

MDUFA IV (FY 2018-2022) Performance Report

May 10, 2023, 2:00 – 3:00 pm

Zoom

FDA MDUFA Performance — Actions through March 31, 2023

- Report on decision goals

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CDRH Performance Data ----
Actions through 31 March 2023**

Table of Contents

Acronyms and Abbreviations	6
Section 1: PMA Originals and Panel Track Supplements	7
PMA Originals and Panel Track Supplements – Center Level	17
PMA Originals and Panel Track Supplements – Office Level	
OHT1	23
OHT2	29
OHT3	35
OHT4	41
OHT5	47
OHT6	53
OHT7	59
OHT8	65
Section 2: PMA 180 Day Supplements	71
PMA 180 Day Supplements – Center Level	76
PMA 180 Day Supplements – Office Level	
OHT1	77
OHT2	78
OHT3	79
OHT4	80
OHT5	81
OHT6	82
OHT7	83
OHT8	84
Section 3: PMA Real Time Supplements	85
PMA Real Time Supplements – Center Level	90
PMA Real Time Supplements – Office Level	
OHT1	91
OHT2	92
OHT3	93
OHT4	94
OHT5	95
OHT6	96
OHT7	97
OHT8	98
Section 4: Pre-Market Report Submissions	99
Section 5: PMA Annual Metrics and Goals	100

Section 6: 510(k) MDUFA IV Performance ----- 101

510(k) MDUFA IV Performance – Center Level----- 111

510(k) MDUFA IV Performance – Office Level

OHT1----- 116

OHT2----- 121

OHT3----- 126

OHT4----- 131

OHT5----- 136

OHT6----- 141

OHT7----- 146

OHT8----- 151

Section 7: 510(k) Annual General Metrics ----- 154

Section 8: De Novo MDUFA IV Performance ----- 155

De Novo MDUFA IV Performance – Center Level----- 165

De Novo MDUFA IV Performance – Office Level

OHT1----- 168

OHT2----- 171

OHT3----- 174

OHT4----- 177

OHT5----- 180

OHT6----- 183

OHT7----- 186

OHT8----- 189

Section 9: Pre-Submissions----- 192

Pre-Submissions – Center Level----- 197

Pre-Submissions – Office Level

OHT1----- 199

OHT2----- 201

OHT3----- 203

OHT4----- 205

OHT5----- 207

OHT6----- 209

OHT7----- 211

OHT8----- 213

Section 10: Investigational Device Exemptions (IDEs)	215
IDEs – Center Level	225
IDEs – Office Level	
OHT1	226
OHT2	226
OHT3	226
OHT4	226
OHT5	227
OHT6	227
OHT7	227
OHT8	227
Section 11: CLIA Waiver Annual Metrics	228
Section 12: Dual (510(k) and CLIA Waiver) Annual Metrics	229
Appendix A: Variable Definitions	230

Acronyms and Abbreviations

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

Office Organizations

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

OHT2: Office of Cardiovascular Devices

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

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

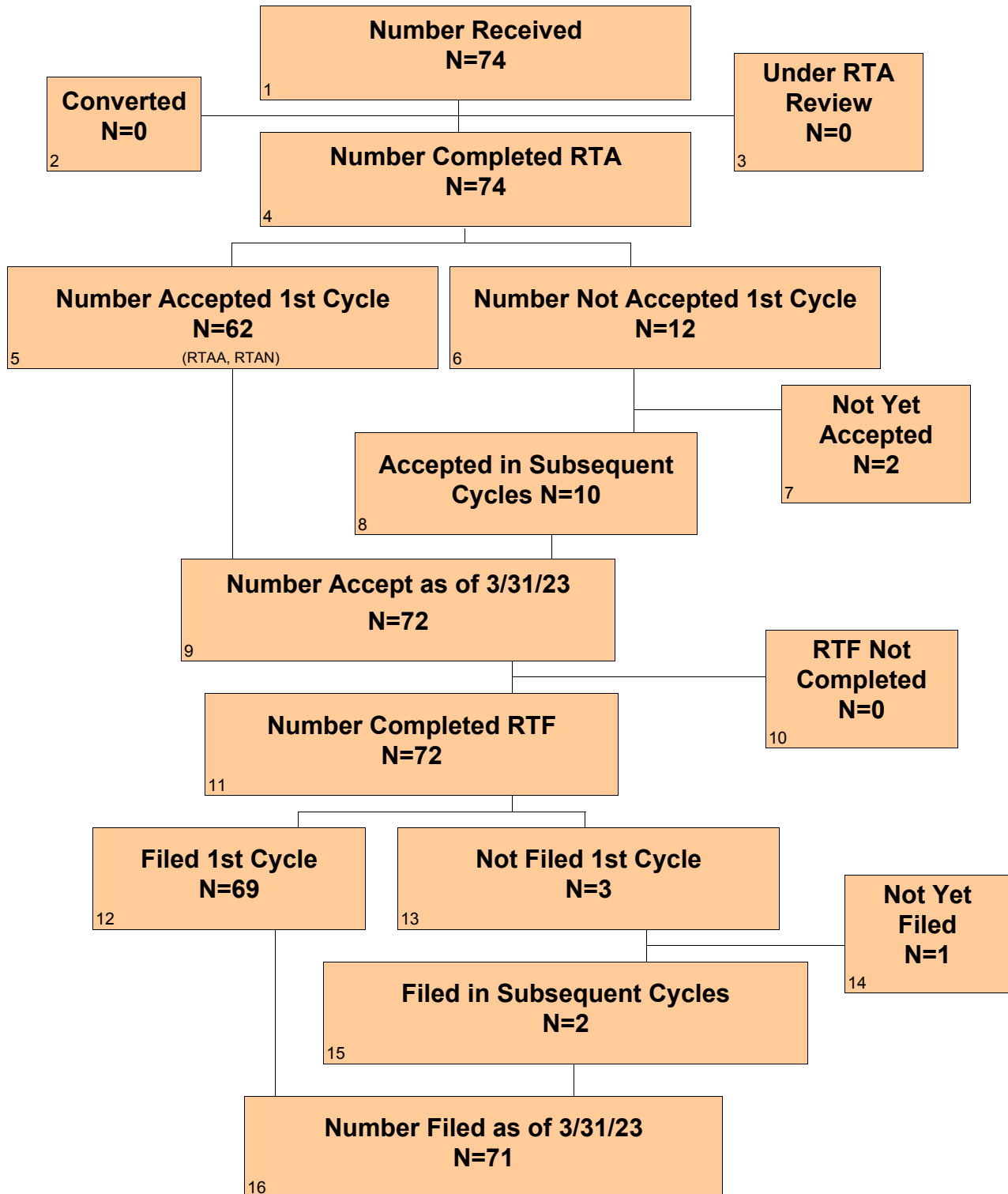
OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics

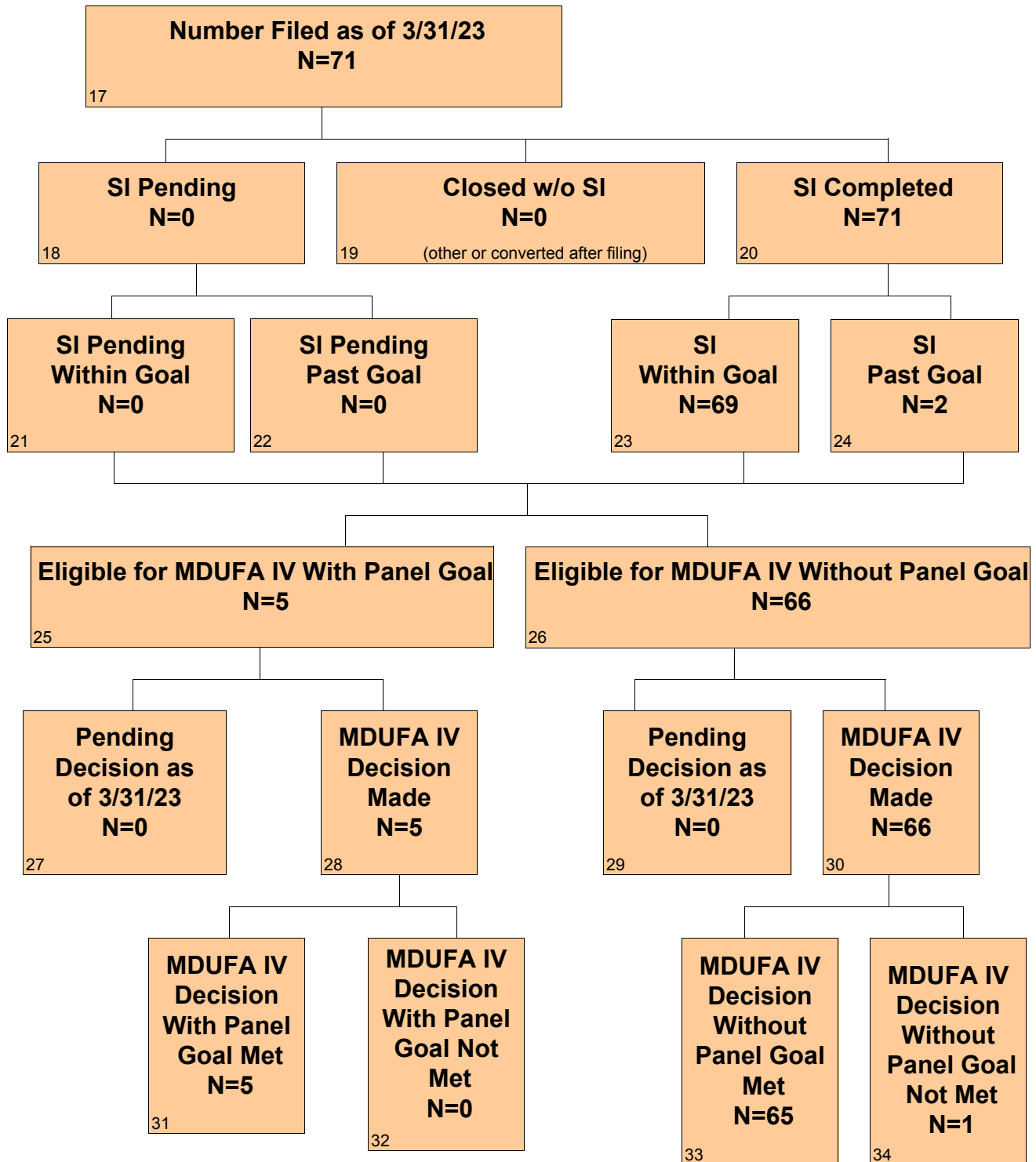
OHT8: Office of Radiological Health

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

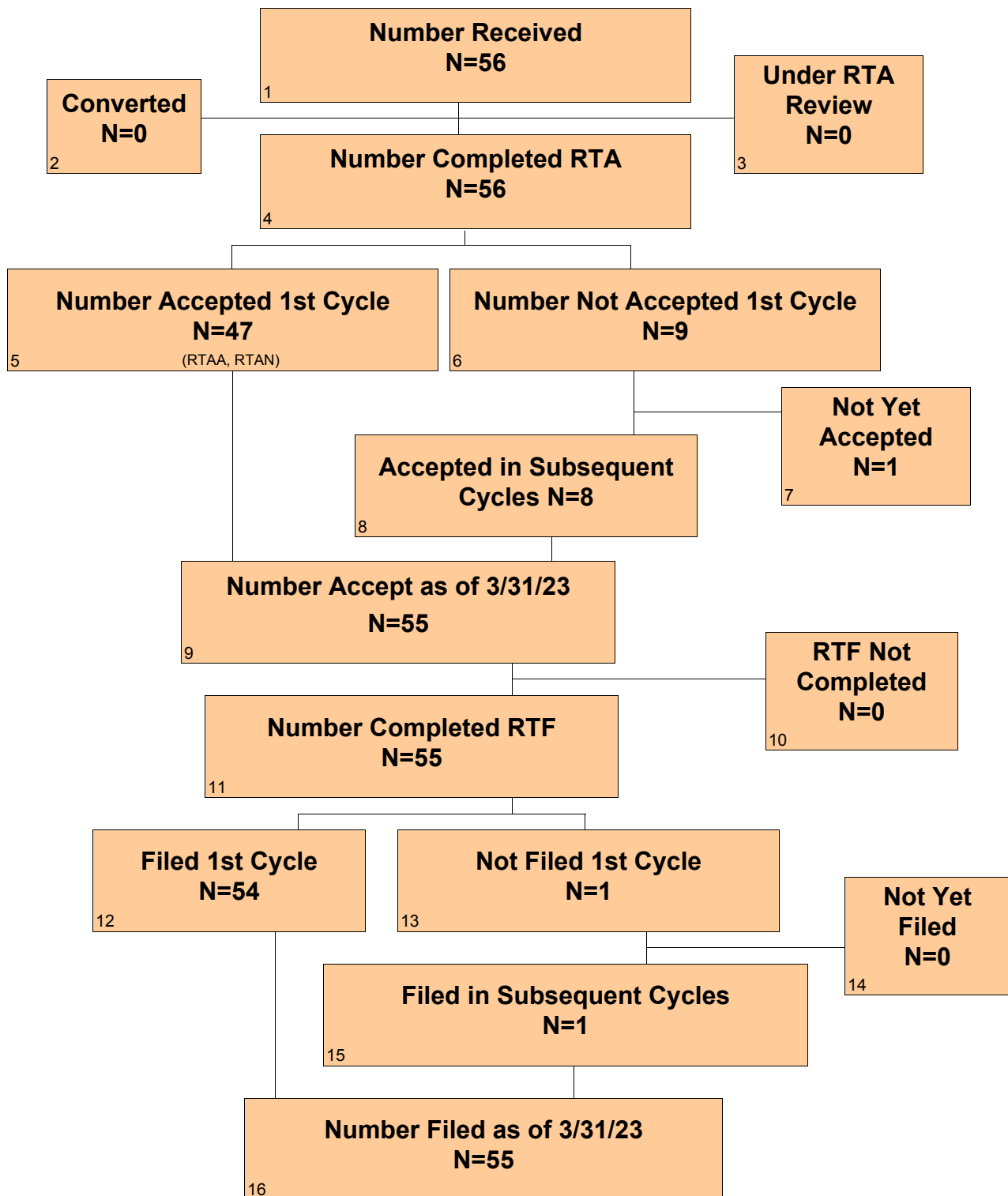
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/23



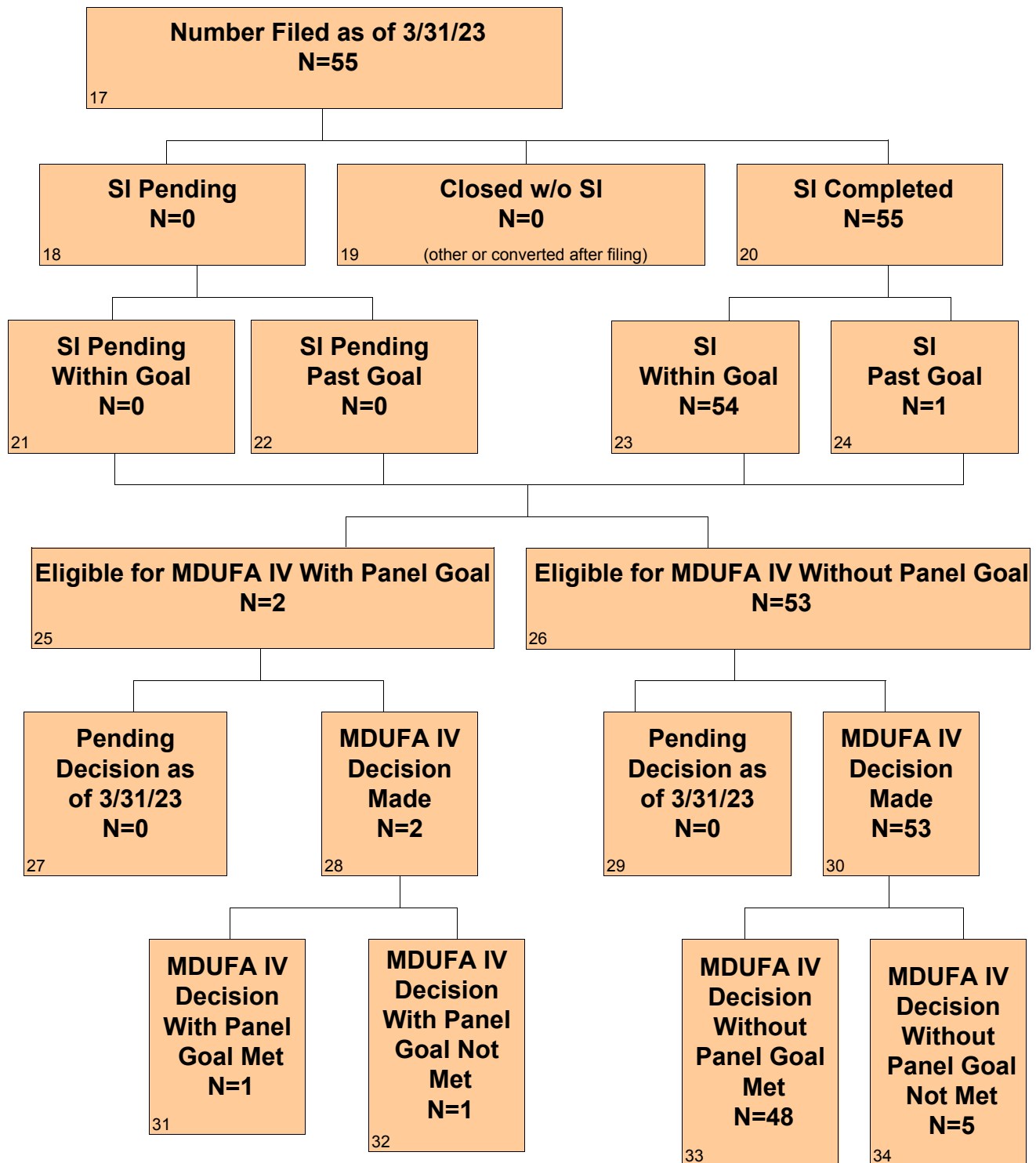
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 3/31/23 Continued



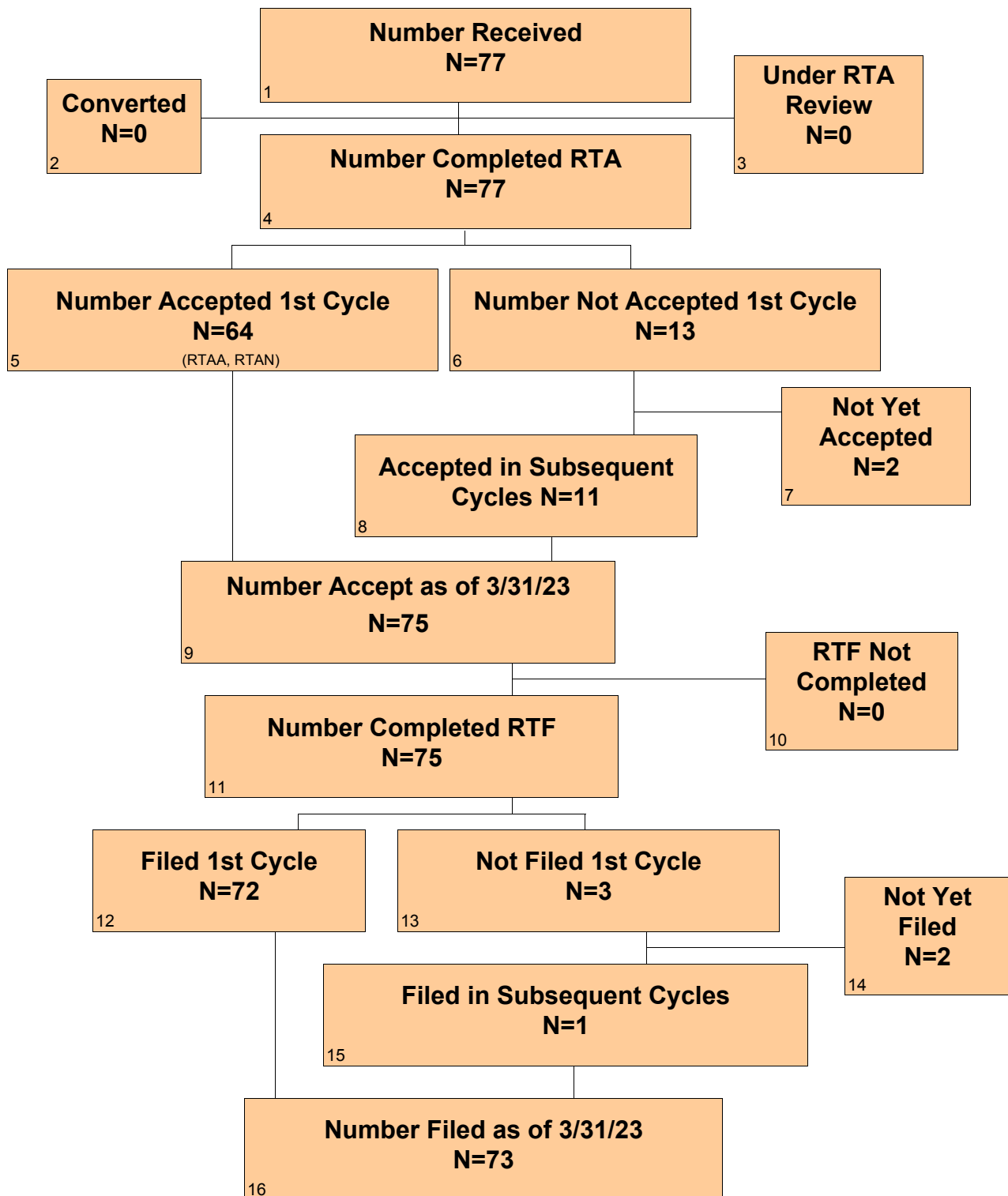
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/23



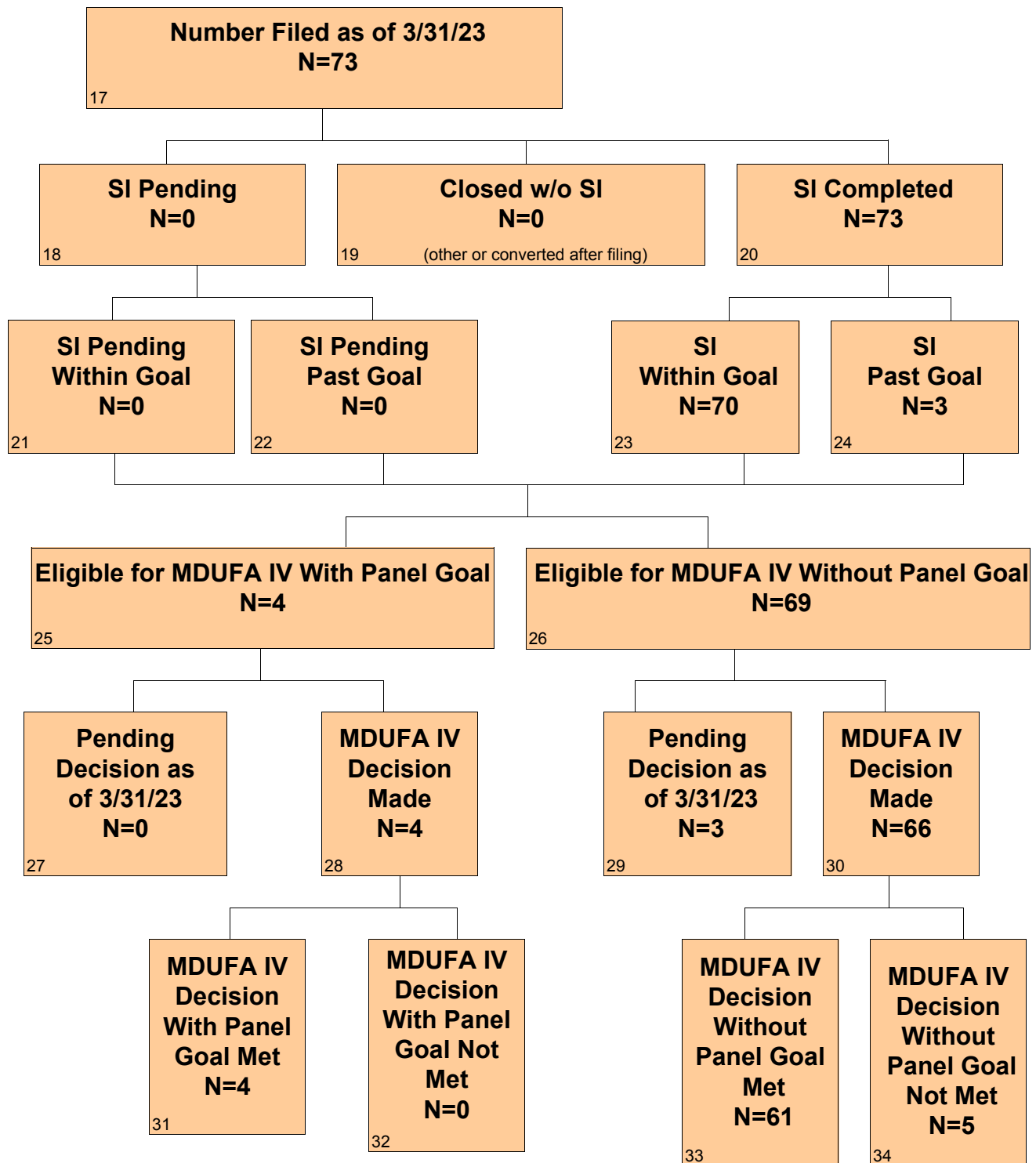
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 3/31/23 Continued



