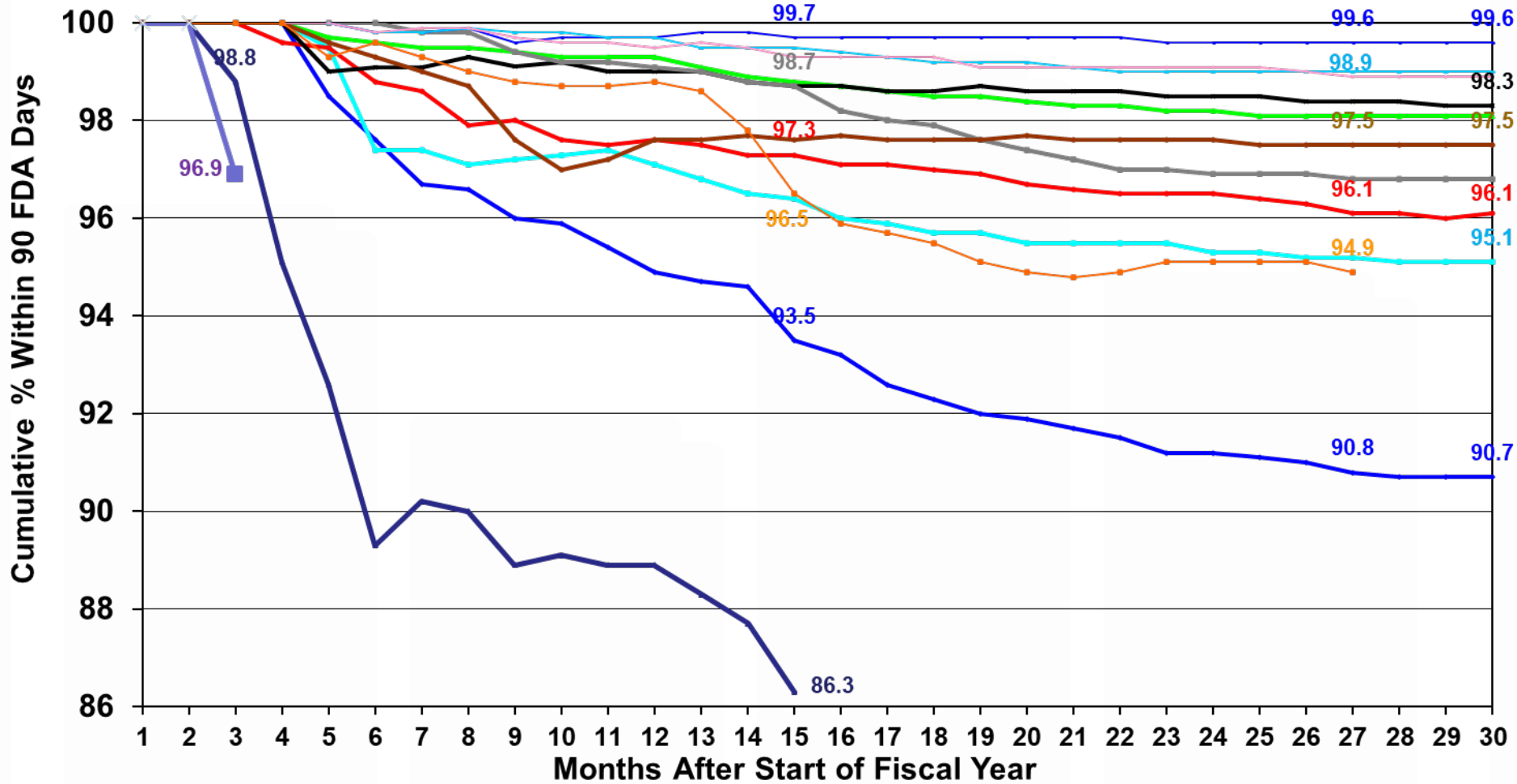


510(k) Average Days to MDUFA (SE/NSE) Decision at 65.8 % Cohort Closure by FY of Receipt



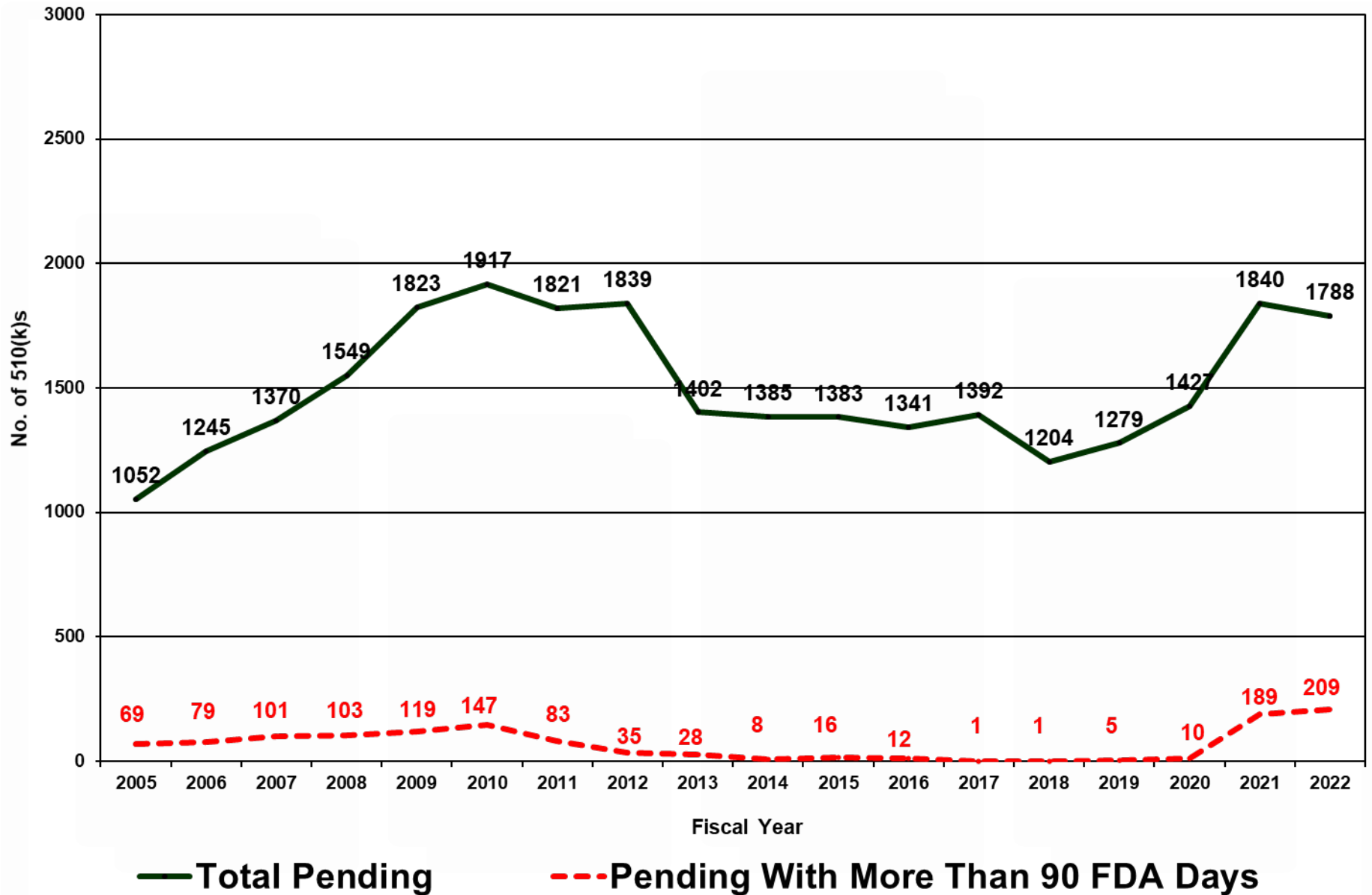
Trend in 510(k) MDUFA Decision Goal Performance

Comparison of FY10 – FY22 Receipt Cohorts



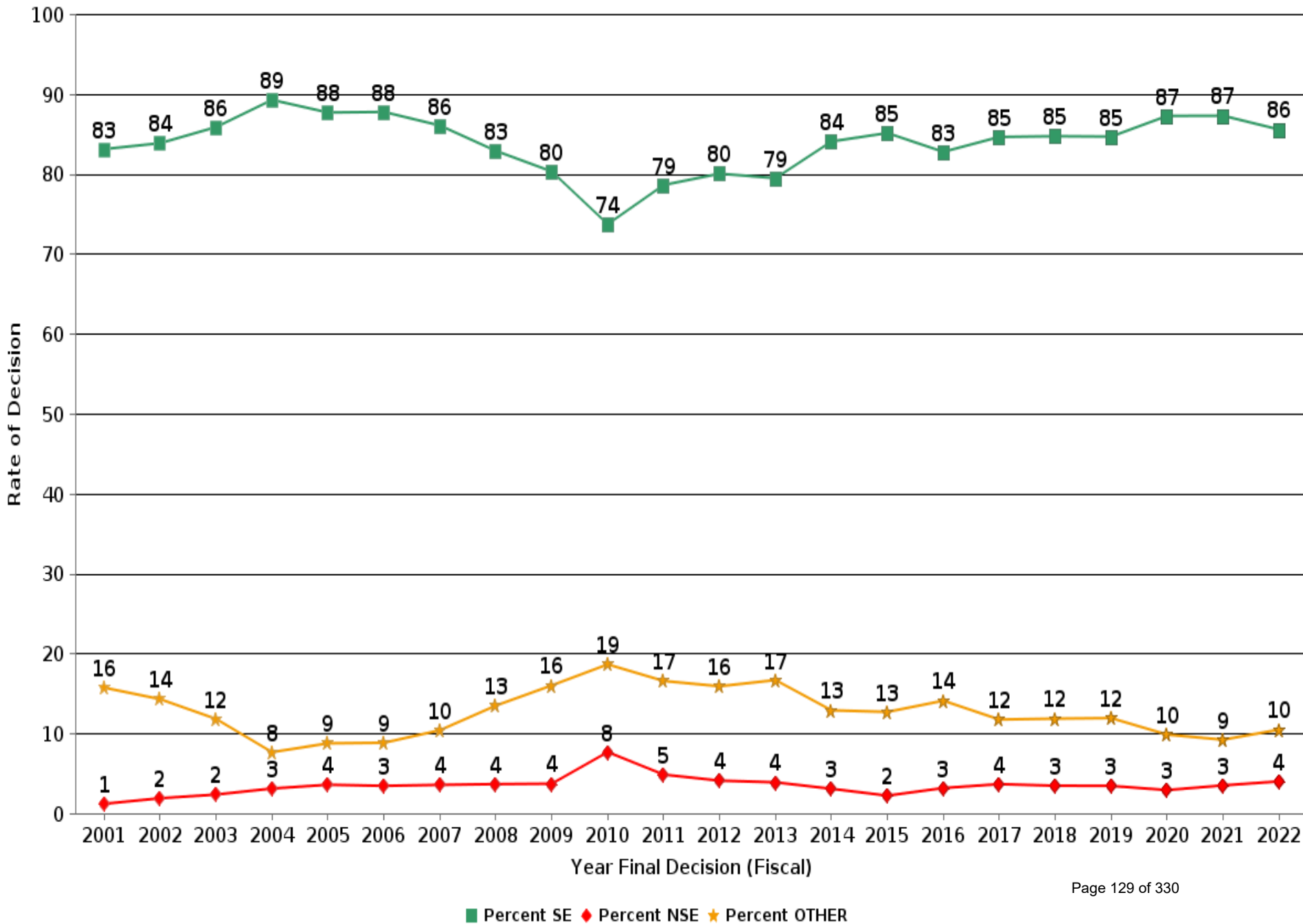
- FY10 Receipt Cohort
- FY11 Receipt Cohort
- FY12 Receipt Cohort
- FY13 Receipt Cohort
- FY14 Receipt Cohort
- FY15 Receipt Cohort
- FY16 Receipt Cohort
- FY17 Receipt Cohort
- FY18 Receipt Cohort
- FY19 Receipt Cohort
- FY20 Receipt Cohort
- FY21 Receipt Cohort
- FY22 Receipt

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



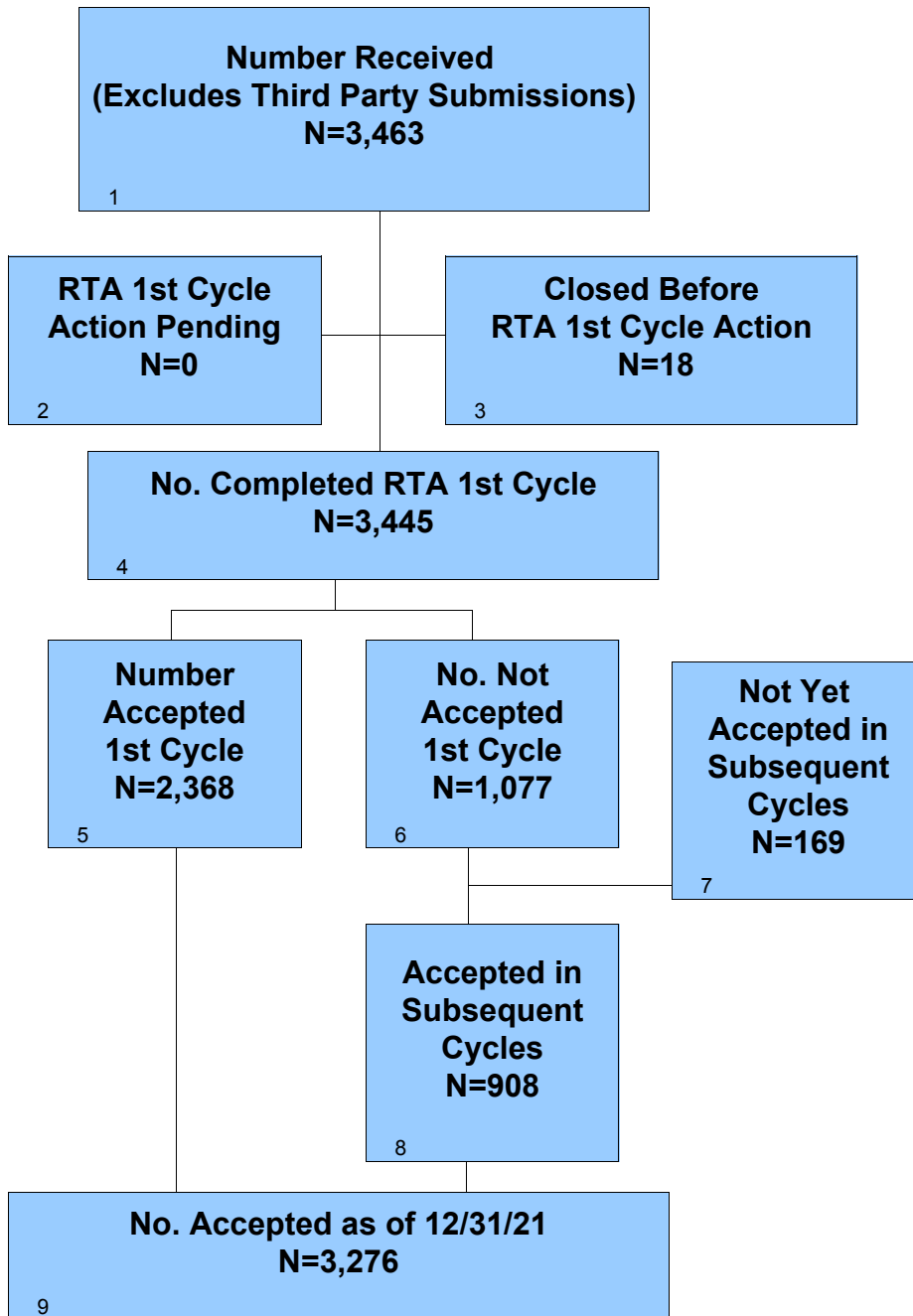
“Pending” means 510ks under review or on hold following a positive RTA decision (FY13 and later).

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

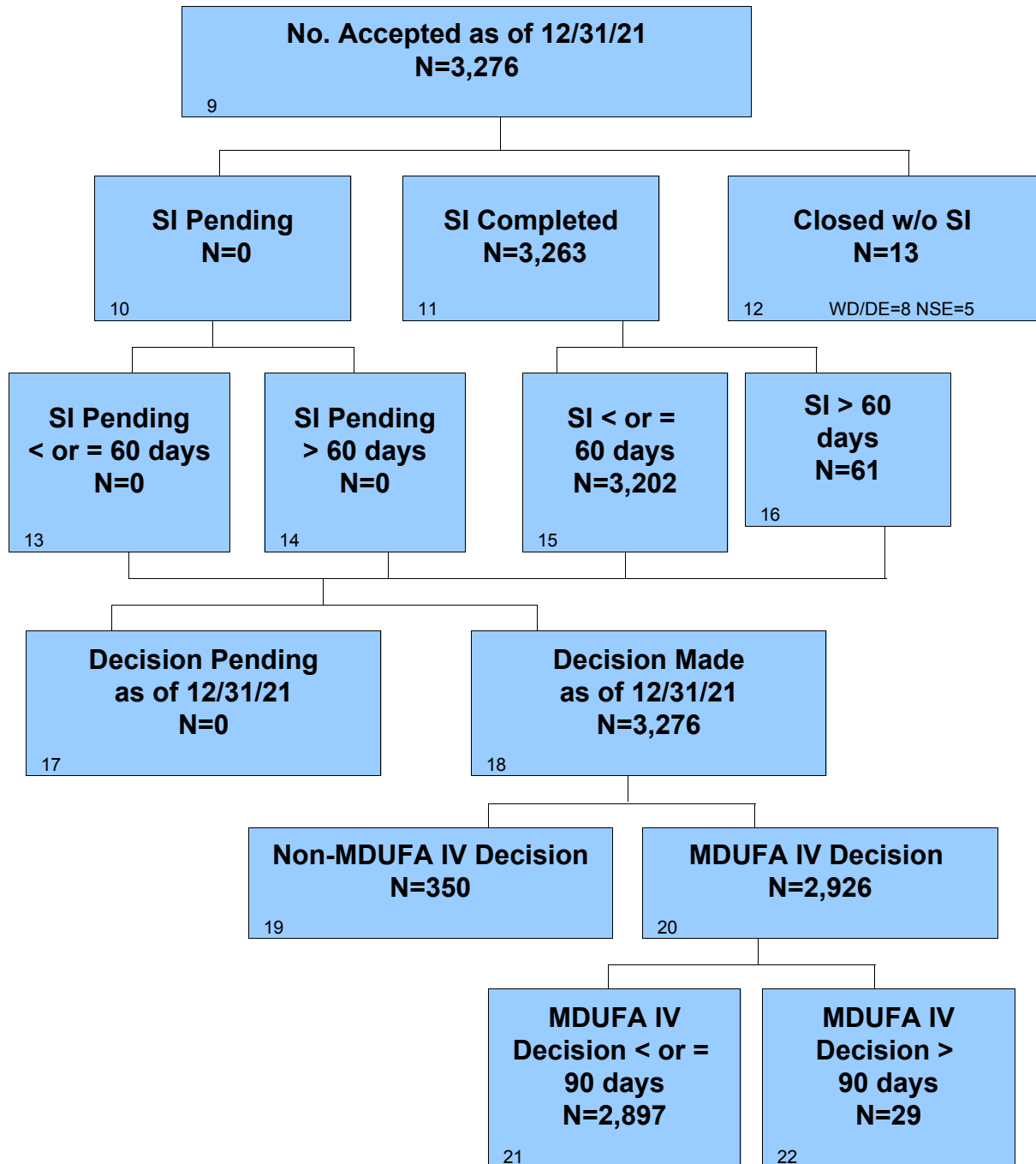


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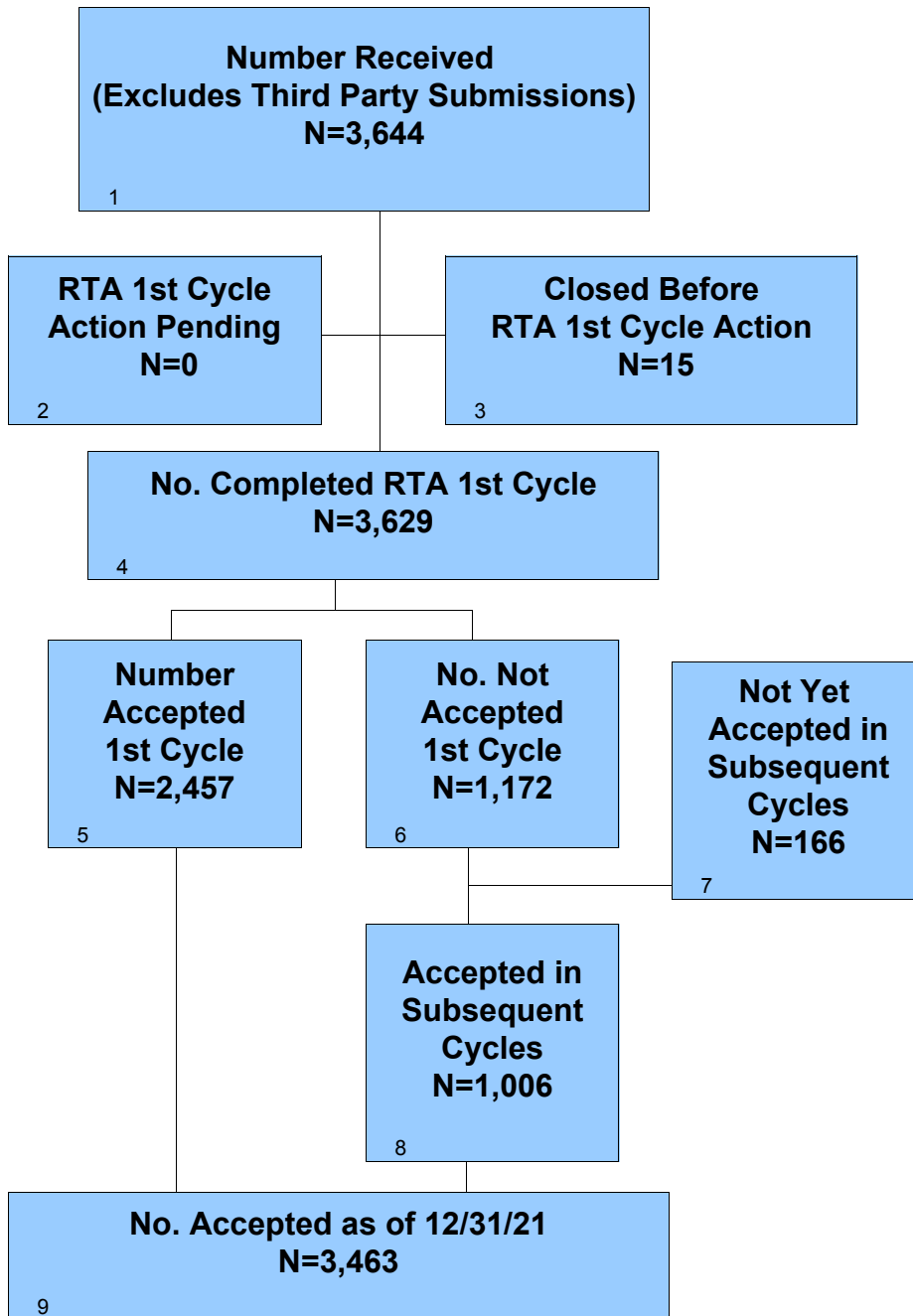
CDRH 510(k)s - FY 2018 as of 12/31/21



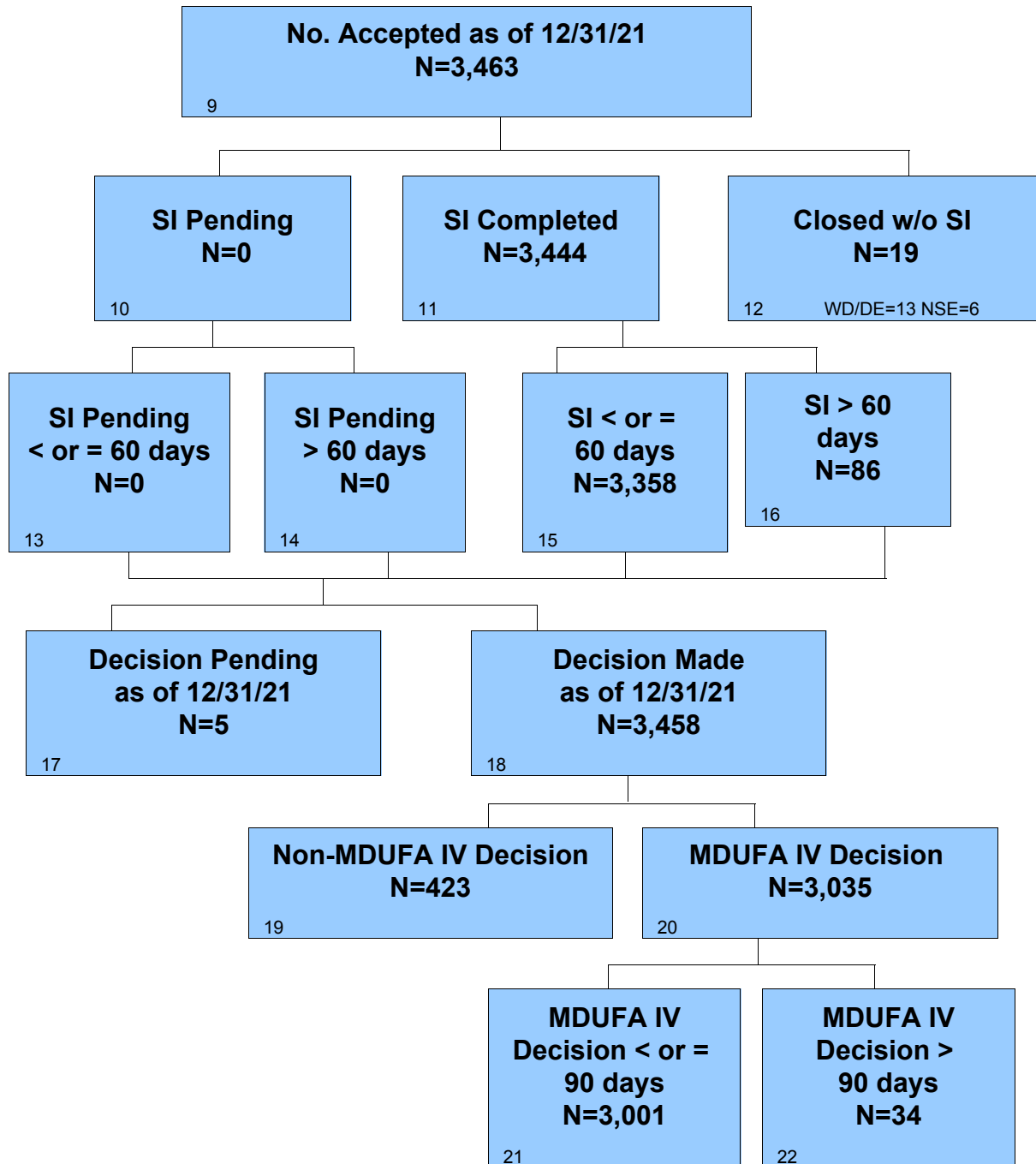
CDRH 510(k)s - FY 2018 as of 12/31/21 Continued