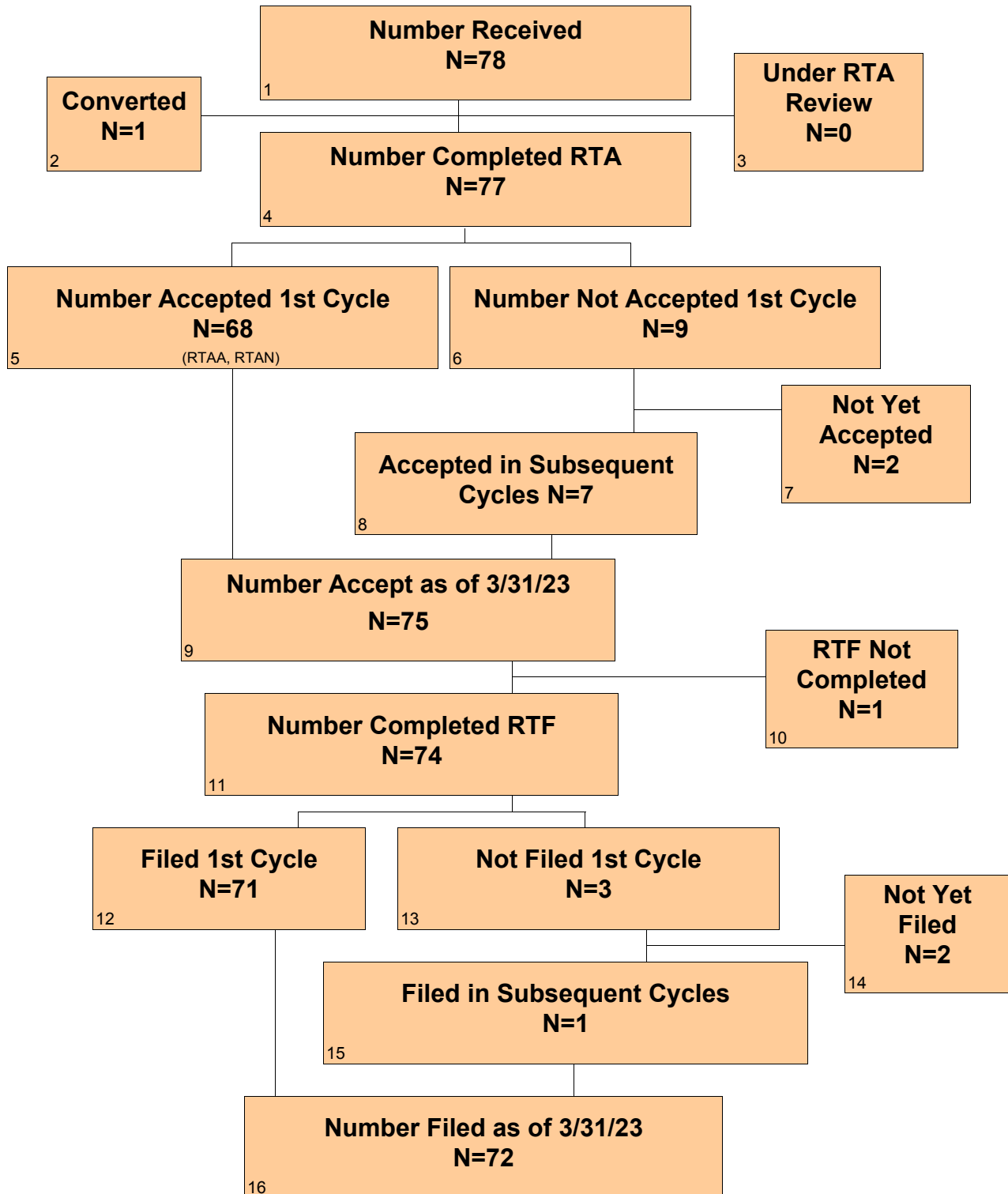
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 3/31/23



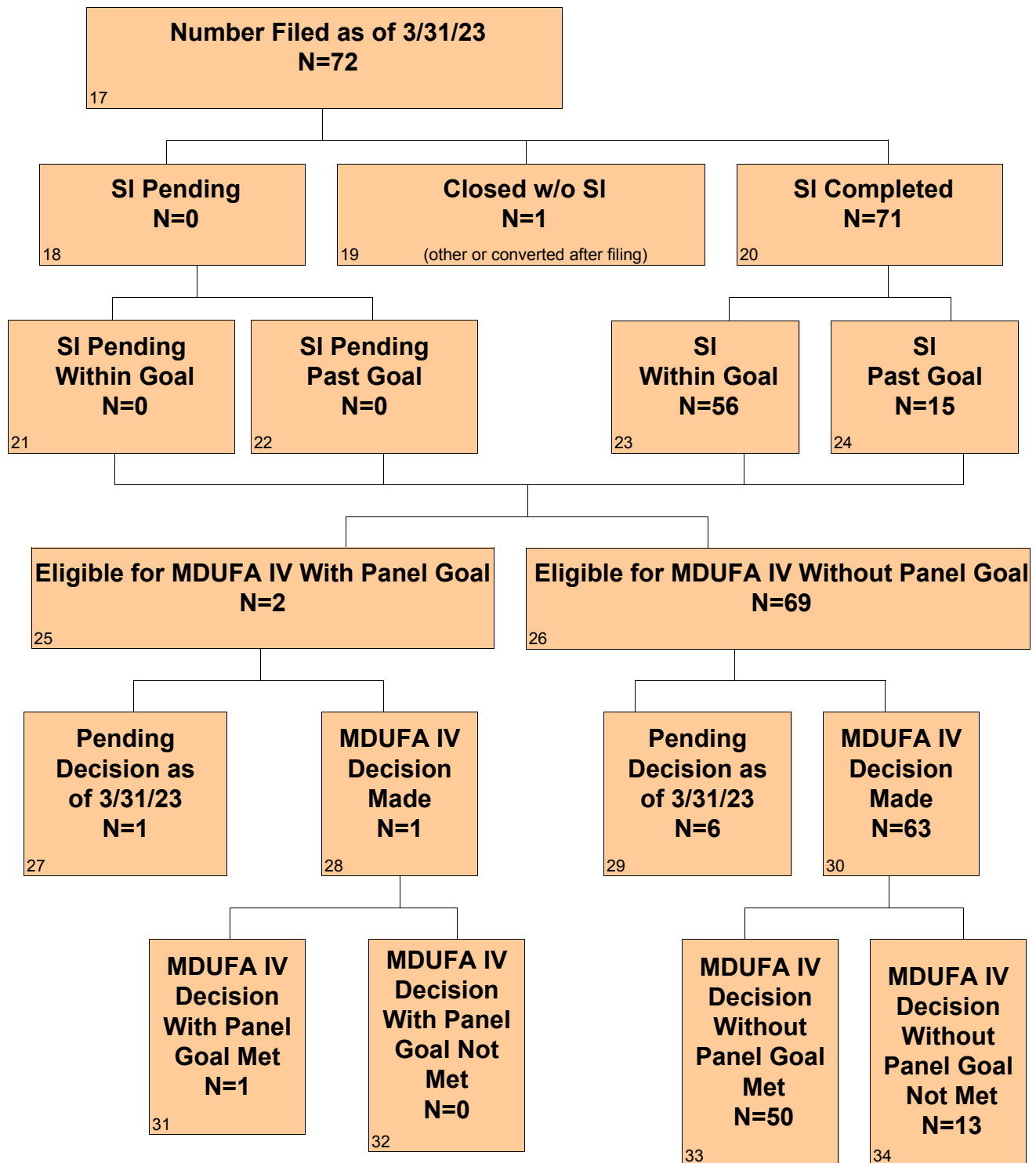
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 3/31/23 Continued



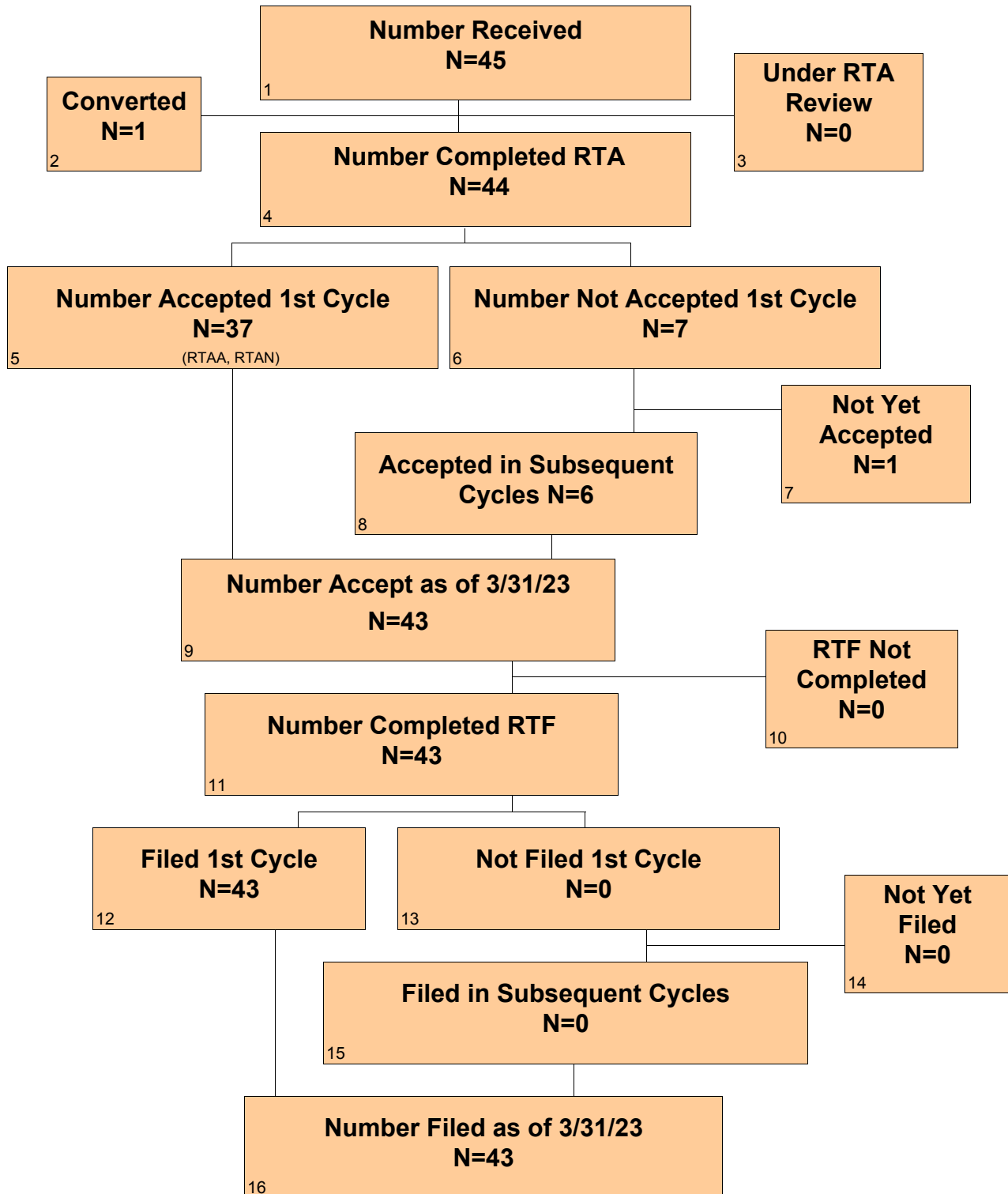
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 3/31/23



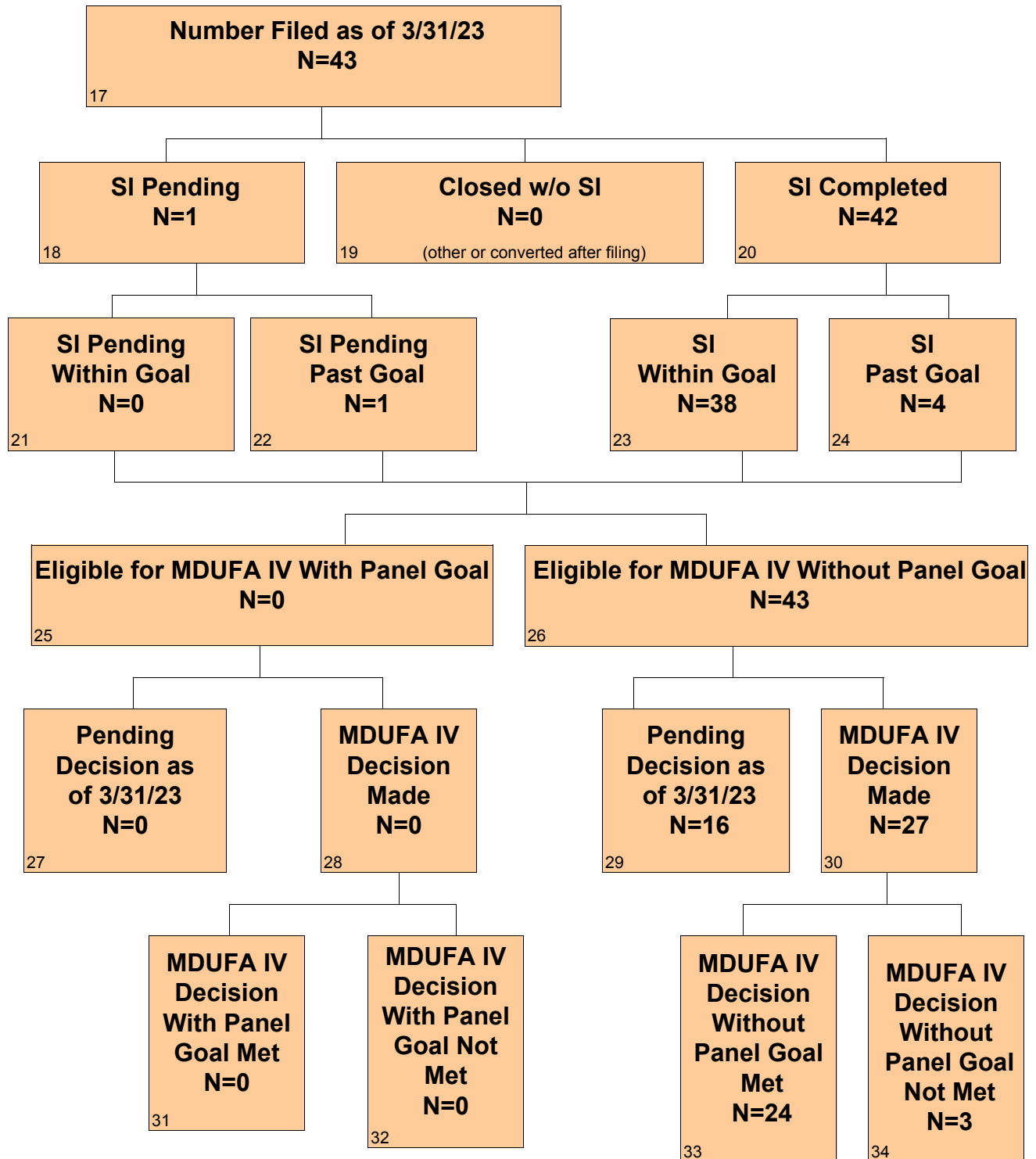
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 3/31/23 Continued



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 3/31/23



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 3/31/23 Continued



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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	74	56	77	78	45
Closed Before RTA Action	0	0	0	1	1
Number with Accepted RTA Review	62	46	63	59	37
Number Without a RTA Review and > 15 Days Since Date Received	0	1	1	9	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	12	9	13	9	7
Rate of Submissions Not Accepted for Filing Review	16.22%	16.07%	16.88%	11.69%	15.91%

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	45
Number Accepted	62	47	64	68	37
Completed RTF	72	55	75	74	43
Number Not Filed	3	1	3	3	0
Rate of Submissions Not Filed	4.17%	1.82%	4.00%	4.05%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	71	55	73	72	43
SI Goal Met	69	54	70	56	38
SI Goal Not Met	2	1	3	15	4
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	1
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	97.18%	98.18%	95.89%	78.87%	88.37%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	71	55	73	71	42
Average Number of FDA Days to Substantive Interaction	87.03	89.95	91.74	125.73	91.17
20th Percentile FDA Days to Substantive Interaction	84	87	88	87	87
40th Percentile FDA Days to Substantive Interaction	88	88	88	89	88
60th Percentile FDA Days to Substantive Interaction	90	89	90	90	90
80th Percentile FDA Days to Substantive Interaction	90	90	90	91	90
Maximum FDA Days to Substantive Interaction	178	246	325	598	176

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

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	66	53	69	70	43
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	66	53	66	63	27
MDUFA IV Decision Goal Met	65	48	61	50	24
PMAs Pending MDUFA IV Decision	0	0	3	6	16
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	5	1
Current Performance Percent Goal Met	98.48%	90.57%	92.42%	73.53%	85.71%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	66	53	66	63	27
Average FDA Days to MDUFA IV Decision	163.12	180.74	178.47	188.32	168.37
20th Percentile FDA Days to MDUFA IV Decision	146	147	175	165	171
40th Percentile FDA Days to MDUFA IV Decision	177	178	179	178	178
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	180	180
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	181	180
Maximum FDA Days to MDUFA IV Decision	279	338	501	648	197
Average Industry Days to MDUFA IV Decision	99.89	127.28	108.71	139.65	70.33
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	2
40th Percentile Industry Days to MDUFA IV Decision	26	31	36	35	36
60th Percentile Industry Days to MDUFA IV Decision	90	130	81	92	61
80th Percentile Industry Days to MDUFA IV Decision	163	192	207	303	129
Maximum Industry Days to MDUFA IV Decision	536	540	521	540	357
Average Total Days to MDUFA IV Decision	263.02	308.02	287.18	327.97	238.70
20th Percentile Total Days to MDUFA IV Decision	168	175	177	179	180
40th Percentile Total Days to MDUFA IV Decision	180	204	213	223	202
60th Percentile Total Days to MDUFA IV Decision	258	310	261	291	240
80th Percentile Total Days to MDUFA IV Decision	350	440	398	503	311
Maximum Total Days to MDUFA IV Decision	762	718	836	750	444

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	66	53	69	70	43
Number with MDUFA IV Decision	66	53	66	63	27
Number of Withdrawal	6	3	5	5	2
Number of Not Approvable	8	7	5	8	4
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	9.09%	5.66%	7.58%	7.94%	7.41%
Rate of Not Approvable	12.12%	13.21%	7.58%	12.70%	14.81%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	5	5	18	4
Mean FDA Days for Submissions that Missed the Goal	226.00	266.60	285.00	319.00	241.00
Mean Industry Days for Submissions that Missed the Goal	536.00	235.00	135.00	208.72	79.50

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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	1	4	11	5	6
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	11	4	4
MDUFA IV Decision Goal Met	1	4	11	3	3
PMAs Pending MDUFA IV Decision	0	0	0	1	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	1	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	60.00%	75.00%

*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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 90% Within 320 FDA Days
Number of PMAs Filed	15	17	15	20	9
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	15	7
MDUFA IV Decision Goal Met	15	13	12	8	6
PMAs Pending MDUFA IV Decision	0	0	1	4	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	4	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	42.11%	85.71%

*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	5
Closed Before RTA Action	0	0	0	0	1
Number with Accepted RTA Review	11	6	4	6	2
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	5	1	2	2	2
Rate of Submissions Not Accepted for Filing Review	31.25%	14.29%	33.33%	25.00%	50.00%

Table 1.2 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device

PMA Original and Panel-Track Supplements - Filing Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	7	6	8	5
Number Accepted	11	6	4	6	2
Completed RTF	16	7	6	7	4
Number Not Filed	1	1	0	0	0
Rate of Submissions Not Filed	6.25%	14.29%	0.00%	0.00%	0.00%

Table 1.3 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device

PMA Original and Panel-Track Supplements Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	16	7	6	7	4
SI Goal Met	16	7	6	6	4
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%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	16	7	6	7	4
Average Number of FDA Days to Substantive Interaction	87.13	88.86	88.00	98.71	89.50
20th Percentile FDA Days to Substantive Interaction	86	88	87	89	89
40th Percentile FDA Days to Substantive Interaction	87	89	88	90	89
60th Percentile FDA Days to Substantive Interaction	90	90	88	90	90
80th Percentile FDA Days to Substantive Interaction	90	90	88	90	90
Maximum FDA Days to Substantive Interaction	90	90	90	154	90

**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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	15	7	6	7	4
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	15	7	6	7	3
MDUFA IV Decision Goal Met	15	7	6	6	3
PMAs Pending MDUFA IV Decision	0	0	0	0	1
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	85.71%	100.00%

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

Performance Metric	FY 2018 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	7	3
Average FDA Days to MDUFA IV Decision	177.33	179.14	180.00	169.57	180.00
20th Percentile FDA Days to MDUFA IV Decision	176	179	180	178	180
40th Percentile FDA Days to MDUFA IV Decision	178	180	180	179	180
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	180	180
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	180
Maximum FDA Days to MDUFA IV Decision	180	180	180	201	180
Average Industry Days to MDUFA IV Decision	130.93	65.43	160.17	197.00	48.33
20th Percentile Industry Days to MDUFA IV Decision	0	4	68	56	40
40th Percentile Industry Days to MDUFA IV Decision	52	20	81	109	47
60th Percentile Industry Days to MDUFA IV Decision	141	50	108	256	52
80th Percentile Industry Days to MDUFA IV Decision	278	148	277	351	57
Maximum Industry Days to MDUFA IV Decision	360	180	400	387	62
Average Total Days to MDUFA IV Decision	308.27	244.57	340.17	366.57	228.33
20th Percentile Total Days to MDUFA IV Decision	178	184	248	235	220
40th Percentile Total Days to MDUFA IV Decision	232	200	261	288	227
60th Percentile Total Days to MDUFA IV Decision	321	230	288	394	232
80th Percentile Total Days to MDUFA IV Decision	450	328	457	499	237
Maximum Total Days to MDUFA IV Decision	528	359	580	588	242

**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	4
Number with MDUFA IV Decision	15	7	6	7	3
Number of Withdrawal	0	0	0	1	0
Number of Not Approvable	4	1	2	1	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	0.00%	14.29%	0.00%
Rate of Not Approvable	26.67%	14.29%	33.33%	14.29%	0.00%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	1	0
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	201.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	387.00	0.00

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

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

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

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	13
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	20	11	21	18	13
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	3	3	2	1	0
Rate of Submissions Not Accepted for Filing Review	13.04%	21.43%	8.70%	5.26%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	23	14	23	19	13
Number Accepted	20	11	21	18	13
Completed RTF	22	14	23	19	13
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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	22	14	23	19	13
SI Goal Met	22	14	23	19	13
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

Table 1.4 OHT2 - Office of Cardiovascular Devices**PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	22	14	23	19	13
Average Number of FDA Days to Substantive Interaction	83.36	85.21	88.26	88.74	88.15
20th Percentile FDA Days to Substantive Interaction	84	85	87	88	87
40th Percentile FDA Days to Substantive Interaction	87	88	88	89	88
60th Percentile FDA Days to Substantive Interaction	89	89	90	90	89
80th Percentile FDA Days to Substantive Interaction	90	90	90	90	90
Maximum FDA Days to Substantive Interaction	90	90	90	90	90

Table 1.5 OHT2 -Office of Cardiovascular Devices**PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	21	12	22	19	13
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	21	12	20	19	8
MDUFA IV Decision Goal Met	21	12	20	19	8
PMAs Pending MDUFA IV Decision	0	0	2	0	5
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

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

Table 1.7 OHT2 - Office of Cardiovascular Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	21	12	20	19	8
Average FDA Days to MDUFA IV Decision	174.00	178.92	178.15	175.74	177.63
20th Percentile FDA Days to MDUFA IV Decision	161	159	176	177	175
40th Percentile FDA Days to MDUFA IV Decision	178	178	179	178	180
60th Percentile FDA Days to MDUFA IV Decision	179	180	180	179	180
80th Percentile FDA Days to MDUFA IV Decision	180	180	180	180	180
Maximum FDA Days to MDUFA IV Decision	279	295	180	180	180
Average Industry Days to MDUFA IV Decision	51.48	107.00	100.70	99.47	43.00
20th Percentile Industry Days to MDUFA IV Decision	0	10	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	67	18	47	8
60th Percentile Industry Days to MDUFA IV Decision	45	122	62	72	29
80th Percentile Industry Days to MDUFA IV Decision	91	171	160	146	96
Maximum Industry Days to MDUFA IV Decision	162	322	453	393	133
Average Total Days to MDUFA IV Decision	225.48	285.92	278.85	275.21	220.63
20th Percentile Total Days to MDUFA IV Decision	168	170	177	179	176
40th Percentile Total Days to MDUFA IV Decision	180	245	197	225	188
60th Percentile Total Days to MDUFA IV Decision	229	302	240	251	209
80th Percentile Total Days to MDUFA IV Decision	324	363	339	324	276
Maximum Total Days to MDUFA IV Decision	340	501	633	573	311

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	13
Number with MDUFA IV Decision	21	12	20	19	8
Number of Withdrawal	0	0	1	0	1
Number of Not Approvable	1	1	1	2	1
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	5.00%	0.00%	12.50%
Rate of Not Approvable	4.76%	8.33%	5.00%	10.53%	12.50%

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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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	5	4	0
MDUFA IV Decision Goal Met	5	3	4	4	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%	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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	5	4	0
Average FDA Days to MDUFA IV Decision	178.00	228.33	225.60	179.75	0.00
20th Percentile FDA Days to MDUFA IV Decision	159	172	161	180	0
40th Percentile FDA Days to MDUFA IV Decision	177	177	180	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	244	180	0
Maximum FDA Days to MDUFA IV Decision	266	338	501	180	0
Average Industry Days to MDUFA IV Decision	102.20	121.00	340.60	335.25	0.00
20th Percentile Industry Days to MDUFA IV Decision	77	2	299	156	0
40th Percentile Industry Days to MDUFA IV Decision	97	5	333	301	0
60th Percentile Industry Days to MDUFA IV Decision	108	76	337	477	0
80th Percentile Industry Days to MDUFA IV Decision	122	217	376	536	0
Maximum Industry Days to MDUFA IV Decision	163	357	521	537	0
Average Total Days to MDUFA IV Decision	280.20	349.33	566.20	515.00	0.00
20th Percentile Total Days to MDUFA IV Decision	248	247	479	336	0
40th Percentile Total Days to MDUFA IV Decision	270	308	515	481	0
60th Percentile Total Days to MDUFA IV Decision	285	375	555	656	0
80th Percentile Total Days to MDUFA IV Decision	302	450	654	716	0
Maximum Total Days to MDUFA IV Decision	350	524	836	717	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	5	4	0
Number of Withdrawal	1	0	1	0	0
Number of Not Approvable	0	1	1	2	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	20.00%	0.00%	20.00%	0.00%	N/A
Rate of Not Approvable	0.00%	33.33%	20.00%	50.00%	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	501.00	0.00	0.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	335.00	0.00	0.00

**Table 1.12 OHT3 - Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric -
Submissions Missing Performance Goal**

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

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

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	3
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	1	1	3	3	2
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	2	1	2	3	1
Rate of Submissions Not Accepted for Filing Review	66.67%	50.00%	40.00%	50.00%	33.33%

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	3
Number Accepted	1	1	3	3	2
Completed RTF	2	2	4	6	3
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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	2	2	4	5	3
SI Goal Met	1	2	4	4	1
SI Goal Not Met	1	0	0	1	2
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	50.00%	100.00%	100.00%	80.00%	33.33%

Table 1.4 OHT4 - Office of Surgical and Infection Control Devices
PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	2	4	5	3
Average Number of FDA Days to Substantive Interaction	93.50	90.00	89.25	108.20	103.67
20th Percentile FDA Days to Substantive Interaction	90	90	89	86	91
40th Percentile FDA Days to Substantive Interaction	92	90	89	88	92
60th Percentile FDA Days to Substantive Interaction	95	90	90	90	99
80th Percentile FDA Days to Substantive Interaction	97	90	90	110	114
Maximum FDA Days to Substantive Interaction	99	90	90	189	129

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

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

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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	2	2	3	4	1
Average FDA Days to MDUFA IV Decision	192.50	181.00	198.67	214.50	176.00
20th Percentile FDA Days to MDUFA IV Decision	172	179	189	200	176
40th Percentile FDA Days to MDUFA IV Decision	186	180	198	215	176
60th Percentile FDA Days to MDUFA IV Decision	199	182	204	223	176
80th Percentile FDA Days to MDUFA IV Decision	213	183	209	230	176
Maximum FDA Days to MDUFA IV Decision	226	184	214	237	176
Average Industry Days to MDUFA IV Decision	271.00	90.00	41.67	142.00	62.00
20th Percentile Industry Days to MDUFA IV Decision	112	49	27	83	62
40th Percentile Industry Days to MDUFA IV Decision	218	76	31	126	62
60th Percentile Industry Days to MDUFA IV Decision	324	104	40	139	62
80th Percentile Industry Days to MDUFA IV Decision	430	131	55	197	62
Maximum Industry Days to MDUFA IV Decision	536	159	69	277	62
Average Total Days to MDUFA IV Decision	463.50	271.00	240.33	356.50	238.00
20th Percentile Total Days to MDUFA IV Decision	284	231	218	297	238
40th Percentile Total Days to MDUFA IV Decision	404	258	223	328	238
60th Percentile Total Days to MDUFA IV Decision	523	284	237	332	238
80th Percentile Total Days to MDUFA IV Decision	643	311	260	405	238
Maximum Total Days to MDUFA IV Decision	762	337	283	514	238

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	3
Number with MDUFA IV Decision	2	2	3	4	1
Number of Withdrawal	0	0	0	0	0
Number of Not Approvable	1	0	0	0	1
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	0.00%	0.00%	0.00%
Rate of Not Approvable	50.00%	0.00%	0.00%	0.00%	100.00%

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	1	1	2	4	1
Mean FDA Days for Submissions that Missed the Goal	226.00	184.00	208.00	214.50	389.00
Mean Industry Days for Submissions that Missed the Goal	536.00	21.00	46.00	142.00	133.00

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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	5
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	3	4	1	8	4
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	1
Rate of Submissions Not Accepted for Filing Review	25.00%	0.00%	75.00%	11.11%	20.00%

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	5
Number Accepted	3	5	1	8	4
Completed RTF	4	5	3	8	5
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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	4	5	3	8	5
SI Goal Met	3	5	3	8	4
SI Goal Not Met	1	0	0	0	1
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	75.00%	100.00%	100.00%	100.00%	80.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	4	5	3	8	5
Average Number of FDA Days to Substantive Interaction	90.50	84.80	90.00	87.50	90.20
20th Percentile FDA Days to Substantive Interaction	90	84	90	85	89
40th Percentile FDA Days to Substantive Interaction	90	90	90	87	90
60th Percentile FDA Days to Substantive Interaction	90	90	90	89	90
80th Percentile FDA Days to Substantive Interaction	91	90	90	90	91
Maximum FDA Days to Substantive Interaction	92	90	90	90	94

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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	4	5	2	8	5
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	4	5	2	8	2
MDUFA IV Decision Goal Met	4	5	2	8	1
PMAs Pending MDUFA IV Decision	0	0	0	0	3
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	50.00%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	4	5	2	8	2
Average FDA Days to MDUFA IV Decision	180.00	188.00	132.50	175.63	182.00
20th Percentile FDA Days to MDUFA IV Decision	180	162	107	171	180
40th Percentile FDA Days to MDUFA IV Decision	180	180	124	178	181
60th Percentile FDA Days to MDUFA IV Decision	180	180	141	179	183
80th Percentile FDA Days to MDUFA IV Decision	180	206	158	180	184
Maximum FDA Days to MDUFA IV Decision	180	310	175	180	185
Average Industry Days to MDUFA IV Decision	186.75	172.00	32.00	141.50	74.00
20th Percentile Industry Days to MDUFA IV Decision	56	96	13	0	34
40th Percentile Industry Days to MDUFA IV Decision	134	151	26	0	61
60th Percentile Industry Days to MDUFA IV Decision	253	184	38	24	87
80th Percentile Industry Days to MDUFA IV Decision	320	224	51	336	114
Maximum Industry Days to MDUFA IV Decision	360	343	64	539	140
Average Total Days to MDUFA IV Decision	366.75	360.00	164.50	317.13	256.00
20th Percentile Total Days to MDUFA IV Decision	236	256	158	178	218
40th Percentile Total Days to MDUFA IV Decision	314	282	162	180	243
60th Percentile Total Days to MDUFA IV Decision	433	325	167	200	269
80th Percentile Total Days to MDUFA IV Decision	500	430	171	510	294
Maximum Total Days to MDUFA IV Decision	540	653	175	719	319

Table 1.8 OHT5 - Office of Neurological and Physical Medicine Devices
PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Time to
MDUFA IV Decision

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	4	5	2	8	5
Number with MDUFA IV Decision	4	5	2	8	2
Number of Withdrawal	0	1	1	0	0
Number of Not Approvable	0	2	0	2	1
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	20.00%	50.00%	0.00%	0.00%
Rate of Not Approvable	0.00%	40.00%	0.00%	25.00%	50.00%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	1
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	185.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	8.00

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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	3
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	2	2	2	3	2
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	0	2	0	1	1
Rate of Submissions Not Accepted for Filing Review	0.00%	50.00%	0.00%	25.00%	33.33%

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	3
Number Accepted	2	2	2	3	2
Completed RTF	2	3	2	4	2
Number Not Filed	0	0	0	0	0
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	0.00%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	3	2	4	2
Average Number of FDA Days to Substantive Interaction	86.50	88.67	88.50	85.50	87.00
20th Percentile FDA Days to Substantive Interaction	84	88	88	81	86
40th Percentile FDA Days to Substantive Interaction	86	89	88	84	87
60th Percentile FDA Days to Substantive Interaction	87	89	89	88	87
80th Percentile FDA Days to Substantive Interaction	89	90	89	90	88
Maximum FDA Days to Substantive Interaction	90	90	89	90	89

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

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

Table 1.6 OHT6 - Office of Orthopedic Devices**PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision****Performance Goal**

Performance Metric	FY 2018 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	3	2
Average FDA Days to MDUFA IV Decision	180.00	146.33	178.50	142.00	176.50
20th Percentile FDA Days to MDUFA IV Decision	180	121	178	116	174
40th Percentile FDA Days to MDUFA IV Decision	180	156	178	143	176
60th Percentile FDA Days to MDUFA IV Decision	180	174	179	161	177
80th Percentile FDA Days to MDUFA IV Decision	180	177	179	170	179
Maximum FDA Days to MDUFA IV Decision	180	179	180	180	180
Average Industry Days to MDUFA IV Decision	141.50	203.67	103.50	180.00	118.00
20th Percentile Industry Days to MDUFA IV Decision	57	67	41	0	60
40th Percentile Industry Days to MDUFA IV Decision	113	122	83	0	99
60th Percentile Industry Days to MDUFA IV Decision	170	209	124	108	137
80th Percentile Industry Days to MDUFA IV Decision	226	330	166	324	176
Maximum Industry Days to MDUFA IV Decision	283	450	207	540	214
Average Total Days to MDUFA IV Decision	321.50	350.00	282.00	322.00	294.50
20th Percentile Total Days to MDUFA IV Decision	237	191	219	166	239
40th Percentile Total Days to MDUFA IV Decision	293	282	261	175	276
60th Percentile Total Days to MDUFA IV Decision	350	387	303	270	313
80th Percentile Total Days to MDUFA IV Decision	406	505	345	450	350
Maximum Total Days to MDUFA IV Decision	463	623	387	630	387

Table 1.8 OHT6 - Office of Orthopedic Devices

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

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

Table 1.9 OHT6 - Office of Orthopedic Devices**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	2	4	2
Number with MDUFA IV Decision	2	3	2	3	2
Number of Withdrawal	0	1	0	1	0
Number of Not Approvable	0	1	0	0	1
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	33.33%	0.00%	33.33%	0.00%
Rate of Not Approvable	0.00%	33.33%	0.00%	0.00%	50.00%

Table 1.10 OHT6 - Office of Orthopedic Devices**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Rates of Withdrawal, Not Approvable and Deleted**

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

Table 1.11 OHT6 - Office of Orthopedic Devices**PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Submissions Missing Performance Goal**

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

Table 1.12 OHT6 - Office of Orthopedic Devices**PMA Original and Panel-Track Supplements (with Panel Review) Performance Metric - Submissions Missing Performance Goal**

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

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

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Goal Met	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
PMAs Pending MDUFA IV Decision Past Goal	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Goal Met	N/A	N/A	N/A	N/A	N/A

*Includes submission that went to panel

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	21	27	28	15
Closed Before RTA Action	0	0	0	1	0
Number with Accepted RTA Review	16	19	23	17	13
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	2
Rate of Submissions Not Accepted for Filing Review	0.00%	9.52%	14.81%	3.70%	13.33%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	21	27	28	15
Number Accepted	16	19	23	26	13
Completed RTF	16	21	27	26	15
Number Not Filed	0	0	2	2	0
Rate of Submissions Not Filed	0.00%	0.00%	7.41%	7.69%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	16	21	26	25	15
SI Goal Met	16	20	23	11	13
SI Goal Not Met	0	1	3	13	1
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	1
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	100.00%	95.24%	88.46%	45.83%	86.67%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	16	21	26	24	14
Average Number of FDA Days to Substantive Interaction	85.63	87.76	97.35	192.25	92.79
20th Percentile FDA Days to Substantive Interaction	84	87	86	88	87
40th Percentile FDA Days to Substantive Interaction	88	88	88	90	87
60th Percentile FDA Days to Substantive Interaction	90	89	90	178	89
80th Percentile FDA Days to Substantive Interaction	90	90	90	283	90
Maximum FDA Days to Substantive Interaction	90	91	325	598	176

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

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	16	21	26	24	15
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	16	21	25	18	11
MDUFA IV Decision Goal Met	16	17	23	10	9
PMAs Pending MDUFA IV Decision	0	0	1	5	4
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	5	0
Current Performance Percent Goal Met	100.00%	80.95%	92.00%	43.48%	81.82%

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

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

Table 1.7 OHT7 - Office of In Vitro Diagnostics

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	16	21	25	18	11
Average FDA Days to MDUFA IV Decision	127.13	178.67	170.04	218.33	153.82
20th Percentile FDA Days to MDUFA IV Decision	90	134	129	105	120
40th Percentile FDA Days to MDUFA IV Decision	112	173	179	146	143
60th Percentile FDA Days to MDUFA IV Decision	146	177	180	188	180
80th Percentile FDA Days to MDUFA IV Decision	175	180	180	288	180
Maximum FDA Days to MDUFA IV Decision	180	299	406	648	197
Average Industry Days to MDUFA IV Decision	91.56	142.38	65.20	108.22	87.64
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	16	22	26	48
60th Percentile Industry Days to MDUFA IV Decision	75	81	58	104	60
80th Percentile Industry Days to MDUFA IV Decision	158	325	127	177	131
Maximum Industry Days to MDUFA IV Decision	336	540	257	452	357
Average Total Days to MDUFA IV Decision	218.69	321.05	235.24	326.56	241.45
20th Percentile Total Days to MDUFA IV Decision	90	155	156	151	156
40th Percentile Total Days to MDUFA IV Decision	146	179	182	215	203
60th Percentile Total Days to MDUFA IV Decision	225	257	242	316	253
80th Percentile Total Days to MDUFA IV Decision	270	619	307	471	314
Maximum Total Days to MDUFA IV Decision	511	718	573	750	444

Table 1.8 OHT7 - Office of In Vitro Diagnostics

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	16	21	26	24	15
Number with MDUFA IV Decision	16	21	25	18	11
Number of Withdrawal	4	1	2	3	1
Number of Not Approvable	2	1	1	1	0
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	25.00%	4.76%	8.00%	16.67%	9.09%
Rate of Not Approvable	12.50%	4.76%	4.00%	5.56%	0.00%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	2	13	2
Mean FDA Days for Submissions that Missed the Goal	0.00	287.25	254.00	360.23	195.00
Mean Industry Days for Submissions that Missed the Goal	0.00	288.50	124.00	215.51	88.50

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

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

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

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	1	4	11	5	6
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	11	4	4
MDUFA IV Decision Goal Met	1	4	11	3	3
PMAs Pending MDUFA IV Decision	0	0	0	1	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	1	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	60.00%	75.00%

*Includes submission that went to panel

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

Performance Metric	FY 2018 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 90% Within 320 FDA Days
Number of PMAs Filed	15	17	15	20	9
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	15	7
MDUFA IV Decision Goal Met	15	13	12	8	6
PMAs Pending MDUFA IV Decision	0	0	1	4	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	4	0
Current Performance Percent Goal Met	100.00%	76.47%	85.71%	42.11%	85.71%

*Includes submission that went to panel

Table 1.1 OHT8 - Office of Radiological Health

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

Table 1.2 OHT8 - Office of Radiological Health

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

Table 1.3 OHT8 - Office of Radiological Health

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

Table 1.4 OHT8 - Office of Radiological Health**PMA Original and Panel-Track Supplements Substantive Interaction Metric - Time to Substantive Interaction**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	1	0	3	0	1
Average Number of FDA Days to Substantive Interaction	63.00	0.00	89.67	0.00	90.00
20th Percentile FDA Days to Substantive Interaction	63	0	89	0	90
40th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
60th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
80th Percentile FDA Days to Substantive Interaction	63	0	90	0	90
Maximum FDA Days to Substantive Interaction	63	0	90	0	90

Table 1.5 OHT8 - Office of Radiological Health**PMA Original and Panel-Track Supplements (Without Panel Review) MDUFA IV Decision Performance Goal**

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

Table 1.6 OHT8 - Office of Radiological Health**PMA Original and Panel-Track Supplements (with Panel Review) MDUFA IV Decision Performance Goal**

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

Table 1.7 OHT8 - Office of Radiological Health
PMA Original and Panel-Track Supplements (Without Panel Review) Performance Metric - Time
to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV Decision	1	0	3	0	0
Average FDA Days to MDUFA IV Decision	63.00	0.00	179.67	0.00	0.00
20th Percentile FDA Days to MDUFA IV Decision	63	0	179	0	0
40th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
60th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
80th Percentile FDA Days to MDUFA IV Decision	63	0	180	0	0
Maximum FDA Days to MDUFA IV Decision	63	0	180	0	0
Average Industry Days to MDUFA IV Decision	0.00	0.00	157.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	0	118	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	150	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	0	177	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	0	198	0	0
Maximum Industry Days to MDUFA IV Decision	0	0	219	0	0
Average Total Days to MDUFA IV Decision	63.00	0.00	336.67	0.00	0.00
20th Percentile Total Days to MDUFA IV Decision	63	0	298	0	0
40th Percentile Total Days to MDUFA IV Decision	63	0	330	0	0
60th Percentile Total Days to MDUFA IV Decision	63	0	356	0	0
80th Percentile Total Days to MDUFA IV Decision	63	0	377	0	0
Maximum Total Days to MDUFA IV Decision	63	0	398	0	0

Table 1.8 OHT8 - Office of Radiological Health

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

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

Table 1.9 OHT8 - Office of Radiological Health

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

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

Table 1.10 OHT8 - Office of Radiological Health

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

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

Table 1.11 OHT8 - Office of Radiological Health

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

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

Table 1.12 OHT8 - Office of Radiological Health

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

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

**Table 1.13 OHT8 - Office of Radiological Health
LDT PMA Original and Panel-Track Supplements Metric***

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

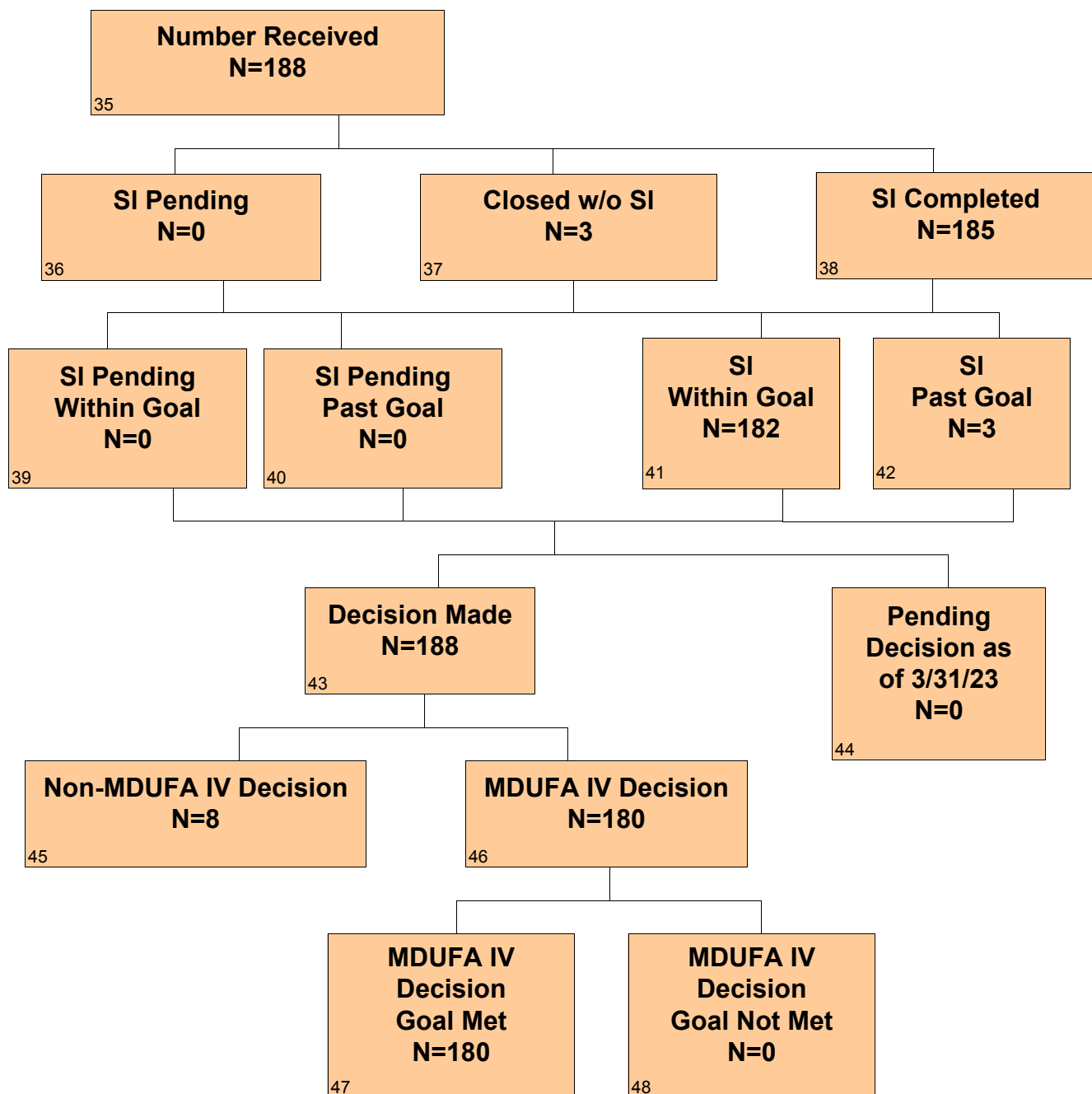
*Includes submission that went to panel

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

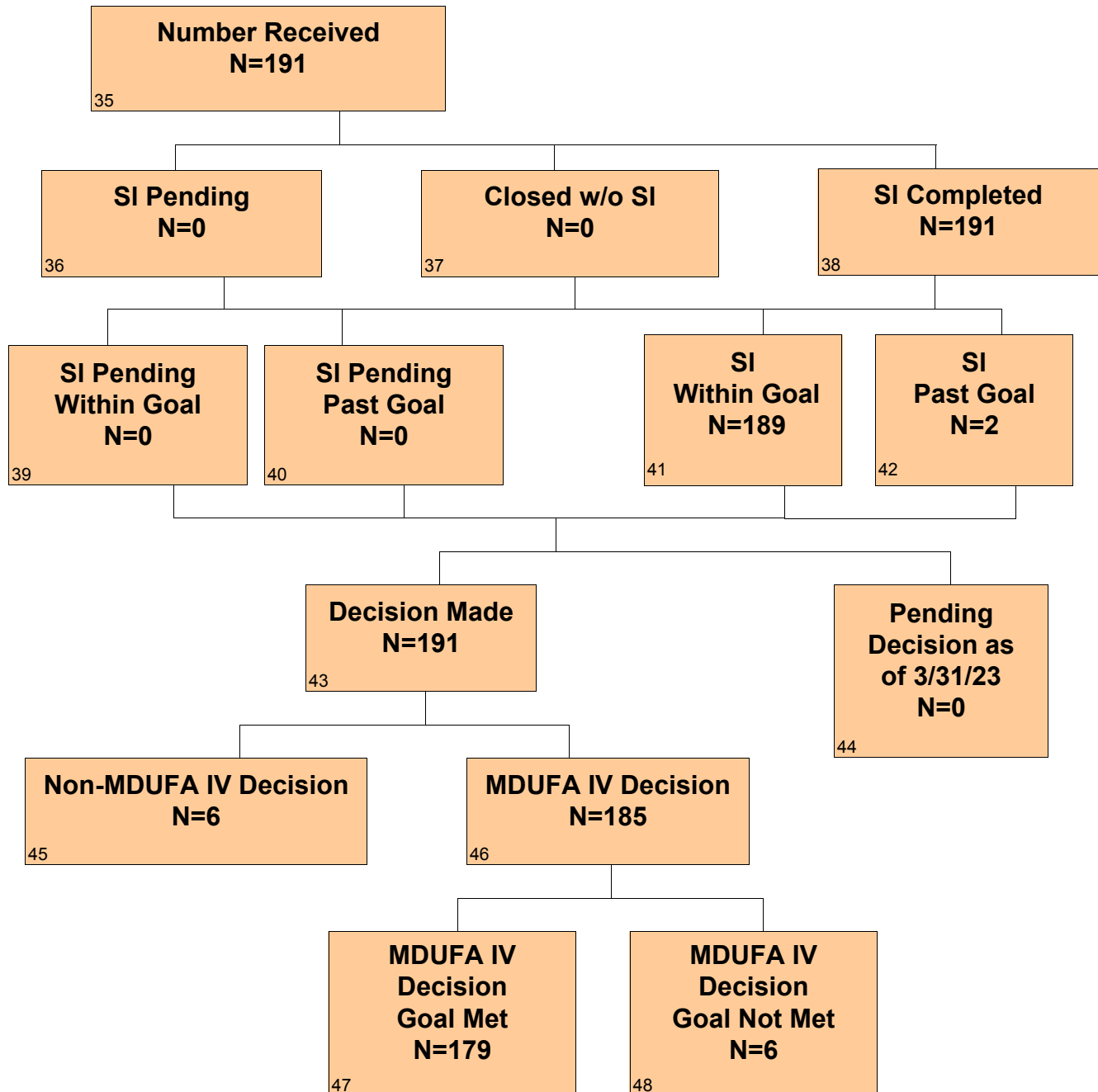
Performance Metric	FY 2018 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA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