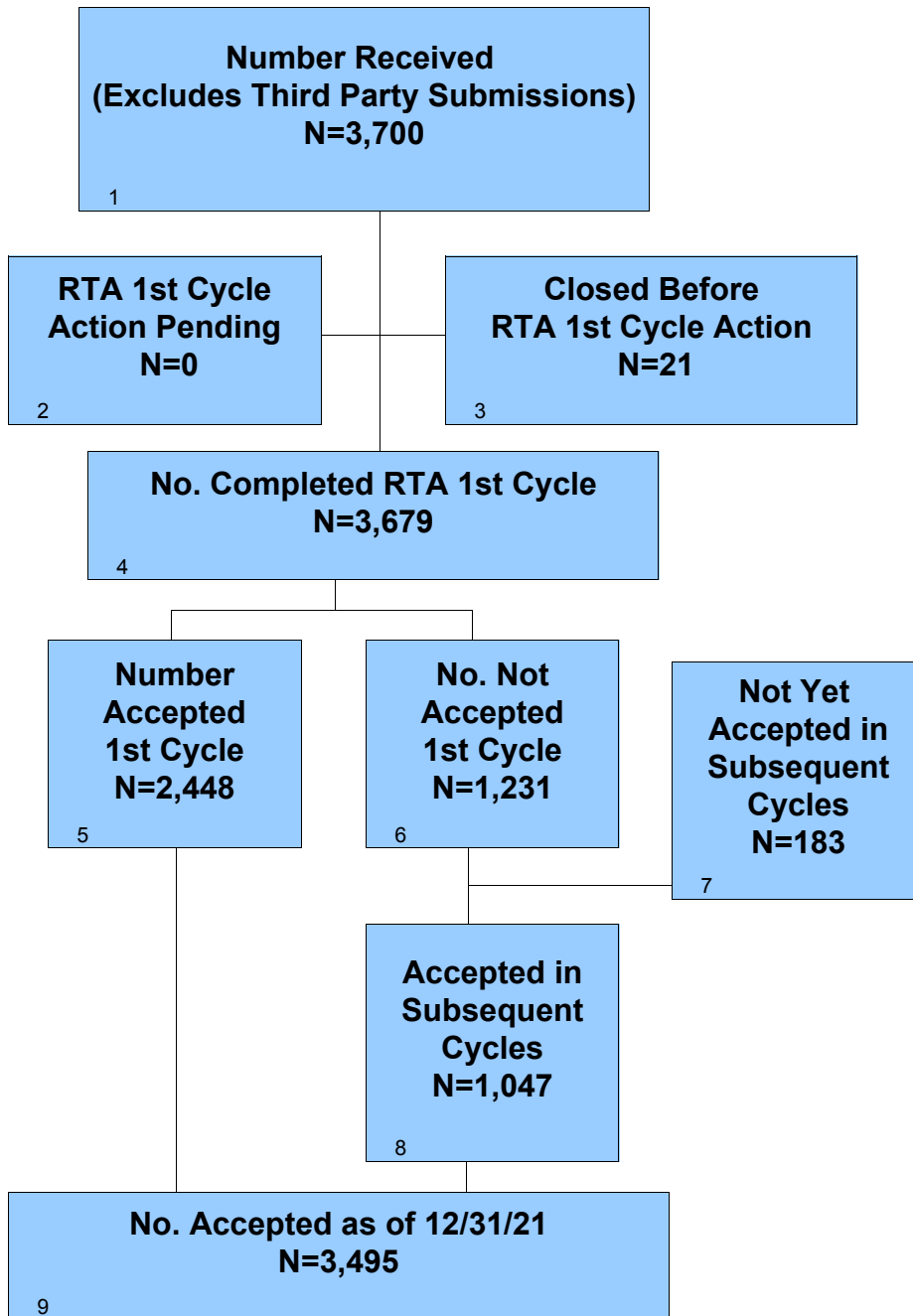
CDRH 510(k)s - FY 2019 as of 12/31/21



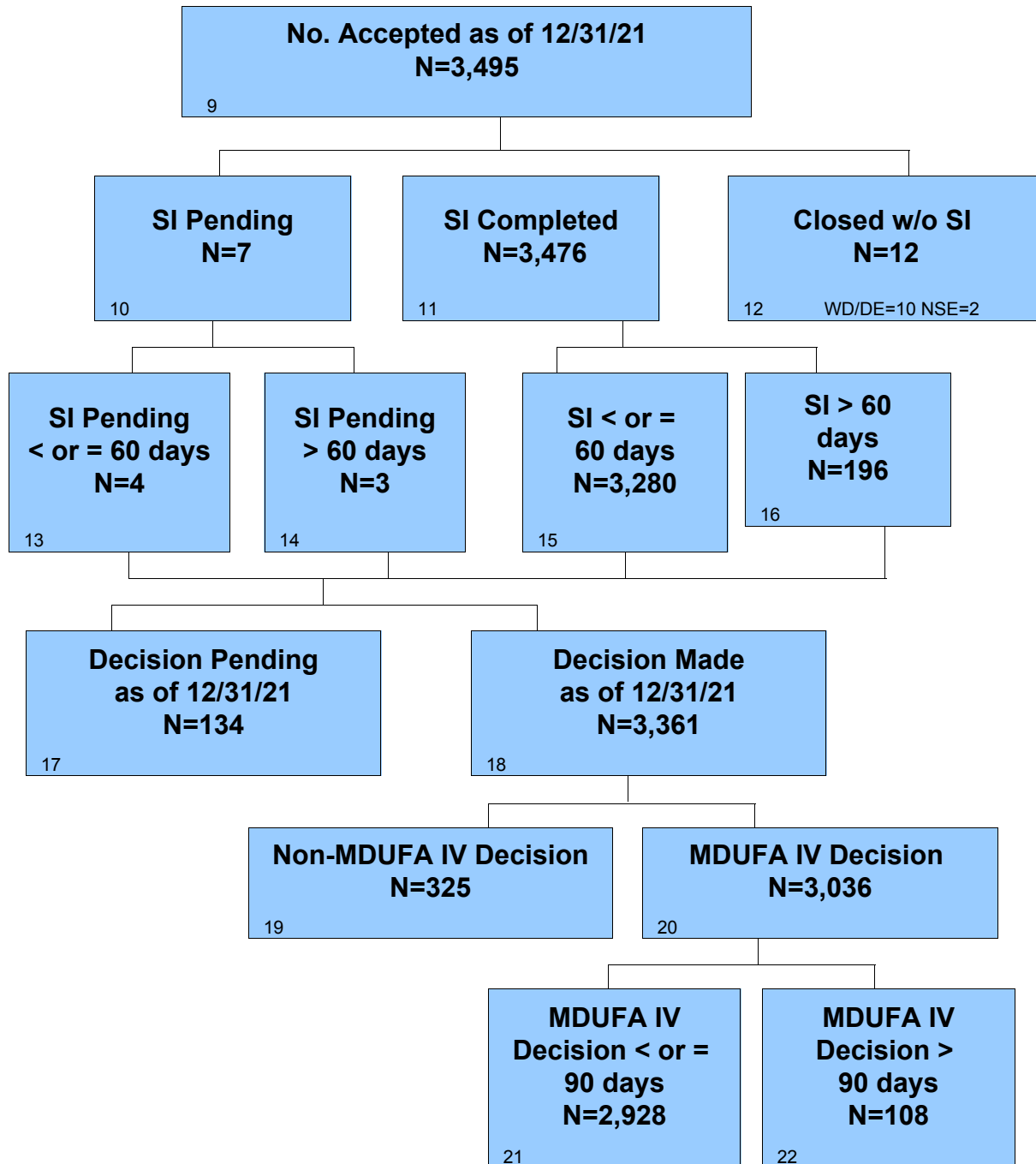
CDRH 510(k)s - FY 2019 as of 12/31/21 Continued



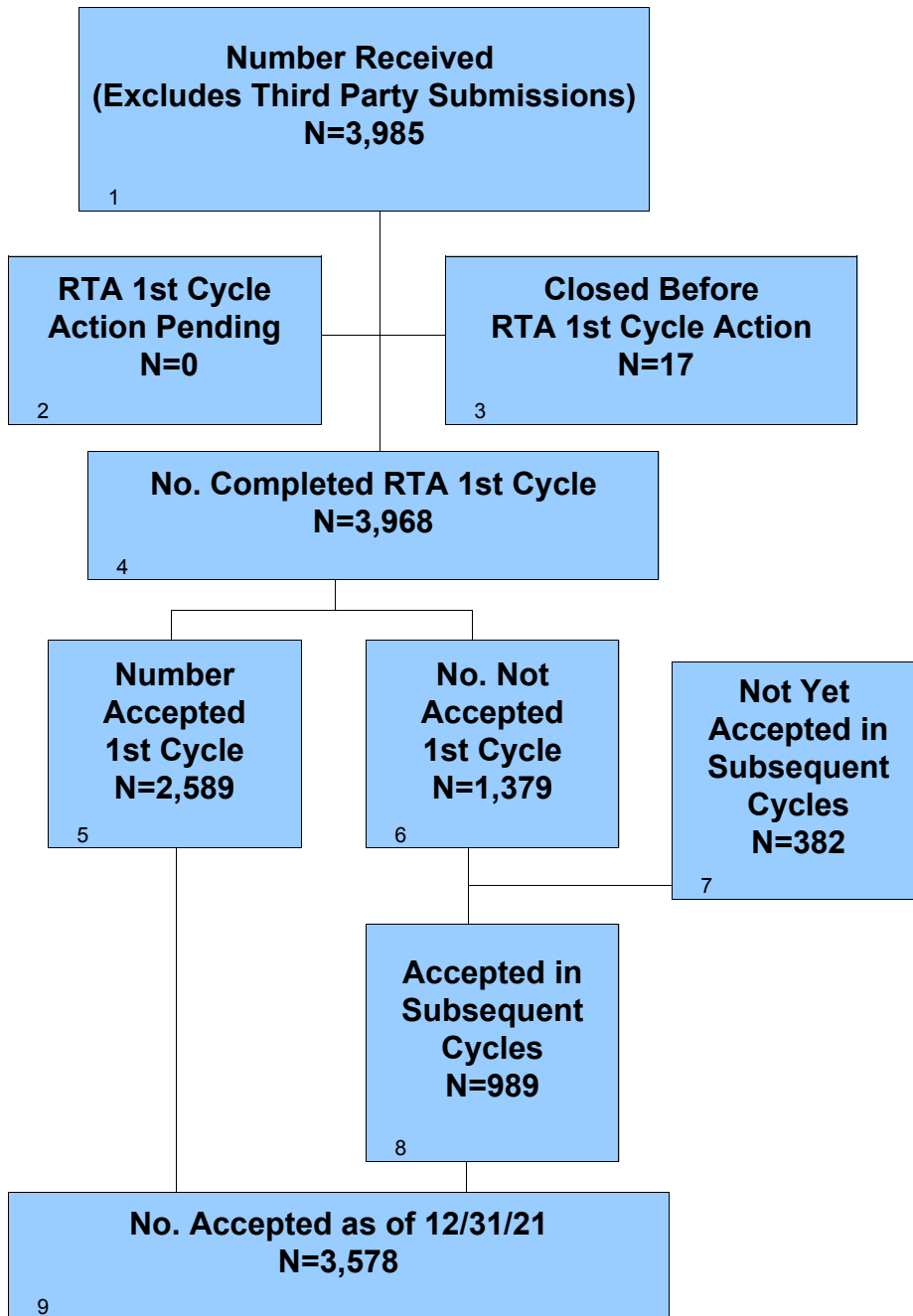
CDRH 510(k)s - FY 2020 as of 12/31/21



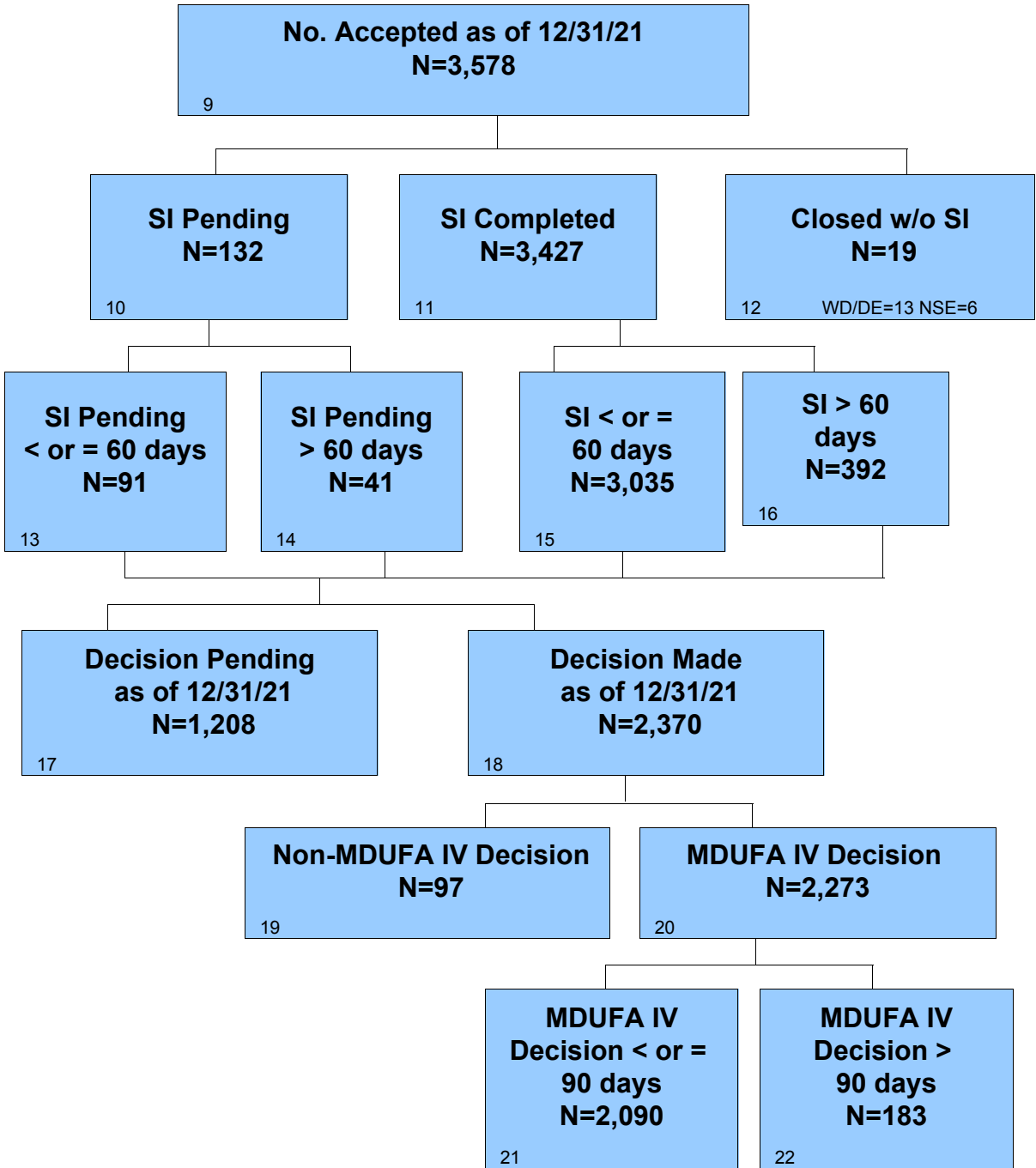
CDRH 510(k)s - FY 2020 as of 12/31/21 Continued



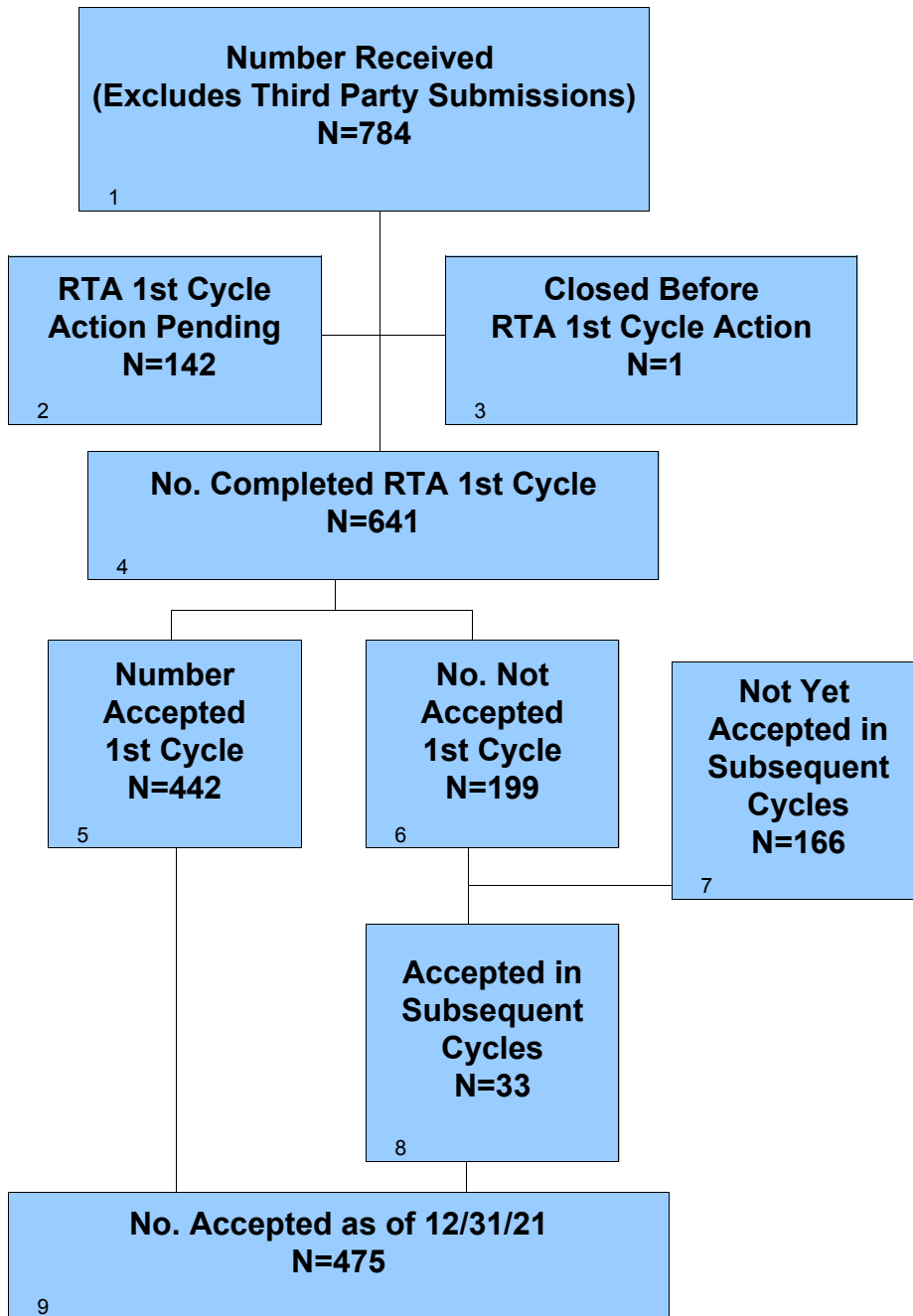
CDRH 510(k)s - FY 2021 as of 12/31/21



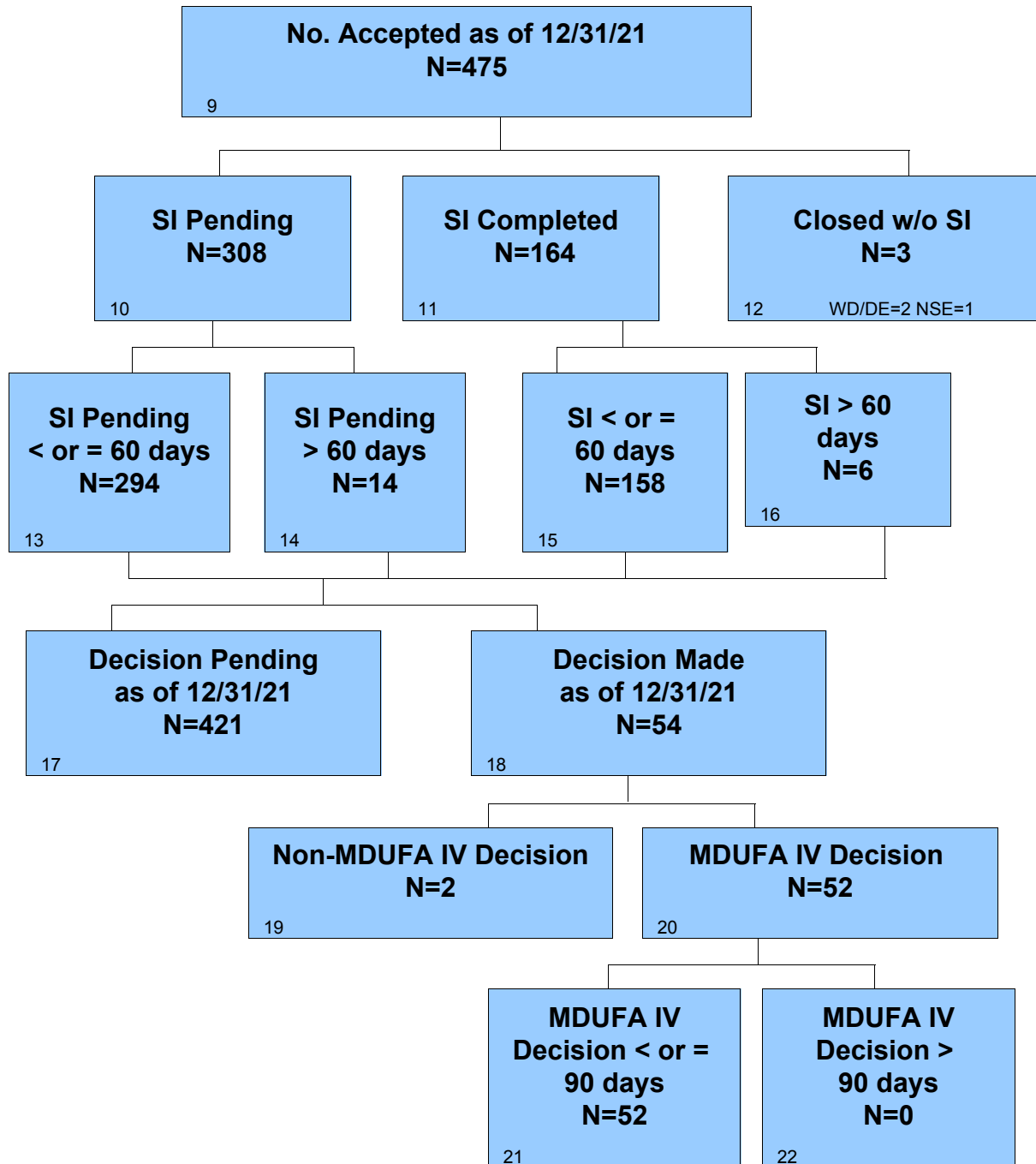
CDRH 510(k)s - FY 2021 as of 12/31/21 Continued



CDRH 510(k)s - FY 2022 as of 12/31/21



CDRH 510(k)s - FY 2022 as of 12/31/21 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	3,700	3,985	784
Closed Before RTA Action	18	15	21	17	1
Number Accepted	2,353	2,403	2,399	2,369	393
Number Without a RTA Review and > 15 Days Since Date Received	15	54	49	220	49
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	142
Number Not Accepted	1,077	1,172	1,231	1,379	199
Rate of Submissions Not Accepted for Review	31.26%	32.30%	33.46%	34.75%	31.05%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	3,276	3,463	3,495	3,578	475
Deleted or Withdrawn Prior to SI	8	13	10	13	2
SI Within 60 FDA Days	3,202	3,358	3,280	3,035	158
SI Over 60 FDA Days	61	86	196	392	6
SI Pending Within 60 FDA Days	0	0	4	91	294
SI Pending Over 60 FDA Days	0	0	3	41	14
510(k)s NSE Without SI	5	6	2	6	1
Current SI Performance Percent Within 60 FDA Days	97.98%	97.33%	94.23%	87.36%	88.27%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	3,263	3,444	3,476	3,427	164
Average Number of FDA Days to Substantive Interaction	51.04	51.42	54.98	58.66	47.46
20th Percentile FDA Days to Substantive Interaction	43	43	45	50	29
40th Percentile FDA Days to Substantive Interaction	55	56	56	57	51
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	57
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	59
Maximum FDA Days to Substantive Interaction	86	90	496	381	66

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

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	3,276	3,463	3,495	3,578	475					
Non-MDUFA IV Decision	350	423	325	97	2					
MDUFA IV Decision (SE/NSE)	2,926	3,035	3,036	2,273	52					
MDUFA IV Decision Within 90 FDA Days	2,897	3,001	2,928	2,090	52					
510(k)s Pending MDUFA IV Decision	0	5	134	1,208	421					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	50	160	3					
Current Performance Percent Within 90 FDA Days	99.01%	98.88%	94.88%	85.90%	94.55%					

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	1.62	1.62	1.63	1.52	1.02
Number With MDUFA IV Decision	2,926	3,035	3,036	2,273	52
Average Number of FDA Days to MDUFA IV Decision	72.62	73.52	77.05	74.31	37.31
20th Percentile FDA Days to MDUFA IV Decision	54	55	54	52	23
40th Percentile FDA Days to MDUFA IV Decision	79	82	83	76	28
60th Percentile FDA Days to MDUFA IV Decision	87	88	88	87	33
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	55
Maximum FDA Days to MDUFA IV Decision	220	655	673	381	81
Average Number of Industry Days to MDUFA IV Decision	54.69	60.09	65.31	35.79	0.27
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	5	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	44	49	51	24	0
80th Percentile Industry Days to MDUFA IV Decision	127	138	139	70	0
Maximum Industry Days to MDUFA IV Decision	563	448	571	333	14
Average Number of Total Days to MDUFA IV Decision	127.31	133.61	142.36	110.10	37.58
20th Percentile Total Days to MDUFA IV Decision	57	57	56	54	23
40th Percentile Total Days to MDUFA IV Decision	89	90	90	86	28
60th Percentile Total Days to MDUFA IV Decision	128	133	137	111	33
80th Percentile Total Days to MDUFA IV Decision	212	224	230	161	56
Maximum Total Days to MDUFA IV Decision	783	871	775	419	81

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	3,276	3,463	3,495	3,578	475
Number With MDUFA IV Decision	2,926	3,035	3,036	2,273	52
Number of SE Decision	2,810	2,920	2,942	2,211	51
Number of NSE Decision	116	115	94	62	1
Number of Withdrawal	185	213	192	88	2
Number of Deleted	156	192	128	6	0
Rate of SE Decision	96.04%	96.21%	96.90%	97.27%	98.08%
Rate of NSE Decision	3.96%	3.79%	3.10%	2.73%	1.92%
Rate of Withdrawal	5.65%	6.15%	5.49%	2.46%	0.42%
Rate of Deleted	4.76%	5.54%	3.66%	0.17%	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	108	183	0
Mean FDA Days for Submissions that Missed the Goal	111.38	141.53	207.01	131.62	0.00
Mean Industry Days for Submissions that Missed the Goal	136.24	192.97	135.59	43.44	0.00

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

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

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

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days
510(k)s Accepted		272		278		253		189		35
Non-MDUFA IV Decision		41		37		33		9		1
MDUFA IV Decision (SE/NSE)		231		241		180		64		0
MDUFA IV Decision Within 90 FDA Days		230		237		122		13		0
510(k)s Pending MDUFA IV Decision		0		0		40		116		34
510(k)s Pending MDUFA IV Decision Over 90 FDA Days		0		0		38		105		2
Current Performance Percent Within 90 FDA Days		99.57%		98.34%		55.96%		7.69%		0.00%

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	534	113
Closed Before RTA Action	1	1	0	0	1
Number Accepted	208	207	226	207	36
Number Without a RTA Review and > 15 Days Since Date Received	0	12	8	11	2
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	24
Number Not Accepted	343	373	302	316	50
Rate of Submissions Not Accepted for Review	62.25%	63.01%	56.34%	59.18%	56.82%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	494	550	502	446	47
Deleted or Withdrawn Prior to SI	2	6	0	0	0
SI Within 60 FDA Days	477	489	411	370	20
SI Over 60 FDA Days	14	54	89	54	1
SI Pending Within 60 FDA Days	0	0	2	22	25
SI Pending Over 60 FDA Days	0	0	0	0	1
510(k)s NSE Without SI	1	1	0	0	0
Current SI Performance Percent Within 60 FDA Days	96.95%	89.89%	82.20%	87.26%	90.91%

**Table 6.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	491	543	500	424	21
Average Number of FDA Days to Substantive Interaction	55.63	56.03	55.35	55.45	44.48
20th Percentile FDA Days to Substantive Interaction	54	54	51	53	27
40th Percentile FDA Days to Substantive Interaction	58	58	57	57	48
60th Percentile FDA Days to Substantive Interaction	59	59	60	59	54
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	59
Maximum FDA Days to Substantive Interaction	78	87	94	88	65

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

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	494	550	502	446	47					
Non-MDUFA IV Decision	74	84	49	23	0					
MDUFA IV Decision (SE/NSE)	420	465	427	253	8					
MDUFA IV Decision Within 90 FDA Days	417	463	423	253	8					
510(k)s Pending MDUFA IV Decision	0	1	26	170	39					
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%	99.06%	99.61%	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	1.57	1.00
Number With MDUFA IV Decision	420	465	427	253	8
Average Number of FDA Days to MDUFA IV Decision	81.05	82.39	79.76	75.93	29.13
20th Percentile FDA Days to MDUFA IV Decision	77	84	76	58	23
40th Percentile FDA Days to MDUFA IV Decision	87	88	87	84	27
60th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	28
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	89	30
Maximum FDA Days to MDUFA IV Decision	148	153	115	90	52
Average Number of Industry Days to MDUFA IV Decision	65.45	68.64	69.22	43.72	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	18	20	15	0	0
60th Percentile Industry Days to MDUFA IV Decision	63	67	61	31	0
80th Percentile Industry Days to MDUFA IV Decision	152	153	148	92	0
Maximum Industry Days to MDUFA IV Decision	389	356	449	293	0
Average Number of Total Days to MDUFA IV Decision	146.51	151.03	148.99	119.65	29.13
20th Percentile Total Days to MDUFA IV Decision	79	88	83	59	23
40th Percentile Total Days to MDUFA IV Decision	103	106	98	88	27
60th Percentile Total Days to MDUFA IV Decision	148	153	147	119	28
80th Percentile Total Days to MDUFA IV Decision	241	242	234	179	30
Maximum Total Days to MDUFA IV Decision	479	446	539	379	52

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	494	550	502	446	47
Number With MDUFA IV Decision	420	465	427	253	8
Number of SE Decision	402	442	413	245	8
Number of NSE Decision	18	23	14	8	0
Number of Withdrawal	35	48	32	21	0
Number of Deleted	39	33	17	0	0
Rate of SE Decision	95.71%	95.05%	96.72%	96.84%	100.00%
Rate of NSE Decision	4.29%	4.95%	3.28%	3.16%	0.00%
Rate of Withdrawal	7.09%	8.73%	6.37%	4.71%	0.00%
Rate of Deleted	7.89%	6.00%	3.39%	0.00%	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	0	0
Mean FDA Days for Submissions that Missed the Goal	115.33	133.50	101.25	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	107.67	258.00	167.75	0.00	0.00

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

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

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

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days
510(k)s Accepted	0		0		0		0		0	
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 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	380	393	80
Closed Before RTA Action	4	2	1	2	0
Number Accepted	237	266	282	278	48
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4	17	4
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	15
Number Not Accepted	114	100	93	96	13
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.54%	24.55%	20.00%