*Includes submission that went to panel

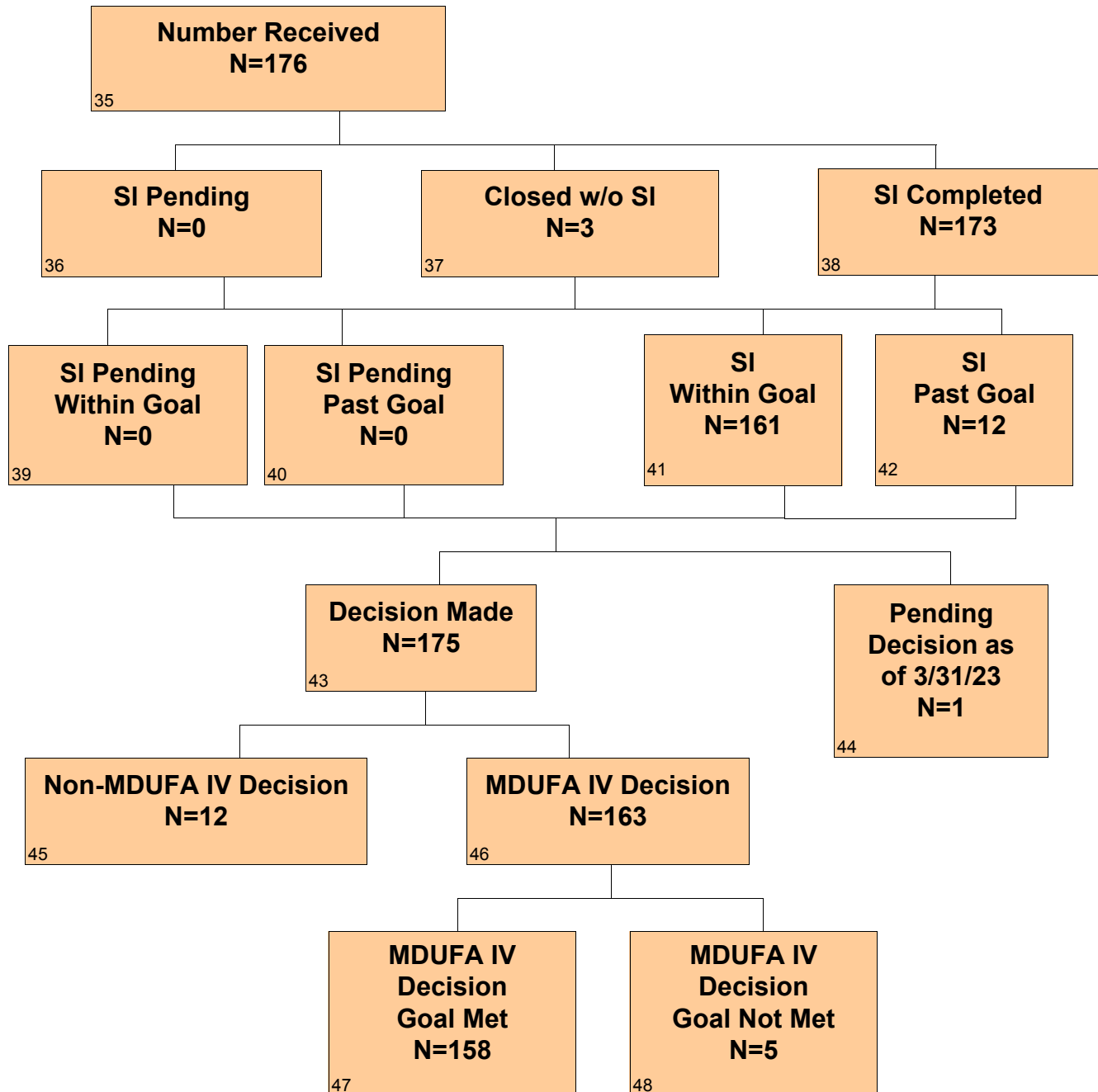
CDRH PMA 180 Day Supplements - FY 2018 as of 3/31/23



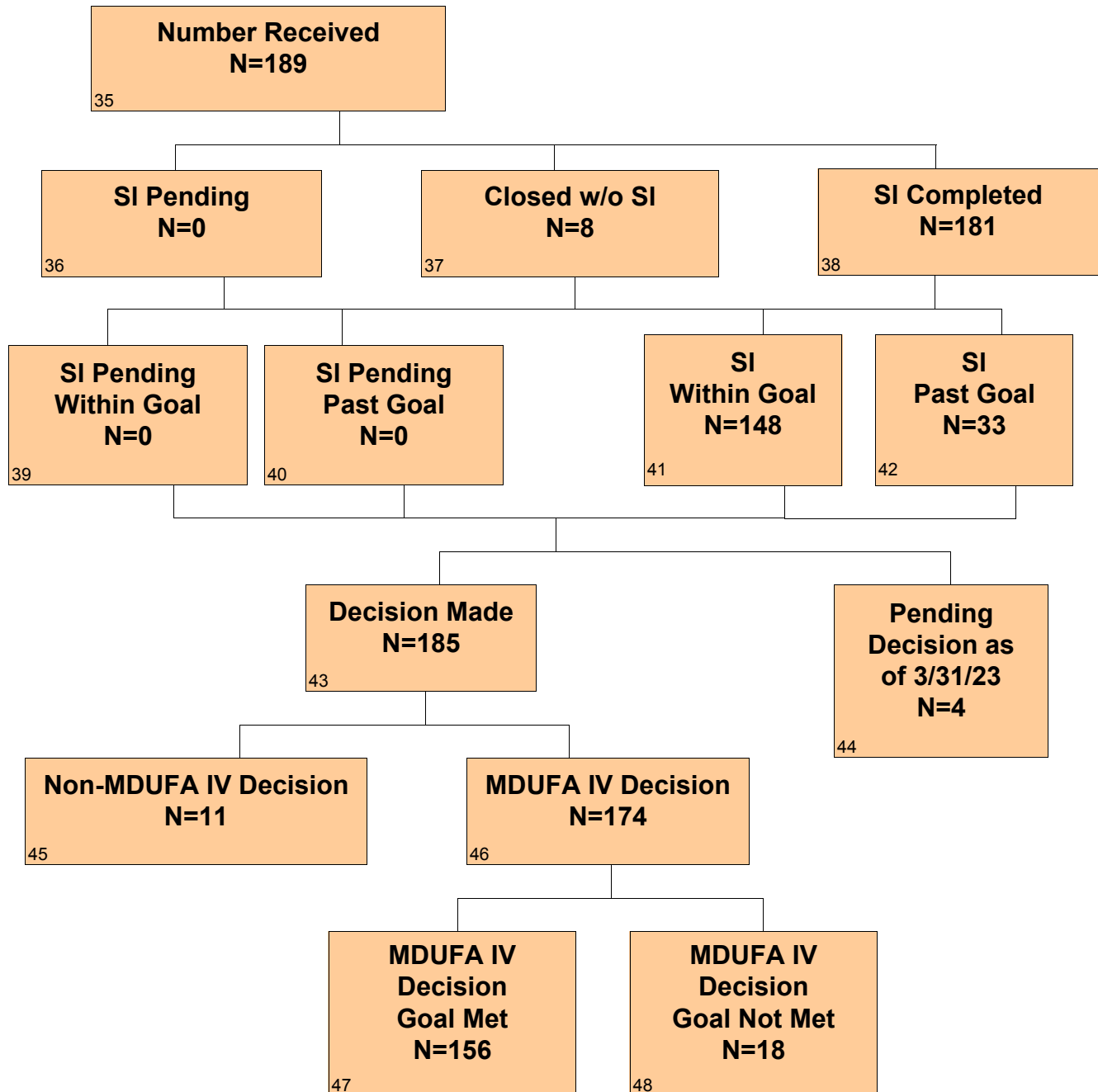
CDRH PMA 180 Day Supplements - FY 2019 as of 3/31/23



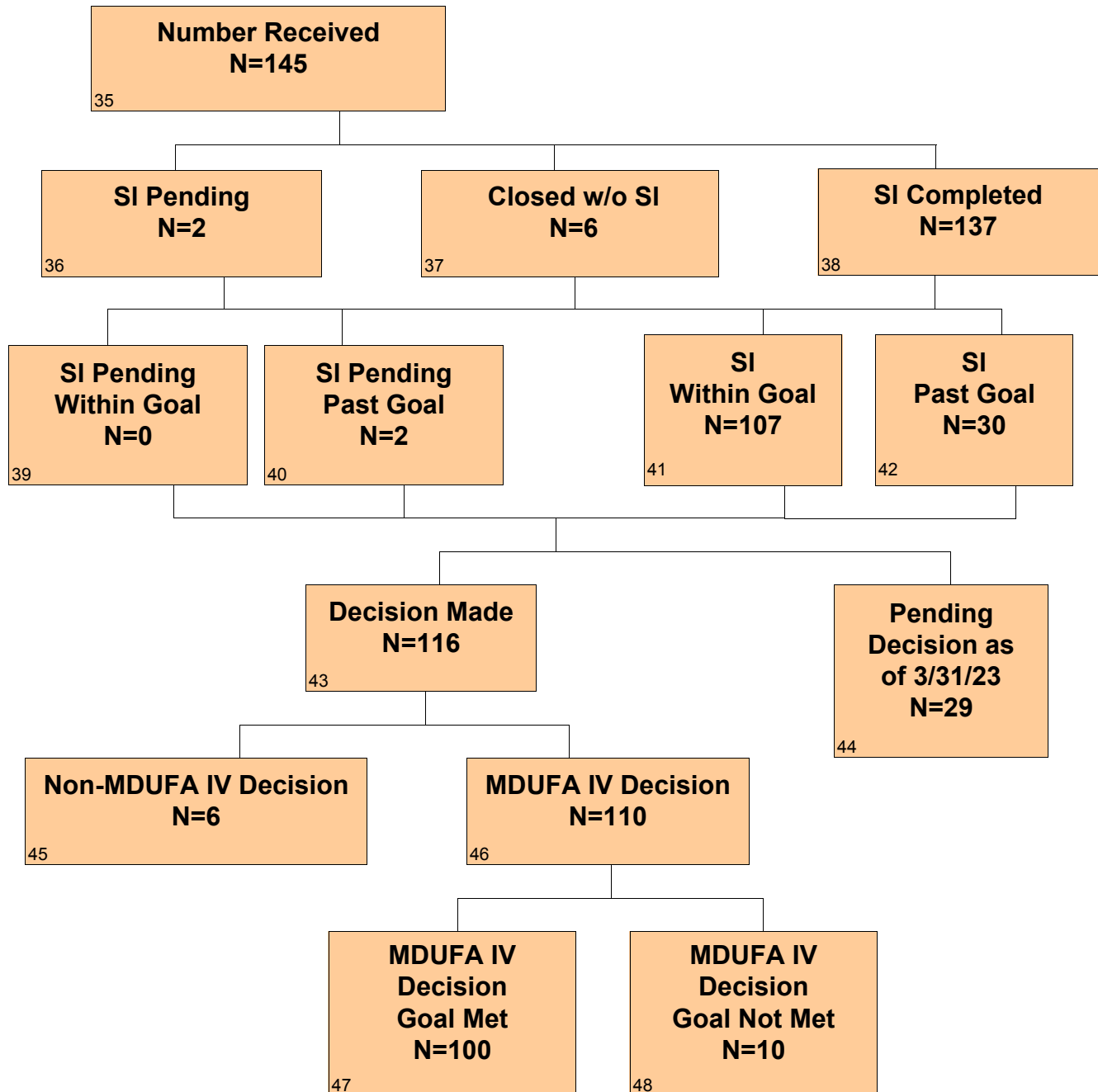
CDRH PMA 180 Day Supplements - FY 2020 as of 3/31/23



CDRH PMA 180 Day Supplements - FY 2021 as of 3/31/23



CDRH PMA 180 Day Supplements - FY 2022 as of 3/31/23



Section 2 PMA 180-Day Supplements - Center Level Metric

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	188	191	176	189	145
SI Goal Met	182	189	161	148	107
SI Goal Not Met	3	2	12	33	30
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	2
Closed Without SI	3	0	3	8	6
Current SI Performance Percent Goal Met	98.38%	98.95%	93.06%	81.77%	76.98%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	188	191	176	189	145
Non-MDUFA IV Decision	8	6	12	11	6
MDUFA IV Decision	180	185	163	174	110
MDUFA IV Decision Goal Met	180	179	158	156	100
Supplements Pending MDUFA IV Decision	0	0	1	4	29
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	2	6
Current Performance Percent Goal Met	100.00%	96.76%	96.93%	88.64%	86.21%

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	189	145
Number with MDUFA IV Decision	180	185	163	174	110
Number of Not Approvable	13	10	9	13	6
Rate of Not Approvable	7.22%	5.41%	5.52%	7.47%	5.45%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	6	5	20	16
Mean FDA Days for Submissions that Missed the Goal	0.00	263.33	419.00	239.15	229.88
Mean Industry Days for Submissions that Missed the Goal	0.00	69.67	99.80	61.15	59.31

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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	20	36	28	15	21
SI Goal Met	20	36	28	14	19
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	2
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	93.33%	100.00%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	20	36	28	15	21
Non-MDUFA IV Decision	0	0	0	1	1
MDUFA IV Decision	20	36	28	14	17
MDUFA IV Decision Goal Met	20	35	28	14	17
Supplements Pending MDUFA IV Decision	0	0	0	0	3
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	97.22%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	20	36	28	15	21
Number with MDUFA IV Decision	20	36	28	14	17
Number of Not Approvable	1	1	1	2	2
Rate of Not Approvable	5.00%	2.78%	3.57%	14.29%	11.76%

**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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	94	81	70	94	51
SI Goal Met	91	81	66	79	40
SI Goal Not Met	1	0	4	7	10
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	1
Closed Without SI	2	0	0	8	0
Current SI Performance Percent Goal Met	98.91%	100.00%	94.29%	91.86%	78.43%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	94	81	70	94	51
Non-MDUFA IV Decision	2	3	2	8	0
MDUFA IV Decision	92	78	67	85	42
MDUFA IV Decision Goal Met	92	78	67	85	39
Supplements Pending MDUFA IV Decision	0	0	1	1	9
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	1
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	90.70%

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	51
Number with MDUFA IV Decision	92	78	67	85	42
Number of Not Approvable	6	6	4	10	0
Rate of Not Approvable	6.52%	7.69%	5.97%	11.76%	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	4
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	230.50
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	16.00

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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	15	16	19	19	16
SI Goal Met	14	15	16	18	14
SI Goal Not Met	1	1	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	3	0	2
Current SI Performance Percent Goal Met	93.33%	93.75%	100.00%	94.74%	100.00%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	15	16	19	19	16
Non-MDUFA IV Decision	0	2	7	2	2
MDUFA IV Decision	15	14	12	17	14
MDUFA IV Decision Goal Met	15	14	12	16	14
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	94.12%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	15	16	19	19	16
Number with MDUFA IV Decision	15	14	12	17	14
Number of Not Approvable	0	2	3	0	0
Rate of Not Approvable	0.00%	14.29%	25.00%	0.00%	0.00%

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

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

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	9	10	7	15	11
SI Goal Met	9	9	6	5	6
SI Goal Not Met	0	1	1	10	4
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	1
Current SI Performance Percent Goal Met	100.00%	90.00%	85.71%	33.33%	60.00%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	9	10	7	15	11
Non-MDUFA IV Decision	1	1	0	0	1
MDUFA IV Decision	8	9	7	14	8
MDUFA IV Decision Goal Met	8	5	6	9	6
Supplements Pending MDUFA IV Decision	0	0	0	1	2
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	2
Current Performance Percent Goal Met	100.00%	55.56%	85.71%	60.00%	60.00%

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	11
Number with MDUFA IV Decision	8	9	7	14	8
Number of Not Approvable	0	0	0	1	1
Rate of Not Approvable	0.00%	0.00%	0.00%	7.14%	12.50%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	4	1	6	4
Mean FDA Days for Submissions that Missed the Goal	0.00	258.50	383.00	258.17	280.50
Mean Industry Days for Submissions that Missed the Goal	0.00	91.00	223.00	39.17	26.50

Table 2.1 OHT5 - Office of Neurological and Physical Medicine Devices
PMA 180-Day Supplements Substantive Interaction Goal

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	13	16	23	20	18
SI Goal Met	12	16	23	19	14
SI Goal Not Met	0	0	0	1	3
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	1
Closed Without SI	1	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	95.00%	77.78%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	13	16	23	20	18
Non-MDUFA IV Decision	2	0	2	0	0
MDUFA IV Decision	11	16	21	19	12
MDUFA IV Decision Goal Met	11	15	21	18	11
Supplements Pending MDUFA IV Decision	0	0	0	1	6
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	1
Current Performance Percent Goal Met	100.00%	93.75%	100.00%	94.74%	84.62%

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	18
Number with MDUFA IV Decision	11	16	21	19	12
Number of Not Approvable	2	0	1	0	2
Rate of Not Approvable	18.18%	0.00%	4.76%	0.00%	16.67%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	1	0	1	2
Mean FDA Days for Submissions that Missed the Goal	0.00	244.00	0.00	181.00	197.00
Mean Industry Days for Submissions that Missed the Goal	0.00	13.00	0.00	75.00	73.00

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	0	6	2	4	3
SI Goal Met	0	6	2	4	3
SI Goal Not Met	0	0	0	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	N/A	100.00%	100.00%	100.00%	100.00%

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

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

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	3
Number with MDUFA IV Decision	0	6	1	4	2
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	N/A	0.00%	0.00%	0.00%	0.00%

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	103.50

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	35	23	25	22	24
SI Goal Met	34	23	18	9	10
SI Goal Not Met	1	0	7	13	13
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	1
Current SI Performance Percent Goal Met	97.14%	100.00%	72.00%	40.91%	43.48%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	35	23	25	22	24
Non-MDUFA IV Decision	2	0	0	0	2
MDUFA IV Decision	33	23	25	21	14
MDUFA IV Decision Goal Met	33	23	21	10	10
Supplements Pending MDUFA IV Decision	0	0	0	1	8
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	2
Current Performance Percent Goal Met	100.00%	100.00%	84.00%	45.45%	62.50%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	35	23	25	22	24
Number with MDUFA IV Decision	33	23	25	21	14
Number of Not Approvable	4	1	0	0	1
Rate of Not Approvable	12.12%	4.35%	0.00%	0.00%	7.14%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	4	12	6
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	428.00	235.00	206.67
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	69.00	72.00	79.17

**Table 2.1 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Substantive Interaction Goal**

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

**Table 2.2 OHT8 - Office of Radiological Health
PMA 180-Day Supplements MDUFA IV Decision Performance Goal**

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

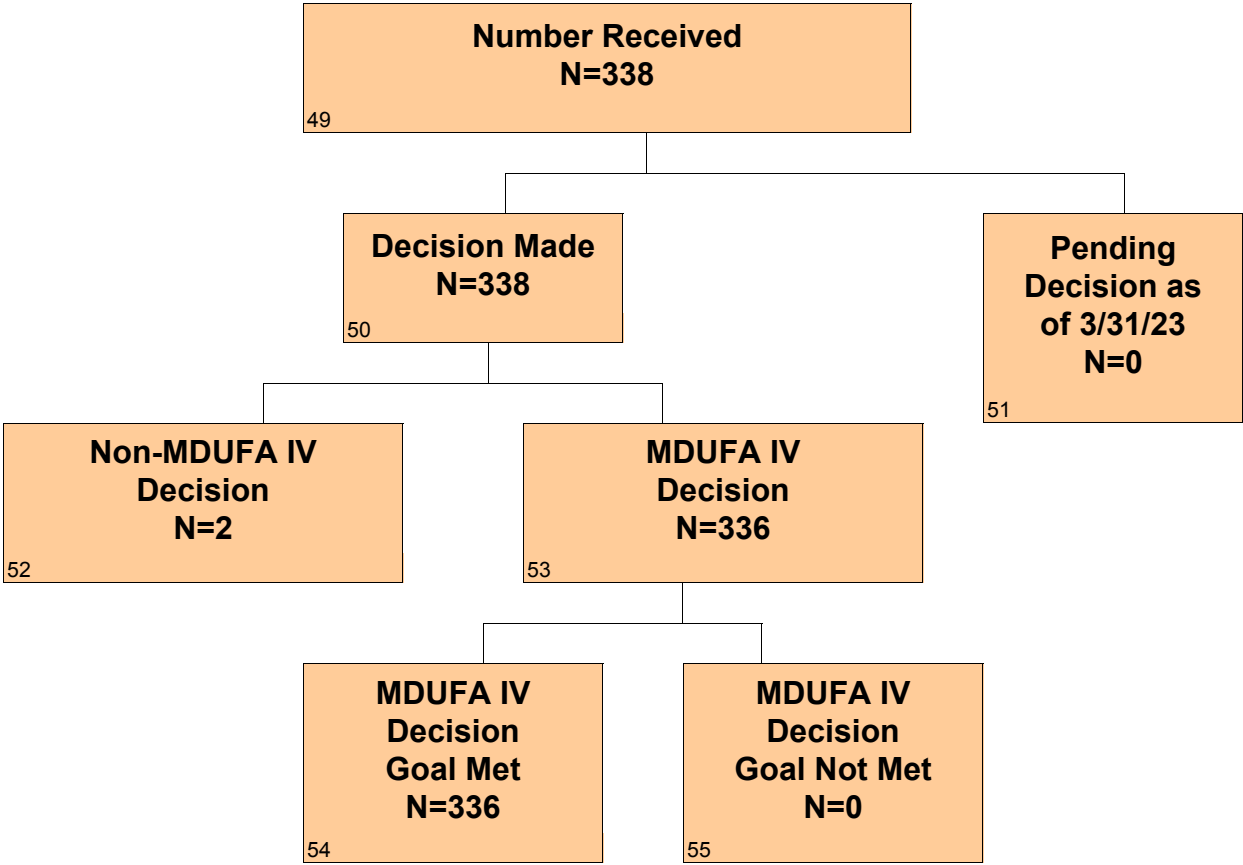
**Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

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

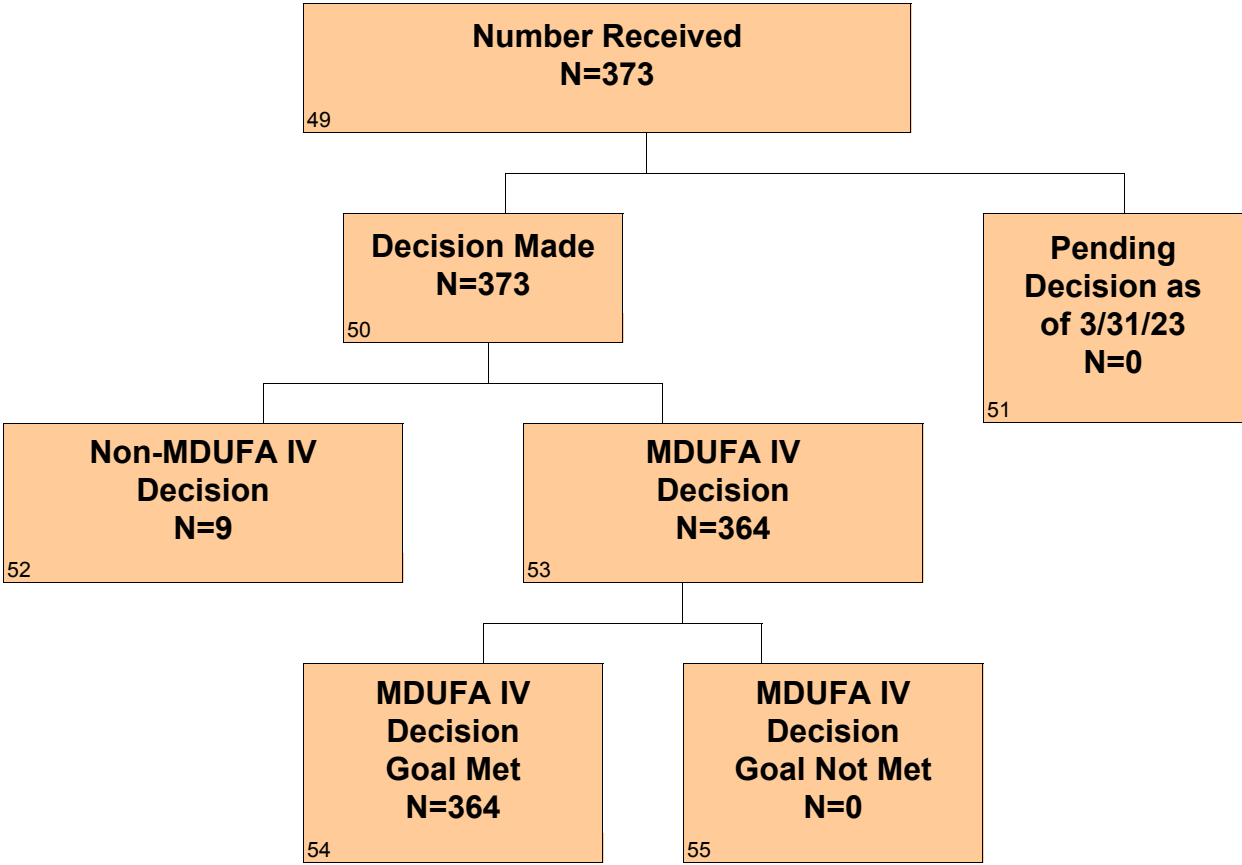
**Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