**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	370	373	54
Deleted or Withdrawn Prior to SI	4	0	1	1	1
SI Within 60 FDA Days	324	358	355	336	28
SI Over 60 FDA Days	13	8	12	19	2
SI Pending Within 60 FDA Days	0	0	0	7	23
SI Pending Over 60 FDA Days	0	0	1	9	0
510(k)s NSE Without SI	0	0	1	1	0
Current SI Performance Percent Within 60 FDA Days	96.14%	97.81%	96.21%	92.05%	93.33%

**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	367	355	30
Average Number of FDA Days to Substantive Interaction	49.74	50.76	51.61	51.03	47.30
20th Percentile FDA Days to Substantive Interaction	30	30	36	30	30
40th Percentile FDA Days to Substantive Interaction	53	56	57	57	48
60th Percentile FDA Days to Substantive Interaction	58	59	59	59	58
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	59
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	370	373	54					
Non-MDUFA IV Decision	32	52	28	9	1					
MDUFA IV Decision (SE/NSE)	309	314	329	217	7					
MDUFA IV Decision Within 90 FDA Days	303	303	317	214	7					
510(k)s Pending MDUFA IV Decision	0	0	13	147	46					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	4	10	0					
Current Performance Percent Within 90 FDA Days	98.06%	96.50%	95.20%	94.27%	100.00%					

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.71	1.70	1.81	1.64	1.00
Number With MDUFA IV Decision	309	314	329	217	7
Average Number of FDA Days to MDUFA IV Decision	71.68	71.37	74.71	65.93	37.00
20th Percentile FDA Days to MDUFA IV Decision	50	49	55	29	23
40th Percentile FDA Days to MDUFA IV Decision	80	80	86	59	29
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	87	39
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	89	53
Maximum FDA Days to MDUFA IV Decision	159	117	245	100	60
Average Number of Industry Days to MDUFA IV Decision	64.80	66.25	82.64	47.09	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	19	20	28	8	0
60th Percentile Industry Days to MDUFA IV Decision	65	68	76	41	0
80th Percentile Industry Days to MDUFA IV Decision	146	140	154	84	0
Maximum Industry Days to MDUFA IV Decision	292	359	571	295	0
Average Number of Total Days to MDUFA IV Decision	136.48	137.61	157.35	113.02	37.00
20th Percentile Total Days to MDUFA IV Decision	55	51	56	29	23
40th Percentile Total Days to MDUFA IV Decision	102	98	115	75	29
60th Percentile Total Days to MDUFA IV Decision	150	148	159	123	39
80th Percentile Total Days to MDUFA IV Decision	228	227	240	173	53
Maximum Total Days to MDUFA IV Decision	370	447	672	395	60

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	370	373	54
Number With MDUFA IV Decision	309	314	329	217	7
Number of SE Decision	291	289	305	203	7
Number of NSE Decision	18	25	24	14	0
Number of Withdrawal	20	31	19	8	1
Number of Deleted	10	20	9	1	0
Rate of SE Decision	94.17%	92.04%	92.71%	93.55%	100.00%
Rate of NSE Decision	5.83%	7.96%	7.29%	6.45%	0.00%
Rate of Withdrawal	5.87%	8.47%	5.14%	2.14%	1.85%
Rate of Deleted	2.93%	5.46%	2.43%	0.27%	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	12	3	0
Mean FDA Days for Submissions that Missed the Goal	107.17	99.82	112.83	96.67	0.00
Mean Industry Days for Submissions that Missed the Goal	131.50	159.09	202.25	185.33	0.00

Table 6.8 OHT2 - Office of Cardiovascular Devices

LDT 510(k) MDUFA IV Decision Metric

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	455	476	443	520	81
Closed Before RTA Action	3	4	4	6	0
Number Accepted	334	349	289	295	46
Number Without a RTA Review and > 15 Days Since Date Received	2	6	2	14	3
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	7
Number Not Accepted	116	117	148	205	25
Rate of Submissions Not Accepted for Review	25.66%	24.79%	33.71%	39.88%	33.78%

**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	453	418	444	53
Deleted or Withdrawn Prior to SI	0	1	1	2	0
SI Within 60 FDA Days	427	447	402	396	20
SI Over 60 FDA Days	6	4	13	20	0
SI Pending Within 60 FDA Days	0	0	1	14	33
SI Pending Over 60 FDA Days	0	0	1	10	0
510(k)s NSE Without SI	3	1	0	2	0
Current SI Performance Percent Within 60 FDA Days	97.94%	98.89%	96.63%	92.52%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	433	451	415	416	20
Average Number of FDA Days to Substantive Interaction	51.10	52.58	53.36	53.71	50.55
20th Percentile FDA Days to Substantive Interaction	44	48	51	52	30
40th Percentile FDA Days to Substantive Interaction	55	57	57	57	57
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	67	78	68	73	60

**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	453	418	444	53					
Non-MDUFA IV Decision	50	77	49	11	0					
MDUFA IV Decision (SE/NSE)	386	376	348	243	3					
MDUFA IV Decision Within 90 FDA Days	382	371	341	240	3					
510(k)s Pending MDUFA IV Decision	0	0	21	190	50					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	4	10	0					
Current Performance Percent Within 90 FDA Days	98.96%	98.67%	96.88%	94.86%	100.00%					

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.74	1.85	1.82	1.69	1.33
Number With MDUFA IV Decision	386	376	348	243	3
Average Number of FDA Days to MDUFA IV Decision	75.68	78.15	78.38	75.79	34.33
20th Percentile FDA Days to MDUFA IV Decision	58	60	64	56	26
40th Percentile FDA Days to MDUFA IV Decision	84	87	87	86	29
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	88	34
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	42
Maximum FDA Days to MDUFA IV Decision	118	150	135	199	50
Average Number of Industry Days to MDUFA IV Decision	74.93	95.90	99.67	57.66	4.67
20th Percentile Industry Days to MDUFA IV Decision	0	5	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	29	54	52	23	0
60th Percentile Industry Days to MDUFA IV Decision	94	118	120	62	3
80th Percentile Industry Days to MDUFA IV Decision	165	174	178	117	8
Maximum Industry Days to MDUFA IV Decision	214	444	490	225	14
Average Number of Total Days to MDUFA IV Decision	150.61	174.06	178.05	133.45	39.00
20th Percentile Total Days to MDUFA IV Decision	64	87	86	60	26
40th Percentile Total Days to MDUFA IV Decision	113	140	136	109	29
60th Percentile Total Days to MDUFA IV Decision	177	205	209	150	37
80th Percentile Total Days to MDUFA IV Decision	248	261	266	203	50
Maximum Total Days to MDUFA IV Decision	304	540	580	338	64

**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	453	418	444	53
Number With MDUFA IV Decision	386	376	348	243	3
Number of SE Decision	361	353	328	225	3
Number of NSE Decision	25	23	20	18	0
Number of Withdrawal	20	31	25	9	0
Number of Deleted	30	44	23	2	0
Rate of SE Decision	93.52%	93.88%	94.25%	92.59%	100.00%
Rate of NSE Decision	6.48%	6.12%	5.75%	7.41%	0.00%
Rate of Withdrawal	4.59%	6.84%	5.98%	2.03%	0.00%
Rate of Deleted	6.88%	9.71%	5.50%	0.45%	0.00%

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

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

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

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

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

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days
510(k)s Accepted	0	0	0	0	0	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	720	1,029	188
Closed Before RTA Action	2	0	3	4	0
Number Accepted	368	392	447	601	83
Number Without a RTA Review and > 15 Days Since Date Received	6	7	5	36	13
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	45
Number Not Accepted	176	205	265	388	47
Rate of Submissions Not Accepted for Review	32.00%	33.94%	36.96%	37.85%	32.87%

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	651	906	105
Deleted or Withdrawn Prior to SI	0	3	2	3	0
SI Within 60 FDA Days	512	543	624	719	20
SI Over 60 FDA Days	4	12	23	145	3
SI Pending Within 60 FDA Days	0	0	1	29	79
SI Pending Over 60 FDA Days	0	0	0	10	3
510(k)s NSE Without SI	0	1	1	0	0
Current SI Performance Percent Within 60 FDA Days	99.22%	97.66%	96.30%	82.27%	76.92%

**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	647	864	23
Average Number of FDA Days to Substantive Interaction	52.60	52.19	53.92	56.70	52.26
20th Percentile FDA Days to Substantive Interaction	50	48	52	53	44
40th Percentile FDA Days to Substantive Interaction	57	56	57	57	53
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	106	66

**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	651	906	105					
Non-MDUFA IV Decision	68	74	73	14	0					
MDUFA IV Decision (SE/NSE)	448	484	559	598	2					
MDUFA IV Decision Within 90 FDA Days	440	480	534	474	2					
510(k)s Pending MDUFA IV Decision	0	1	19	294	103					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	4	31	1					
Current Performance Percent Within 90 FDA Days	98.21%	99.17%	94.85%	75.36%	66.67%					

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	1.57	1.00
Number With MDUFA IV Decision	448	484	559	598	2
Average Number of FDA Days to MDUFA IV Decision	73.88	73.11	76.30	79.94	44.00
20th Percentile FDA Days to MDUFA IV Decision	57	55	59	60	39
40th Percentile FDA Days to MDUFA IV Decision	79	81	84	86	42
60th Percentile FDA Days to MDUFA IV Decision	87	87	87	88	46
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	91	49
Maximum FDA Days to MDUFA IV Decision	220	207	179	242	53
Average Number of Industry Days to MDUFA IV Decision	48.98	54.82	64.96	34.56	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	10	0	0
60th Percentile Industry Days to MDUFA IV Decision	31	41	61	21	0
80th Percentile Industry Days to MDUFA IV Decision	110	128	137	69	0
Maximum Industry Days to MDUFA IV Decision	563	355	391	232	0
Average Number of Total Days to MDUFA IV Decision	122.86	127.93	141.26	114.50	44.00
20th Percentile Total Days to MDUFA IV Decision	59	57	60	70	39
40th Percentile Total Days to MDUFA IV Decision	88	87	91	90	42
60th Percentile Total Days to MDUFA IV Decision	110	125	145	109	46
80th Percentile Total Days to MDUFA IV Decision	193	210	226	156	49
Maximum Total Days to MDUFA IV Decision	783	511	497	399	53

**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	651	906	105
Number With MDUFA IV Decision	448	484	559	598	2
Number of SE Decision	437	470	547	591	2
Number of NSE Decision	11	14	12	7	0
Number of Withdrawal	36	37	36	12	0
Number of Deleted	31	35	35	1	0
Rate of SE Decision	97.54%	97.11%	97.85%	98.83%	100.00%
Rate of NSE Decision	2.46%	2.89%	2.15%	1.17%	0.00%
Rate of Withdrawal	6.98%	6.62%	5.53%	1.32%	0.00%
Rate of Deleted	6.01%	6.26%	5.38%	0.11%	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	25	124	0
Mean FDA Days for Submissions that Missed the Goal	119.50	121.00	101.52	99.87	0.00
Mean Industry Days for Submissions that Missed the Goal	168.63	132.50	130.60	51.03	0.00

**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%	0%	0%	0%	0%

**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%		0%		0%		0%		0%

**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	275	261	276	61
Closed Before RTA Action	3	0	3	1	0
Number Accepted	147	156	110	135	25
Number Without a RTA Review and > 15 Days Since Date Received	3	7	5	8	4
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	16
Number Not Accepted	107	112	143	132	16
Rate of Submissions Not Accepted for Review	41.63%	40.73%	55.43%	48.00%	35.56%

**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	261	237	241	33
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	232	258	228	232	9
SI Over 60 FDA Days	4	3	9	2	0
SI Pending Within 60 FDA Days	0	0	0	7	24
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	0	0
Current SI Performance Percent Within 60 FDA Days	98.31%	98.85%	96.20%	99.15%	100.00%

**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	261	237	234	9
Average Number of FDA Days to Substantive Interaction	53.91	54.56	53.49	53.39	48.00
20th Percentile FDA Days to Substantive Interaction	53	54	50	53	29
40th Percentile FDA Days to Substantive Interaction	58	58	58	58	54
60th Percentile FDA Days to Substantive Interaction	60	60	59	59	58
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	86	63	87	66	60

**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	261	237	241	33					
Non-MDUFA IV Decision	30	30	16	7	0					
MDUFA IV Decision (SE/NSE)	206	228	217	151	3					
MDUFA IV Decision Within 90 FDA Days	201	221	217	150	3					
510(k)s Pending MDUFA IV Decision	0	3	4	83	30					
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%	96.93%	100.00%	99.34%	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	1.43	1.00
Number With MDUFA IV Decision	206	228	217	151	3
Average Number of FDA Days to MDUFA IV Decision	76.47	80.33	75.59	70.99	28.33
20th Percentile FDA Days to MDUFA IV Decision	60	68	61	44	27
40th Percentile FDA Days to MDUFA IV Decision	86	88	87	78	28
60th Percentile FDA Days to MDUFA IV Decision	89	90	89	88	28
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	29
Maximum FDA Days to MDUFA IV Decision	170	152	90	131	30
Average Number of Industry Days to MDUFA IV Decision	42.60	53.86	57.55	33.46	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	38	37	23	11	0
80th Percentile Industry Days to MDUFA IV Decision	84	123	119	69	0
Maximum Industry Days to MDUFA IV Decision	187	391	360	262	0
Average Number of Total Days to MDUFA IV Decision	119.07	134.19	133.14	104.44	28.33
20th Percentile Total Days to MDUFA IV Decision	61	82	61	49	27
40th Percentile Total Days to MDUFA IV Decision	89	90	89	85	28
60th Percentile Total Days to MDUFA IV Decision	117	123	110	90	28
80th Percentile Total Days to MDUFA IV Decision	171	215	205	152	29
Maximum Total Days to MDUFA IV Decision	346	543	449	352	30

**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	261	237	241	33
Number With MDUFA IV Decision	206	228	217	151	3
Number of SE Decision	198	221	206	147	3
Number of NSE Decision	8	7	11	4	0
Number of Withdrawal	17	16	13	7	0
Number of Deleted	10	13	3	0	0
Rate of SE Decision	96.12%	96.93%	94.93%	97.35%	100.00%
Rate of NSE Decision	3.88%	3.07%	5.07%	2.65%	0.00%
Rate of Withdrawal	7.20%	6.13%	5.49%	2.90%	0.00%
Rate of Deleted	4.24%	4.98%	1.27%	0.00%	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	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 OHT6 - Office of Orthopedic Devices
510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	606	634	655	575	105
Closed Before RTA Action	2	4	5	2	0
Number Accepted	466	489	493	435	60
Number Without a RTA Review and > 15 Days Since Date Received	0	5	6	6	3
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	12
Number Not Accepted	138	136	151	132	30
Rate of Submissions Not Accepted for Review	22.85%	21.59%	23.23%	23.04%	32.26%

**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	546	66
Deleted or Withdrawn Prior to SI	0	2	3	1	0
SI Within 60 FDA Days	575	617	634	541	27
SI Over 60 FDA Days	19	3	1	1	0
SI Pending Within 60 FDA Days	0	0	0	3	39
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	96.80%	99.52%	99.84%	99.82%	100.00%

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	542	27
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.83	50.11	48.11
20th Percentile FDA Days to Substantive Interaction	39	30	30	30	32
40th Percentile FDA Days to Substantive Interaction	55	56	56	55	52
60th Percentile FDA Days to Substantive Interaction	57	58	58	58	56
80th Percentile FDA Days to Substantive Interaction	59	60	60	59	58
Maximum FDA Days to Substantive Interaction	78	64	61	90	59

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	546	66					
Non-MDUFA IV Decision	40	47	59	19	0					
MDUFA IV Decision (SE/NSE)	554	575	570	406	13					
MDUFA IV Decision Within 90 FDA Days	552	574	570	405	13					
510(k)s Pending MDUFA IV Decision	0	0	9	121	53					
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%	99.75%	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	1.50	1.39	1.00
Number With MDUFA IV Decision	554	575	570	406	13
Average Number of FDA Days to MDUFA IV Decision	71.36	70.57	66.72	61.50	45.23
20th Percentile FDA Days to MDUFA IV Decision	52	51	35	30	29
40th Percentile FDA Days to MDUFA IV Decision	74	76	60	57	37
60th Percentile FDA Days to MDUFA IV Decision	86	87	86	72	52
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	87	57
Maximum FDA Days to MDUFA IV Decision	135	91	90	151	81
Average Number of Industry Days to MDUFA IV Decision	48.84	50.98	49.22	24.13	0.00
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	19	0	0
80th Percentile Industry Days to MDUFA IV Decision	103	103	94	44	0
Maximum Industry Days to MDUFA IV Decision	340	444	402	333	0
Average Number of Total Days to MDUFA IV Decision	120.19	121.55	115.94	85.62	45.23
20th Percentile Total Days to MDUFA IV Decision	57	56	37	30	29
40th Percentile Total Days to MDUFA IV Decision	86	87	66	58	37
60th Percentile Total Days to MDUFA IV Decision	115	111	101	87	52
80th Percentile Total Days to MDUFA IV Decision	189	185	181	127	57
Maximum Total Days to MDUFA IV Decision	430	533	491	419	81

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	546	66
Number With MDUFA IV Decision	554	575	570	406	13
Number of SE Decision	540	563	566	404	13
Number of NSE Decision	14	12	4	2	0
Number of Withdrawal	24	28	37	17	0
Number of Deleted	16	19	22	2	0
Rate of SE Decision	97.47%	97.91%	99.30%	99.51%	100.00%
Rate of NSE Decision	2.53%	2.09%	0.70%	0.49%	0.00%
Rate of Withdrawal	4.04%	4.50%	5.80%	3.11%	0.00%
Rate of Deleted	2.69%	3.05%	3.45%	0.37%	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 and Radiological Health

510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	681	684	705	658	156
Closed Before RTA Action	3	4	5	2	0
Number Accepted	593	544	552	418	95
Number Without a RTA Review and > 15 Days Since Date Received	2	7	19	128	20
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	23
Number Not Accepted	83	129	129	110	18
Rate of Submissions Not Accepted for Review	12.24%	18.97%	18.43%	16.77%	13.53%

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

510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	659	652	679	622	117
Deleted or Withdrawn Prior to SI	2	1	3	6	1
SI Within 60 FDA Days	655	646	626	441	34
SI Over 60 FDA Days	1	2	49	151	0
SI Pending Within 60 FDA Days	0	0	0	9	71
SI Pending Over 60 FDA Days	0	0	1	12	10
510(k)s NSE Without SI	1	3	0	3	1
Current SI Performance Percent Within 60 FDA Days	99.70%	99.23%	92.60%	72.65%	75.56%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	656	648	675	592	34
Average Number of FDA Days to Substantive Interaction	46.54	46.73	63.91	81.77	43.71
20th Percentile FDA Days to Substantive Interaction	30	29	30	46	26
40th Percentile FDA Days to Substantive Interaction	48	49	51	55	43
60th Percentile FDA Days to Substantive Interaction	56	56	57	59	55
80th Percentile FDA Days to Substantive Interaction	58	59	59	120	58
Maximum FDA Days to Substantive Interaction	61	61	496	381	60

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

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	659	652	679	622	117					
Non-MDUFA IV Decision	56	59	51	14	1					
MDUFA IV Decision (SE/NSE)	603	593	586	405	16					
MDUFA IV Decision Within 90 FDA Days	602	589	526	354	16					
510(k)s Pending MDUFA IV Decision	0	0	42	203	100					
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	38	108	2					
Current Performance Percent Within 90 FDA Days	99.83%	99.33%	84.29%	69.01%	88.89%					

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

510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.51	1.44	1.53	1.41	1.00
Number With MDUFA IV Decision	603	593	586	405	16
Average Number of FDA Days to MDUFA IV Decision	64.21	65.35	86.89	82.65	36.50
20th Percentile FDA Days to MDUFA IV Decision	30	30	30	43	22
40th Percentile FDA Days to MDUFA IV Decision	59	59	65	68	27
60th Percentile FDA Days to MDUFA IV Decision	81	81	85	86	29
80th Percentile FDA Days to MDUFA IV Decision	88	88	89	89	58
Maximum FDA Days to MDUFA IV Decision	93	655	673	381	61
Average Number of Industry Days to MDUFA IV Decision	42.78	42.94	51.18	26.04	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	25	13	35	4	0
80th Percentile Industry Days to MDUFA IV Decision	91	90	107	49	0
Maximum Industry Days to MDUFA IV Decision	231	448	360	275	0
Average Number of Total Days to MDUFA IV Decision	106.99	108.29	138.08	108.70	36.50
20th Percentile Total Days to MDUFA IV Decision	30	30	30	43	22
40th Percentile Total Days to MDUFA IV Decision	72	61	77	77	27
60th Percentile Total Days to MDUFA IV Decision	104	90	120	113	29
80th Percentile Total Days to MDUFA IV Decision	177	173	215	155	58
Maximum Total Days to MDUFA IV Decision	321	871	775	384	61

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	659	652	679	622	117
Number With MDUFA IV Decision	603	593	586	405	16
Number of SE Decision	581	582	577	396	15
Number of NSE Decision	22	11	9	9	1
Number of Withdrawal	33	22	30	14	1
Number of Deleted	20	28	19	0	0
Rate of SE Decision	96.35%	98.15%	98.46%	97.78%	93.75%
Rate of NSE Decision	3.65%	1.85%	1.54%	2.22%	6.25%
Rate of Withdrawal	5.01%	3.37%	4.42%	2.25%	0.85%
Rate of Deleted	3.03%	4.29%	2.80%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	4	60	51	0
Mean FDA Days for Submissions that Missed the Goal	93.00	370.00	288.33	207.98	0.00
Mean Industry Days for Submissions that Missed the Goal	202.00	268.00	121.10	10.80	0.00

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

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

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

Performance Metric	FY 2018		FY 2019		FY 2020		FY 2021		FY 2022	
	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days	95%	Within 90 FDA Days
510(k)s Accepted		272		278		253		189		35
Non-MDUFA IV Decision		41		37		33		9		1
MDUFA IV Decision (SE/NSE)		231		241		180		64		0
MDUFA IV Decision Within 90 FDA Days		230		237		122		13		0
510(k)s Pending MDUFA IV Decision		0		0		40		116		34
510(k)s Pending MDUFA IV Decision Over 90 FDA Days		0		0		38		105		2
Current Performance Percent Within 90 FDA Days		99.57%		98.34%		55.96%		7.69%		0.00%

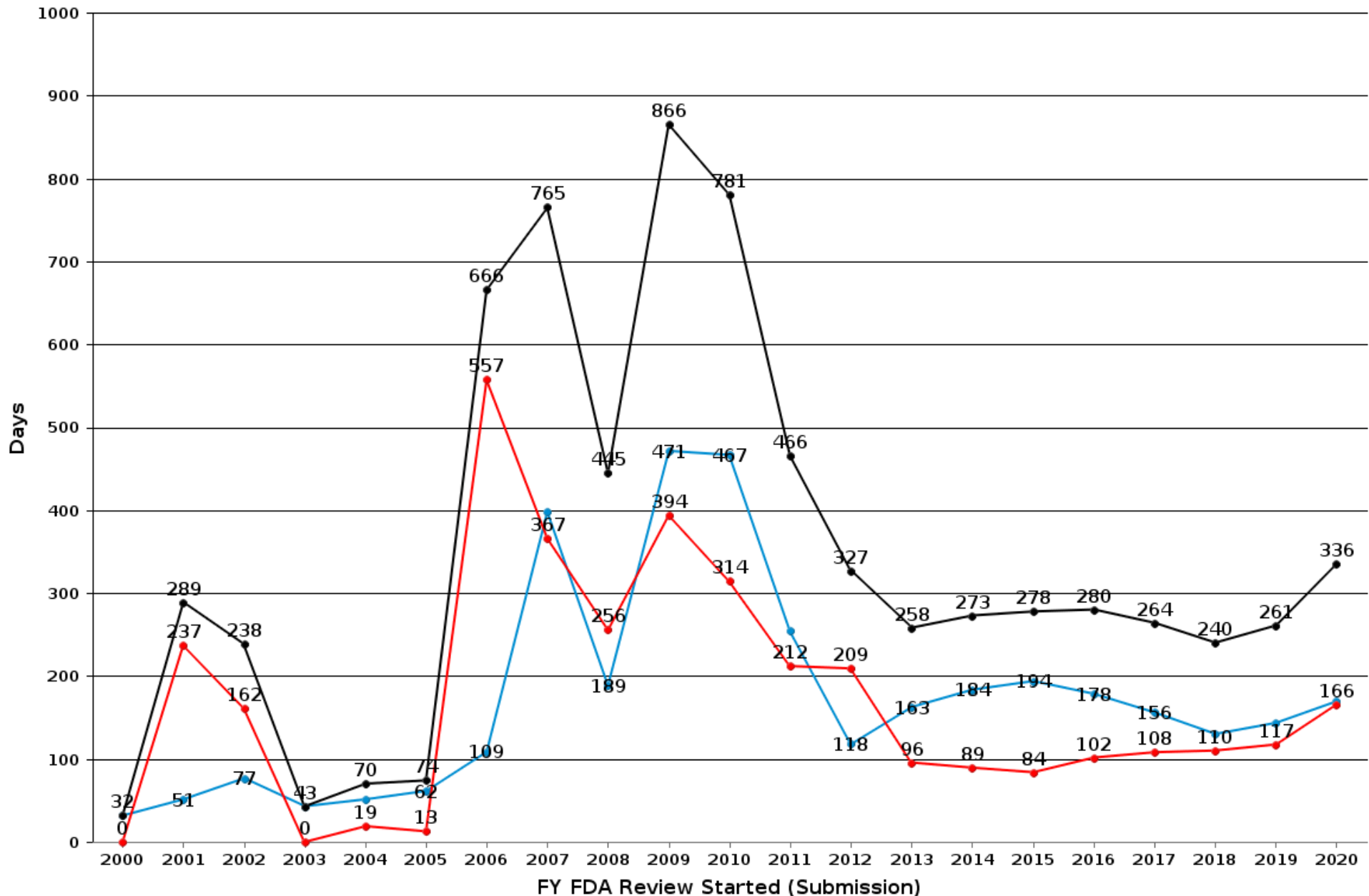
Section 7 510(k) Annual General Metrics - Annual Metrics and Goals will be reported in the Annual Report.

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De Novos

Q1FY2022

De Novo Average Days to MDUFA Decision as of: 12/31/21

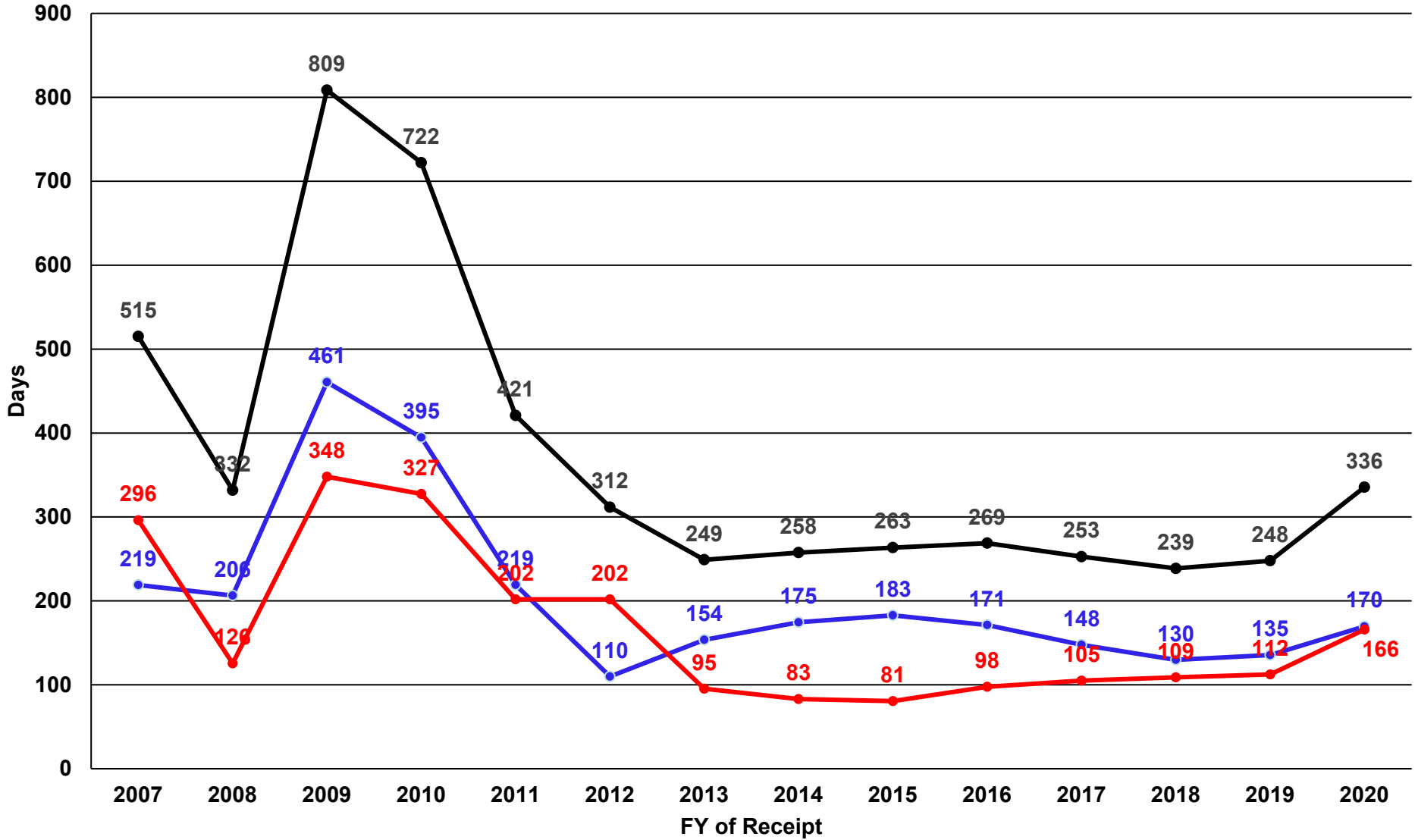


Cohorts not yet closed: 2020: 89.06%

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

Average Time to MDUFA Decision: De Novos

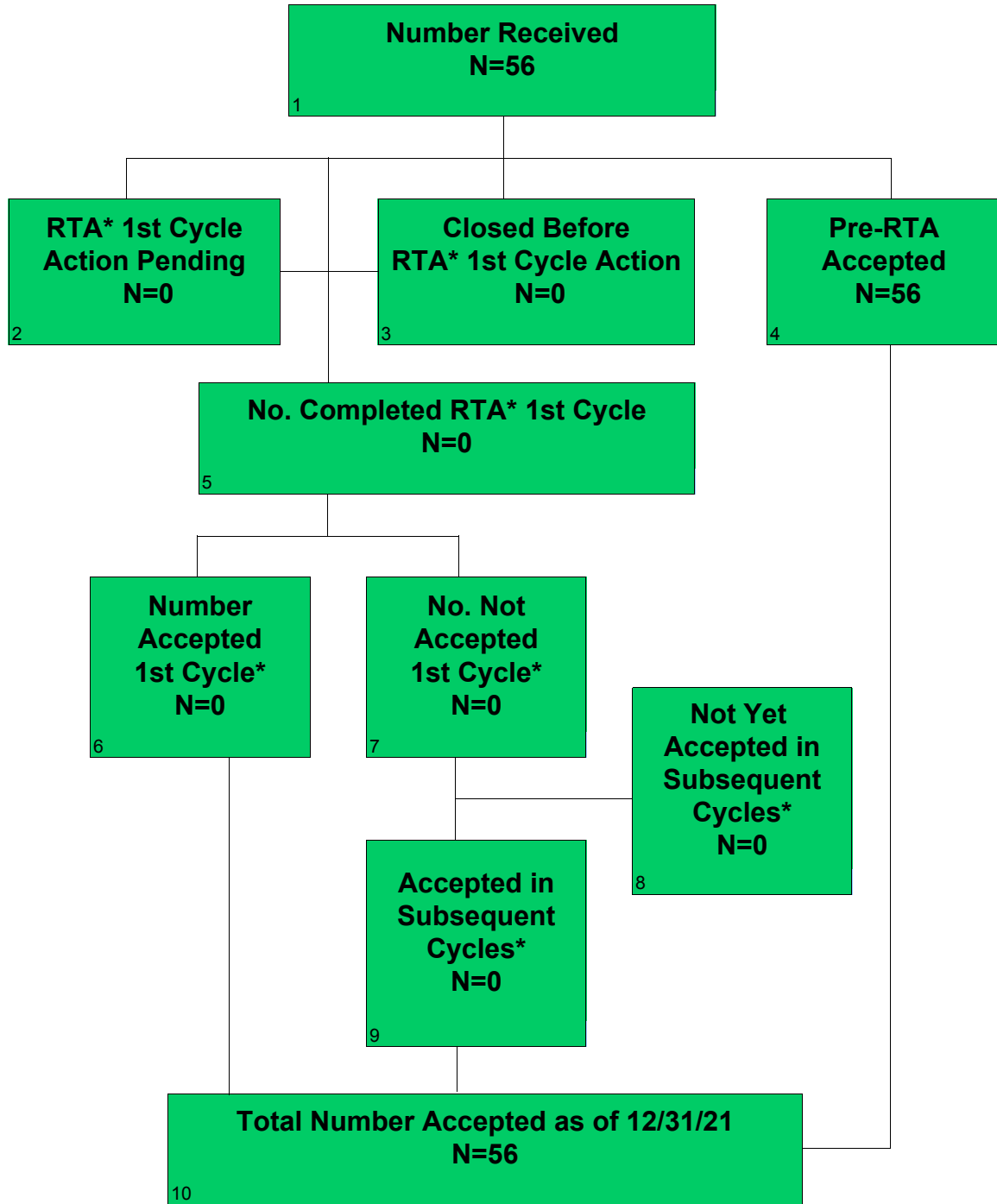
(89.1% closure comparison)



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

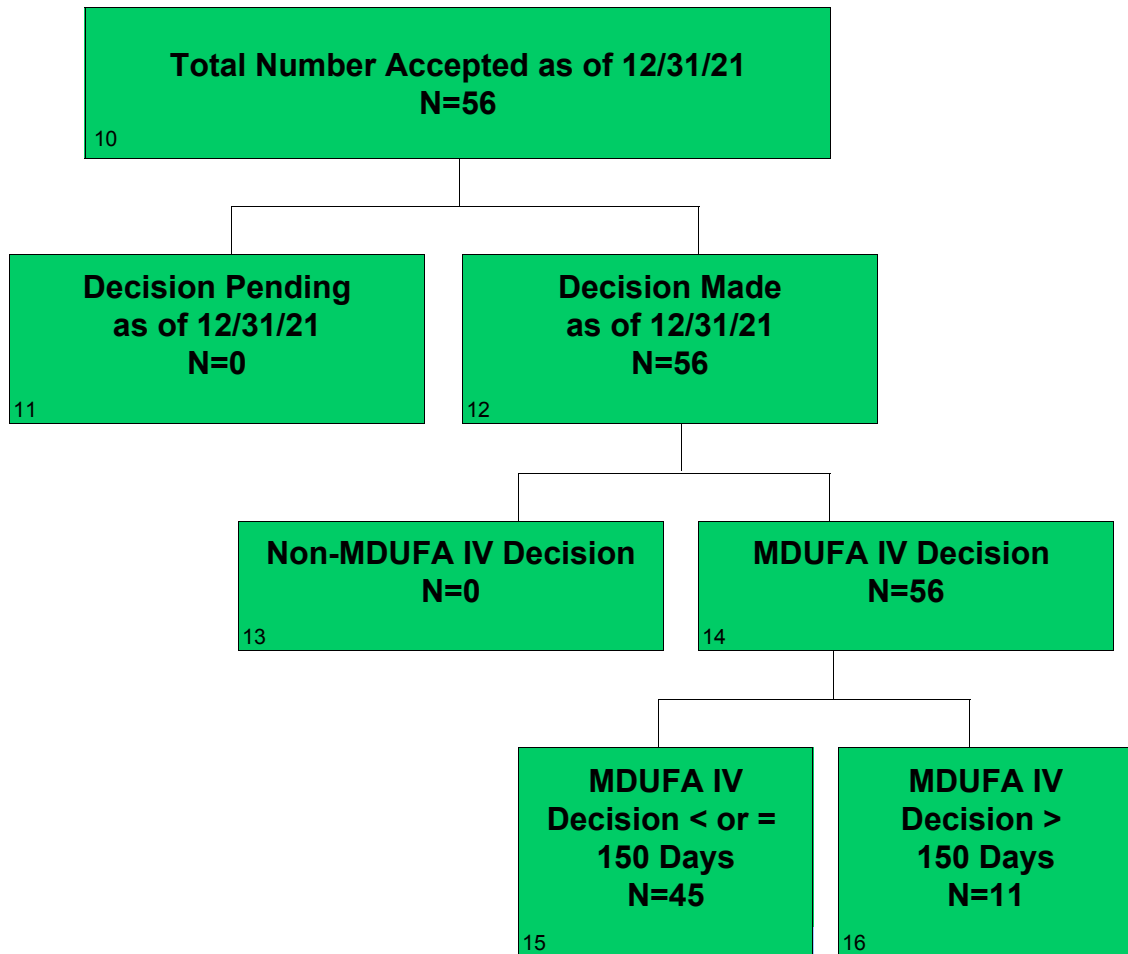
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CDRH De Novo - FY 2018 as of 12/31/21

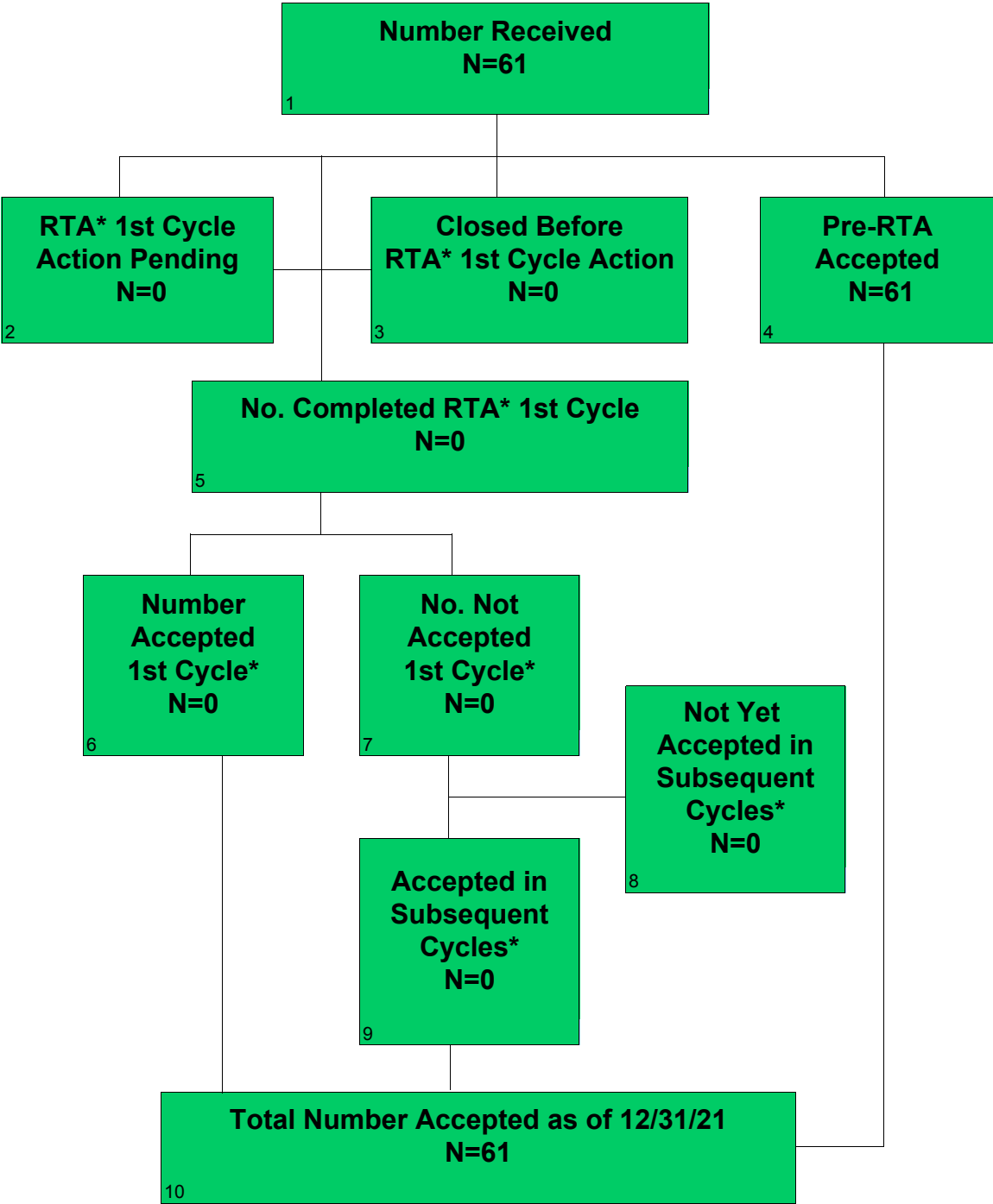


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018 as of 12/31/21 Continued

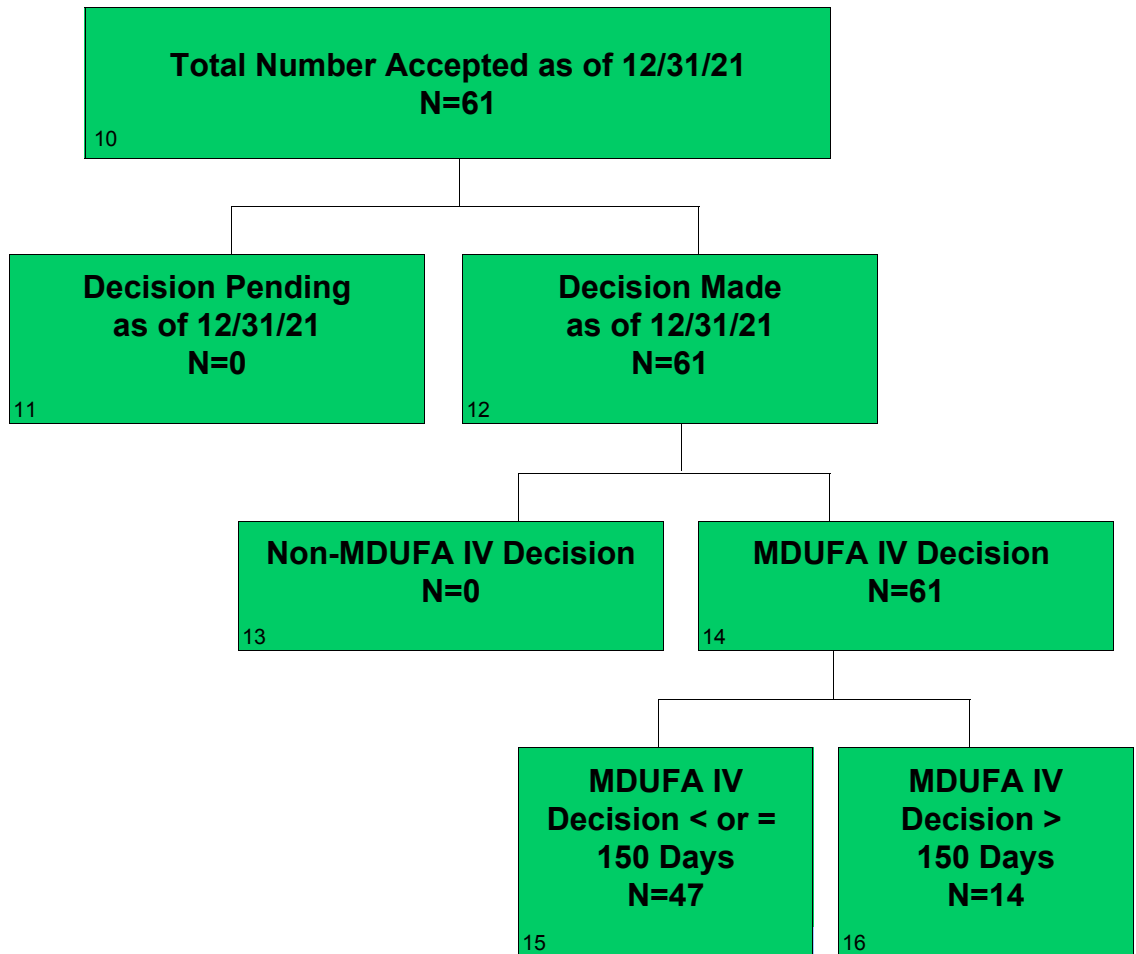


CDRH De Novo - FY 2019 as of 12/31/21

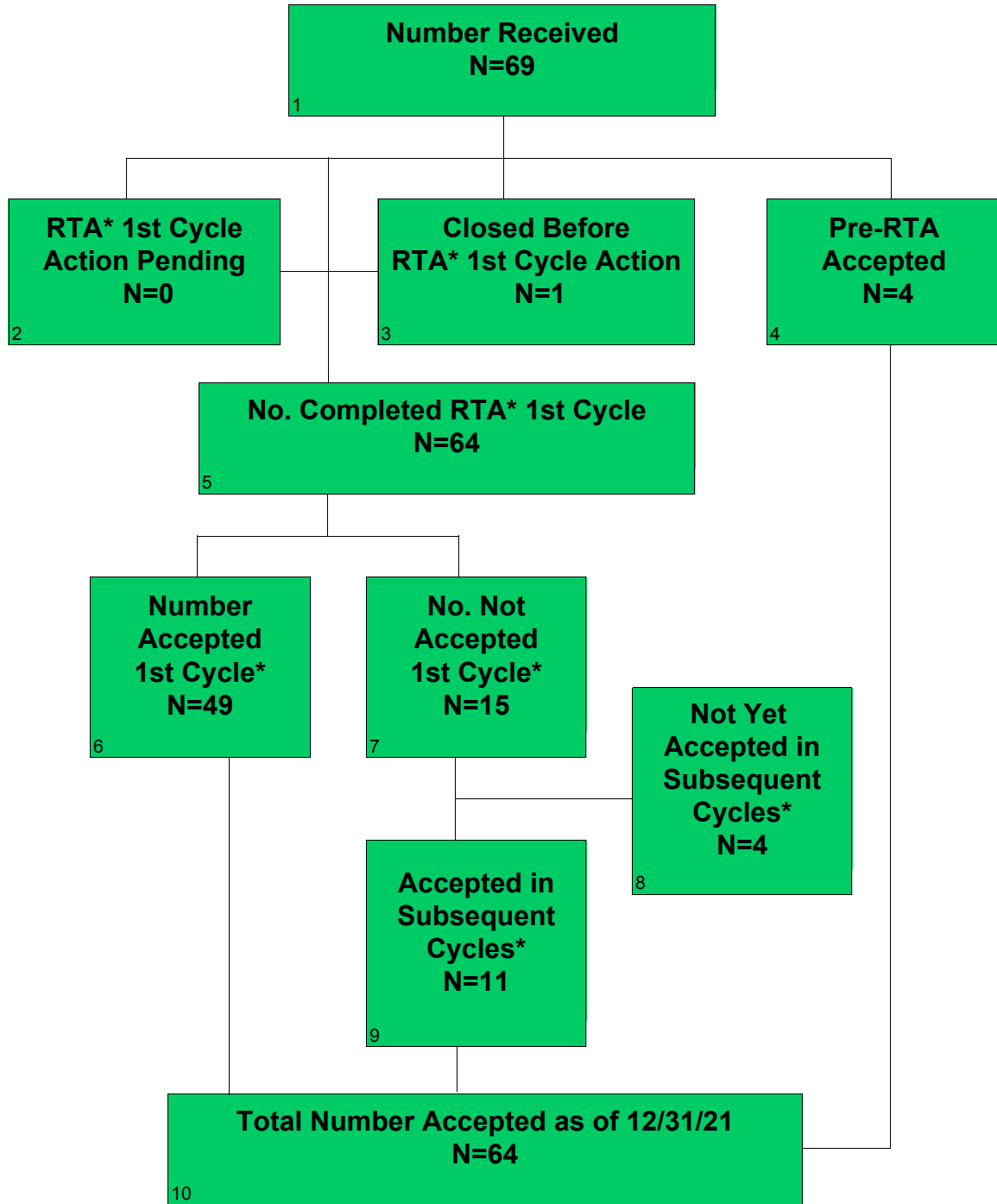


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019 as of 12/31/21 Continued

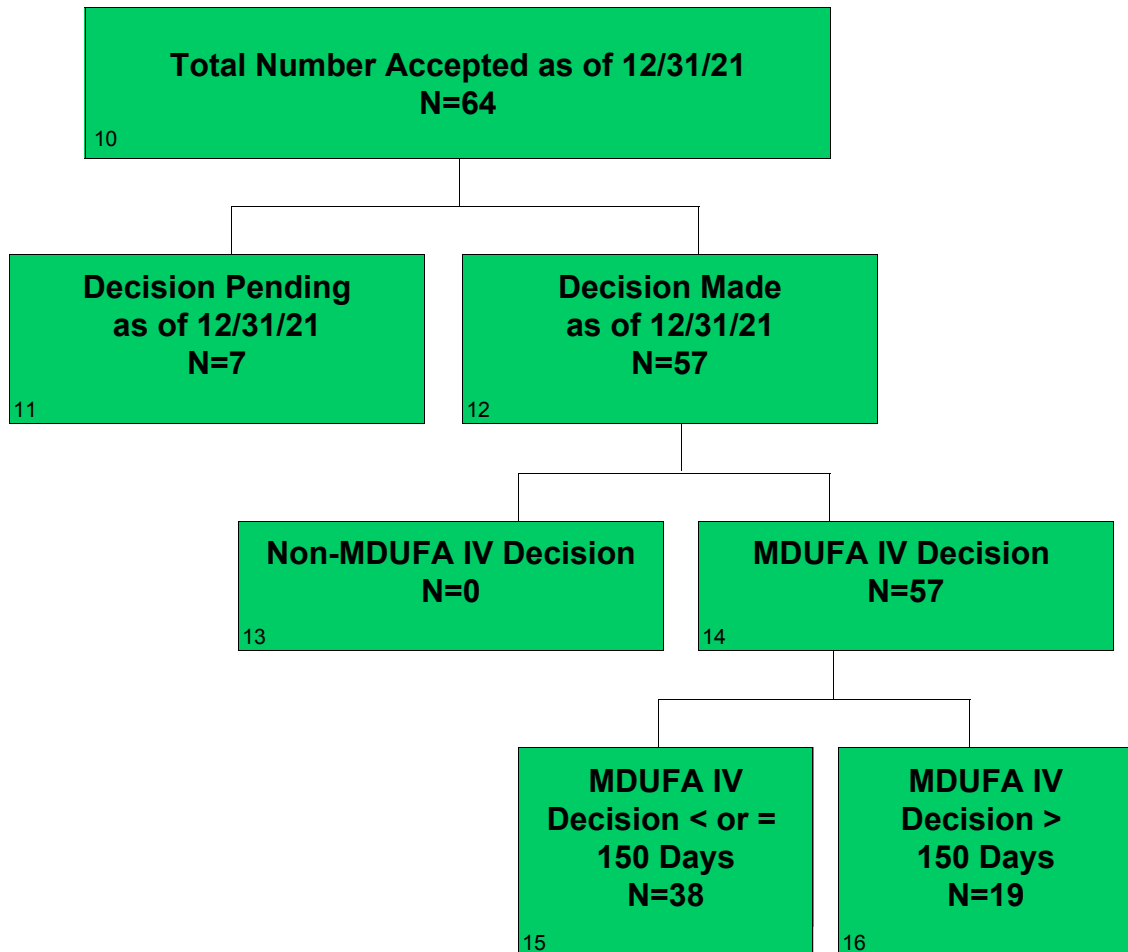


CDRH De Novo - FY 2020 as of 12/31/21

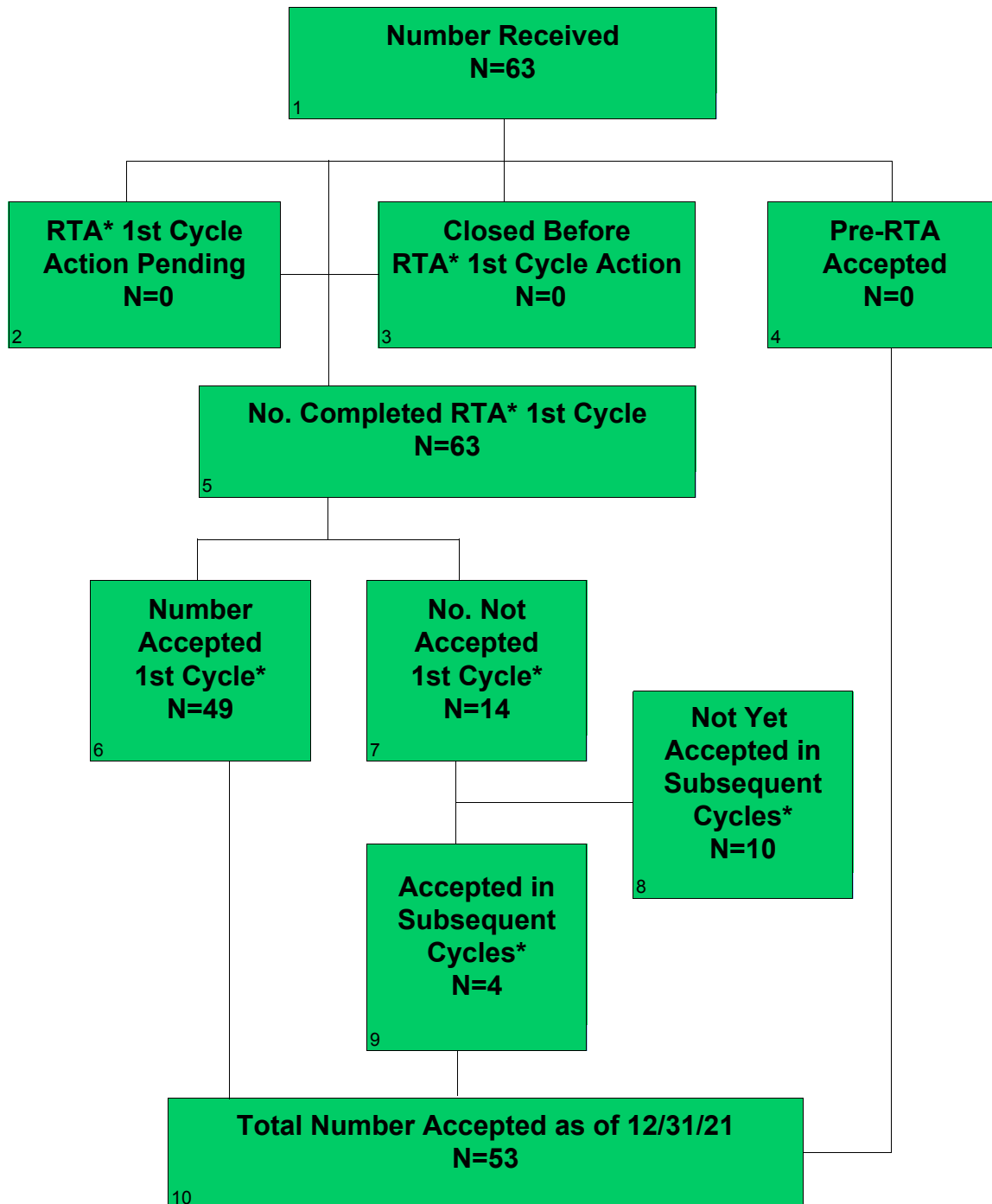


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020 as of 12/31/21 Continued