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

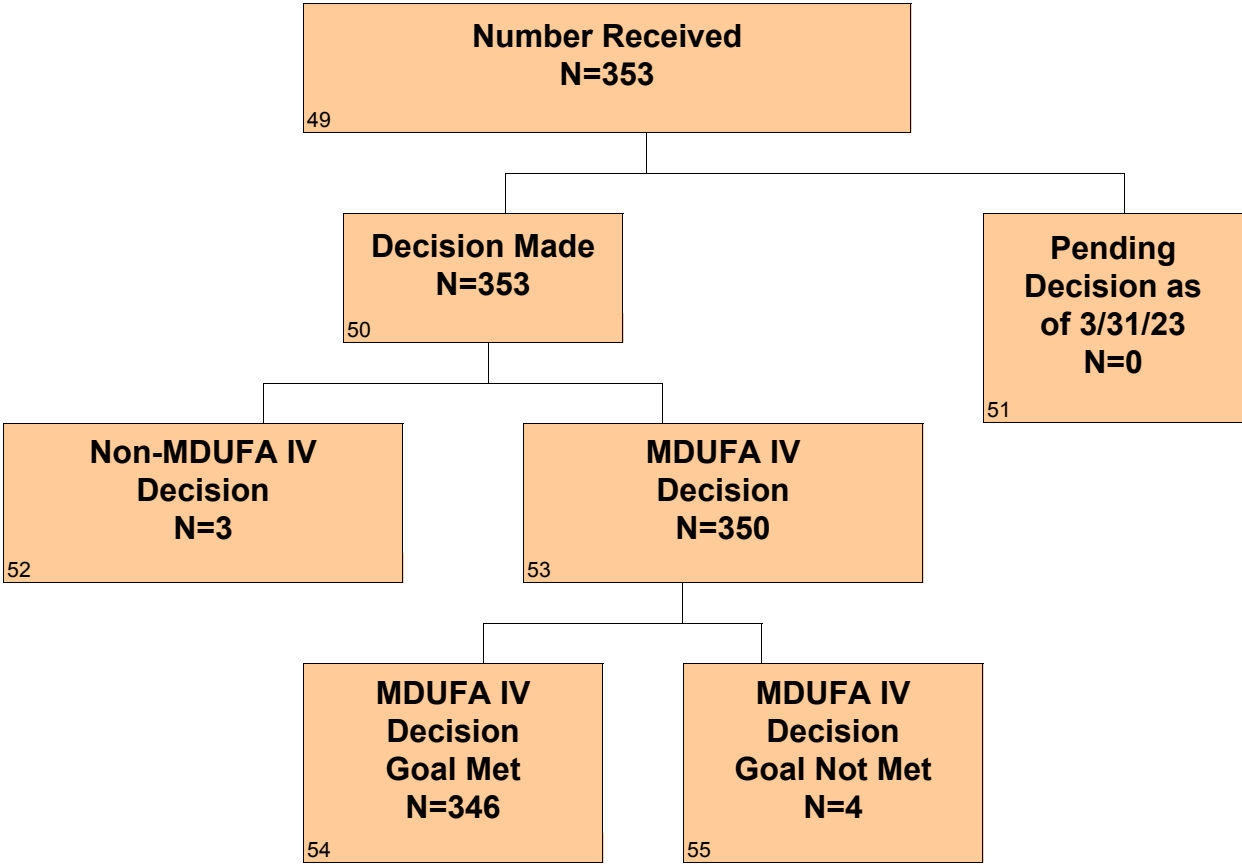
CDRH PMA Real Time Supplements - FY 2018 as of 3/31/23



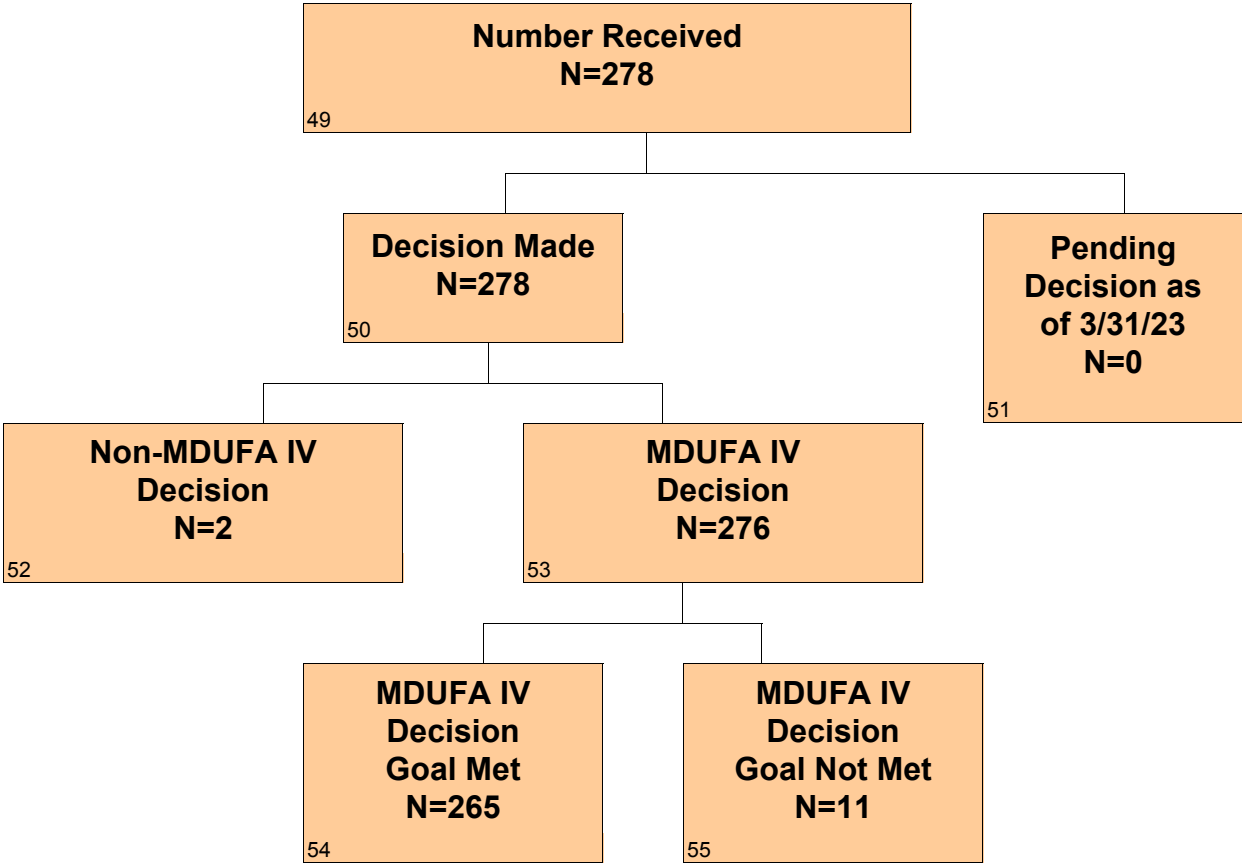
CDRH PMA Real Time Supplements - FY 2019 as of 3/31/23



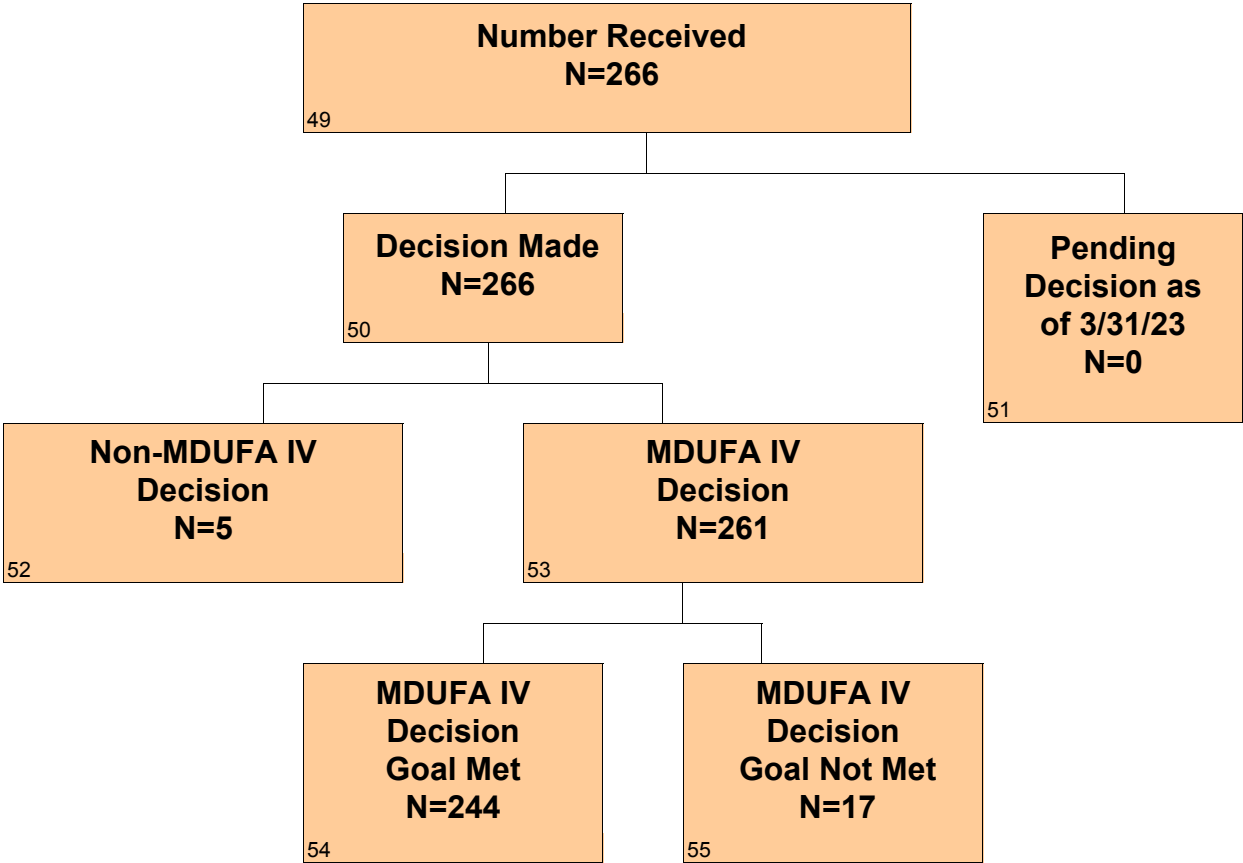
CDRH PMA Real Time Supplements - FY 2020 as of 3/31/23



CDRH PMA Real Time Supplements - FY 2021 as of 3/31/23



CDRH PMA Real Time Supplements - FY 2022 as of 3/31/23



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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	338	373	353	278	266
Non-MDUFA IV Decision	2	9	3	2	5
MDUFA IV Decision	336	364	350	276	261
MDUFA IV Decision Goal Met	336	364	346	265	244
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	98.86%	96.01%	93.49%

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	266
Number With MDUFA IV Decision	336	364	350	276	261
Number of Not Approvable	20	29	6	10	11
Rate of Not Approvable	5.95%	7.97%	1.71%	3.62%	4.21%

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	17
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.25	194.55	142.53
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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	23	40	16	21	24
Non-MDUFA IV Decision	0	2	1	0	1
MDUFA IV Decision	23	38	15	21	23
MDUFA IV Decision Goal Met	23	38	15	21	23
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	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	24
Number With MDUFA IV Decision	23	38	15	21	23
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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	154	173	193	147	122
Non-MDUFA IV Decision	0	3	2	0	1
MDUFA IV Decision	154	170	191	147	121
MDUFA IV Decision Goal Met	154	170	190	146	121
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	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	122
Number With MDUFA IV Decision	154	170	191	147	121
Number of Not Approvable	12	15	1	2	3
Rate of Not Approvable	7.79%	8.82%	0.52%	1.36%	2.48%

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

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

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	20	39	36	16	27
Non-MDUFA IV Decision	0	1	0	2	0
MDUFA IV Decision	20	38	36	14	27
MDUFA IV Decision Goal Met	20	38	36	14	27
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	20	39	36	16	27
Number with MDUFA IV Decision	20	38	36	14	27
Number of Not Approvable	1	8	1	0	5
Rate of Not Approvable	5.00%	21.05%	2.78%	0.00%	18.52%

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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	13	18	13	13	6
Non-MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision	12	18	13	13	6
MDUFA IV Decision Goal Met	12	18	13	10	2
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	76.92%	33.33%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	13	18	13	13	6
Number with MDUFA IV Decision	12	18	13	13	6
Number of Not Approvable	4	0	0	1	0
Rate of Not Approvable	33.33%	0.00%	0.00%	7.69%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	3	4
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	205.33	257.00
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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	16	32	24	22	31
Non-MDUFA IV Decision	0	0	0	0	1
MDUFA IV Decision	16	32	24	22	30
MDUFA IV Decision Goal Met	16	32	24	22	30
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	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	31
Number with MDUFA IV Decision	16	32	24	22	30
Number of Not Approvable	0	2	3	1	1
Rate of Not Approvable	0.00%	6.25%	12.50%	4.55%	3.33%

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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	17	22	9	3	9
Non-MDUFA IV Decision	0	0	0	0	1
MDUFA IV Decision	17	22	9	3	8
MDUFA IV Decision Goal Met	17	22	9	3	8
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	17	22	9	3	9
Number with MDUFA IV Decision	17	22	9	3	8
Number of Not Approvable	2	2	1	1	1
Rate of Not Approvable	11.76%	9.09%	11.11%	33.33%	12.50%

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

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

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	93	48	61	55	47
Non-MDUFA IV Decision	1	3	0	0	1
MDUFA IV Decision	92	45	61	55	46
MDUFA IV Decision Goal Met	92	45	58	48	33
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	95.08%	87.27%	71.74%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	93	48	61	55	47
Number with MDUFA IV Decision	92	45	61	55	46
Number of Not Approvable	0	1	0	5	1
Rate of Not Approvable	0.00%	2.22%	0.00%	9.09%	2.17%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	3	7	13
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	98.00	198.57	107.31
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	0.00

Table 3.1 OHT8 - Office of Radiological Health**PMA Real-Time Supplements MDUFA IV Decision Performance Goal**

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

Table 3.2 OHT8 - Office of Radiological Health**PMA Real-Time Supplements Performance Metric - Rate of Not Approvable**

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

Table 3.3 OHT8 - Office of Radiological Health**PMA Real-Time Supplements Performance Metric - Submissions Missing Performance Goal**

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

Section 4 Pre-Market Report Submissions

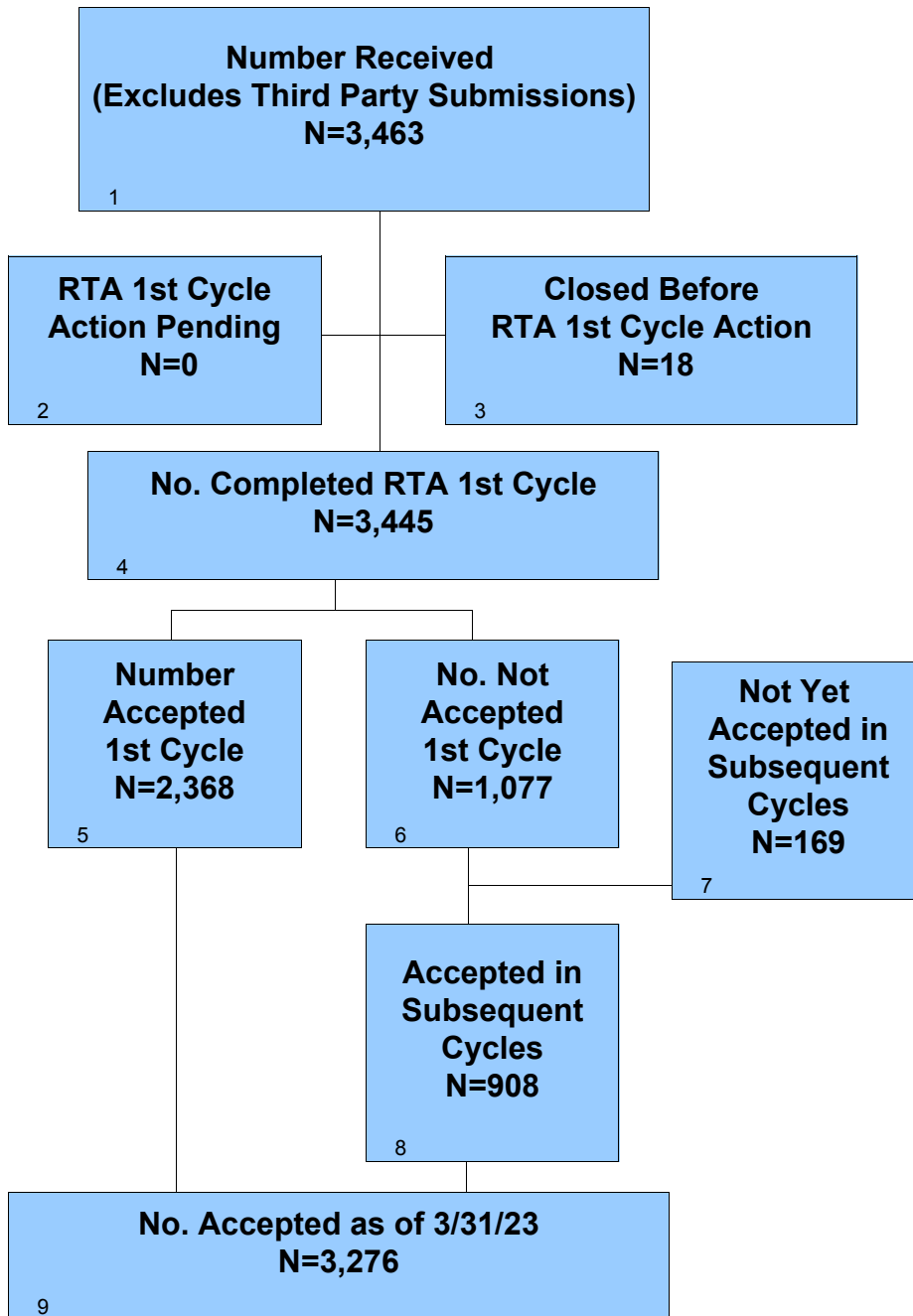
There were no pre-market reports received by FDA between October 1, 2022 and March 31, 2023.

Section 5 PMA Annual Metrics and Goals

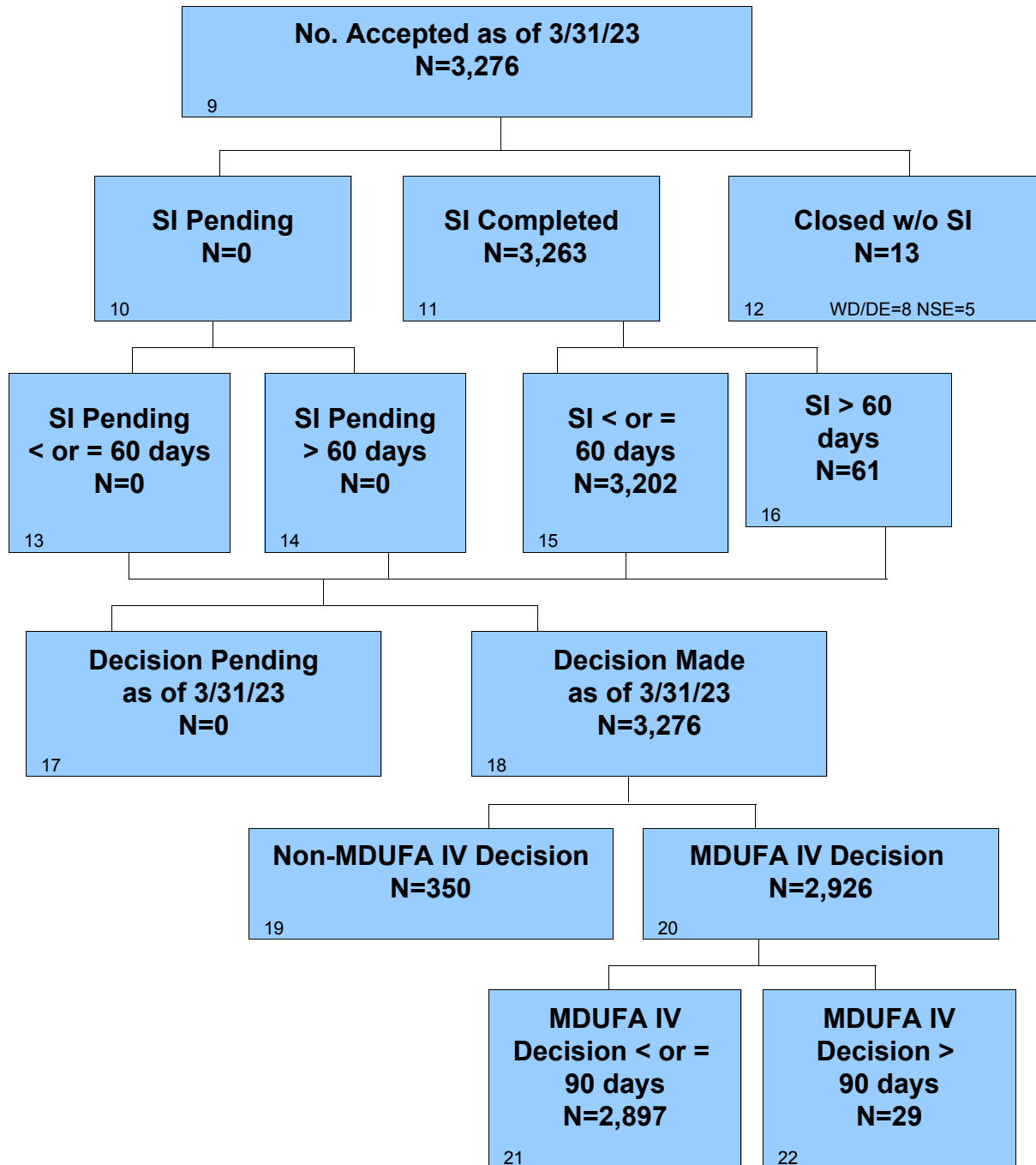
PMA Annual Metrics and Goals will be reported in the Annual Report.