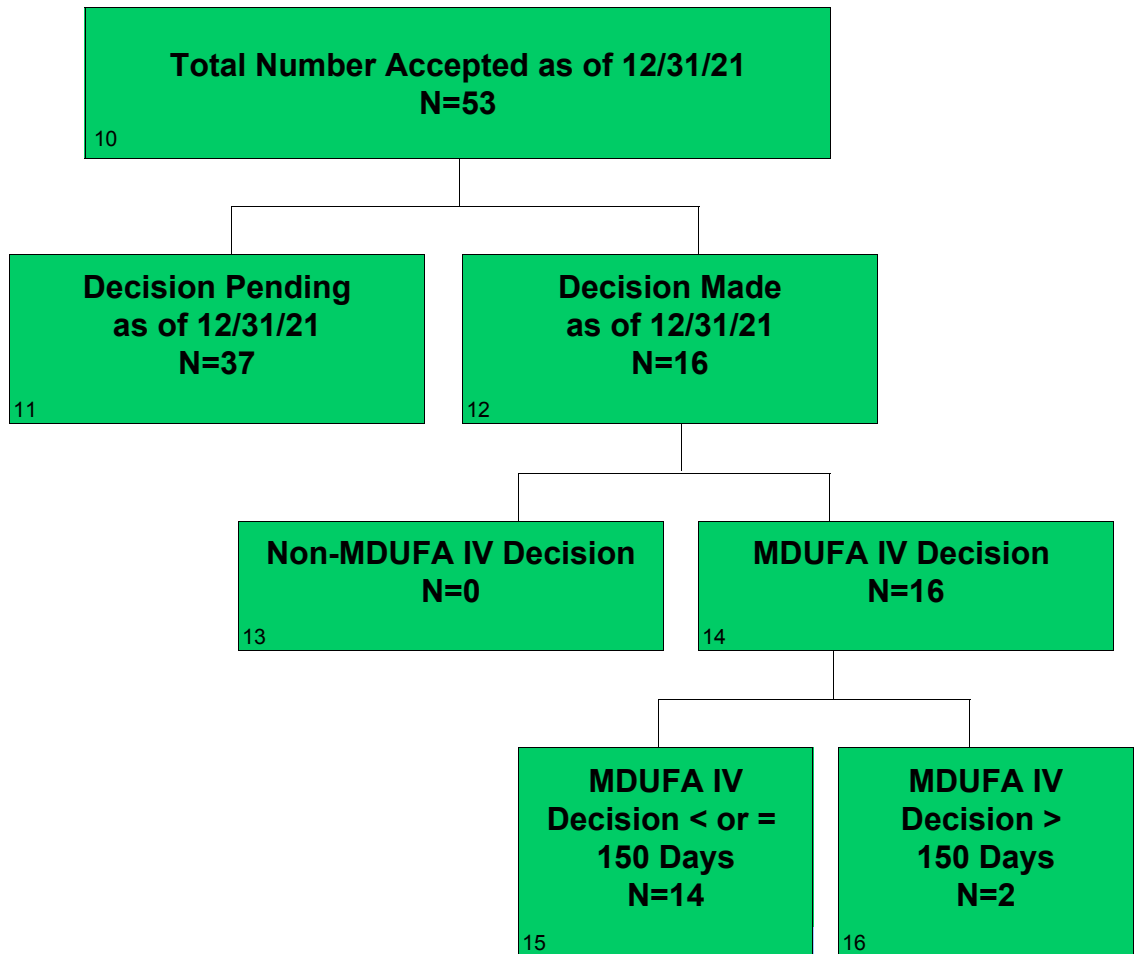


CDRH De Novo - FY 2021 as of 12/31/21

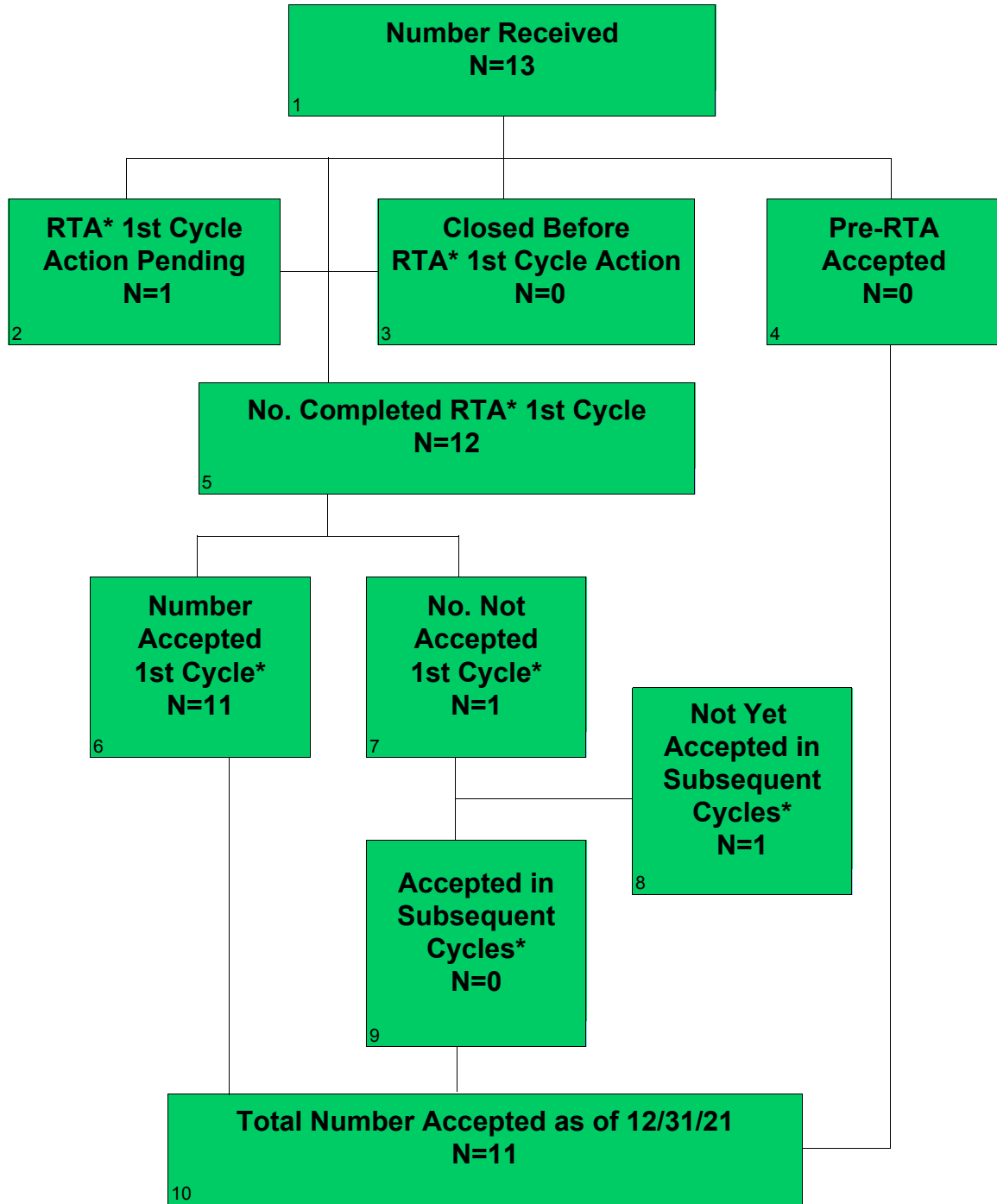


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2021 as of 12/31/21 Continued

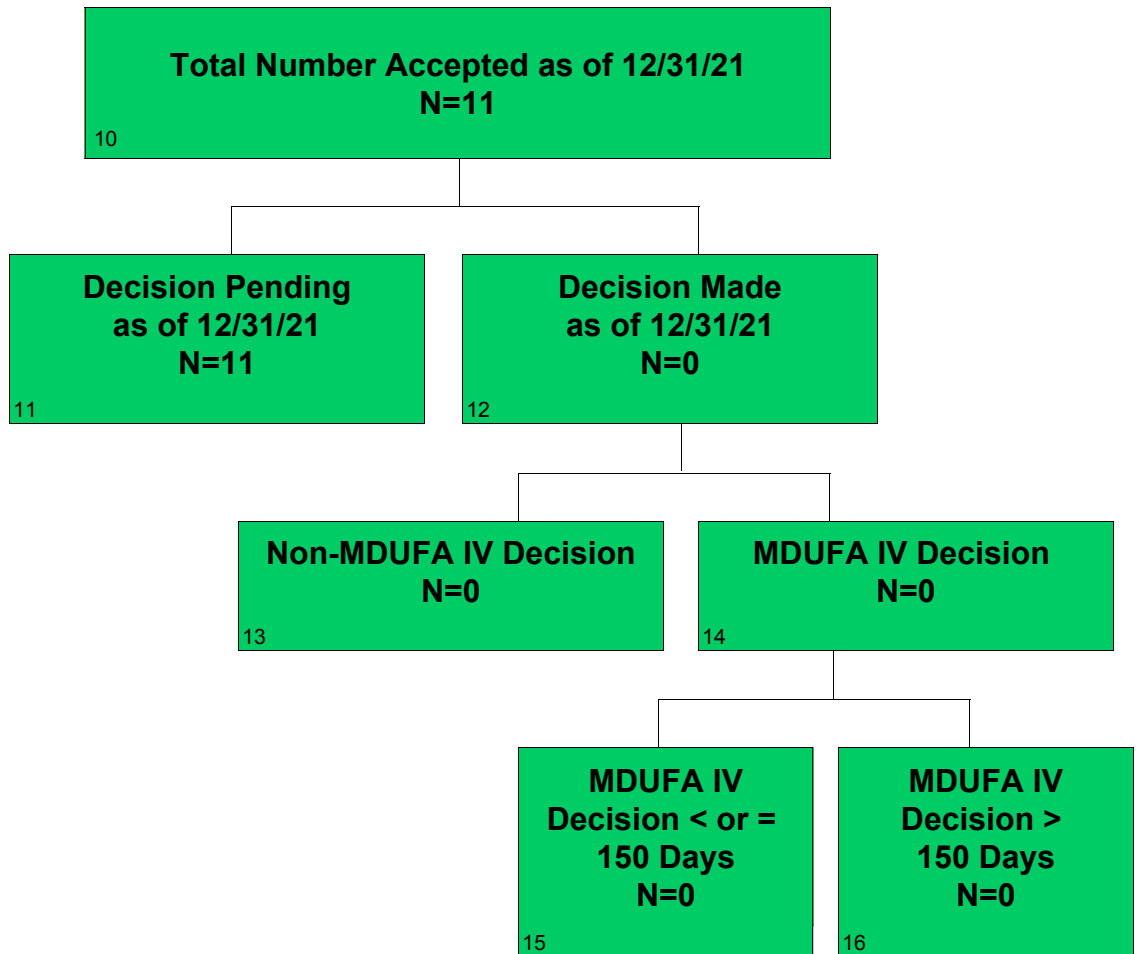


CDRH De Novo - FY 2022 as of 12/31/21



*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 12/31/21 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	13
Closed Before RTA Action	N/A	N/A	1	0	0
Number Accepted First RTA Cycle	N/A	N/A	46	41	10
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	3	8	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	15	14	1
Rate of Submissions Not Accepted for Review	N/A	N/A	23.44%	22.22%	8.33%

*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 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	53	11
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	56	61	57	16	0
MDUFA IV Decisions Within 150 FDA Days	45	47	38	14	0
De Novos Pending MDUFA IV Decision	0	0	7	37	11
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	5	8	0
Current Performance Percent Within 150 FDA Days	80.36%	77.05%	61.29%	58.33%	0.00%

Table 8.3 CDRH - De Novo Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.57	1.61	1.77	1.81	0.00
Number With MDUFA IV Decision	56	61	57	16	0
Average FDA Days to MDUFA IV Decision	130.13	143.57	169.58	148.88	0.00
20th Percentile FDA Days to MDUFA IV Decision	75	76	118	141	0
40th Percentile FDA Days to MDUFA IV Decision	145	130	149	148	0
60th Percentile FDA Days to MDUFA IV Decision	150	148	150	149	0
80th Percentile FDA Days to MDUFA IV Decision	150	180	210	150	0
Maximum FDA Days to MDUFA IV Decision	254	485	467	223	0
Average Industry Days to MDUFA IV Decision	110.13	117.44	165.93	69.63	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	22	37	0
40th Percentile Industry Days to MDUFA IV Decision	89	29	121	62	0
60th Percentile Industry Days to MDUFA IV Decision	166	177	195	80	0
80th Percentile Industry Days to MDUFA IV Decision	180	204	284	98	0
Maximum Industry Days to MDUFA IV Decision	389	373	427	177	0
Average Total Days to MDUFA IV Decision	240.25	261.02	335.51	218.50	0.00
20th Percentile Total Days to MDUFA IV Decision	145	107	209	179	0
40th Percentile Total Days to MDUFA IV Decision	251	179	305	213	0
60th Percentile Total Days to MDUFA IV Decision	292	304	380	233	0
80th Percentile Total Days to MDUFA IV Decision	324	388	441	264	0
Maximum Total Days to MDUFA IV Decision	463	680	668	326	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	56	61	64	53	11
Number With MDUFA IV Decisions	56	61	57	16	0
Number With Granted Decisions	25	28	29	10	0
Number With Declined Decisions	15	15	16	3	0
Number of Withdrawals	10	13	8	3	0
Number Deleted	6	5	4	0	0
Rate of Granted Decisions	44.64%	45.90%	50.88%	62.50%	0.00%
Rate of Declined Decisions	26.79%	24.59%	28.07%	18.75%	0.00%
Rate of Withdrawals	17.86%	21.31%	14.04%	18.75%	0.00%
Rate of Deleted	10.71%	8.20%	7.02%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	11	14	19	2	0
Mean FDA Days for Submissions that Missed the Goal	192.45	248.29	261.47	213.50	0.00
Mean Industry Days for Submissions that Missed the Goal	127.27	218.64	180.11	69.50	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	1	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	5	0	0	0
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	0
De Novos Pending MDUFA IV Decision	0	0	1	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	0	0
Current Performance Percent Within 150 FDA Days	100.00%	40.00%	0.00%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14	17	13	4
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	14	2	0
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	3	11	4
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	3	6	0
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	52.94%	12.50%	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	1
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	10	8	1
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	2	3	0
Rate of Submissions Not Accepted for Review	N/A	N/A	16.67%	27.27%	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 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	9	1
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	8	5	12	2	0
MDUFA IV Decisions Within 150 FDA Days	5	4	10	2	0
De Novos Pending MDUFA IV Decision	0	0	1	7	1
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	1.625	1.80	1.75	2.00	0.00
Number With MDUFA IV Decision	8	5	12	2	0
Average FDA Days to MDUFA IV Decision	141.25	124.80	138.17	149.50	0.00
20th Percentile FDA Days to MDUFA IV Decision	110	75	74	149	0
40th Percentile FDA Days to MDUFA IV Decision	149	119	148	149	0
60th Percentile FDA Days to MDUFA IV Decision	153	148	149	150	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	106.125	195.20	197.50	79.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	9	185	108	77	0
40th Percentile Industry Days to MDUFA IV Decision	45	192	152	78	0
60th Percentile Industry Days to MDUFA IV Decision	75	199	259	80	0
80th Percentile Industry Days to MDUFA IV Decision	167	206	312	81	0
Maximum Industry Days to MDUFA IV Decision	389	212	366	83	0
Average Total Days to MDUFA IV Decision	247.375	320.00	335.67	228.50	0.00
20th Percentile Total Days to MDUFA IV Decision	157	268	262	226	0
40th Percentile Total Days to MDUFA IV Decision	199	304	313	228	0
60th Percentile Total Days to MDUFA IV Decision	260	336	370	229	0
80th Percentile Total Days to MDUFA IV Decision	332	360	435	231	0
Maximum Total Days to MDUFA IV Decision	463	392	653	233	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	9	1
Number With MDUFA IV Decisions	8	5	12	2	0
Number With Granted Decisions	5	2	5	1	0
Number With Declined Decisions	2	1	4	1	0
Number of Withdrawals	0	0	2	0	0
Number Deleted	1	2	1	0	0
Rate of Granted Decisions	62.50%	40.00%	41.67%	50.00%	0.00%
Rate of Declined Decisions	25.00%	20.00%	33.33%	50.00%	0.00%
Rate of Withdrawals	0.00%	0.00%	16.67%	0.00%	0.00%
Rate of Deleted	12.50%	40.00%	8.33%	0.00%	0.00%

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

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	9	8	6	0
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	6	4	0
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	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	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	5	9	8	2	0
MDUFA IV Decisions Within 150 FDA Days	5	8	3	2	0
De Novos Pending MDUFA IV Decision	0	0	0	3	0
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	2.00	0.00
Number With MDUFA IV Decision	5	9	8	2	0
Average FDA Days to MDUFA IV Decision	74.00	144.00	200.50	146.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	32	86	150	144	0
40th Percentile FDA Days to MDUFA IV Decision	58	132	162	145	0
60th Percentile FDA Days to MDUFA IV Decision	79	148	214	147	0
80th Percentile FDA Days to MDUFA IV Decision	98	150	253	148	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	70.50	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	24	50	0
40th Percentile Industry Days to MDUFA IV Decision	98	6	96	64	0
60th Percentile Industry Days to MDUFA IV Decision	171	64	177	77	0
80th Percentile Industry Days to MDUFA IV Decision	188	163	279	91	0
Maximum Industry Days to MDUFA IV Decision	217	207	427	104	0
Average Total Days to MDUFA IV Decision	186.40	215.11	362.25	216.50	0.00
20th Percentile Total Days to MDUFA IV Decision	32	117	286	194	0
40th Percentile Total Days to MDUFA IV Decision	173	153	350	209	0
60th Percentile Total Days to MDUFA IV Decision	277	213	363	224	0
80th Percentile Total Days to MDUFA IV Decision	296	281	448	239	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	0
Number With MDUFA IV Decisions	5	9	8	2	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	0	0
Number Deleted	2	1	0	0	0
Rate of Granted Decisions	60.00%	22.22%	62.50%	100.00%	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%	0.00%	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	2
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	4	5	2
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	2	1	0
Rate of Submissions Not Accepted for Review	N/A	N/A	33.33%	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 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	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	11	6	1	0
MDUFA IV Decisions Within 150 FDA Days	3	5	4	1	0
De Novos Pending MDUFA IV Decision	0	0	0	5	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	75.00%	45.45%	66.67%	100.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.82	1.83	2.00	0.00
Number With MDUFA IV Decision	4	11	6	1	0
Average FDA Days to MDUFA IV Decision	100.00	186.55	161.50	147.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	57	148	148	147	0
40th Percentile FDA Days to MDUFA IV Decision	97	150	150	147	0
60th Percentile FDA Days to MDUFA IV Decision	135	191	150	147	0
80th Percentile FDA Days to MDUFA IV Decision	149	211	203	147	0
Maximum FDA Days to MDUFA IV Decision	151	327	243	147	0
Average Industry Days to MDUFA IV Decision	136.75	168.45	116.83	91.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	100	136	21	91	0
40th Percentile Industry Days to MDUFA IV Decision	169	175	24	91	0
60th Percentile Industry Days to MDUFA IV Decision	175	177	61	91	0
80th Percentile Industry Days to MDUFA IV Decision	187	241	222	91	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	238.00	0.00
20th Percentile Total Days to MDUFA IV Decision	179	283	209	238	0
40th Percentile Total Days to MDUFA IV Decision	293	347	213	238	0
60th Percentile Total Days to MDUFA IV Decision	312	368	267	238	0
80th Percentile Total Days to MDUFA IV Decision	321	416	372	238	0
Maximum Total Days to MDUFA IV Decision	325	617	438	238	0

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

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

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

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	5	6	8	8	3
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	3	4	2
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	1	1	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	1
Number Not Accepted	N/A	N/A	3	3	0
Rate of Submissions Not Accepted for Review	N/A	N/A	42.86%	37.50%	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 OHT4 - Office of Surgical and Infection Control Devices
De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	5	6	7	5	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	5	6	6	0	0
MDUFA IV Decisions Within 150 FDA Days	3	4	2	0	0
De Novos Pending MDUFA IV Decision	0	0	1	5	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	1	0
Current Performance Percent Within 150 FDA Days	60.00%	66.67%	33.33%	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	1.67	0.00	0.00
Number With MDUFA IV Decision	5	6	6	0	0
Average FDA Days to MDUFA IV Decision	147.40	182.50	174.50	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	133	93	129	0	0
40th Percentile FDA Days to MDUFA IV Decision	150	98	172	0	0
60th Percentile FDA Days to MDUFA IV Decision	151	107	175	0	0
80th Percentile FDA Days to MDUFA IV Decision	167	236	192	0	0
Maximum FDA Days to MDUFA IV Decision	221	485	323	0	0
Average Industry Days to MDUFA IV Decision	90.80	125.83	209.67	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	12	0	141	0	0
40th Percentile Industry Days to MDUFA IV Decision	65	0	242	0	0
60th Percentile Industry Days to MDUFA IV Decision	124	187	257	0	0
80th Percentile Industry Days to MDUFA IV Decision	165	195	273	0	0
Maximum Industry Days to MDUFA IV Decision	179	373	345	0	0
Average Total Days to MDUFA IV Decision	238.20	308.33	384.17	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	145	93	313	0	0
40th Percentile Total Days to MDUFA IV Decision	215	107	402	0	0
60th Percentile Total Days to MDUFA IV Decision	275	285	417	0	0
80th Percentile Total Days to MDUFA IV Decision	332	609	449	0	0
Maximum Total Days to MDUFA IV Decision	400	680	668	0	0

Table 8.4 OHT4 - Office of Surgical and Infection Control Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	5	6	7	5	2
Number With MDUFA IV Decisions	5	6	6	0	0
Number With Granted Decisions	3	1	1	0	0
Number With Declined Decisions	1	3	3	0	0
Number of Withdrawals	1	1	2	0	0
Number Deleted	0	1	0	0	0
Rate of Granted Decisions	60.00%	16.67%	16.67%	0.00%	0.00%
Rate of Declined Decisions	20.00%	50.00%	50.00%	0.00%	0.00%
Rate of Withdrawals	20.00%	16.67%	33.33%	0.00%	0.00%
Rate of Deleted	0.00%	16.67%	0.00%	0.00%	0.00%

Table 8.5 OHT4 - Office of Surgical and Infection Control Devices

De Novo Performance Metrics-Submissions Missing Performance Goals

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

Table 8.6 OHT4 - Office of Surgical and Infection Control Devices

LDT De Novo MDUFA IV Decision Metrics

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

Table 8.7 OHT4 - Office of Surgical and Infection Control Devices

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

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	13	6	6	7	1
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	13	6	5	5	0
MDUFA IV Decisions Within 150 FDA Days	9	6	4	5	0
De Novos Pending MDUFA IV Decision	0	0	1	2	1
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	1	0
Current Performance Percent Within 150 FDA Days	69.23%	100.00%	80.00%	83.33%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.77	1.33	1.80	1.80	0.00
Number With MDUFA IV Decision	13	6	5	5	0
Average FDA Days to MDUFA IV Decision	153.00	113.33	136.40	133.60	0.00
20th Percentile FDA Days to MDUFA IV Decision	104	76	131	133	0
40th Percentile FDA Days to MDUFA IV Decision	148	127	149	149	0
60th Percentile FDA Days to MDUFA IV Decision	150	136	149	149	0
80th Percentile FDA Days to MDUFA IV Decision	219	149	155	150	0
Maximum FDA Days to MDUFA IV Decision	254	150	175	150	0
Average Industry Days to MDUFA IV Decision	106.08	20.17	78.40	66.80	0.00
20th Percentile Industry Days to MDUFA IV Decision	39	0	11	41	0
40th Percentile Industry Days to MDUFA IV Decision	82	0	56	58	0
60th Percentile Industry Days to MDUFA IV Decision	164	0	100	69	0
80th Percentile Industry Days to MDUFA IV Decision	174	45	134	92	0
Maximum Industry Days to MDUFA IV Decision	183	76	169	141	0
Average Total Days to MDUFA IV Decision	259.08	133.50	214.80	200.40	0.00
20th Percentile Total Days to MDUFA IV Decision	226	76	142	175	0
40th Percentile Total Days to MDUFA IV Decision	266	127	206	207	0
60th Percentile Total Days to MDUFA IV Decision	316	136	250	219	0
80th Percentile Total Days to MDUFA IV Decision	323	195	288	242	0
Maximum Total Days to MDUFA IV Decision	371	225	344	289	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	13	6	6	7	1
Number With MDUFA IV Decisions	13	6	5	5	0
Number With Granted Decisions	3	2	5	3	0
Number With Declined Decisions	7	0	0	1	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%	60.00%	0.00%
Rate of Declined Decisions	53.85%	0.00%	0.00%	20.00%	0.00%
Rate of Withdrawals	23.08%	66.67%	0.00%	20.00%	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	0	0
Mean FDA Days for Submissions that Missed the Goal	229.25	0.00	175.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	82.75	0.00	169.00	0.00	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	1
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	5	5	1
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	0	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	1
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	4	5	3	0
MDUFA IV Decisions Within 150 FDA Days	3	3	5	2	0
De Novos Pending MDUFA IV Decision	0	0	0	3	1
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%	66.67%	0.00%

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

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

Table 8.4 OHT6 - Office of Orthopedic Devices

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

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

Table 8.5 OHT6 - Office of Orthopedic Devices

De Novo Performance Metrics-Submissions Missing Performance Goals

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

Table 8.6 OHT6 - Office of Orthopedic Devices

LDT De Novo MDUFA IV Decision Metrics

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

Table 8.7 OHT6 - Office of Orthopedic Devices

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	20	22	17	5
Closed Before RTA Action	N/A	N/A	1	0	0
Number Accepted First RTA Cycle	N/A	N/A	13	8	3
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	1
Rate of Submissions Not Accepted for Review	N/A	N/A	25.00%	11.76%	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 OHT7 - Office of In Vitro Diagnostics and Radiological Health
De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	50% Within 150 FDA Days	55% Within 150 FDA Days	60% Within 150 FDA Days	60% Within 150 FDA Days	70% Within 150 FDA Days
De Novos Accepted	17	20	19	15	4
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	17	20	15	3	0
MDUFA IV Decisions Within 150 FDA Days	17	17	10	2	0
De Novos Pending MDUFA IV Decision	0	0	4	12	4
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	4	6	0
Current Performance Percent Within 150 FDA Days	100.00%	85.00%	52.63%	22.22%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.47	1.60	1.60	1.67	0.00
Number With MDUFA IV Decision	17	20	15	3	0
Average FDA Days to MDUFA IV Decision	125.18	121.60	197.93	164.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	108	73	107	132	0
40th Percentile FDA Days to MDUFA IV Decision	127	121	144	143	0
60th Percentile FDA Days to MDUFA IV Decision	146	148	150	164	0
80th Percentile FDA Days to MDUFA IV Decision	150	150	315	193	0
Maximum FDA Days to MDUFA IV Decision	150	243	467	223	0
Average Industry Days to MDUFA IV Decision	101.88	105.25	185.33	72.67	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	57	16	0
40th Percentile Industry Days to MDUFA IV Decision	84	0	163	33	0
60th Percentile Industry Days to MDUFA IV Decision	169	168	213	68	0
80th Percentile Industry Days to MDUFA IV Decision	179	220	333	123	0
Maximum Industry Days to MDUFA IV Decision	189	276	364	177	0
Average Total Days to MDUFA IV Decision	227.06	226.85	383.27	236.67	0.00
20th Percentile Total Days to MDUFA IV Decision	137	99	198	178	0
40th Percentile Total Days to MDUFA IV Decision	183	150	370	235	0
60th Percentile Total Days to MDUFA IV Decision	277	278	440	276	0
80th Percentile Total Days to MDUFA IV Decision	313	337	503	301	0
Maximum Total Days to MDUFA IV Decision	327	509	668	326	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	17	20	19	15	4
Number With MDUFA IV Decisions	17	20	15	3	0
Number With Granted Decisions	10	12	7	1	0
Number With Declined Decisions	1	0	3	1	0
Number of Withdrawals	5	7	3	1	0
Number Deleted	1	1	2	0	0
Rate of Granted Decisions	58.82%	60.00%	46.67%	33.33%	0.00%
Rate of Declined Decisions	5.88%	0.00%	20.00%	33.33%	0.00%
Rate of Withdrawals	29.41%	35.00%	20.00%	33.33%	0.00%
Rate of Deleted	5.88%	5.00%	13.33%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	3	5	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	209.33	353.60	223.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	217.67	179.80	41.00	0.00

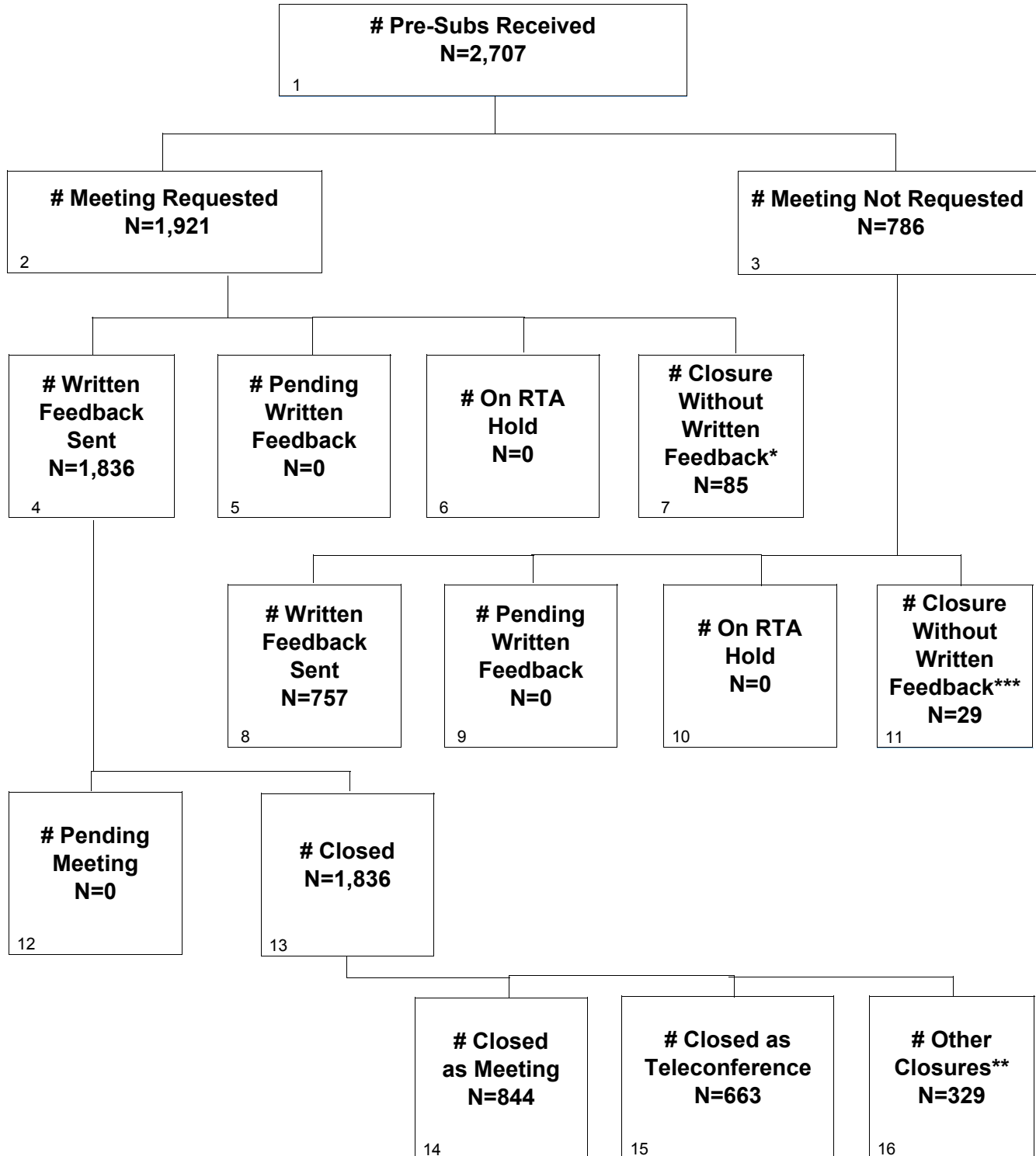
**Table 8.6 OHT7 - Office of In Vitro Diagnostics and Radiological Health
LDT De Novo MDUFA IV Decision Metrics**

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

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

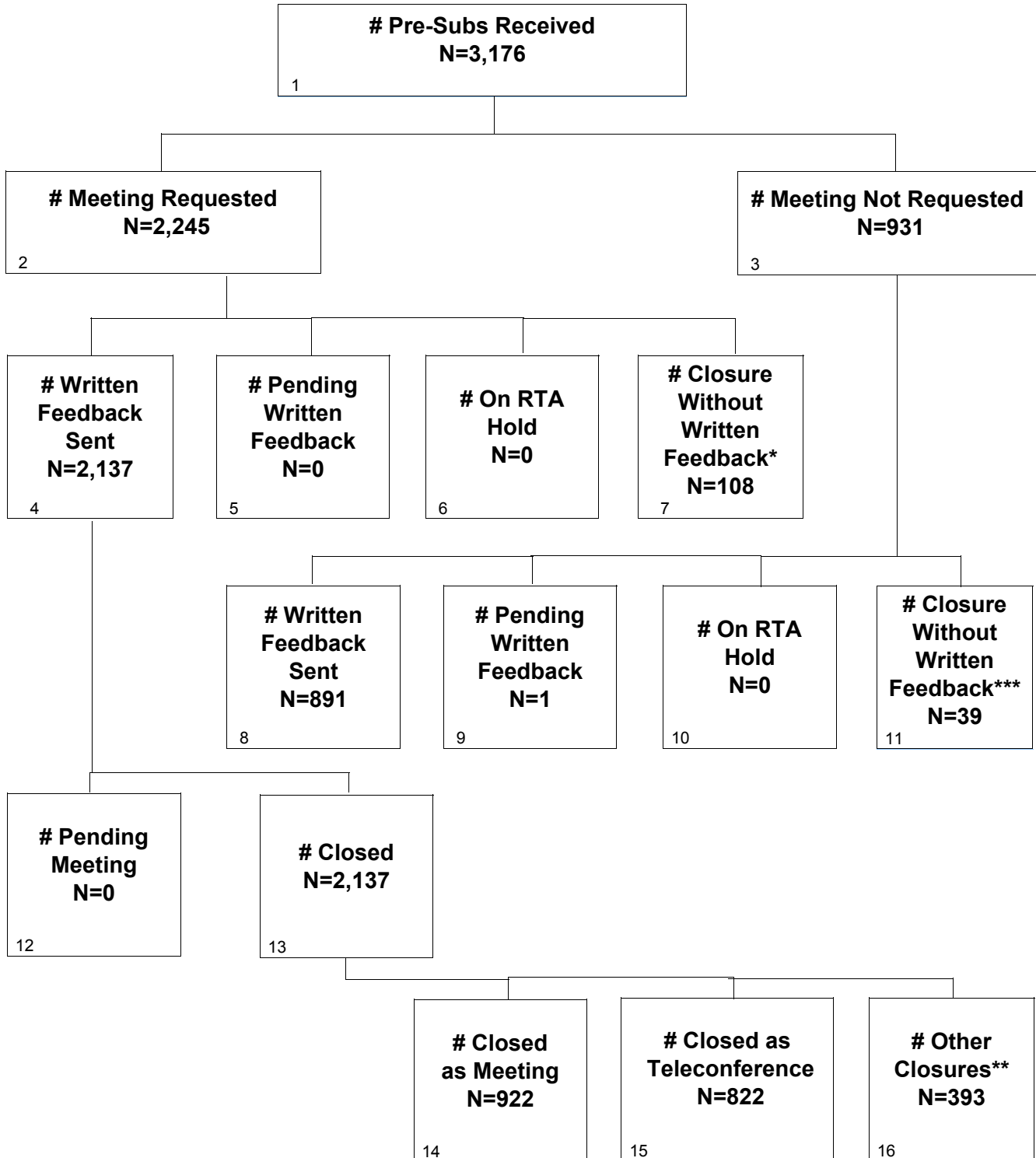
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14	17	13	4
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	14	2	0
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	3	11	4
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	3	6	0
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	52.94%	12.50%	0.00%

CDRH Pre-Sub - FY 2018 as of 12/31/21



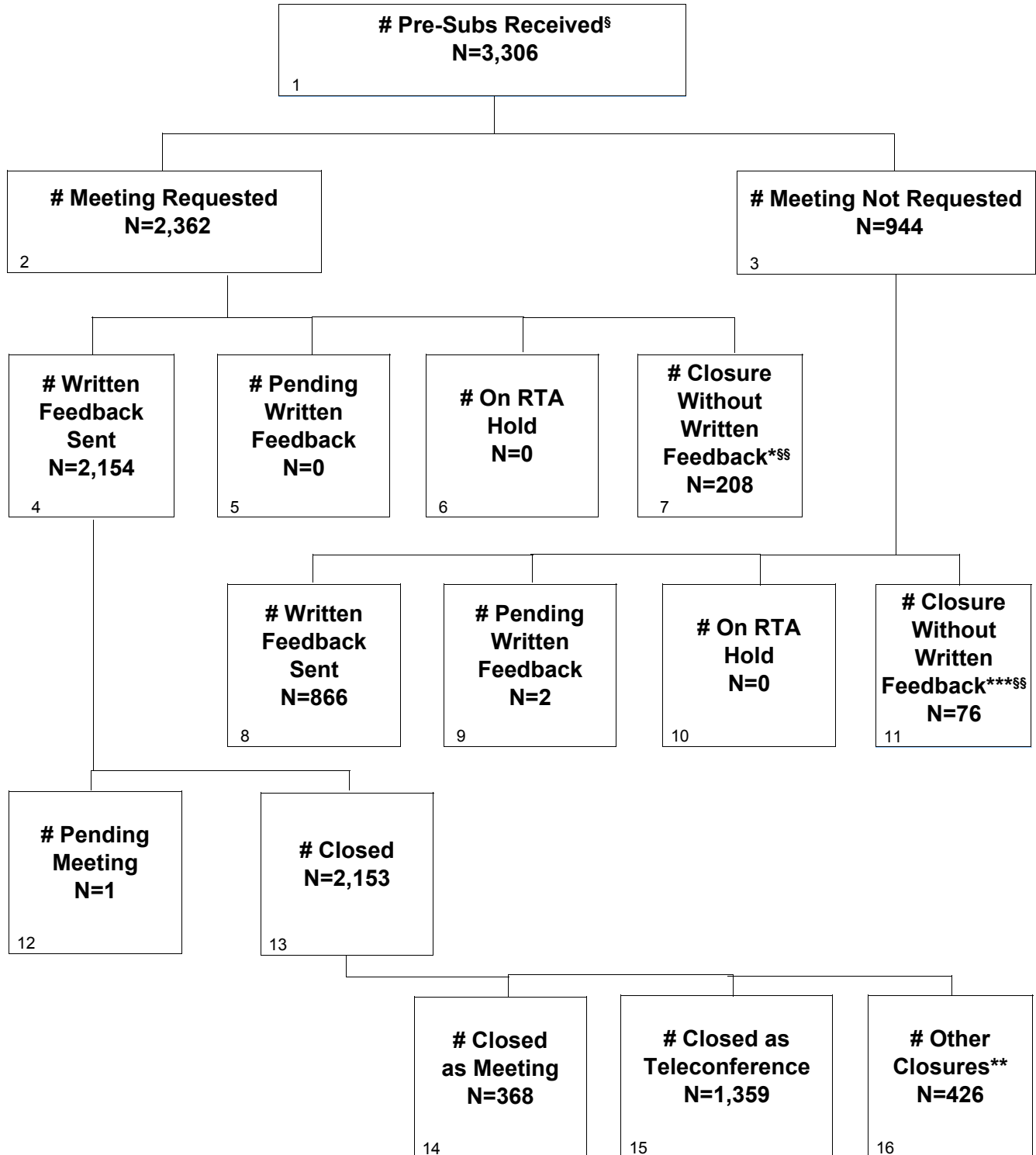
* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR
 ** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR
 *** Closures include JTRX, JPND, DELE & WTDR

CDRH Pre-Sub - FY 2019 as of 12/31/21



* 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 2020 as of 12/31/21



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

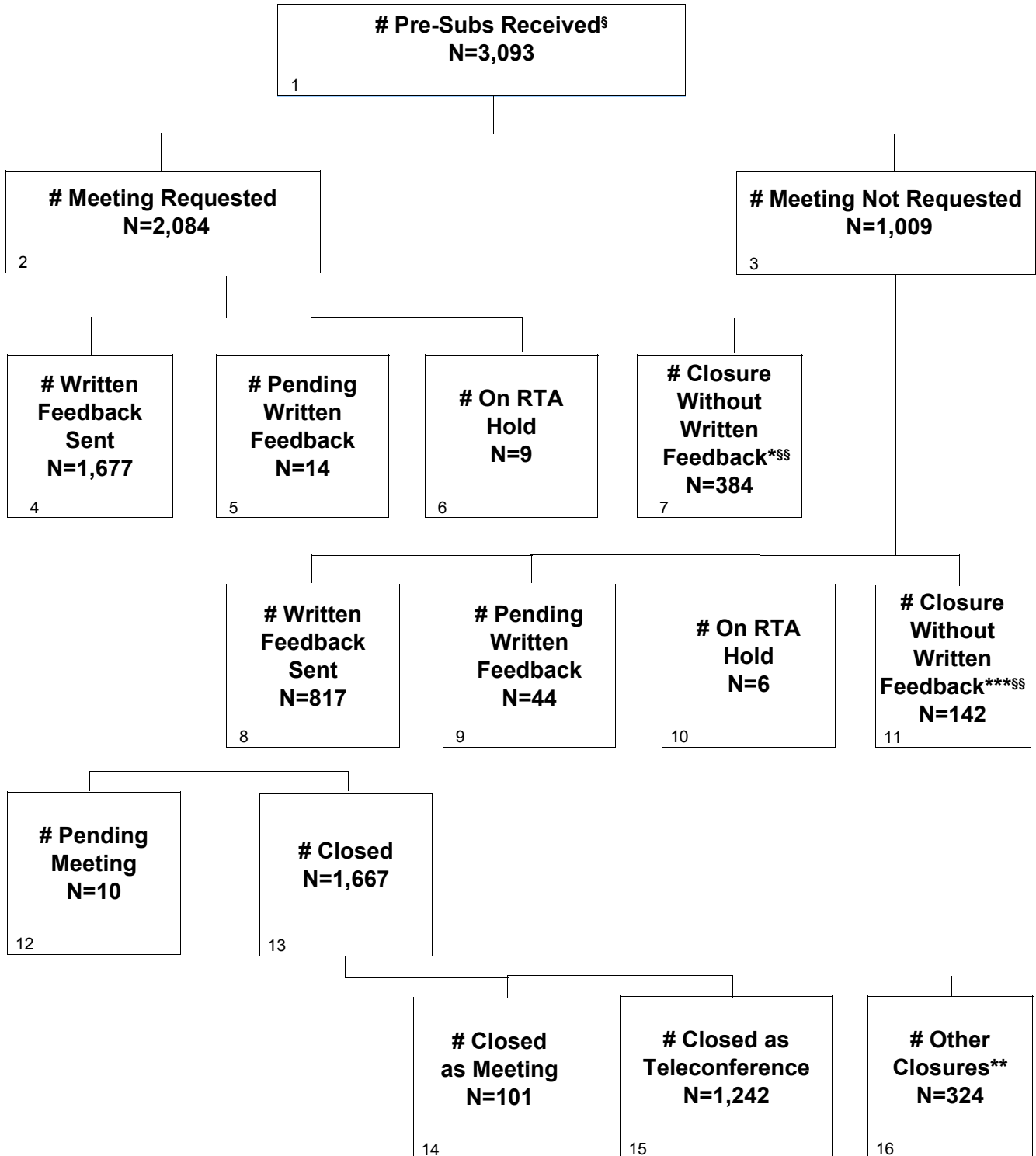
** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

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

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

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

CDRH Pre-Sub - FY 2021 as of 12/31/21



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

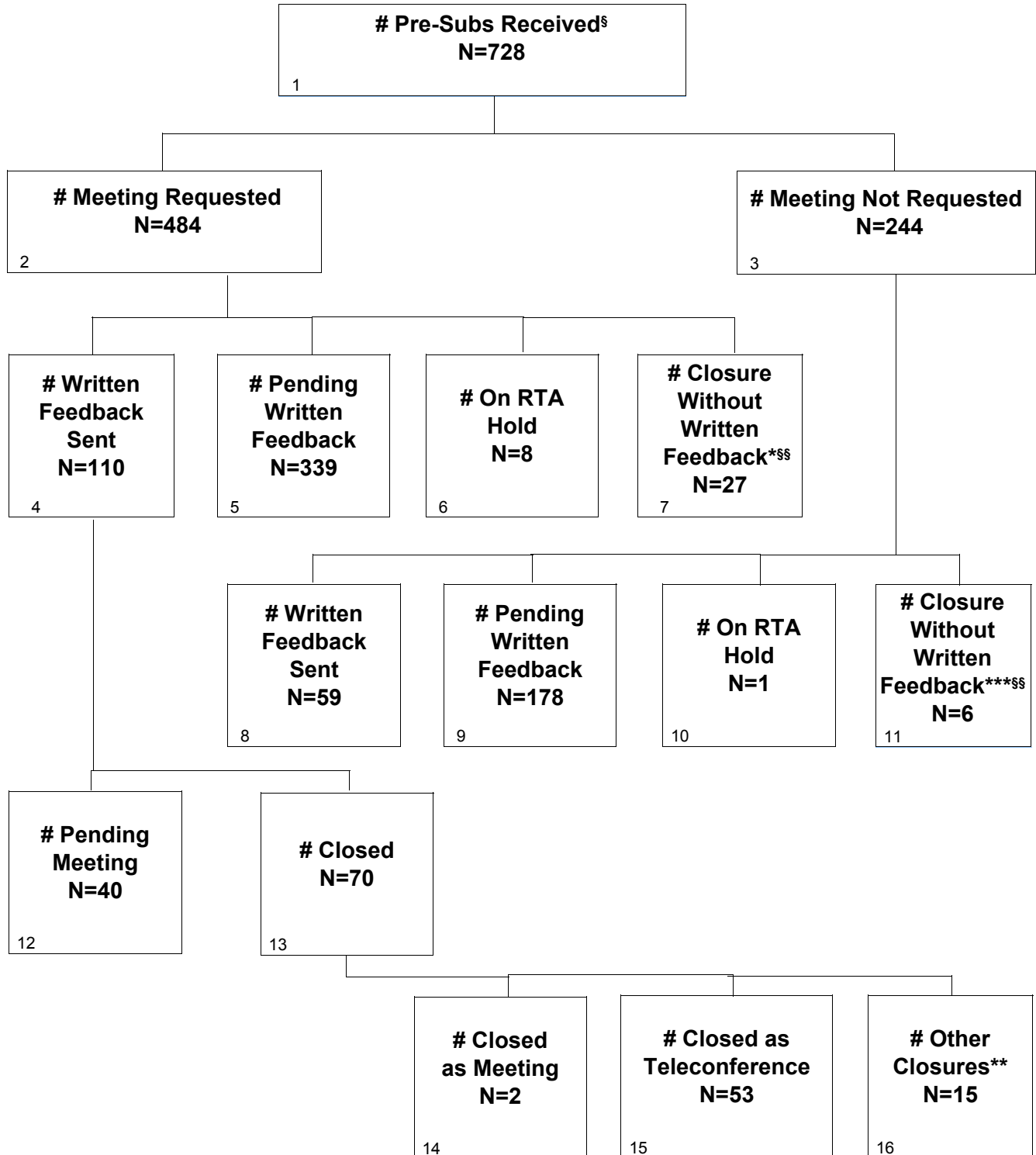
** Closures include CNLR, CNLF, JTRX, JPND, DELE & WTDR

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

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

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

CDRH Pre-Sub - FY 2022 as of 12/31/21



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

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

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

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

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

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Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2,707	3,176	3,306	3,093	728
Closed Before RTA Action**	27	41	109	388	24
Number Accepted First RTA Cycle**	2,565	3,004	3,035	2,452	576
Number Without a RTA Review and > 15 Days Since Date Received**	49	71	121	224	48
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	69
Number Not Accepted	66	60	41	29	11
Rate of Submissions Not Accepted for Review	2.46%	1.91%	1.28%	1.07%	1.73%

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

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

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

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	≥ 1530 Submissions	≥ 1645 Submissions	≥ 1765 Submissions	≥ 1880 Submissions	≥ 1950 Submissions
Written Feedback Sent	2,594	3,028	3,020	2,494	169
Written Feedback Provided Within MDUFA IV Goal	2,439	2,848	2,652	2,023	159

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	2,594	3,028	3,020	2,494	169
Average FDA Days to Written Feedback	58.86	59.93	63.26	65.37	54.62
20th Percentile FDA Days to Written Feedback	49	49	52	52	45
40th Percentile FDA Days to Written Feedback	59	60	62	63	53
60th Percentile FDA Days to Written Feedback	65	65	66	67	59
80th Percentile FDA Days to Written Feedback	69	70	70	70	65
Maximum FDA Days to Written Feedback	172	397	389	307	88

*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	16
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.62	43.33	48.15	40.13

*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	1,343	55
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,113	1,110	885	33
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	8
Meeting Minutes Past 15 Days of Meeting	483	560	539	408	3
Meeting Minutes Not Submitted and >15 Days Since Meeting	53	71	78	50	11
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.43%	63.82%	64.27%	65.90%	70.21%

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

Section 9 Pre-Sub Office Level Metrics

**Table 9.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Pre-Sub Acceptance Review Decision***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	319	389	429	401	112
Closed Before RTA Action**	0	6	5	8	0
Number Accepted First RTA Cycle**	284	359	406	376	96
Number Without a RTA Review and > 15 Days Since Date Received**	8	9	10	13	4
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	12
Number Not Accepted	27	15	8	4	0
Rate of Submissions Not Accepted for Review	8.46%	3.92%	1.89%	1.02%	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 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
MDUFA IV Pre-Sub Performance Goals***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	298	359	401	373	22
Written Feedback Provided Within MDUFA IV Goal	256	314	279	225	20

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	298	359	401	373	22
Average FDA Days to Written Feedback	64.18	64.05	73.33	72.54	61.91
20th Percentile FDA Days to Written Feedback	56	57	62	63	56
40th Percentile FDA Days to Written Feedback	64	65	66	67	58
60th Percentile FDA Days to Written Feedback	69	69	70	70	63
80th Percentile FDA Days to Written Feedback	70	70	74	79	69
Maximum FDA Days to Written Feedback	168	119	389	219	88

*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	4
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75	34.00	42.40	60.50	39.00

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	183	224	242	219	5
Meeting Minutes Submitted Within 15 Days of Meeting	126	151	151	142	1
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	1
Meeting Minutes Past 15 Days of Meeting	50	68	80	73	1
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	11	4	2
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.85%	67.41%	62.40%	64.84%	25.00%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	530	582	675	774	170
Closed Before RTA Action**	6	7	4	7	0
Number Accepted First RTA Cycle**	506	555	648	739	152
Number Without a RTA Review and > 15 Days Since Date Received**	12	14	14	24	5
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	11
Number Not Accepted	6	6	9	4	2
Rate of Submissions Not Accepted for Review	1.15%	1.04%	1.34%	0.52%	1.26%

*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	54
Written Feedback Provided Within MDUFA IV Goal	482	535	610	676	53

*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	54
Average FDA Days to Written Feedback	53.02	55.51	56.18	58.60	53.41
20th Percentile FDA Days to Written Feedback	39	44	45	45	43
40th Percentile FDA Days to Written Feedback	50	53	55	57	52
60th Percentile FDA Days to Written Feedback	59	63	63	64	58
80th Percentile FDA Days to Written Feedback	67	69	69	69	65
Maximum FDA Days to Written Feedback	91	115	143	190	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 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	0
Average Days to Scheduling for Meetings Scheduled After Day 30	32.13	39.89	38.75	41.00	0.00

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

**Table 9.5 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	21
Meeting Minutes Submitted Within 15 Days of Meeting	183	199	212	248	14
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	3
Meeting Minutes Past 15 Days of Meeting	119	105	123	123	1
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	20	22	14	3
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	58.47%	61.42%	59.38%	64.42%	77.78%

*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	381	399	377	88
Closed Before RTA Action**	5	7	11	30	1
Number Accepted First RTA Cycle**	307	358	376	326	70
Number Without a RTA Review and > 15 Days Since Date Received**	11	7	3	16	3
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	11
Number Not Accepted	11	9	9	5	3
Rate of Submissions Not Accepted for Review	3.34%	2.41%	2.32%	1.44%	3.95%

*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	353	372	336	20
Written Feedback Provided Within MDUFA IV Goal	300	343	352	294	19

*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	353	372	336	20
Average FDA Days to Written Feedback	60.53	60.84	61.36	65.67	57.05
20th Percentile FDA Days to Written Feedback	53	53	51	58	48
40th Percentile FDA Days to Written Feedback	61	61	61	64	59
60th Percentile FDA Days to Written Feedback	65	66	66	67	63
80th Percentile FDA Days to Written Feedback	69	69	70	70	66
Maximum FDA Days to Written Feedback	156	148	168	204	70

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

**Table 9.4 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	2
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	36.88	36.00	52.11	36.00

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

**Table 9.5 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	203	220	194	6
Meeting Minutes Submitted Within 15 Days of Meeting	112	125	156	138	5
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	1
Meeting Minutes Past 15 Days of Meeting	64	72	61	51	0
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3	5	0
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.92%	61.58%	70.91%	71.13%	100.00%

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

**Table 9.1 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	278	337	316	73
Closed Before RTA Action**	4	5	21	119	1
Number Accepted First RTA Cycle**	234	253	304	165	59
Number Without a RTA Review and > 15 Days Since Date Received**	6	11	7	29	4
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	8
Number Not Accepted	7	9	5	3	1
Rate of Submissions Not Accepted for Review	2.83%	3.30%	1.58%	1.52%	1.56%

*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	256	300	175	11
Written Feedback Provided Within MDUFA IV Goal	215	224	264	118	9

*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	256	300	175	11
Average FDA Days to Written Feedback	60.70	62.62	63.10	68.03	53.45
20th Percentile FDA Days to Written Feedback	52	55	56	55	50
40th Percentile FDA Days to Written Feedback	59	63	62	63	51
60th Percentile FDA Days to Written Feedback	65	66	66	69	58
80th Percentile FDA Days to Written Feedback	69	70	70	76	64
Maximum FDA Days to Written Feedback	121	106	268	150	74

*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	1
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25	34.25	42.80	42.84	34.00

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

**Table 9.5 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	142	180	94	6
Meeting Minutes Submitted Within 15 Days of Meeting	92	95	118	67	3
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	26	42	50	23	0
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	5	12	4	3
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.19%	66.90%	65.56%	71.28%	50.00%

*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	308	340	78
Closed Before RTA Action**	3	2	2	1	1
Number Accepted First RTA Cycle**	232	253	285	316	64
Number Without a RTA Review and > 15 Days Since Date Received**	7	10	16	15	4
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	5
Number Not Accepted	7	12	5	8	4
Rate of Submissions Not Accepted for Review	2.85%	4.36%	1.63%	2.36%	5.56%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	260	297	311	13
Written Feedback Provided Within MDUFA IV Goal	202	219	184	216	12

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	235	260	297	311	13
Average FDA Days to Written Feedback	64.73	72.86	80.73	76.08	58.31
20th Percentile FDA Days to Written Feedback	58	63	65	64	49
40th Percentile FDA Days to Written Feedback	65	68	70	68	59
60th Percentile FDA Days to Written Feedback	69	70	70	70	64
80th Percentile FDA Days to Written Feedback	70	70	84	78	67
Maximum FDA Days to Written Feedback	172	397	385	307	70

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

**Table 9.4 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	4
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	33.00	37.50	38.50	32.00

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	156	174	176	172	4
Meeting Minutes Submitted Within 15 Days of Meeting	99	103	107	107	1
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	50	59	62	54	0
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	12	7	11	3
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.46%	59.20%	60.80%	62.21%	25.00%

*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	171	179	241	62
Closed Before RTA Action**	1	3	1	2	1
Number Accepted First RTA Cycle**	127	160	168	230	54
Number Without a RTA Review and > 15 Days Since Date Received**	5	6	7	6	2
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	5
Number Not Accepted	0	2	3	3	0
Rate of Submissions Not Accepted for Review	0.0%	1.19%	1.69%	1.26%	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 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	165	173	227	21
Written Feedback Provided Within MDUFA IV Goal	115	152	169	224	21

*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	165	173	227	21
Average FDA Days to Written Feedback	61.91	61.14	62.34	58.92	47.62
20th Percentile FDA Days to Written Feedback	52	55	57	45	41
40th Percentile FDA Days to Written Feedback	62	63	63	60	43
60th Percentile FDA Days to Written Feedback	67	66	69	65	55
80th Percentile FDA Days to Written Feedback	70	70	70	70	59
Maximum FDA Days to Written Feedback	106	92	105	78	69

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

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	77	87	79	100	4
Meeting Minutes Submitted Within 15 Days of Meeting	55	53	61	63	3
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	1
Meeting Minutes Past 15 Days of Meeting	19	29	15	34	0
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5	3	3	0
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	60.92%	77.22%	63.00%	100.00%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	891	1,098	979	644	145
Closed Before RTA Action**	8	11	65	221	20
Number Accepted First RTA Cycle**	875	1,066	848	300	81
Number Without a RTA Review and > 15 Days Since Date Received**	0	14	64	121	26
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	17
Number Not Accepted	8	7	2	2	1
Rate of Submissions Not Accepted for Review	0.91%	0.64%	0.22%	0.47%	0.93%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	873	1,072	817	326	28
Written Feedback Provided Within MDUFA IV Goal	869	1,061	794	270	25

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	873	1,072	817	326	28
Average FDA Days to Written Feedback	57.35	56.61	58.79	65.17	53.50
20th Percentile FDA Days to Written Feedback	48	45	50	50	47
40th Percentile FDA Days to Written Feedback	57	56	58	57	50
60th Percentile FDA Days to Written Feedback	63	63	64	64	57
80th Percentile FDA Days to Written Feedback	68	68	69	70	61
Maximum FDA Days to Written Feedback	85	307	190	295	76

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	6	5	6	5	4
Average Days to Scheduling for Meetings Scheduled After Day 30	33.83	35.60	53.50	83.00	53.75

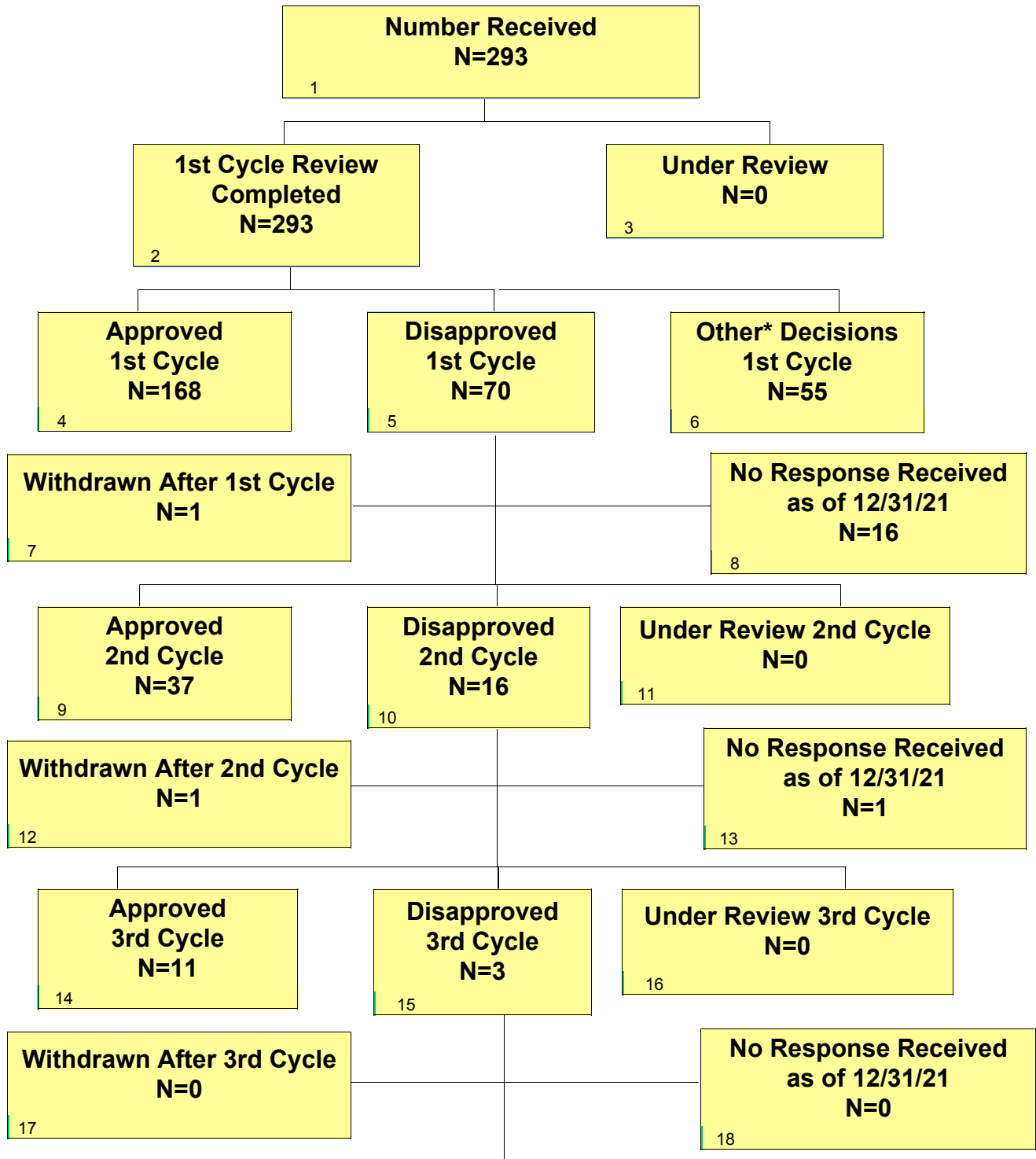
*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	476	590	473	179	9
Meeting Minutes Submitted Within 15 Days of Meeting	304	387	305	120	6
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	2
Meeting Minutes Past 15 Days of Meeting	155	185	148	50	1
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	18	20	9	0
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.87%	65.59%	64.48%	67.04%	85.71%