CDRH 510(k)s - FY 2018

as of 3/31/23

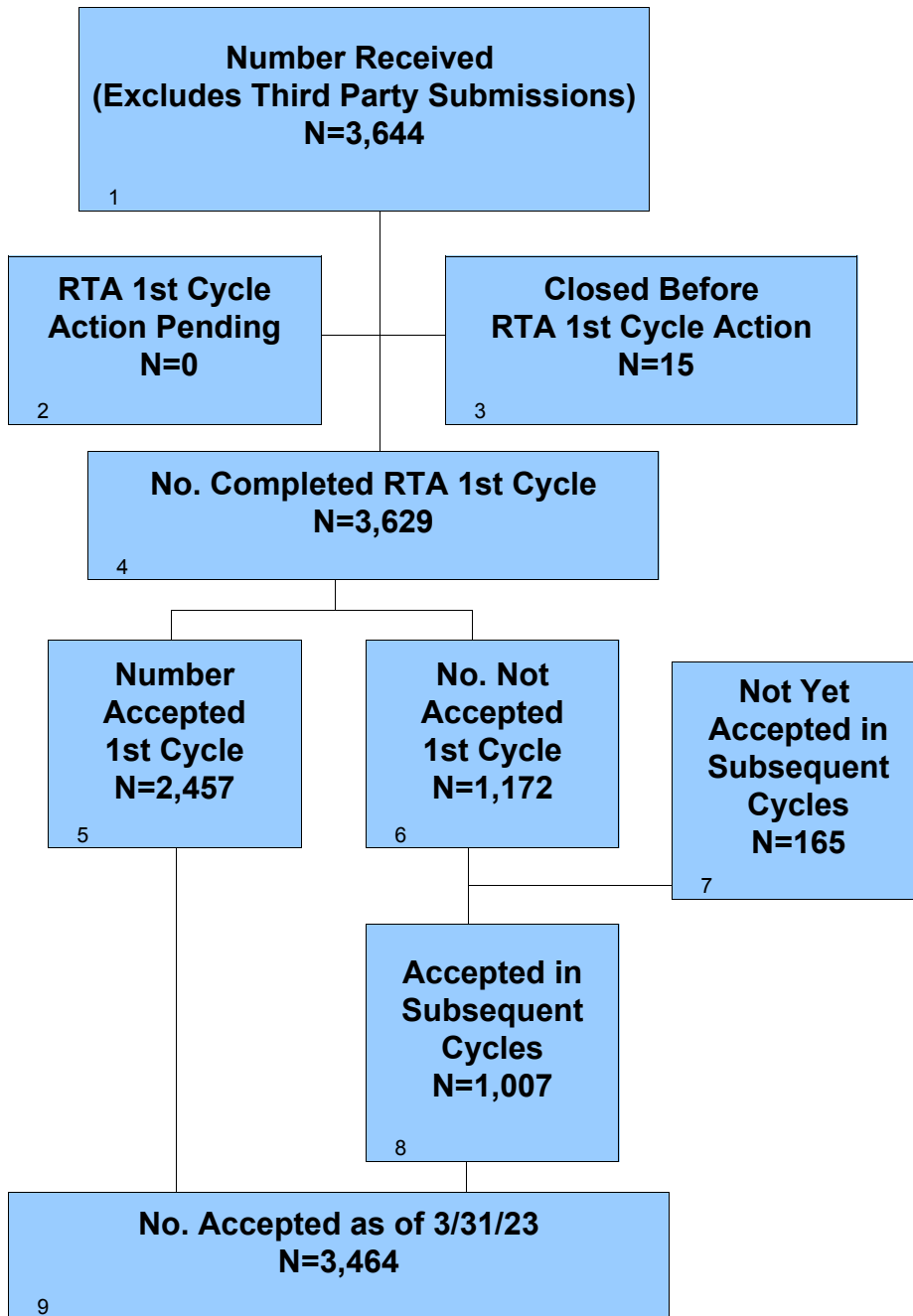


CDRH 510(k)s - FY 2018 as of 3/31/23 Continued

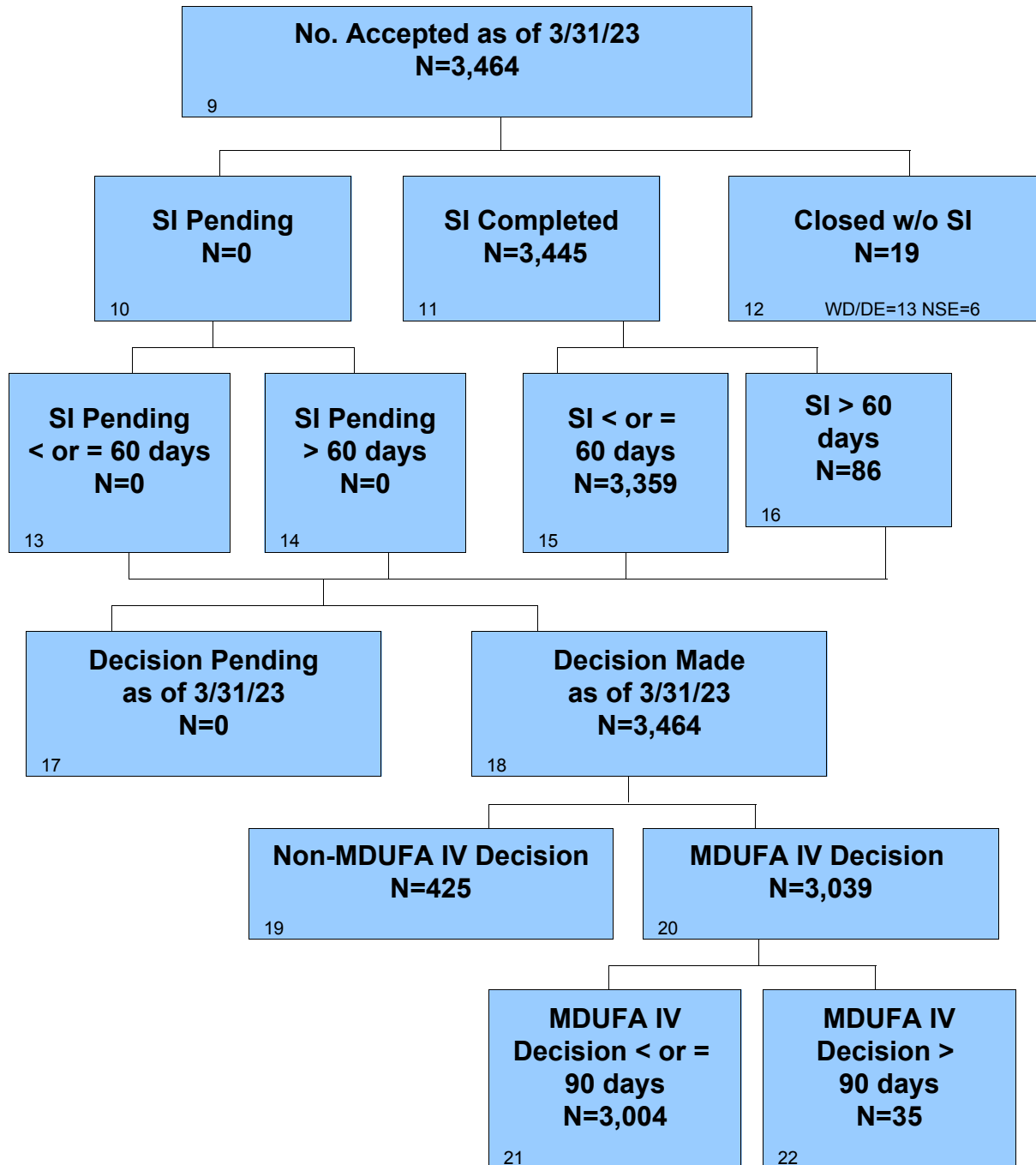


CDRH 510(k)s - FY 2019

as of 3/31/23

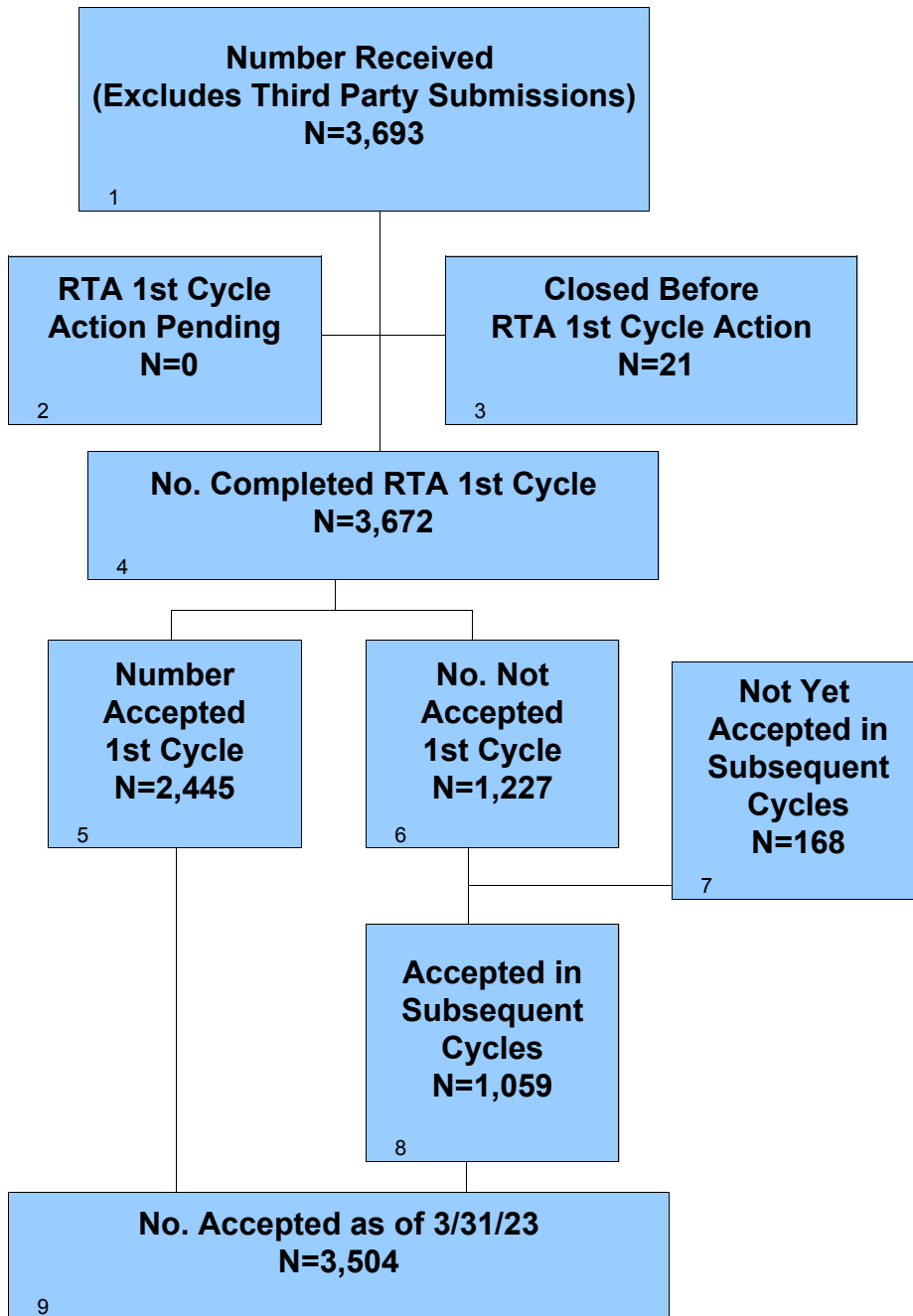


CDRH 510(k)s - FY 2019 as of 3/31/23 Continued

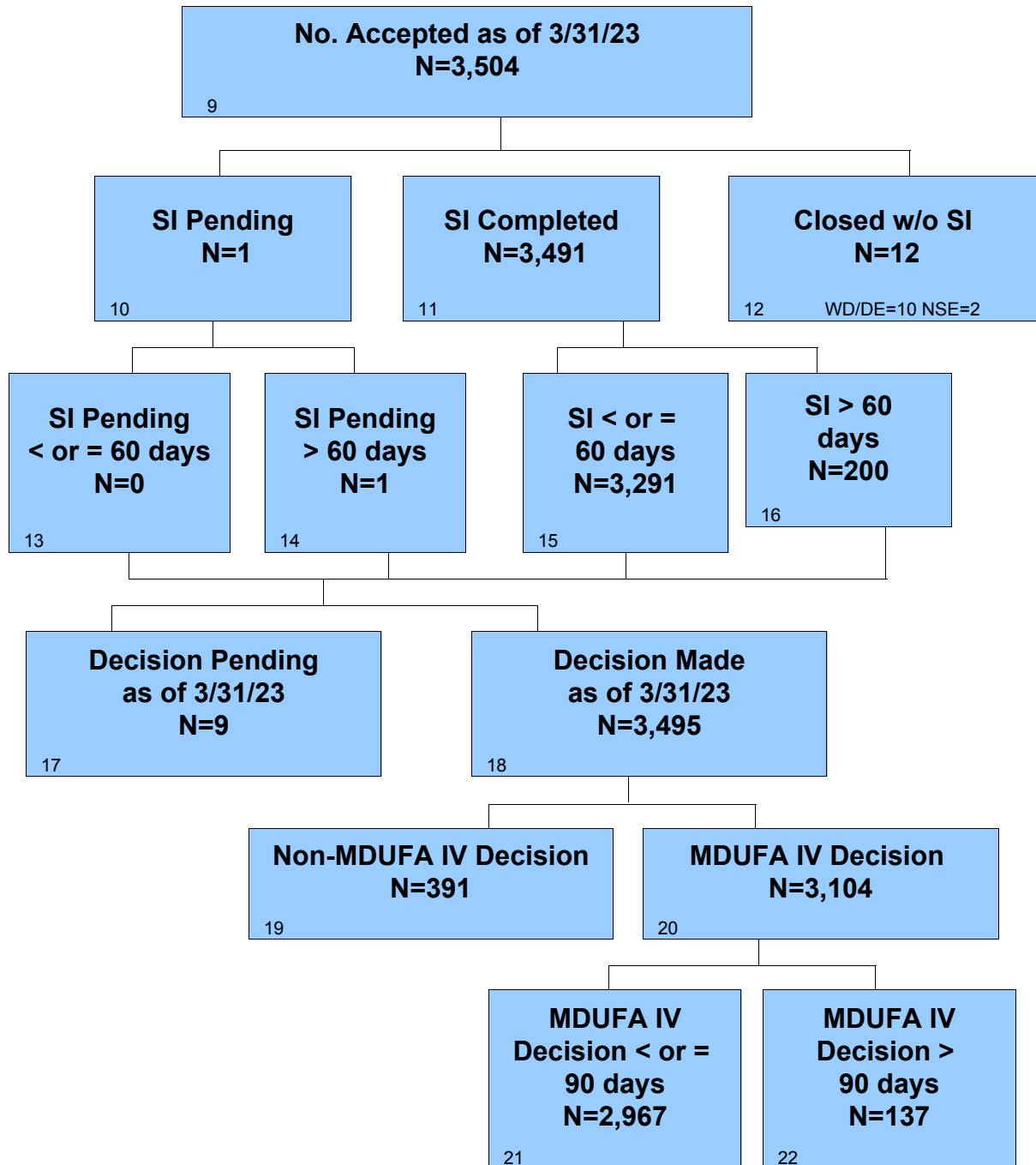


CDRH 510(k)s - FY 2020

as of 3/31/23

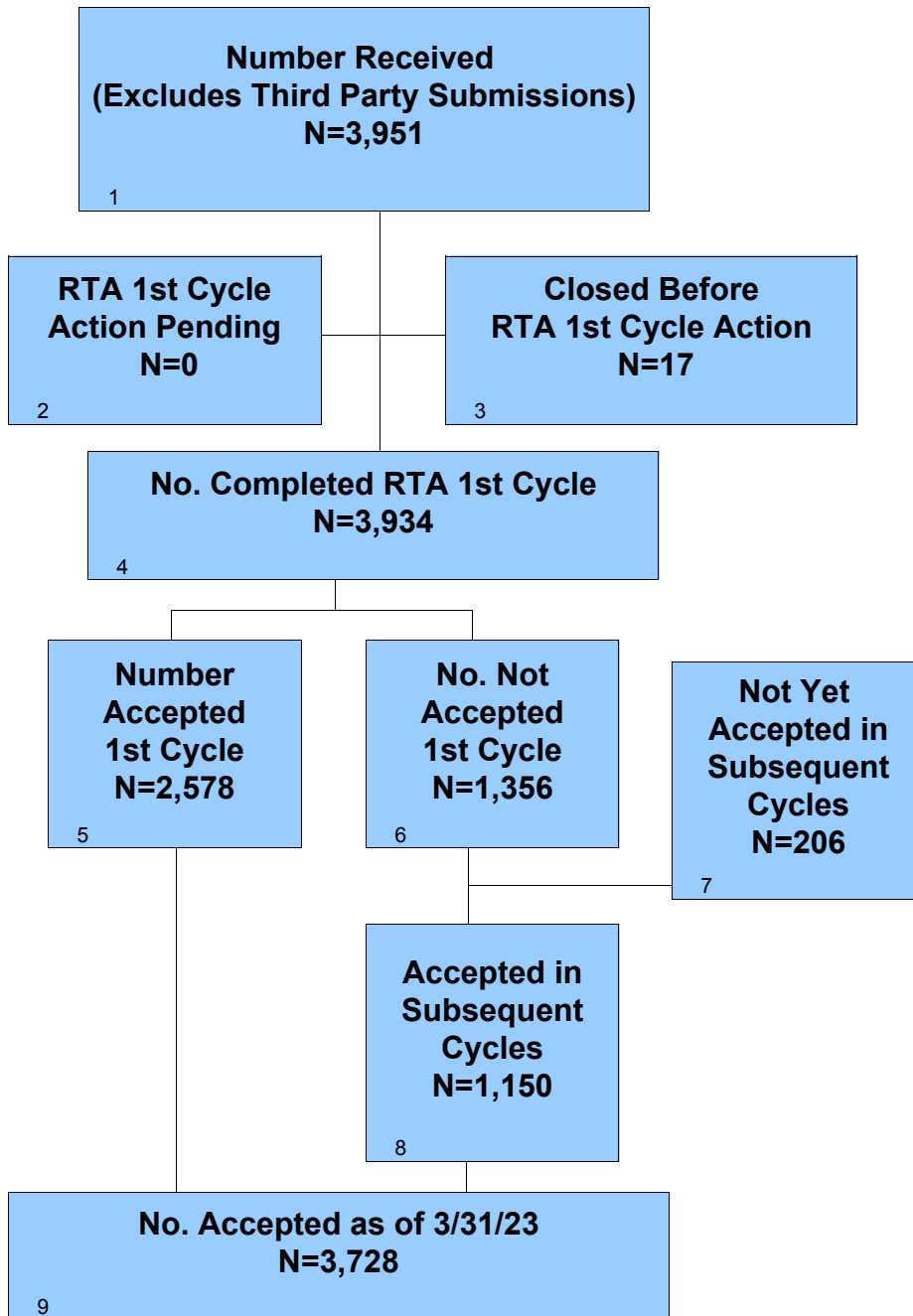


CDRH 510(k)s - FY 2020 as of 3/31/23 Continued

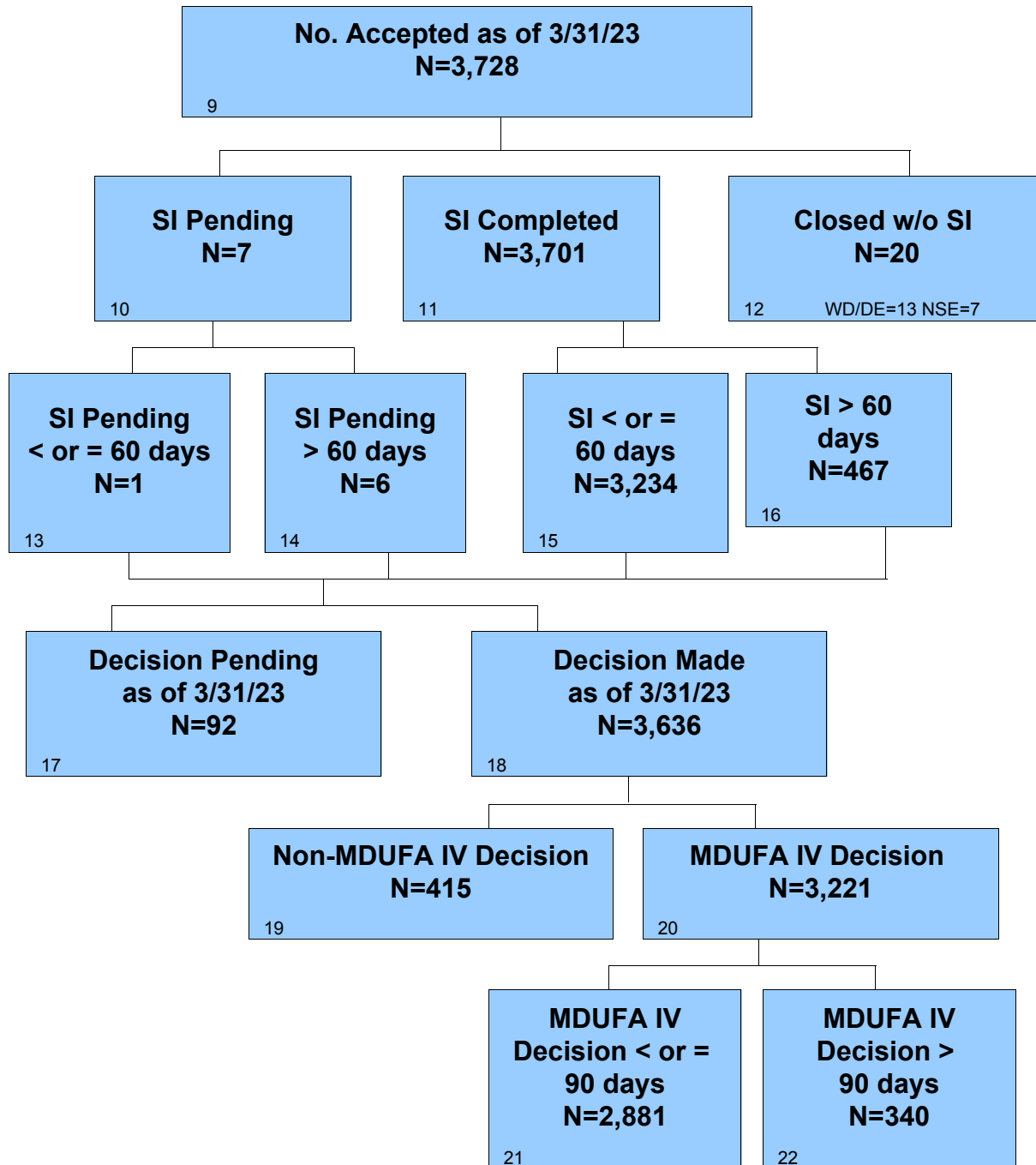


CDRH 510(k)s - FY 2021

as of 3/31/23

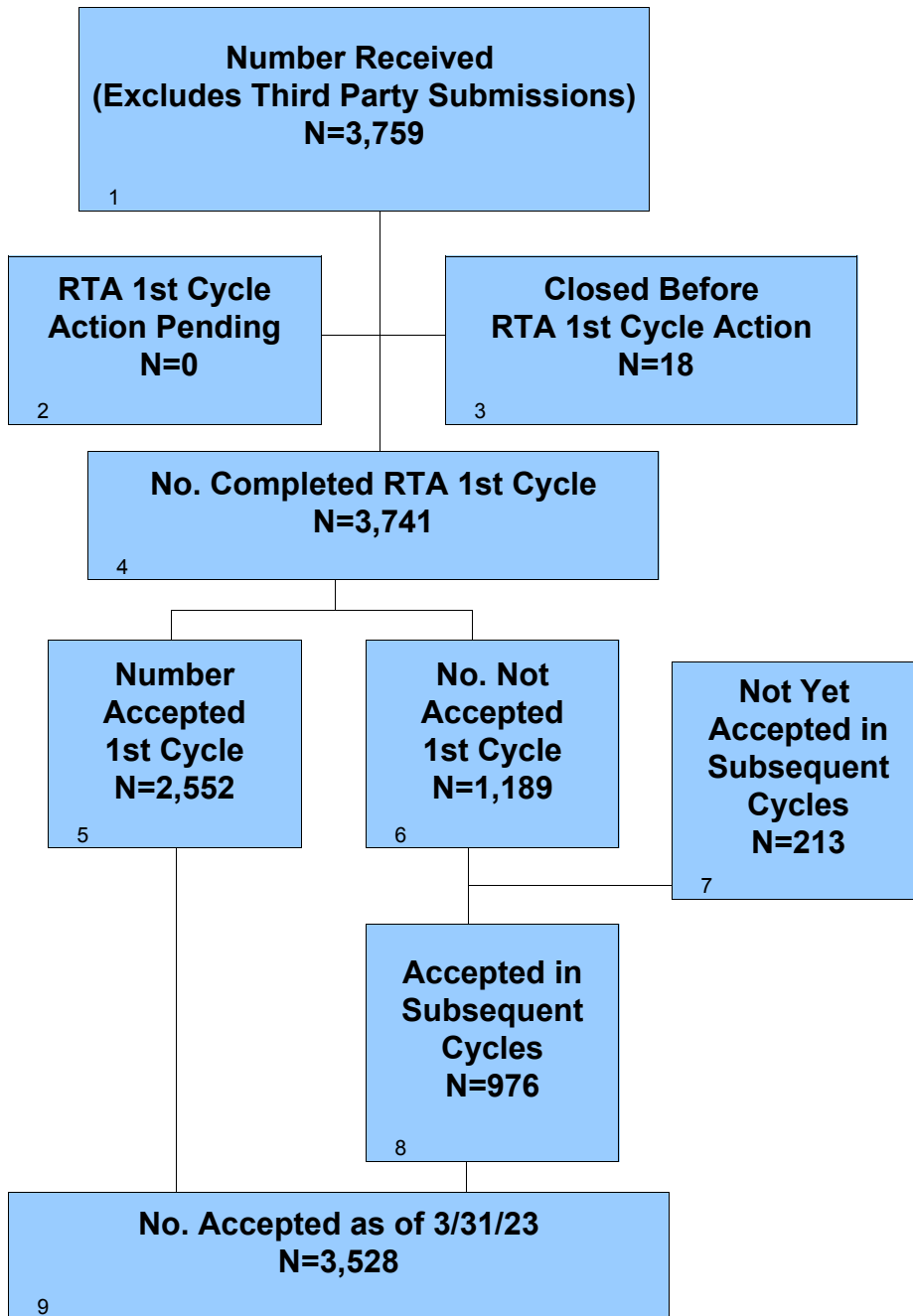


CDRH 510(k)s - FY 2021 as of 3/31/23 Continued

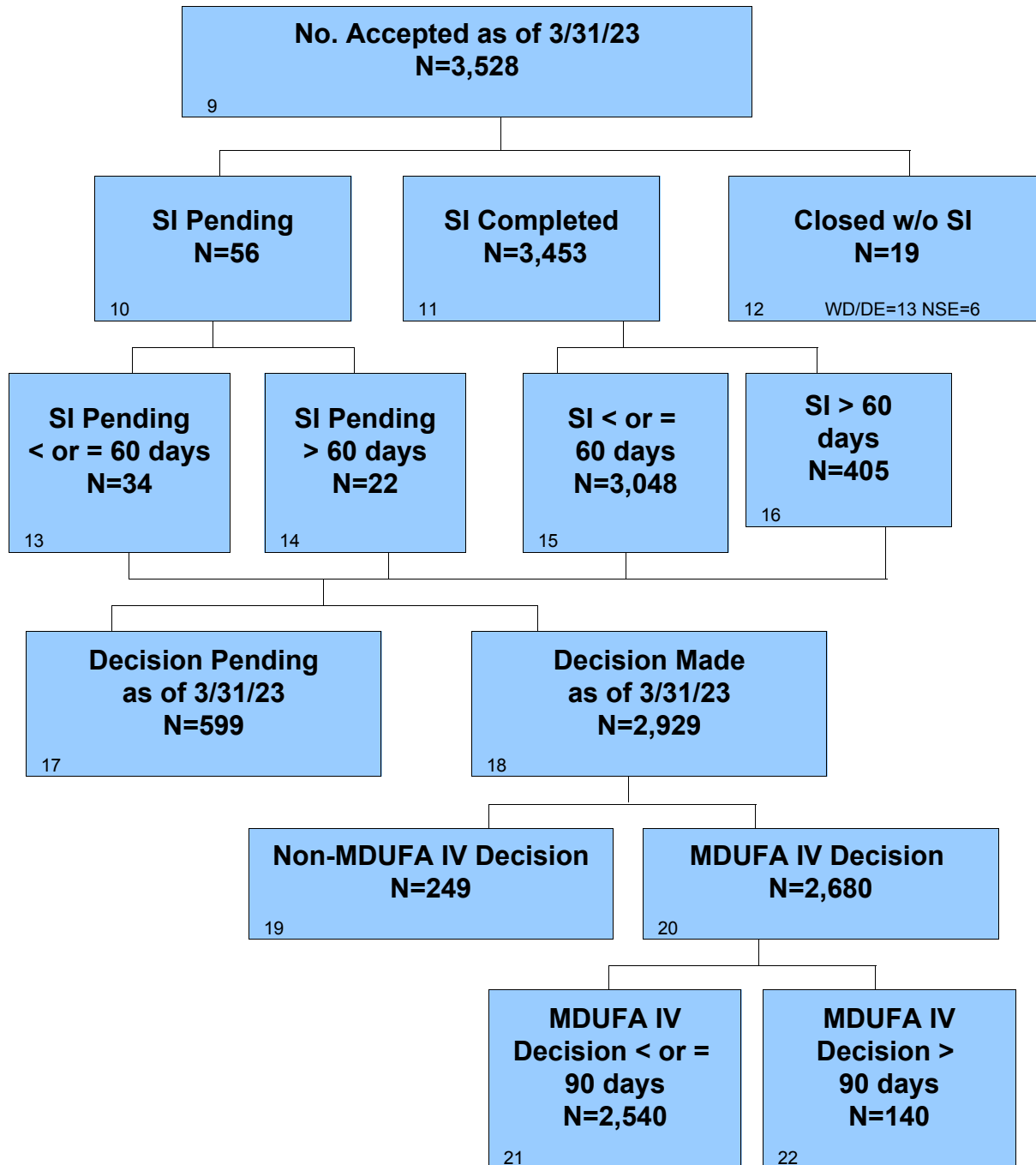


CDRH 510(k)s - FY 2022

as of 3/31/23



CDRH 510(k)s - FY 2022 as of 3/31/23 Continued



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

Table 6.1 CDRH - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3,463	3,644	3,693	3,951	3,759
Closed Before RTA Action or TS	18	15	21	17	18
Number Accepted	2,353	2,403	2,396	2,358	2,175
Number Without a RTA Review and > 15 Days Since Date Received	15	54	49	220	377
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	1,077	1,172	1,227	1,356	1,189
Rate of Submissions Not Accepted for Review	31.26%	32.30%	33.42%	34.47%	31.78%