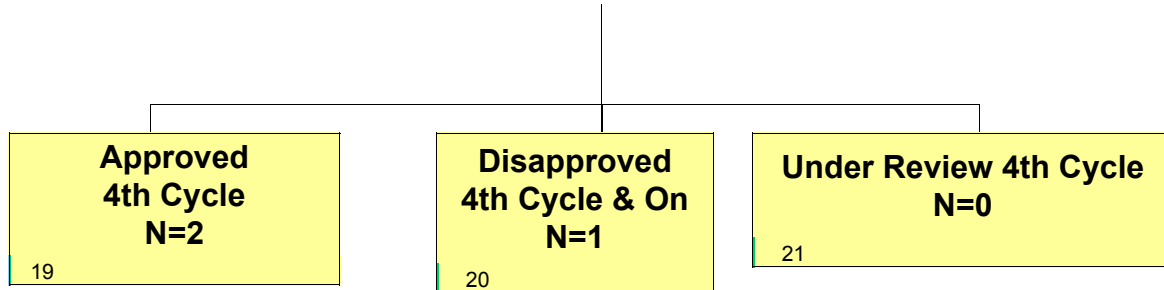
*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

CDRH IDEs - FY 2018 as of 12/31/21

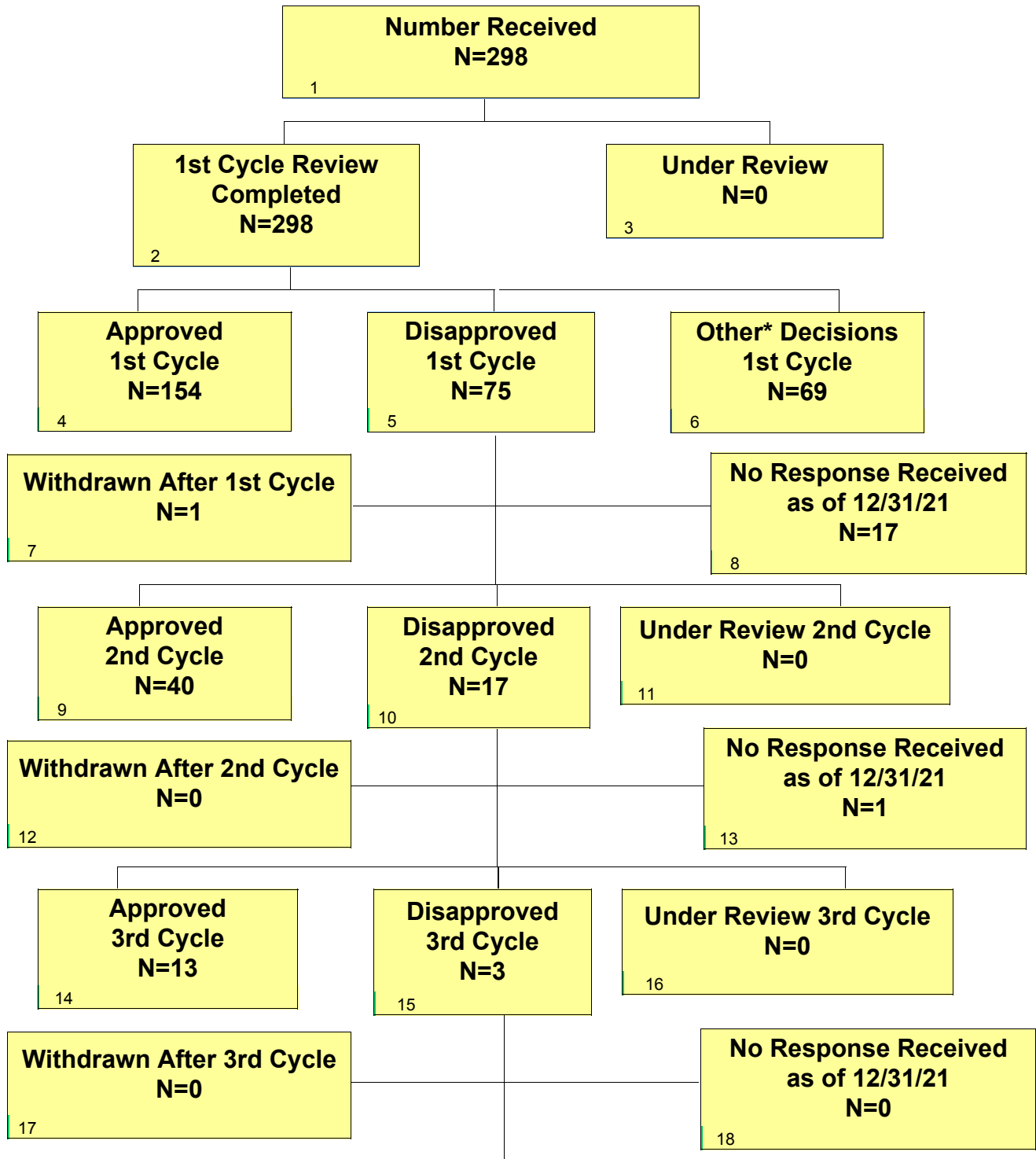


* Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

CDRH IDEs - FY 2018 as of 12/31/21

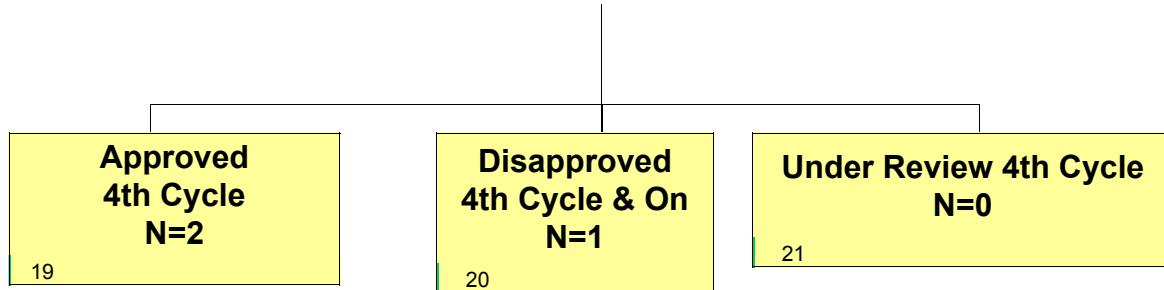


CDRH IDEs - FY 2019 as of 12/31/21

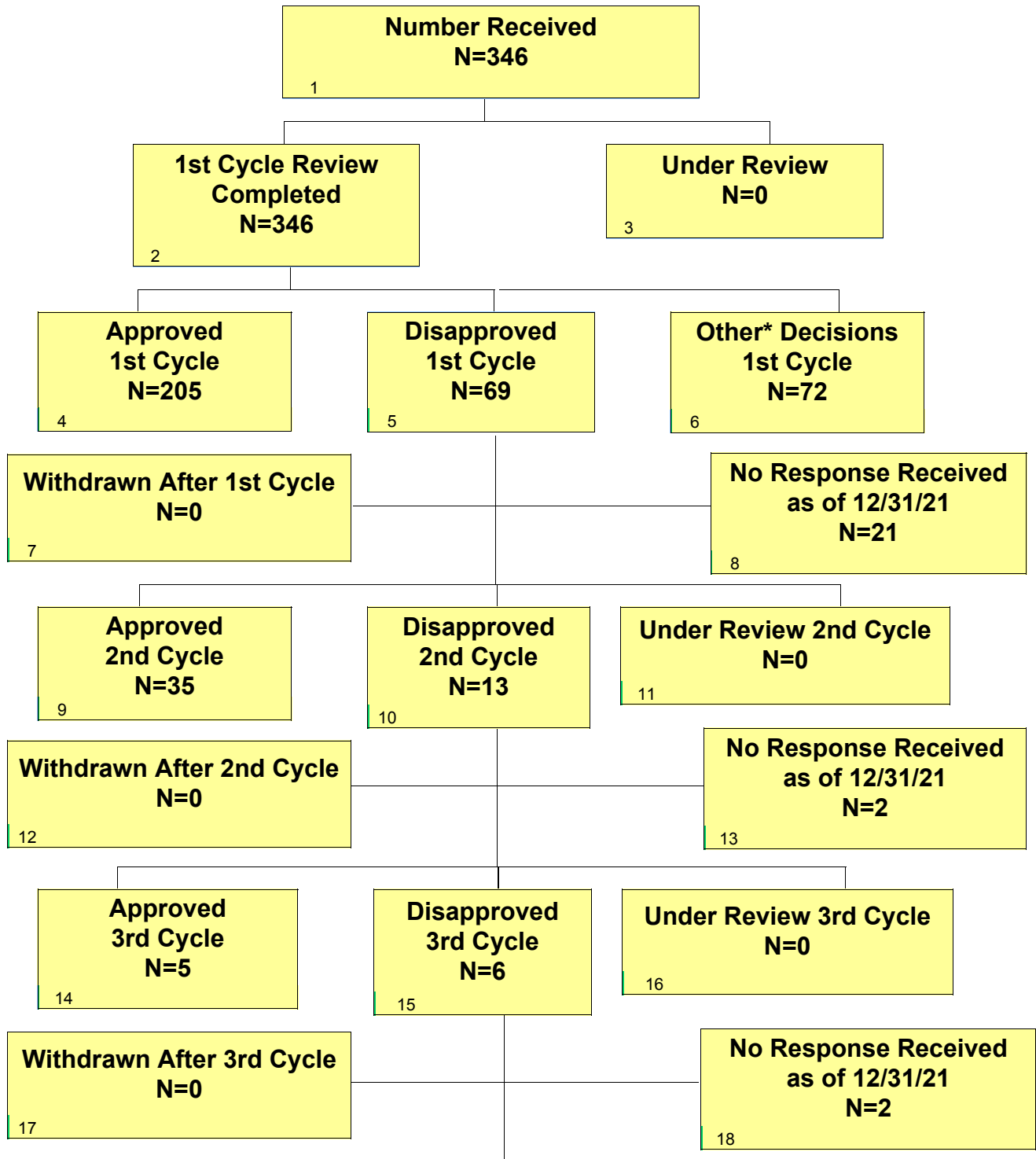


* Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).

CDRH IDEs - FY 2019 as of 12/31/21

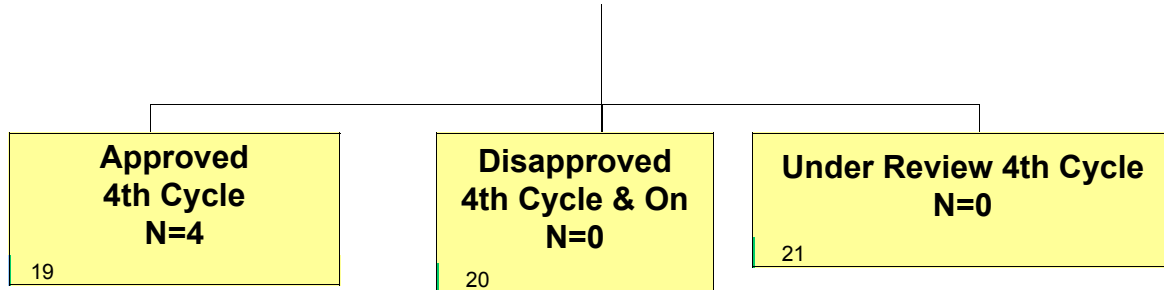


CDRH IDEs - FY 2020 as of 12/31/21

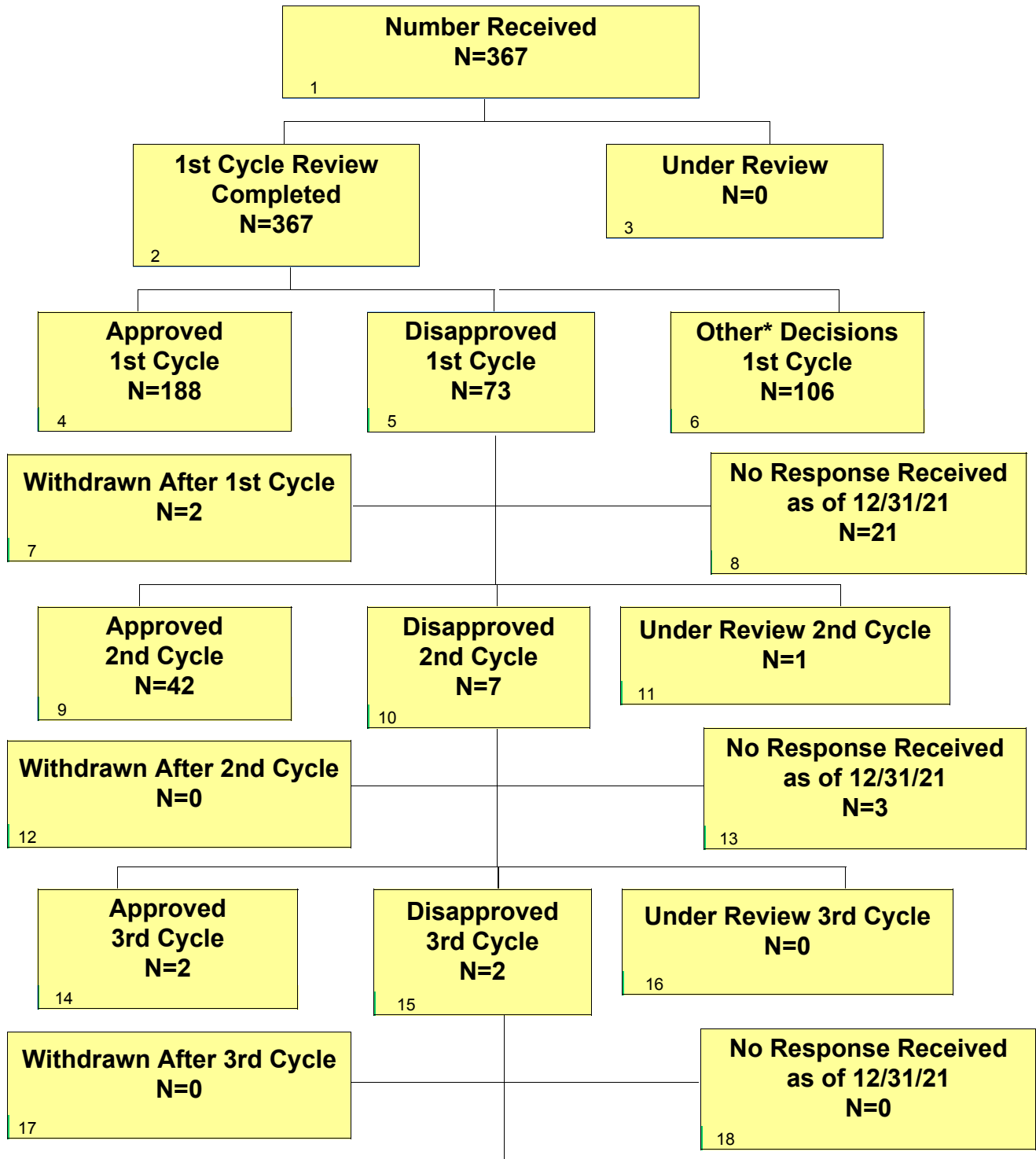


* Other decisions include withdrawn (N=12), withdrawn and converted (N=37), RTA (N=0), nonsignificant risk device (N=15), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).

CDRH IDEs - FY 2020 as of 12/31/21

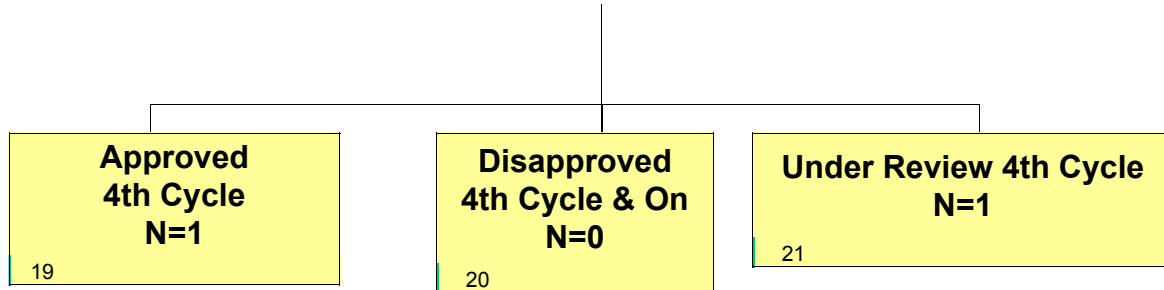


CDRH IDEs - FY 2021 as of 12/31/21

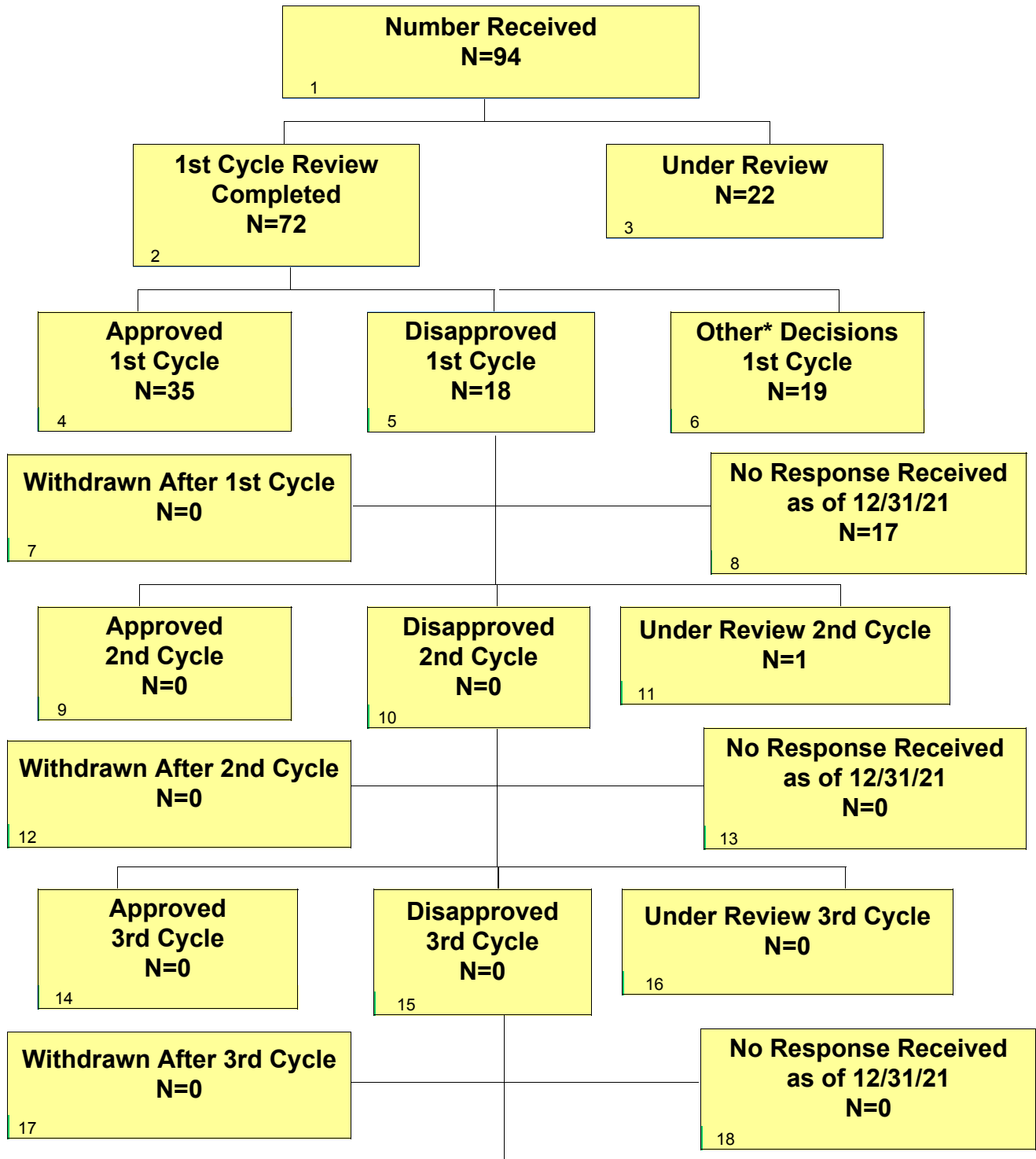


* Other decisions include withdrawn (N=26), withdrawn and converted (N=56), RTA (N=0), nonsignificant risk device (N=17), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=3), Basic Physiological Research (N=0).

CDRH IDEs - FY 2021 as of 12/31/21

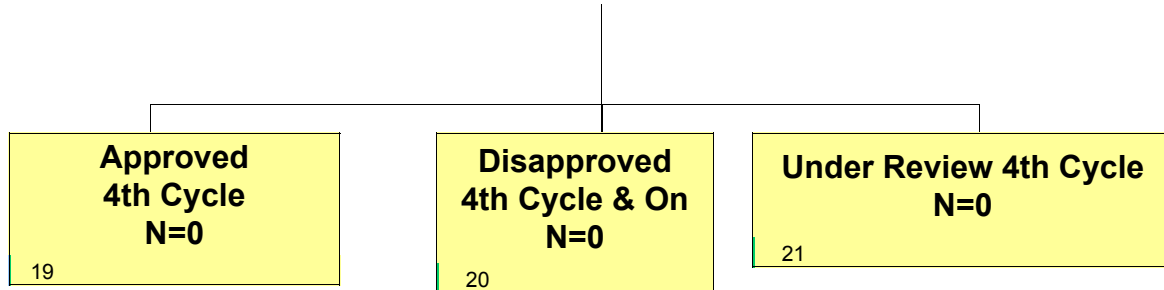


CDRH IDEs - FY 2022 as of 12/31/21



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

CDRH IDEs - FY 2022 as of 12/31/21



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	94
Average Number of Cycles to IDE Approval or Conditional Approval	1.32	1.34	1.23	1.21	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.34	0.23	0.21	0.00

* The number of IDEs received in FY2021 has been updated to reflect a submission that was received on September 30, 2021 and was previously not captured in the reporting due to a delay in submission processing.

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	10
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.36	1.32	1.43	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.36	0.32	0.43	0.00

**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	22
Average Number of Cycles to IDE Approval or Conditional Approval	1.58	1.43	1.41	1.38	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.43	0.41	0.38	0.00

**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	9
Average Number of Cycles to IDE Approval or Conditional Approval	1.6	1.5	1.45	1.37	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.6	0.5	0.45	0.37	0.00

**Table 10.1 OHT4 - Office of Surgical and Infection Control Devices
IDE MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	29	32	42	42	12
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.11	1.15	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.11	0.15	0.00

**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	19
Average Number of Cycles to IDE Approval or Conditional Approval	1.16	1.47	1.16	1.10	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.16	0.10	0.00

**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	6
Average Number of Cycles to IDE Approval or Conditional Approval	1.18	1.20	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.18	0.20	0.00	0.00	0.00

**Table 10.1 OHT7 - Office of In Vitro Diagnostics and Radiological Health
IDE MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	52	50	63	86	16
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.03	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.03	0.00	0.00	0.00

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Section 11 CLIA Waiver Annual Metrics

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

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

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

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Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

Table 1.1 and Tables 1.1.x PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number with accepted RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer.
4	Number without RTA Review and > 15 Days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number without RTA Review and <= 15 Days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of submissions not accepted for filing review	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

Table 1.2 and Tables 1.2.x**PMA Original and Panel Track Supplements – Filing Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	Number Accepted [#]	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAN decision in the first RTA review cycle entered by reviewer.
3	Number with completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

Table 1.3 and Tables 1.3.x**PMA Originals & Panel Track Supplements Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under review with no SI past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 1.4 and Tables 1.4.x**PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 1.5 and Tables 1.5.x PMA Originals & Panel-Track Supplements (without Panel Review)
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.6 and Tables 1.6.x**PMA Originals & Panel Track Supplements (with Panel Review)
MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 1.7 and Tables 1.7.x**PMA Original and Panel Track Supplements (without Panel Review)
Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

Table 1.8 and Tables 1.8.x**PMA Original and Panel Track Supplements (with Panel Review)
Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA IV Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

Table 1.9 and Tables 1.9.x**PMA Originals and Panel Track Supplements (without Panel Review)
Performance Metrics – Rate of Withdrawal and Not Approvable -
Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number with MDUFA IV decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line 2).

Table 1.10 and Tables 1.10.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Number of Deleted	Number of submissions filed (line 1) with MDUFA decision of DELE (Deleted).
6	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
7	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

Table 1.11 and Tables 1.11.x PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Table 1.12 and Tables 1.12.x PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Tables 1.13 and Tables 1.13.x LDT PMA Originals & Panel-Track Supplements Metric* MDUFA Decision Performance Goals - Definitions

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Tables 1.14 and Tables 1.14.x Conventional IVD (Non-LDT) PMA Originals & Panel-Track Supplements Metric* MDUFA Decision Performance Goals - Definitions

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	Non-MDUFA IV Decisions	Submissions filed (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA IV Decisions	Submissions filed (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	PMAs pending MDUFA IV Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA IV decision or final decision.
6	PMAs pending MDUFA IV Decision Past Goal	Number of submissions pending MDUFA IV Decision (line 5) past goal. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA IV Decisions made on time (line 4) divided by the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

*Includes submissions that went to panel

Section 2 PMA 180 Day Supplements

Table 2.1 and Tables 2.1.x PMA 180 Day Supplements Substantive Interaction Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA (other than APPR) or NON-MDUFA decision but without an SI
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

Table 2.2 and Tables 2.2.x PMA 180 Day Supplements MDUFA Decision Performance Goals – Definitions

#	Measure	Description
1	Supplements filed	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA IV Decisions	Supplements received (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) made before or on the MDUFA goal due date.
5	Supplements pending MDUFA IV Decision	Number of supplements received (line 1) that do not have a MDUFA IV decision or a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 2.3 and Tables 2.3.x PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

Table 2.4 and Tables 2.4.x PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA IV decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

Section 3 PMA Real Time Supplements

Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions

#	Measure	Description
1	Supplements received	Number of Real Time PMA supplements that were received in this fiscal year.
2	Non-MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA IV decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA IV Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA IV decision.
4	MDUFA IV Decisions Goal Met	Submissions with MDUFA IV decisions (line 3) within goal.
5	Supplements pending MDUFA IV Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA IV decision and are not closed with a final decision.
6	Supplements pending MDUFA IV Decision Past Goal	Number of supplements pending MDUFA IV Decision (line 5) past goal. These supplements already failed the MDUFA IV review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA IV Decisions made on time (line 4) divided by the total number of supplements with MDUFA IV Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable – Definitions

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

Table 3.3 and Tables 3.3.x**Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

Section 5 PMA Annual Metrics and Goals

Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to “Yes”, received in this fiscal year.
2	Original PMAs (Panel) – Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
3	Original PMAs (No Panel) – Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
4	Original PMAs (Panel) – Non- Breakthrough	Number of PMA Original submissions with Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Breakthrough	Number of PMA Original submissions with no Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
7	Panel Track Supplements (No Panel) – Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to “Yes”, received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Breakthrough	Number of PMA Panel Track Supplements with no Panel review requested and Breakthrough flag set to “No” or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

Table 5.2 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number with a decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MUDFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

Table 5.3 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision – Definitions

#	Measure	Description
1	Number with MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with MDUFA decision after trimming the upper and lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA IV decision and 5% of submissions with the highest number of Total Days to MDUFA IV decision.
3	Three-year Rolling Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY 2011 and FY 2012 Total Time to MDUFA II (two) decision will be used.

Section 6 510(k) MDUFA IV Performance (Quarterly Data Exclude Third Party Review)

Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that received an “RTA Accepted” (RTAA) decision in the first RTA review cycle.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that received a “Did not perform RTA” (RTAN, RTAS or RTAW) decision in the first RTA review cycle. An RTAN decision is automatically recorded by CTS at the end of day 15 of RTA review, if no other RTA decision is made. This RTA decision means that the 510(k) is deemed accepted.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle and have not yet reached the 15 th day of that cycle..
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a “Not Accepted” decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage of the sum of the Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goal – Definitions

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions accepted or deemed accepted via the RTA process as of quarter end date (RTAA, RTAN, RTAW or RTAS).
2	Deleted or Withdrawn Prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made as of the quarter end date and before any SI action: WTDR, DELE.
3	SI Within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI Over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI Pending within 60 FDA days	Submissions that are awaiting SI and where 60 days have not yet elapsed.
6	SI Pending over 60 FDA days	Submissions that are under review over 60 FDA days and that do not have an SI.
7	510(k)s NSE Without SI	Number of 510(k) submissions that are closed with an NSE decision (and did not have an SI).
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) expressed as a percentage of the sum of the number of submissions that either had an SI (line 3 and line 4), the number of submissions that received an SI after 60 days had elapsed (line 6), and the number of submissions that were found NSE without first receiving an SI (line 7).

Table 6.3 and Tables 6.3.x**510(k) Substantive Interaction Metric – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interaction	Number of 510(k) submissions accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to substantive interaction across all 510(k) submissions with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

Tables 6.4 and Tables 6.4.x 510(k) MDUFA Decision Performance Goal – Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of submissions with MDUFA IV decision (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Within 90 FDA Days	Number of submissions with MDUFA IV Decisions within 90 FDA Days (line 4) expressed as a percentage of the sum of the number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 6.5 and Tables 6.5.x 510(k) Time to MDUFA IV Decision – Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days to MDUFA IV decision.

Table 6.6 and Tables 6.6.x**510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decision – Definitions**

#	Measure	Description
1	510(k) Accepted	Number of 510(k) submissions accepted in this fiscal year.
2	Number with MDUFA IV Decision	Number submissions accepted (line 1) that had a MDUFA decision.
3	Number of SE Decision	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE Decision	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawal	Number of submissions accepted (line 1) and closed with Withdrawal final decision.
6	Number Deleted	Number of submissions accepted (line 1) and closed with Delete final decision.
7	Rate of SE Decision	Number of SE decisions (line 3) expressed as a percentage of the Number with MDUFA decision (line 2).
8	Rate of NSE Decision	Number of NSE decisions (line 4) expressed as a percentage of the Number with MDUFA decision (line 2).
9	Rate of Withdrawal	Number of Withdrawals (line 5) expressed as a percentage of the Number Accepted (line 1).
10	Rate of Deleted	Number of Deleted (line 6) expressed as a percentage of the by Number Accepted (line 1).

Table 6.7 and Tables 6.7.x**510(k) Performance Metric – Submissions Missing Performance Goal – Definitions**

#	Measure	Description
1	Number of Submissions that Missed the Goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days.
2	Mean FDA Days for Submissions that Missed the Goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

Tables 6.8 and Tables 6.8.x LDT 510(k) MDUFA IV Decision Metric – Definitions

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA IV Decision over 90 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

Tables 6.9 and Tables 6.9.x Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric – Definitions

#	Measure	Description
1	510(k)s Accepted	Number of 510(k) submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not SE or NSE).
3	MDUFA IV Decision (SE/NSE)	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (SE or NSE).
4	MDUFA IV Decision within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 90 FDA days.
5	510(k)s Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	510(k) Pending MDUFA IV Decision Over 90 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 90 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 90 FDA Days (line 4) divided by the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).

Section 7 510(k) Annual General Metrics (Annual data includes Third Party reviews)**Table 7.1 CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type – Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal – Definitions

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. This metric includes Third Party 510(k) submissions..
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA IV decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA IV Decision	Number of 510(k) submissions accepted (line 1) that had a MDUFA IV decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) expressed as a percentage of the sum of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA IV decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA IV Decision (line 4) excluding the 2% of submissions with the lowest number of Total Days to MDUFA IV decision and the 2% of submissions with the highest number of Total Days to MDUFA IV decision.
7	Average Total Time to MDUFA IV decision	Average Total Time (FDA and Industry) to MDUFA decision, where the denominator is the trimmed number with MDUFA decision (line 6). If the cohort has not yet reached 99% closure, "N/A" shall be displayed instead.

Table 7.3 CDRH - 510(k) Third Party Performance – Definitions

#	Measure	Description
1	Number of Third Party Submissions	Number of Third Party 510(k) submissions received in this fiscal year.
2	90 th Percentile FDA Days to MDUFA IV Decision	The 90 th percentile of FDA days to MDUFA IV decision on 3 rd Party 510(k) submissions received in this fiscal year

Section 8 De Novo MDUFA IV Performance

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

#	Measure	Description
1	Number Received	Number of De Novo submissions received in this fiscal year.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number Without a RTA Review and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Not Accepted" decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) expressed as a percentage the sum of the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

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

Tables 8.2 and Tables 8.2.x De Novo MDUFA IV Decision Performance Goals – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted/Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (Granted/Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos pending MDUFA IV Decision	Number of submissions accepted (line 1) and still under review.
6	De Novos pending MDUFA IV Decision over 150 FDA days	Number of submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of submissions with MDUFA IV Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

Table 8.3 and Tables 8.3.x De Novo Time to MDUFA IV Decision – Definitions

#	Measure	Description
1	Average Review Cycles	Average number of review cycles (after submission is accepted for review) for De Novos with a MDUFA IV decision (line 2).
2	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days to MDUFA IV decision.

Table 8.4 and Tables 8.4.x**De Novo Performance Metrics – Rate of Grant, Decline, Withdrawal and Delete Decisions – Definitions**

#	Measure	Description
1	De Novos Accepted	Number of De Novos submissions accepted in this fiscal year.
2	Number with MDUFA IV Decisions	Number submissions accepted (line 1) that had a MDUFA IV decision.
3	Number with Granted Decisions	Number of submissions accepted (line 1) that had a Granted MDUFA IV decision.
4	Number with Declined Decisions	Number of submissions accepted (line 1) that had a Declined MDUFA IV decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) that had a Withdrawn MDUFA IV decision.
6	Number of Deleted	Number of submissions accepted (line 1) and closed that had a Deleted MDUFA IV decision
7	Rate of Granted Decisions	Number of Granted decisions (line 3) divided by Number with MDUFA IV decision (line 2).
8	Rate of Declined Decisions	Number of Declined decisions (line 4) divided by Number with MDUFA IV decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number with MDUFA IV decision (line 2).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number with MDUFA IV decision (line 2).

Table 8.5 and Tables 8.5.x**De Novo Performance Metrics – Submissions Missing Performance Goals – Definitions**

#	Measure	Description
1	Number of Submissions that Mssed the Goal	Number of De Novo submissions accepted in this fiscal year that had a MDUFA IV decision with more than 150 FDA days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean Industry Days for Submissions that Missed the Goal	Mean industry days for submissions that missed the goal (line 1).

Tables 8.6 and Tables 8.6.x LDT De Novo MDUFA IV Decision Metrics – Definitions

#	Measure	Description
1	De Novos accepted	Number of De Novo submissions for LDTs accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of LDT submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions Within 150 FDA Days	Number of LDT submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of LDT submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV Decision over 150 FDA days	Number of LDT submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent within 150 FDA Days	Number of LDT submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of LDT submissions with MDUFA IV Decisions (line 3) and pending LDT submissions that already failed the MDUFA goal (line 6).

Tables 8.7 and Tables 8.7.x Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics – Definitions

#	Measure	Description
1	De Novos Accepted	Number of De Novo submissions for non-LDT IVDs accepted in this fiscal year.
2	Non-MDUFA IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a non-MDUFA IV decision (not Granted, Declined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of non-LDT IVD submissions accepted (line 1) and closed with a MDUFA IV decision (Granted, Declined, Withdrawn or Deleted).
4	MDUFA IV Decisions within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV decisions (line 3) made within 150 FDA days.
5	De Novos Pending MDUFA IV Decision	Number of non-LDT IVD submissions accepted (line 1) and still under review.
6	De Novos Pending MDUFA IV Decision Over 150 FDA Days	Number of non-LDT IVD submissions pending MDUFA IV Decision (line 5) for more than 150 FDA Days. These submissions already failed the MDUFA IV review goal.
7	Current Performance Percent Within 150 FDA Days	Number of non-LDT IVD submissions with MDUFA IV Decisions within 150 FDA Days (line 4) expressed as a percentage of the sum of the total number of non-LDT IVD submissions with MDUFA IV Decisions (line 3) and pending non-LDT IVD submissions that already failed the MDUFA goal (line 6).

Section 8 Annual Metrics for De Novo Requests

Table 8.8 CDRH – Annual General Metric Report for De Novo Requests - Definitions

#	Measure	Description
1	Number Accepted First RTA Cycle	Number of De Novo submissions accepted in the first RTA cycle in this fiscal year as of the report cutoff date.
4	Average Number of Days to Accept/Refuse to Accept*	Average number of days in the first RTA review cycle De Novo submissions..

*RTA will be implemented when the guidance, including the submission checklist, is finalized.

Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Sub Acceptance Review Decision – Definitions

#	Measure	Description
1	Number Received	Number of Pre-Subs submissions received in this fiscal year.
2	Closed before RTA Action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted First RTA Cycle	Number Received (line 1) that had “RTA Accepted” (RTAA) decision in the first RTA review cycle entered by reviewer.
4	Number Without a RTA Review and > 15 days Since Date Received	Number Received (line 1) that had “Did not perform RTA” (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review.
5	Number Without a RTA Review and <= 15 days Since Date Received	Number Received (line 1) that are still in the first RTA review cycle at the quarter end date.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that had “Refuse to accept” (RTA1) decision in the first RTA review cycle.
7	Rate of Submissions Not Accepted for Review	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

Table 9.2 and Tables 9.2.x Pre-Submissions Performance Metrics – Definitions

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either “Email Reply” (EMAL) or “Email Feedback Sent Before Meeting” (EMFB) in CTS. EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Written Feedback Provided Within MDUFA IV Goal	Number of Pre-Subs that had Written Feedback sent (line 1) by Day 70 (for Pre-Subs without a meeting request), or by 5 Days before the Meeting Date or Day 70, whichever is sooner (for Pre-Subs with a meeting request).

Table 9.3 and Tables 9.3.x Pre-Sub Time to MDUFA IV Metrics – Definitions

#	Measure	Description
1	Written Feedback Sent	Number of Pre-Subs for which Written Feedback was sent to the sponsor by the reviewer entering a MDUFA IV Decision of either “Email Reply” (EMAL) or “Email Feedback Sent Before Meeting” (EMFB) EMAL is used for Pre-Subs where there is no meeting requested. EMFB is used for Pre-Subs when a meeting is requested.
2	Average FDA Days to Written Feedback	Average number of days from the start of FDA review to MDUFA IV Decision (EMAL or EMFB) for Pre-Subs with Written Feedback sent (line 1).
3	20 th Percentile FDA Days to Written Feedback	20 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
4	40 th Percentile FDA Days to Written Feedback	40 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
5	60 th Percentile FDA Days to Written Feedback	60 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
6	80 th Percentile FDA Days to Written Feedback	80 th percentile FDA days to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).
7	Maximum FDA Days to Written Feedback	Maximum FDA days (100 th percentile) to Written Feedback for Pre-Subs with MDUFA IV Decision EMAL or EMFB (line 1).

Table 9.4 and Tables 9.4.x Pre-Submissions Performance Metrics Meeting Scheduling-Definitions

#	Measure	Description
1	Meetings Not Scheduled by Day 30	Number of Pre-Subs for which a Meeting was Requested and a Meeting Date was not confirmed by the reviewer in CTS by day 30.
2	Average Days to Scheduling for Meetings Scheduled After Day 30	Average days to confirming a Meeting Date in CTS for Meetings not scheduled by Day 30 (line 1).

Table 9.5 and Tables 9.5.x Pre-Submissions Performance Metrics Meeting Minutes- Definitions

#	Measure	Description
1	Meetings Held	Number of Pre-Sub Meeting Requests for which a Meeting was held and reviewer closed the submission in CTS by the quarter end date.
2	Meeting Minutes Submitted Within 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received within 15 days after Meeting Date.
3	Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and it is still under 15 days since meeting (as of end of quarter).
4	Meeting Minutes Past 15 Days of Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes were received more than 15 days after Meeting Date.
5	Meeting Minutes Not Submitted and >15 Days Since Meeting	Number of Pre-Sub Meeting Requests with Meetings held (line 1), for which Meeting Minutes have not been received and more than 15 days have passed since the Meeting Date (as of end of quarter).
6	Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	Number of Meeting Minutes received within 15 days (line 2) divided by the total of Number of Meeting Minutes received within 15 days (line 2), Number of Meeting Minutes received past 15 days (line 4), and Number of Meeting Minutes which have not been received and >15 days since Meeting Date (line 5).

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn within 90 FDA days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

Table 11.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications accepted in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all CLIA Waivers with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 11.3 CLIA Waiver (without Panel Review) MDUFA IV Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA IV Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn).
3	MDUFA IV Decisions	Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn).
4	MDUFA IV Decisions within 150 FDA Days	Number of submissions with MDUFA IV decisions made within 150 FDA days.
5	CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	Number of submissions pending MDUFA IV Decision for more than 150 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 150 FDA Days	Number of submissions with MDUFA IV Decisions within 150 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

Table 11.4 CLIA Waiver (with Panel Review) MDUFA IV Decision Performance Goals) – Definitions

#	Measure	Description
1	Eligible for MDUFA IV Decisions	Number of CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with a non-MDUFA IV decision (not Approved, Denied, or Withdrawn).
3	MDUFA IV Decisions	Number of submissions closed with a MDUFA IV decision (Approved, Denied, or Withdrawn).
4	MDUFA IV Decisions within 320 FDA Days	Number of submissions with MDUFA IV decisions made within 320 FDA days.
5	CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

Table 11.5 CLIA Waiver (without Panel Review) Time to MDUFA IV Decision – Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

Table 11.6 CLIA Waiver (with Panel Review) Time to MDUFA IV Decision - Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision (Approved, Denied, or Withdrawn), and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

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

Table 12.1 Dual 510(k) and CLIA Waiver Substantive Interaction Performance Goals – Definitions

#	Measure	Description
1	Eligible for SI	Number of Dual 510(k) and CLIA Waiver by Applications with 510(k) RTA review accepted in this fiscal year.
2	Withdrawn prior to SI	Number of submissions that were Withdrawn prior to 90 days.
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days.
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
5	SI pending within 90 FDA days	Submissions that are awaiting SI and where 90 days have not yet elapsed.
6	SI pending over 90 FDA days	Submissions that have been under review over 90 FDA days and that do not have an SI.
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior.
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within goal (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

Table 12.2 Dual 510(k) and CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions

#	Measure	Description
1	Number of Substantive Interactions	Number of Dual 510(k) and CLIA Waiver by Applications accepted in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days to SI across all Dual 510(k) and CLIA Waivers with SI (line 1).
3	20 th Percentile FDA days to Substantive Interaction	20 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 th Percentile FDA days to Substantive Interaction	40 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 th Percentile FDA days to Substantive Interaction	60 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 th Percentile FDA days to Substantive Interaction	80 th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 th percentile) to Substantive Interaction for submissions with SI (line 1).

Table 12.3 Dual 510(k) and CLIA Waiver (without panel review) MDUFA IV Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA IV Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and did not have a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with non-MDUFA IV decisions.
3	MDUFA IV Decisions	Number of submissions closed with MDUFA IV decisions.
4	MDUFA IV Decisions within 180 FDA Days	Number of submissions with MDUFA IV decisions made within 180 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	Number of submissions pending MDUFA IV Decision for more than 180 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA IV Decisions within 180 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

Table 12.4 Dual 510(k) and CLIA Waiver (with panel review) MDUFA IV Decision Performance Goals – Definitions

#	Measure	Description
1	Eligible for MDUFA IV Decision	Number of Dual 510(k) and CLIA Waiver by Applications that were accepted in this fiscal year, and had a panel review.
2	Non-MDUFA IV Decisions	Number of submissions closed with non-MDUFA IV decisions.
3	MDUFA IV Decisions	Number of submissions closed with MDUFA IV decisions.
4	MDUFA IV Decisions within 320FDA Days	Number of submissions with MDUFA IV decisions made within 320 FDA days.
5	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision	Number of submissions still under review.
6	Dual 510(k) and CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	Number of submissions pending MDUFA IV Decision for more than 320 FDA days. These submissions already failed the MDUFA IV Decision goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA IV Decisions within 320 FDA days (line 4) divided by the total number of submissions that either had MDUFA IV decisions (line 3) or that already failed the MDUFA IV Decision goal (line 6).

Table 12.5 Dual 510(k) and CLIA Waiver (without panel review) Time to MDUFA IV Decision – Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision), and did not have a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

Table 12.6 Dual 510(k) and CLIA Waiver (with panel review) Time to MDUFA IV Decision – Definitions

#	Measure	Description
1	Number with MDUFA IV Decision	Number of submissions accepted in this fiscal year that had a MDUFA IV decision, and had a panel review.
	Days to MDUFA IV Decision	Table shall show Average Days to MDUFA IV decision as well as quintiles (20 th , 40 th , 60 th , 80 th percentiles) and the Maximum Days (100 th percentile) for FDA days, Industry days, and Total days.

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**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CBER Performance Data ----
Actions through 31 Dec 2021**

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	0
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	1
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	0
Completed RTF	3	3	3	1	0
Number Not Filed	1	0	0	0	0
Rate of Submissions Not Filed	33.33%	0.00%	0.00%	0.00%	N/A

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	0
SI Goal Met	2	3	2	1	0
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%	N/A

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	0
Average Number of FDA Days to Substantive Interaction	69.00	85.33	91.33	86.00	0.00
20th Percentile FDA Days to Substantive Interaction	50.00	82.00	81.00	86.00	0.00
40th Percentile FDA Days to Substantive Interaction	50.00	84.00	89.00	86.00	0.00
60th Percentile FDA Days to Substantive Interaction	88.00	84.00	89.00	86.00	0.00
80th Percentile FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	0.00
Maximum FDA Days to Substantive Interaction	88.00	90.00	104.00	86.00	0.00

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	0
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	0
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	N/A

Table 1.6 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	0
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	0
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	0
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	0
SI Goal Met	8	5	8	4	0
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
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	0
Non-MDUFA IV Decision	0	0	0	3	0
MDUFA IV Decision	8	5	8	2	0
MDUFA IV Decision Goal Met	8	5	8	2	0
Supplements Pending MDUFA IV Decision	0	0	0	2	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 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	0
Number with MDUFA IV Decision	8	5	8	2	0
Number of Not Approvable	0	0	1	0	0
Rate of Not Approvable	0.00%	0.00%	12.50%	0.00%	N/A

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

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

Section 3 PMA Real-Time Supplements - Center Level Metric

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
Supplements Received	3	2	5	9	3
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	3	2	5	9	0
MDUFA IV Decision Goal Met	3	2	5	9	0
Supplements Pending MDUFA IV Decision	0	0	0	0	3
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100%	100%	100%	100%	N/A

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	3
Number With MDUFA IV Decision	3	2	5	9	0
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0%	0%	0%	0%	N/A

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	10
Closed Before RTA Action	0	0	1	1	0
Number Accepted	40	38	34	36	9
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	0
Number Not Accepted	11	15	14	5	1
Rate of Submissions Not Accepted for Review	20.75%	27.78%	28.57%	11.36%	10.00%

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	9
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	49	51	43	40	2
SI Over 60 FDA Days	0	0	1	0	0
SI Pending Within 60 FDA Days	0	0	0	0	7
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	2
Average Number of FDA Days to Substantive Interaction	50.60	45.27	48.98	53.63	44.00
20th Percentile FDA Days to Substantive Interaction	43	21	21	56	30
40th Percentile FDA Days to Substantive Interaction	57	53	55	58	30
60th Percentile FDA Days to Substantive Interaction	59	58	59	59	58
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	58
Maximum FDA Days to Substantive Interaction	60	60	64	60	58

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	9
Non-MDUFA IV Decision	6	5	5	0	0
MDUFA IV Decision (SE/NSE)	43	46	37	26	1
MDUFA IV Decision Within 90 FDA Days	43	46	37	26	1
510(k)s Pending MDUFA IV Decision	0	0	2	14	8
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	1.19	1.00
Number With MDUFA IV Decision	43	46	37	26	1
Average Number of FDA Days to MDUFA IV Decision	75.58	67.48	64.08	71.27	30.00
20th Percentile FDA Days to MDUFA IV Decision	65	28	30	56	30
40th Percentile FDA Days to MDUFA IV Decision	85	77	65	79	30
60th Percentile FDA Days to MDUFA IV Decision	88	87	82	84	30
80th Percentile FDA Days to MDUFA IV Decision	90	89	88	89	30
Maximum FDA Days to MDUFA IV Decision	90	206	90	90	30
Average Number of Industry Days to MDUFA IV Decision	25.26	75.76	16.95	18.31	0.00
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	0.00	0.00
Maximum Industry Days to MDUFA IV Decision	178.00	389.00	199.00	146.00	0.00
Average Number of Total Days to MDUFA IV Decision	100.84	143.24	81.05	89.58	0.00
20th Percentile Total Days to MDUFA IV Decision	76	59	30	56	0
40th Percentile Total Days to MDUFA IV Decision	86	87	65	79	0
60th Percentile Total Days to MDUFA IV Decision	90	141	82	84	0
80th Percentile Total Days to MDUFA IV Decision	147	269	105	90	0
Maximum Total Days to MDUFA IV Decision	268	463	287	236	0

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	9
Number With MDUFA IV Decision	43	46	37	26	1
Number of SE Decision	43	43	35	26	1
Number of NSE Decision	0	3	2	0	0
Number of Withdrawal	2	4	4	0	0
Number of Deleted	3	1	1	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%	0%
Rate of Deleted	6%	2%	2%	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	4
Non-MDUFA IV Decision	0	1	0	0	0
MDUFA IV Decision (SE/NSE)	15	16	7	12	1
MDUFA IV Decision Within 90 FDA Days	15	16	7	12	1
510(k)s Pending MDUFA IV Decision	0	0	0	7	3
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	1
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	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 Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	0	0	1
Rate of Submissions Not Accepted for Review	N/A	N/A	0	0	100.00%

* 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	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

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	0
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	15
Closed Before RTA Action	5	3	10	6	0
Number Accepted First RTA Cycle	69	70	65	64	10
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1	6	2
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	3	3
Number Not Accepted	1	1	1	1	0
Rate of Submissions Not Accepted for Review	1.41%	1.35%	1.49%	1.41%	0.00%

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	70	7
Written Feedback Provided Within MDUFA IV Goal	68	71	63	67	6

*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	70	7
Average FDA Days to Written Feedback	57.86	61.00	56.70	60.94	59.00
20th Percentile FDA Days to Written Feedback	47	55	48	53	51
40th Percentile FDA Days to Written Feedback	58	60	58	62	57
60th Percentile FDA Days to Written Feedback	64	63	64	64	68
80th Percentile FDA Days to Written Feedback	67	68	68	66	68
Maximum FDA Days to Written Feedback	72	75	77	147	75

*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	38	3
Meeting Minutes Submitted Within 15 Days of Meeting	33	30	26	31	2
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	1	0
Meeting Minutes Past 15 Days of Meeting	9	2	1	6	0
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1	0	0	1
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	90.91%	96.30%	83.78%	66.67%

Section 10 IDE- Center Level Metric

Table 10.1 CBER - IDE MDUFA IV Decision Performance Goal

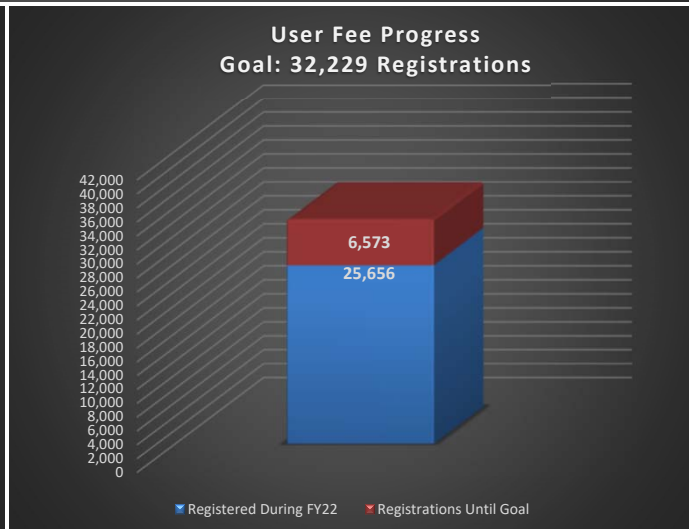
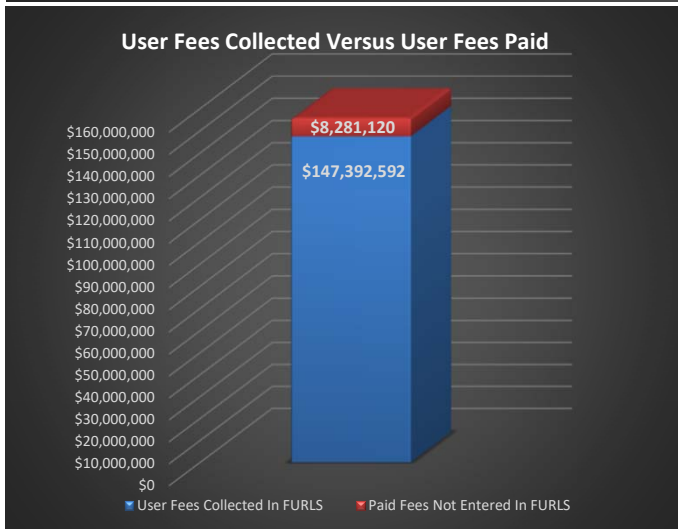
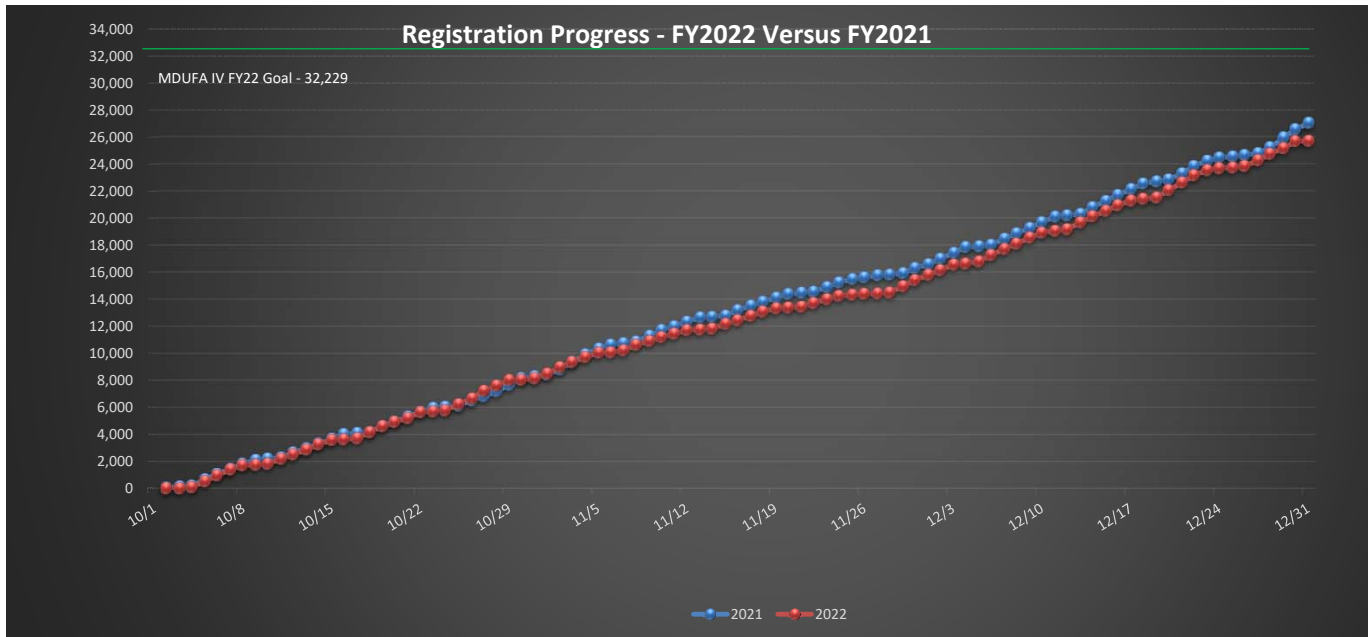
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	15	15	21	20	4
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.63	1.07	1.25	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.63	0.07	0.25	0.00

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MDUFA IV Registrations - 1st Quarter Summary FY2022*

Current Active Registrations by Type	FY22 Q1			FY21 Year End Active Totals			FY22 vs End FY21
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,700	10,445	16,143	6,899	14,017	20,916	77.18%
Contract Manufacturer	1,033	1,557	2,590	1,213	1,745	2,958	87.56%
Contract Sterilizer	61	148	209	70	156	226	92.48%
Specification Developer	1,363	510	1,873	1,785	594	2,379	78.73%
Reprocessor of Single Use Devices	16	4	20	30	8	38	52.63%
U.S. Manufacturer of Export Only Devices	102	0	102	133	0	133	76.69%
Repackager/Relabeler	893	168	1,061	1,186	230	1,416	74.93%
Remanufacturer	12	11	23	17	11	28	82.14%
Foreign Exporter/Private Label Distributor		927	927		1,179	1,179	78.63%
Initial Importer	2,866		2,866	4,125		4,125	69.48%
Unknown	1	4	5	4	5	9	55.56%
Total:	12,047	13,774	25,821	15,462	17,945	33,407	77.29%

*Note: This data is current as of 12/31/2021



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FY 2022 1st QUARTER COLLECTION TABLE

FY 2022 Medical Device User Fee Collections as of December 31th, 2021 Excludes Unearned Fees					
	Receipts	Refunds	Net	Authorized	% of Authorized
Registration Fees	\$145,858,136	\$0	\$145,858,136		
Application Fees	\$14,361,644	\$65,976	\$14,295,668		
Total	\$160,219,779	\$65,976	\$160,153,803	\$243,473,000	66%
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	\$147,161,473	\$137,778,305
	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
MD IV	\$193,472,710	\$202,374,871	\$293,619,866	\$278,137,221	\$160,153,803

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

CDRH Data 1st Quarter FY 2022 by Submission type	# Waived	# Reduced
Full Fee applications^{2/}		
PMA	0	0
PDP	0	0
PMR	0	0
BLA		
BLA efficacy supplement		
Panel Track Supplements	0	0
De Novo Classification	0	7
180-Day Supplements	0	6
Real-Time Supplements	0	9
510(k)s	11	261
30-day Notices	4	18
513(g)s	0	8
PMA Annual Report	0	0
Total	15	309

^{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.