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	3,276	3,464	3,504	3,728	3,528
Deleted or Withdrawn Prior to SI	8	13	10	13	13
SI Within 60 FDA Days	3,202	3,359	3,291	3,234	3,048
SI Over 60 FDA Days	61	86	200	467	405
SI Pending Within 60 FDA Days	0	0	0	1	34
SI Pending Over 60 FDA Days	0	0	1	6	22
510(k)s NSE Without SI	5	6	2	7	6
Current SI Performance Percent Within 60 FDA Days	97.98%	97.33%	94.19%	87.08%	87.56%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	3,263	3,445	3,491	3,701	3,453
Average Number of FDA Days to Substantive Interaction	51.04	51.42	55.02	59.69	57.70
20th Percentile FDA Days to Substantive Interaction	43	43	46	50	50
40th Percentile FDA Days to Substantive Interaction	55	56	56	57	57
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	86	90	496	414	287

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	3,276	3,464	3,504	3,728	3,528
Non-MDUFA IV Decision	350	425	391	415	249
MDUFA IV Decision (SE/NSE)	2,926	3,039	3,104	3,221	2,680
MDUFA IV Decision Within 90 FDA Days	2,897	3,004	2,967	2,881	2,540
510(k)s Pending MDUFA IV Decision	0	0	9	92	599
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	5	45	127
Current Performance Percent Within 90 FDA Days	99.01%	98.85%	95.43%	88.21%	90.49%

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	1.64	1.66	1.60
Number With MDUFA IV Decision	2,926	3,039	3,104	3,221	2,680
Average Number of FDA Days to MDUFA IV Decision	72.62	73.55	79.33	83.40	77.38
20th Percentile FDA Days to MDUFA IV Decision	54	55	55	58	56
40th Percentile FDA Days to MDUFA IV Decision	79	82	84	85	83
60th Percentile FDA Days to MDUFA IV Decision	87	88	88	88	88
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	220	655	673	576	344
Average Number of Industry Days to MDUFA IV Decision	54.69	60.40	70.34	75.82	52.17
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	5	0	5	12	0
60th Percentile Industry Days to MDUFA IV Decision	44	49	54	64	41
80th Percentile Industry Days to MDUFA IV Decision	127	139	146	154	109
Maximum Industry Days to MDUFA IV Decision	563	507	834	613	364
Average Number of Total Days to MDUFA IV Decision	127.31	133.95	149.67	159.22	129.55
20th Percentile Total Days to MDUFA IV Decision	57	57	57	59	57
40th Percentile Total Days to MDUFA IV Decision	89	90	90	99	90
60th Percentile Total Days to MDUFA IV Decision	128	133	140	155	132
80th Percentile Total Days to MDUFA IV Decision	212	224	239	248	201
Maximum Total Days to MDUFA IV Decision	783	871	990	767	526

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	3,276	3,464	3,504	3,728	3,528
Number With MDUFA IV Decision	2,926	3,039	3,104	3,221	2,680
Number of SE Decision	2,810	2,924	3,000	3,082	2,592
Number of NSE Decision	116	115	104	139	88
Number of Withdrawal	185	213	214	233	180
Number of Deleted	156	194	173	179	66
Rate of SE Decision	96.04%	96.22%	96.65%	95.68%	96.72%
Rate of NSE Decision	3.96%	3.78%	3.35%	4.32%	3.28%
Rate of Withdrawal	5.65%	6.15%	6.11%	6.25%	5.10%
Rate of Deleted	4.76%	5.60%	4.94%	4.80%	1.87%

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	35	137	340	140
Mean FDA Days for Submissions that Missed the Goal	111.38	140.80	228.69	163.20	161.09
Mean Industry Days for Submissions that Missed the Goal	136.24	201.94	174.93	98.90	50.78

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	2	1	4	1	3
Non-MDUFA IV Decision	1	0	0	1	0
MDUFA IV Decision (SE/NSE)	1	1	4	0	2
MDUFA IV Decision Within 90 FDA Days	1	1	2	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	1
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	1
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	50.00%	N/A	0.00%

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	272	278	253	195	220
Non-MDUFA IV Decision	41	37	52	43	20
MDUFA IV Decision (SE/NSE)	231	241	198	139	99
MDUFA IV Decision Within 90 FDA Days	230	237	122	13	14
510(k)s Pending MDUFA IV Decision	0	0	3	13	101
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	3	13	97
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	60.70%	8.55%	7.14%

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

**Table 6.1 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	552	593	536	533	593
Closed Before RTA Action	1	1	0	0	2
Number Accepted	208	207	226	207	222
Number Without a RTA Review and > 15 Days Since Date Received	0	12	8	11	35
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	343	373	302	315	334
Rate of Submissions Not Accepted for Review	62.25%	63.01%	56.34%	59.10%	56.51%

**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 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	494	551	506	492	522
Deleted or Withdrawn Prior to SI	2	6	0	0	0
SI Within 60 FDA Days	477	490	415	421	428
SI Over 60 FDA Days	14	54	90	71	81
SI Pending Within 60 FDA Days	0	0	0	0	10
SI Pending Over 60 FDA Days	0	0	1	0	3
510(k)s NSE Without SI	1	1	0	0	0
Current SI Performance Percent Within 60 FDA Days	96.95%	89.91%	82.02%	85.57%	83.59%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	491	544	505	492	509
Average Number of FDA Days to Substantive Interaction	55.63	56.04	55.38	55.98	56.66
20th Percentile FDA Days to Substantive Interaction	54	54	51	54	55
40th Percentile FDA Days to Substantive Interaction	58	58	57	58	58
60th Percentile FDA Days to Substantive Interaction	59	59	60	59	60
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	78	87	94	88	90

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	494	551	506	492	522
Non-MDUFA IV Decision	74	85	66	71	41
MDUFA IV Decision (SE/NSE)	420	466	439	402	346
MDUFA IV Decision Within 90 FDA Days	417	464	435	398	342
510(k)s Pending MDUFA IV Decision	0	0	1	19	135
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	8	4
Current Performance Percent Within 90 FDA Days	99.29%	99.57%	98.86%	97.07%	97.71%

**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	1.70	1.72	1.67
Number With MDUFA IV Decision	420	466	439	402	346
Average Number of FDA Days to MDUFA IV Decision	81.05	82.40	79.92	80.49	79.74
20th Percentile FDA Days to MDUFA IV Decision	77	84	76	73	61
40th Percentile FDA Days to MDUFA IV Decision	87	88	87	87	88
60th Percentile FDA Days to MDUFA IV Decision	89	89	89	89	89
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	148	153	115	191	119
Average Number of Industry Days to MDUFA IV Decision	65.45	68.89	72.39	89.74	63.50
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	18	20	17	27	10
60th Percentile Industry Days to MDUFA IV Decision	63	67	64	90	57
80th Percentile Industry Days to MDUFA IV Decision	152	154	152	172	122
Maximum Industry Days to MDUFA IV Decision	389	356	497	530	363
Average Number of Total Days to MDUFA IV Decision	146.51	151.28	152.30	170.22	143.23
20th Percentile Total Days to MDUFA IV Decision	79	88	84	82	72
40th Percentile Total Days to MDUFA IV Decision	103	106	99	114	96
60th Percentile Total Days to MDUFA IV Decision	148	154	150	178	146
80th Percentile Total Days to MDUFA IV Decision	241	242	241	259	211
Maximum Total Days to MDUFA IV Decision	479	446	585	655	451

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	494	551	506	492	522
Number With MDUFA IV Decision	420	466	439	402	346
Number of SE Decision	402	443	423	383	332
Number of NSE Decision	18	23	16	19	14
Number of Withdrawal	35	48	35	50	30
Number of Deleted	39	34	31	19	11
Rate of SE Decision	95.71%	95.06%	96.36%	95.27%	95.95%
Rate of NSE Decision	4.29%	4.94%	3.64%	4.73%	4.05%
Rate of Withdrawal	7.09%	8.71%	6.92%	10.16%	5.75%
Rate of Deleted	7.89%	6.17%	6.13%	3.86%	2.11%

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	4	4
Mean FDA Days for Submissions that Missed the Goal	115.33	133.50	101.25	129.25	107.00
Mean Industry Days for Submissions that Missed the Goal	107.67	258.00	167.75	362.00	180.25

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

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

**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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	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 (SE/NSE)	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision Within 90 FDA Days	N/A	N/A	N/A	N/A	N/A
510(k)s Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 90 FDA Days	N/A	N/A	N/A	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	357	378	376	384	360
Closed Before RTA Action	4	2	1	2	0
Number Accepted	237	266	281	273	247
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4	17	33
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	114	100	90	92	80
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.00%	24.08%	22.22%

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	341	366	368	375	348
Deleted or Withdrawn Prior to SI	4	0	1	1	7
SI Within 60 FDA Days	324	358	354	354	326
SI Over 60 FDA Days	13	8	12	18	10
SI Pending Within 60 FDA Days	0	0	0	0	3
SI Pending Over 60 FDA Days	0	0	0	0	1
510(k)s NSE Without SI	0	0	1	2	1
Current SI Performance Percent Within 60 FDA Days	96.14%	97.81%	96.46%	94.65%	96.45%

Table 6.3 OHT2 - Office of Cardiovascular Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	337	366	366	372	336
Average Number of FDA Days to Substantive Interaction	49.74	50.76	51.63	51.34	51.68
20th Percentile FDA Days to Substantive Interaction	30	30	36	30	46
40th Percentile FDA Days to Substantive Interaction	53	56	57	57	56
60th Percentile FDA Days to Substantive Interaction	58	59	59	59	58
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	83	71	101	89	66

Table 6.4 OHT2 - Office of Cardiovascular Devices

510(k) MDUFA IV Decision Performance Goal

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	341	366	368	375	348
Non-MDUFA IV Decision	32	52	33	42	39
MDUFA IV Decision (SE/NSE)	309	314	335	330	254
MDUFA IV Decision Within 90 FDA Days	303	303	320	321	250
510(k)s Pending MDUFA IV Decision	0	0	0	3	55
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	1	4
Current Performance Percent Within 90 FDA Days	98.06%	96.50%	95.52%	96.98%	96.90%

Table 6.5 OHT2 - Office of Cardiovascular Devices

510(k) Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.71	1.70	1.82	1.81	1.79
Number With MDUFA IV Decision	309	314	335	330	254
Average Number of FDA Days to MDUFA IV Decision	71.68	71.37	75.07	74.10	73.87
20th Percentile FDA Days to MDUFA IV Decision	50	49	55	55	56
40th Percentile FDA Days to MDUFA IV Decision	80	80	86	86	85
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	89	88
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	89
Maximum FDA Days to MDUFA IV Decision	159	117	245	293	99
Average Number of Industry Days to MDUFA IV Decision	64.80	66.25	89.59	101.95	71.69
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	19	20	29	39	27
60th Percentile Industry Days to MDUFA IV Decision	65	68	81	102	76
80th Percentile Industry Days to MDUFA IV Decision	146	140	159	175	139
Maximum Industry Days to MDUFA IV Decision	292	359	607	516	355
Average Number of Total Days to MDUFA IV Decision	136.48	137.61	164.65	176.04	145.56
20th Percentile Total Days to MDUFA IV Decision	55	51	56	58	60
40th Percentile Total Days to MDUFA IV Decision	102	98	118	123	111
60th Percentile Total Days to MDUFA IV Decision	150	148	166	189	162
80th Percentile Total Days to MDUFA IV Decision	228	227	250	265	227
Maximum Total Days to MDUFA IV Decision	370	447	707	608	443

Table 6.6 OHT2 - Office of Cardiovascular Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	341	366	368	375	348
Number With MDUFA IV Decision	309	314	335	330	254
Number of SE Decision	291	289	308	285	229
Number of NSE Decision	18	25	27	45	25
Number of Withdrawal	20	31	21	27	28
Number of Deleted	10	20	12	15	10
Rate of SE Decision	94.17%	92.04%	91.94%	86.36%	90.16%
Rate of NSE Decision	5.83%	7.96%	8.06%	13.64%	9.84%
Rate of Withdrawal	5.87%	8.47%	5.71%	7.20%	8.05%
Rate of Deleted	2.93%	5.46%	3.26%	4.00%	2.87%

Table 6.7 OHT2 - Office of Cardiovascular Devices

510(k) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	6	11	15	9	4
Mean FDA Days for Submissions that Missed the Goal	107.17	99.82	110.13	119.33	94.75
Mean Industry Days for Submissions that Missed the Goal	131.50	159.09	261.60	262.00	77.75

Table 6.8 OHT2 - Office of Cardiovascular Devices

LDT 510(k) MDUFA IV Decision Metric

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

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	455	477	440	508	444
Closed Before RTA Action	3	4	4	6	2
Number Accepted	334	350	287	292	262
Number Without a RTA Review and > 15 Days Since Date Received	2	6	2	14	42
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	116	117	147	196	138
Rate of Submissions Not Accepted for Review	25.66%	24.74%	33.72%	39.04%	31.22%

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 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	436	454	418	469	426
Deleted or Withdrawn Prior to SI	0	1	1	2	0
SI Within 60 FDA Days	427	448	404	435	399
SI Over 60 FDA Days	6	4	13	25	19
SI Pending Within 60 FDA Days	0	0	0	0	8
SI Pending Over 60 FDA Days	0	0	0	5	0
510(k)s NSE Without SI	3	1	0	2	0
Current SI Performance Percent Within 60 FDA Days	97.94%	98.90%	96.88%	93.15%	95.45%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	433	452	417	460	418
Average Number of FDA Days to Substantive Interaction	51.10	52.60	53.39	54.13	55.26
20th Percentile FDA Days to Substantive Interaction	44	48	51	53	56
40th Percentile FDA Days to Substantive Interaction	55	57	57	57	58
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	67	78	68	77	80

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	436	454	418	469	426
Non-MDUFA IV Decision	50	77	58	49	38
MDUFA IV Decision (SE/NSE)	386	377	359	402	312
MDUFA IV Decision Within 90 FDA Days	382	372	349	393	310
510(k)s Pending MDUFA IV Decision	0	0	1	18	76
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	6	1
Current Performance Percent Within 90 FDA Days	98.96%	98.67%	97.21%	96.32%	99.04%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.74	1.84	1.84	1.83	1.73
Number With MDUFA IV Decision	386	377	359	402	312
Average Number of FDA Days to MDUFA IV Decision	75.68	78.18	78.93	81.06	78.97
20th Percentile FDA Days to MDUFA IV Decision	58	60	67	82	70
40th Percentile FDA Days to MDUFA IV Decision	84	87	87	88	88
60th Percentile FDA Days to MDUFA IV Decision	88	88	89	89	89
80th Percentile FDA Days to MDUFA IV Decision	89	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	118	150	156	199	95
Average Number of Industry Days to MDUFA IV Decision	74.93	95.65	108.07	103.04	70.74
20th Percentile Industry Days to MDUFA IV Decision	0	5	0	1	0
40th Percentile Industry Days to MDUFA IV Decision	29	53	55	62	25
60th Percentile Industry Days to MDUFA IV Decision	94	118	128	117	79
80th Percentile Industry Days to MDUFA IV Decision	165	174	179	173	138
Maximum Industry Days to MDUFA IV Decision	214	444	834	465	364
Average Number of Total Days to MDUFA IV Decision	150.61	173.83	187.01	184.10	149.71
20th Percentile Total Days to MDUFA IV Decision	64	87	87	90	81
40th Percentile Total Days to MDUFA IV Decision	113	140	139	149	112
60th Percentile Total Days to MDUFA IV Decision	177	205	216	203	165
80th Percentile Total Days to MDUFA IV Decision	248	261	266	262	227
Maximum Total Days to MDUFA IV Decision	304	540	990	555	454

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	436	454	418	469	426
Number With MDUFA IV Decision	386	377	359	402	312
Number of SE Decision	361	354	337	369	296
Number of NSE Decision	25	23	22	33	16
Number of Withdrawal	20	31	28	23	24
Number of Deleted	30	44	29	26	14
Rate of SE Decision	93.52%	93.90%	93.87%	91.79%	94.87%
Rate of NSE Decision	6.48%	6.10%	6.13%	8.21%	5.13%
Rate of Withdrawal	4.59%	6.83%	6.70%	4.90%	5.63%
Rate of Deleted	6.88%	9.69%	6.94%	5.54%	3.29%

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	10	9	2
Mean FDA Days for Submissions that Missed the Goal	100.00	111.20	111.50	138.56	93.50
Mean Industry Days for Submissions that Missed the Goal	117.00	332.20	295.80	199.00	37.50

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

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

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

Table 6.1 OHT4 - Office of Surgical and Infection Control Devices
510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	552	604	719	1,016	751
Closed Before RTA Action	2	0	3	4	1
Number Accepted	368	392	447	599	425
Number Without a RTA Review and > 15 Days Since Date Received	6	7	5	36	80
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	176	205	264	377	245
Rate of Submissions Not Accepted for Review	32.00%	33.94%	36.87%	37.25%	32.67%

Table 6.2 OHT4 - Office of Surgical and Infection Control Devices
510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	516	559	654	937	702
Deleted or Withdrawn Prior to SI	0	3	2	3	1
SI Within 60 FDA Days	512	543	626	753	592
SI Over 60 FDA Days	4	12	25	179	98
SI Pending Within 60 FDA Days	0	0	0	1	5
SI Pending Over 60 FDA Days	0	0	0	1	5
510(k)s NSE Without SI	0	1	1	0	1
Current SI Performance Percent Within 60 FDA Days	99.22%	97.66%	96.01%	80.71%	85.06%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	516	555	651	932	690
Average Number of FDA Days to Substantive Interaction	52.60	52.19	53.97	59.22	56.09
20th Percentile FDA Days to Substantive Interaction	50	48	52	54	50
40th Percentile FDA Days to Substantive Interaction	57	56	57	57	57
60th Percentile FDA Days to Substantive Interaction	58	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	69	90	91	414	261

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	516	559	654	937	702
Non-MDUFA IV Decision	68	74	84	112	39
MDUFA IV Decision (SE/NSE)	448	485	568	798	567
MDUFA IV Decision Within 90 FDA Days	440	480	538	608	528
510(k)s Pending MDUFA IV Decision	0	0	2	27	96
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	16	20
Current Performance Percent Within 90 FDA Days	98.21%	98.97%	94.55%	74.69%	89.95%

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	1.68	1.67	1.53
Number With MDUFA IV Decision	448	485	568	798	567
Average Number of FDA Days to MDUFA IV Decision	73.88	73.19	77.57	85.36	74.70
20th Percentile FDA Days to MDUFA IV Decision	57	55	59	74	55
40th Percentile FDA Days to MDUFA IV Decision	79	81	84	87	80
60th Percentile FDA Days to MDUFA IV Decision	87	87	87	89	87
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	92	89
Maximum FDA Days to MDUFA IV Decision	220	207	358	285	231
Average Number of Industry Days to MDUFA IV Decision	48.98	55.75	67.30	65.02	39.92
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	11	8	0
60th Percentile Industry Days to MDUFA IV Decision	31	41	63	48	21
80th Percentile Industry Days to MDUFA IV Decision	110	129	141	128	73
Maximum Industry Days to MDUFA IV Decision	563	507	419	535	361
Average Number of Total Days to MDUFA IV Decision	122.86	128.95	144.87	150.38	114.63
20th Percentile Total Days to MDUFA IV Decision	59	57	60	83	56
40th Percentile Total Days to MDUFA IV Decision	88	88	92	97	86
60th Percentile Total Days to MDUFA IV Decision	110	125	146	141	108
80th Percentile Total Days to MDUFA IV Decision	193	211	229	220	163
Maximum Total Days to MDUFA IV Decision	783	623	717	638	451

Table 6.6 OHT4 - Office of Surgical and Infection Control Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	516	559	654	937	702
Number With MDUFA IV Decision	448	485	568	798	567
Number of SE Decision	437	471	555	787	562
Number of NSE Decision	11	14	13	11	5
Number of Withdrawal	36	37	37	41	28
Number of Deleted	31	35	46	70	10
Rate of SE Decision	97.54%	97.11%	97.71%	98.62%	99.12%
Rate of NSE Decision	2.46%	2.89%	2.29%	1.38%	0.88%
Rate of Withdrawal	6.98%	6.62%	5.66%	4.38%	3.99%
Rate of Deleted	6.01%	6.26%	7.03%	7.47%	1.42%

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	5	30	190	39
Mean FDA Days for Submissions that Missed the Goal	119.50	120.00	120.33	112.88	120.79
Mean Industry Days for Submissions that Missed the Goal	168.63	207.40	154.73	81.41	56.97

Table 6.8 OHT4 - Office of Surgical and Infection Control Devices

LDT 510(k) MDUFA IV Decision Metric

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	260	274	261	276	290
Closed Before RTA Action	3	0	3	1	2
Number Accepted	147	155	110	135	137
Number Without a RTA Review and > 15 Days Since Date Received	3	7	5	8	23
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	107	112	143	132	128
Rate of Submissions Not Accepted for Review	41.63%	40.88%	55.43%	48.00%	44.44%

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	236	260	240	258	257
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	232	257	231	256	250
SI Over 60 FDA Days	4	3	9	2	4
SI Pending Within 60 FDA Days	0	0	0	0	3
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%	96.25%	99.22%	98.43%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	236	260	240	258	254
Average Number of FDA Days to Substantive Interaction	53.91	54.53	53.39	53.68	54.70
20th Percentile FDA Days to Substantive Interaction	53	54	49	54	56
40th Percentile FDA Days to Substantive Interaction	58	58	58	58	58
60th Percentile FDA Days to Substantive Interaction	60	60	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	86	63	87	66	64

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	236	260	240	258	257
Non-MDUFA IV Decision	30	31	17	31	14
MDUFA IV Decision (SE/NSE)	206	229	221	223	205
MDUFA IV Decision Within 90 FDA Days	201	222	221	222	201
510(k)s Pending MDUFA IV Decision	0	0	2	4	38
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	1	0
Current Performance Percent Within 90 FDA Days	97.57%	96.94%	100.00%	99.11%	98.05%

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	1.61	1.64
Number With MDUFA IV Decision	206	229	221	223	205
Average Number of FDA Days to MDUFA IV Decision	76.47	80.32	75.70	76.38	78.10
20th Percentile FDA Days to MDUFA IV Decision	60	69	60	57	59
40th Percentile FDA Days to MDUFA IV Decision	86	88	87	86	87
60th Percentile FDA Days to MDUFA IV Decision	89	90	89	89	89
80th Percentile FDA Days to MDUFA IV Decision	90	90	90	90	90
Maximum FDA Days to MDUFA IV Decision	170	152	90	131	176
Average Number of Industry Days to MDUFA IV Decision	42.60	55.79	61.13	73.86	54.01
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	8
60th Percentile Industry Days to MDUFA IV Decision	38	39	26	65	46
80th Percentile Industry Days to MDUFA IV Decision	84	129	125	159	100
Maximum Industry Days to MDUFA IV Decision	187	391	360	361	357
Average Number of Total Days to MDUFA IV Decision	119.07	136.10	136.83	150.23	132.11
20th Percentile Total Days to MDUFA IV Decision	61	83	60	64	71
40th Percentile Total Days to MDUFA IV Decision	89	90	89	90	91
60th Percentile Total Days to MDUFA IV Decision	117	125	113	149	133
80th Percentile Total Days to MDUFA IV Decision	171	219	212	249	193
Maximum Total Days to MDUFA IV Decision	346	543	449	451	447

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	236	260	240	258	257
Number With MDUFA IV Decision	206	229	221	223	205
Number of SE Decision	198	222	210	210	191
Number of NSE Decision	8	7	11	13	14
Number of Withdrawal	17	16	13	17	9
Number of Deleted	10	14	4	14	5
Rate of SE Decision	96.12%	96.94%	95.02%	94.17%	93.17%
Rate of NSE Decision	3.88%	3.06%	4.98%	5.83%	6.83%
Rate of Withdrawal	7.20%	6.15%	5.42%	6.59%	3.50%
Rate of Deleted	4.24%	5.38%	1.67%	5.43%	1.95%

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	4
Mean FDA Days for Submissions that Missed the Goal	111.40	119.43	0.00	131.00	114.75
Mean Industry Days for Submissions that Missed the Goal	80.60	110.29	0.00	153.00	94.25

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

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

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

Table 6.1 OHT6 - Office of Orthopedic Devices

510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	606	634	656	578	604
Closed Before RTA Action	2	4	5	2	2
Number Accepted	466	489	493	435	386
Number Without a RTA Review and > 15 Days Since Date Received	0	5	6	6	51
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	138	136	152	135	165
Rate of Submissions Not Accepted for Review	22.85%	21.59%	23.35%	23.44%	27.41%

Table 6.2 OHT6 - Office of Orthopedic Devices

510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	594	622	639	562	581
Deleted or Withdrawn Prior to SI	0	2	3	1	2
SI Within 60 FDA Days	575	617	635	560	574
SI Over 60 FDA Days	19	3	1	1	0
SI Pending Within 60 FDA Days	0	0	0	0	2
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	0	3
Current SI Performance Percent Within 60 FDA Days	96.80%	99.52%	99.84%	99.82%	99.48%

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	636	561	574
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.84	50.33	52.14
20th Percentile FDA Days to Substantive Interaction	39	30	30	35	49
40th Percentile FDA Days to Substantive Interaction	55	56	56	55	56
60th Percentile FDA Days to Substantive Interaction	57	58	58	58	58
80th Percentile FDA Days to Substantive Interaction	59	60	60	59	60
Maximum FDA Days to Substantive Interaction	78	64	61	90	60

Table 6.4 OHT6 - Office of Orthopedic Devices**510(k) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	594	622	639	562	581
Non-MDUFA IV Decision	40	47	61	41	33
MDUFA IV Decision (SE/NSE)	554	575	578	517	491
MDUFA IV Decision Within 90 FDA Days	552	574	578	516	491
510(k)s Pending MDUFA IV Decision	0	0	0	4	57
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%	99.81%	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	1.52	1.54	1.49
Number With MDUFA IV Decision	554	575	578	517	491
Average Number of FDA Days to MDUFA IV Decision	71.36	70.57	66.99	66.56	68.23
20th Percentile FDA Days to MDUFA IV Decision	52	51	37	44	49
40th Percentile FDA Days to MDUFA IV Decision	74	76	60	60	62
60th Percentile FDA Days to MDUFA IV Decision	86	87	86	85	85
80th Percentile FDA Days to MDUFA IV Decision	89	89	89	88	88
Maximum FDA Days to MDUFA IV Decision	135	91	90	151	90
Average Number of Industry Days to MDUFA IV Decision	48.84	50.98	54.52	58.68	44.23
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	10	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	34	29	20	32	26
80th Percentile Industry Days to MDUFA IV Decision	103	103	99	111	96
Maximum Industry Days to MDUFA IV Decision	340	444	667	540	360
Average Number of Total Days to MDUFA IV Decision	120.19	121.55	121.51	125.23	112.46
20th Percentile Total Days to MDUFA IV Decision	57	56	38	47	53
40th Percentile Total Days to MDUFA IV Decision	86	87	67	64	71
60th Percentile Total Days to MDUFA IV Decision	115	111	103	110	109
80th Percentile Total Days to MDUFA IV Decision	189	185	184	198	177
Maximum Total Days to MDUFA IV Decision	430	533	756	630	449

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	639	562	581
Number With MDUFA IV Decision	554	575	578	517	491
Number of SE Decision	540	563	574	513	484
Number of NSE Decision	14	12	4	4	7
Number of Withdrawal	24	28	38	30	26
Number of Deleted	16	19	23	11	6
Rate of SE Decision	97.47%	97.91%	99.31%	99.23%	98.57%
Rate of NSE Decision	2.53%	2.09%	0.69%	0.77%	1.43%
Rate of Withdrawal	4.04%	4.50%	5.95%	5.34%	4.48%
Rate of Deleted	2.69%	3.05%	3.60%	1.96%	1.03%

Table 6.7 OHT6 - Office of Orthopedic Devices

510(k) Performance Metric - Submissions Missing Performance Goal

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

Table 6.8 OHT6 - Office of Orthopedic Devices

LDT 510(k) MDUFA IV Decision Metric

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

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

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

Table 6.1 OHT7 - Office of In Vitro Diagnostics

510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	290	300	271	205	242
Closed Before RTA Action	3	3	3	1	7
Number Accepted	245	237	191	56	122
Number Without a RTA Review and > 15 Days Since Date Received	1	4	18	116	83
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	41	56	59	32	30
Rate of Submissions Not Accepted for Review	14.29%	18.86%	22.01%	15.69%	12.77%

Table 6.2 OHT7 - Office of In Vitro Diagnostics

510(k) Substantive Interaction Performance Goal

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	274	279	257	196	223
Deleted or Withdrawn Prior to SI	1	1	3	6	2
SI Within 60 FDA Days	271	273	204	19	15
SI Over 60 FDA Days	1	2	50	171	193
SI Pending Within 60 FDA Days	0	0	0	0	0
SI Pending Over 60 FDA Days	0	0	0	0	13
510(k)s NSE Without SI	1	3	0	0	0
Current SI Performance Percent Within 60 FDA Days	99.27%	98.20%	80.31%	10.00%	6.79%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	272	275	254	190	208
Average Number of FDA Days to Substantive Interaction	50.56	49.13	93.22	162.30	118.18
20th Percentile FDA Days to Substantive Interaction	44	30	45	116	99
40th Percentile FDA Days to Substantive Interaction	54	53	58	128	118
60th Percentile FDA Days to Substantive Interaction	58	58	60	170	120
80th Percentile FDA Days to Substantive Interaction	59	60	60	238	129
Maximum FDA Days to Substantive Interaction	61	61	496	381	287

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	274	279	257	196	223
Non-MDUFA IV Decision	42	37	52	44	20
MDUFA IV Decision (SE/NSE)	232	242	202	139	101
MDUFA IV Decision Within 90 FDA Days	231	238	124	13	14
510(k)s Pending MDUFA IV Decision	0	0	3	13	102
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	3	13	98
Current Performance Percent Within 90 FDA Days	99.57%	98.35%	60.49%	8.55%	7.04%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.51	1.36	1.57	1.55	1.38
Number With MDUFA IV Decision	232	242	202	139	101
Average Number of FDA Days to MDUFA IV Decision	72.98	71.48	161.47	227.68	168.79
20th Percentile FDA Days to MDUFA IV Decision	53	31	56	139	119
40th Percentile FDA Days to MDUFA IV Decision	84	60	87	210	166
60th Percentile FDA Days to MDUFA IV Decision	88	87	90	259	207
80th Percentile FDA Days to MDUFA IV Decision	90	90	306	307	211
Maximum FDA Days to MDUFA IV Decision	93	655	673	576	344
Average Number of Industry Days to MDUFA IV Decision	58.27	46.80	81.54	89.15	33.77
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	52	0	69	93	0
80th Percentile Industry Days to MDUFA IV Decision	145	129	162	179	63
Maximum Industry Days to MDUFA IV Decision	231	448	617	375	303
Average Number of Total Days to MDUFA IV Decision	131.25	118.28	243.00	316.83	202.56
20th Percentile Total Days to MDUFA IV Decision	55	31	58	144	120
40th Percentile Total Days to MDUFA IV Decision	88	67	90	223	189
60th Percentile Total Days to MDUFA IV Decision	134	90	229	371	210
80th Percentile Total Days to MDUFA IV Decision	235	194	472	470	277
Maximum Total Days to MDUFA IV Decision	321	871	876	767	526

Table 6.6 OHT7 - Office of In Vitro Diagnostics

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	274	279	257	196	223
Number With MDUFA IV Decision	232	242	202	139	101
Number of SE Decision	221	234	196	135	101
Number of NSE Decision	11	8	6	4	0
Number of Withdrawal	26	14	29	31	15
Number of Deleted	15	23	22	13	5
Rate of SE Decision	95.26%	96.69%	97.03%	97.12%	100.00%
Rate of NSE Decision	4.74%	3.31%	2.97%	2.88%	0.00%
Rate of Withdrawal	9.49%	5.02%	11.28%	15.82%	6.73%
Rate of Deleted	5.47%	8.24%	8.56%	6.63%	2.24%

Table 6.7 OHT7 - Office of In Vitro Diagnostics

510(k) Performance Metric - Submissions Missing Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	4	78	126	87
Mean FDA Days for Submissions that Missed the Goal	93.00	370.00	314.72	245.39	188.38
Mean Industry Days for Submissions that Missed the Goal	202.00	268.00	150.91	97.61	39.11

Table 6.8 OHT7 - Office of In Vitro Diagnostics

LDT 510(k) MDUFA IV Decision Metric

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	2	1	4	1	3
Non-MDUFA IV Decision	1	0	0	1	0
MDUFA IV Decision (SE/NSE)	1	1	4	0	2
MDUFA IV Decision Within 90 FDA Days	1	1	2	0	0
510(k)s Pending MDUFA IV Decision	0	0	0	0	1
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	1
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	50.00%	N/A	0.00%

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	272	278	253	195	220
Non-MDUFA IV Decision	41	37	52	43	20
MDUFA IV Decision (SE/NSE)	231	241	198	139	99
MDUFA IV Decision Within 90 FDA Days	230	237	122	13	14
510(k)s Pending MDUFA IV Decision	0	0	3	13	101
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	3	13	97
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	60.70%	8.55%	7.14%

Table 6.1 OHT8 - Office of Radiological Health**510(k) Acceptance Review Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	391	384	434	451	475
Closed Before RTA Action	0	1	2	1	2
Number Accepted	348	307	361	361	374
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1	12	30
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	42	73	70	77	69
Rate of Submissions Not Accepted for Review	10.74%	19.06%	16.20%	17.11%	14.59%

Table 6.2 OHT8 - Office of Radiological Health**510(k) Substantive Interaction Performance Goal**

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	385	373	422	439	469
Deleted or Withdrawn Prior to SI	1	0	0	0	1
SI Within 60 FDA Days	384	373	422	436	464
SI Over 60 FDA Days	0	0	0	0	0
SI Pending Within 60 FDA Days	0	0	0	0	3
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	3	1
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	100.00%	99.32%	99.78%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	384	373	422	436	464
Average Number of FDA Days to Substantive Interaction	43.70	44.96	46.49	48.76	49.17
20th Percentile FDA Days to Substantive Interaction	29	28	29	36	39
40th Percentile FDA Days to Substantive Interaction	42	47	49	51	52
60th Percentile FDA Days to Substantive Interaction	52	54	55	56	57
80th Percentile FDA Days to Substantive Interaction	57	58	58	59	59
Maximum FDA Days to Substantive Interaction	60	60	60	60	60

Table 6.4 OHT8 - Office of Radiological Health**510(k) MDUFA IV Decision Performance Goal**

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	385	373	422	439	469
Non-MDUFA IV Decision	14	22	20	25	25
MDUFA IV Decision (SE/NSE)	371	351	402	410	404
MDUFA IV Decision Within 90 FDA Days	371	351	402	410	404
510(k)s Pending MDUFA IV Decision	0	0	0	4	40
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	100.00%

**Table 6.5 OHT8 - Office of Radiological Health
510(k) Time to MDUFA IV Decision**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.50	1.54	1.56	1.55
Number With MDUFA IV Decision	371	351	402	410	404
Average Number of FDA Days to MDUFA IV Decision	58.72	61.13	63.56	68.38	68.02
20th Percentile FDA Days to MDUFA IV Decision	30	28	29	48	49
40th Percentile FDA Days to MDUFA IV Decision	55	58	60	71	68
60th Percentile FDA Days to MDUFA IV Decision	73	77	82	86	85
80th Percentile FDA Days to MDUFA IV Decision	84	86	87	88	89
Maximum FDA Days to MDUFA IV Decision	90	90	90	90	90
Average Number of Industry Days to MDUFA IV Decision	33.09	40.27	44.85	53.62	46.37
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	19	23	32	34	35
80th Percentile Industry Days to MDUFA IV Decision	56	81	87	104	87
Maximum Industry Days to MDUFA IV Decision	181	329	357	613	360
Average Number of Total Days to MDUFA IV Decision	91.81	101.40	108.41	122.00	114.39
20th Percentile Total Days to MDUFA IV Decision	30	28	29	48	50
40th Percentile Total Days to MDUFA IV Decision	58	59	63	80	83
60th Percentile Total Days to MDUFA IV Decision	93	103	114	118	119
80th Percentile Total Days to MDUFA IV Decision	138	165	167	190	169
Maximum Total Days to MDUFA IV Decision	270	416	447	700	445

Table 6.6 OHT8 - Office of Radiological Health

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	385	373	422	439	469
Number With MDUFA IV Decision	371	351	402	410	404
Number of SE Decision	360	348	397	400	397
Number of NSE Decision	11	3	5	10	7
Number of Withdrawal	7	8	13	14	20
Number of Deleted	5	5	6	11	5
Rate of SE Decision	97.04%	99.15%	98.76%	97.56%	98.27%
Rate of NSE Decision	2.96%	0.85%	1.24%	2.44%	1.73%
Rate of Withdrawal	1.82%	2.14%	3.08%	3.19%	4.26%
Rate of Deleted	1.30%	1.34%	1.42%	2.51%	1.07%

Table 6.7 OHT8 - Office of Radiological Health

510(k) Performance Metric - Submissions Missing Performance Goal

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

Table 6.8 OHT8 - Office of Radiological Health

LDT 510(k) MDUFA IV Decision Metric

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

Table 6.9 OHT8 - Office of Radiological Health

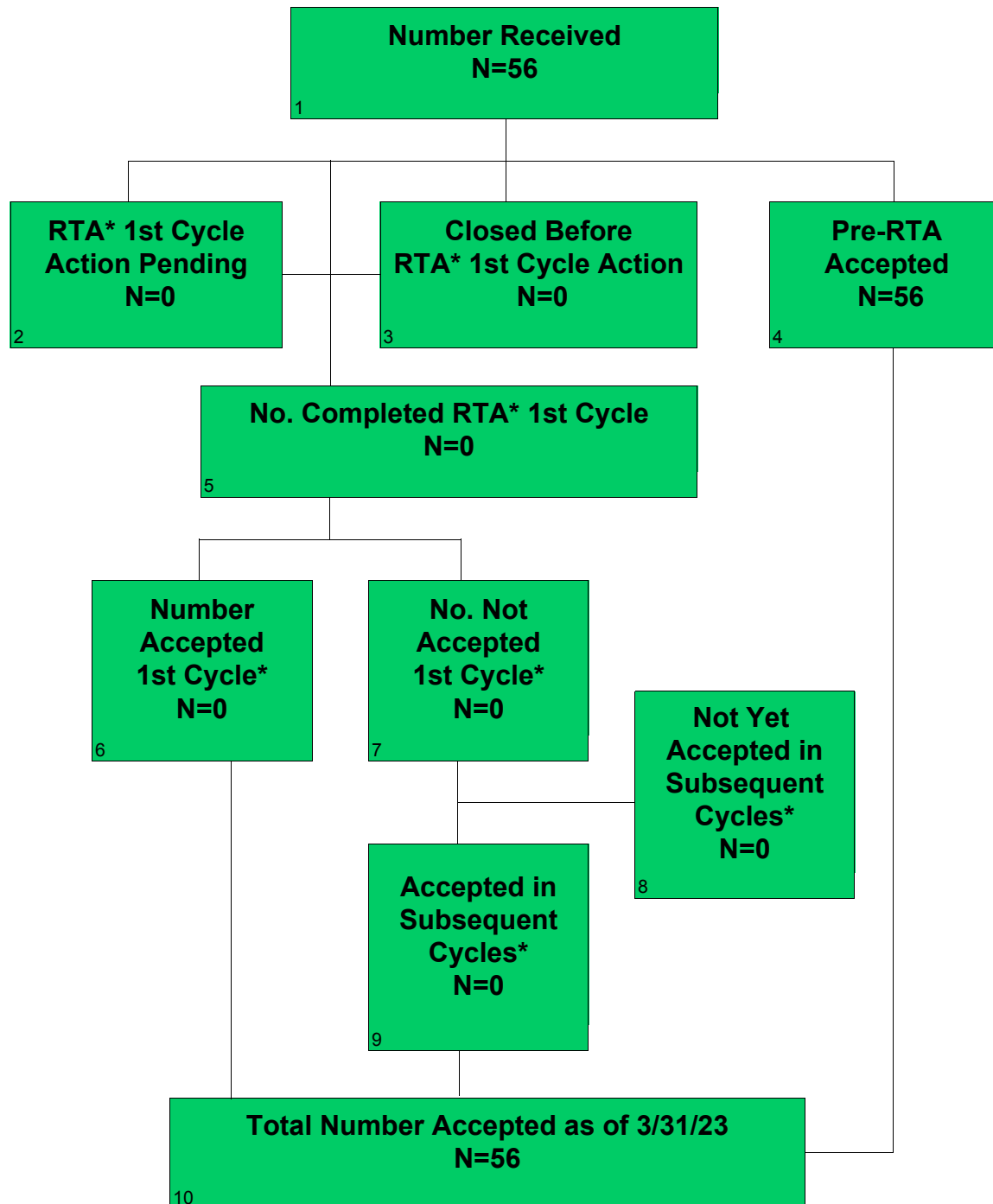
Conventional IVD (Non-LDT) 510(k) MDUFA IV Decision Metric

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

Section 7 510(k) Annual General Metrics

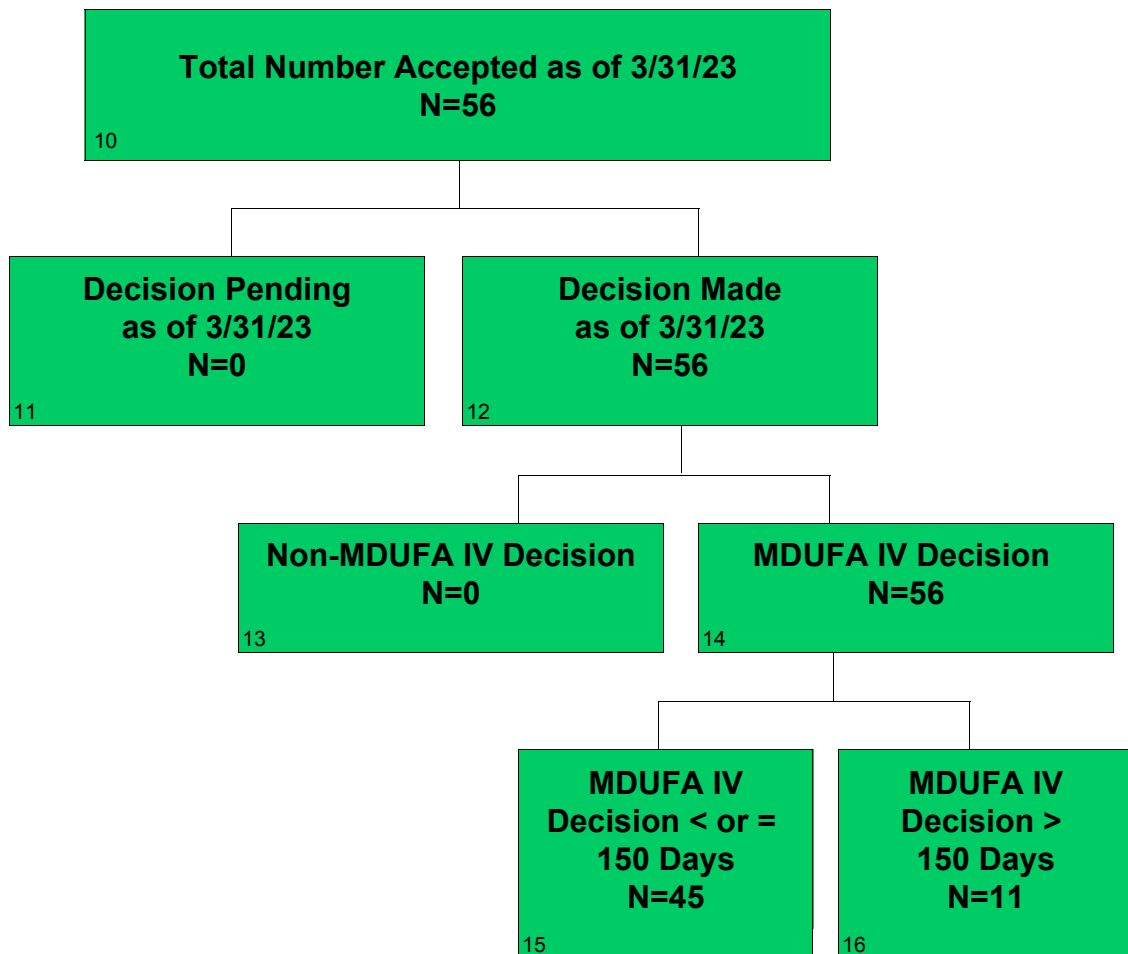
510(k) Annual Metrics and Goals will be reported in the Annual Report.

CDRH De Novo - FY 2018 as of 3/31/23

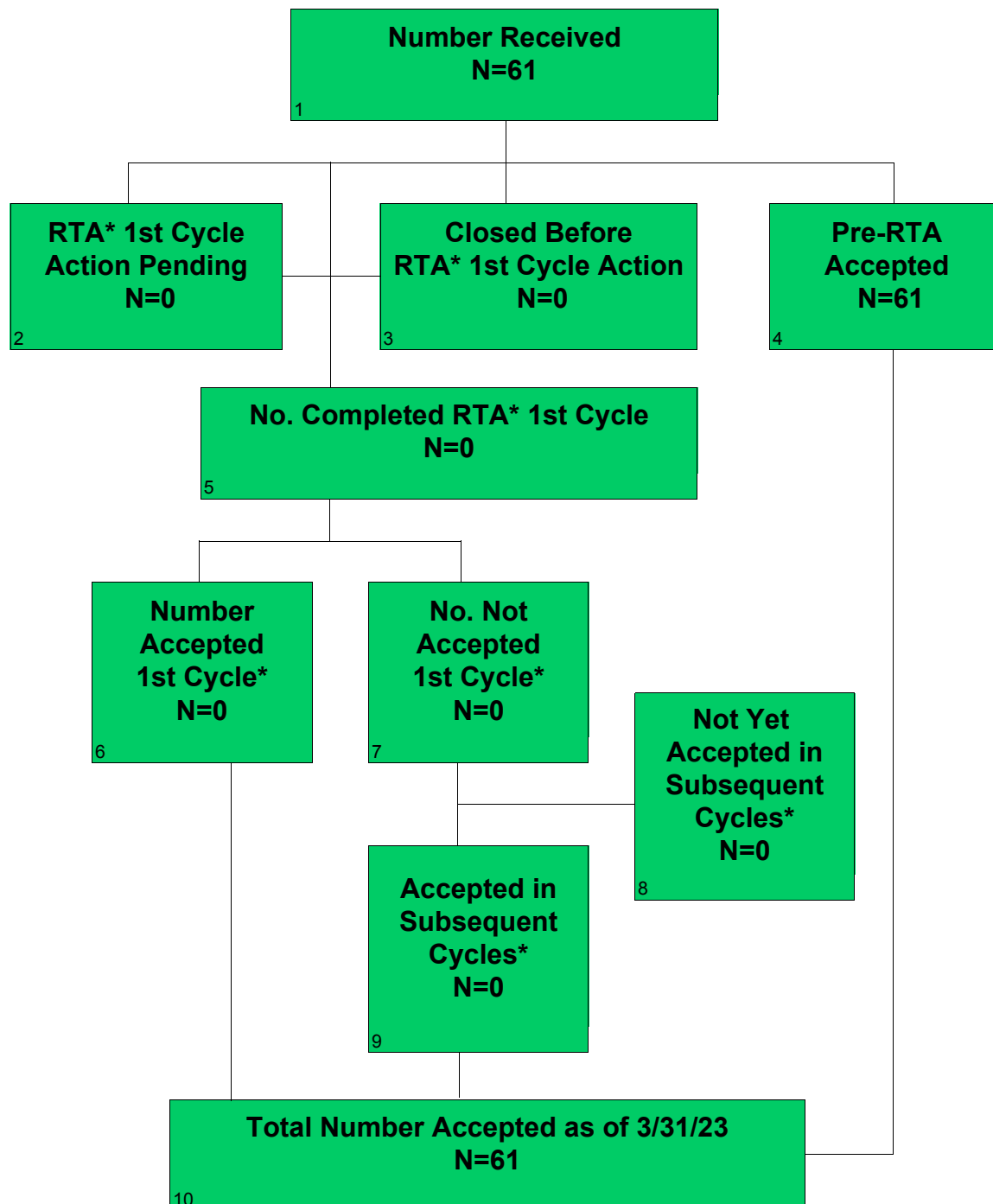


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018 as of 3/31/23 Continued

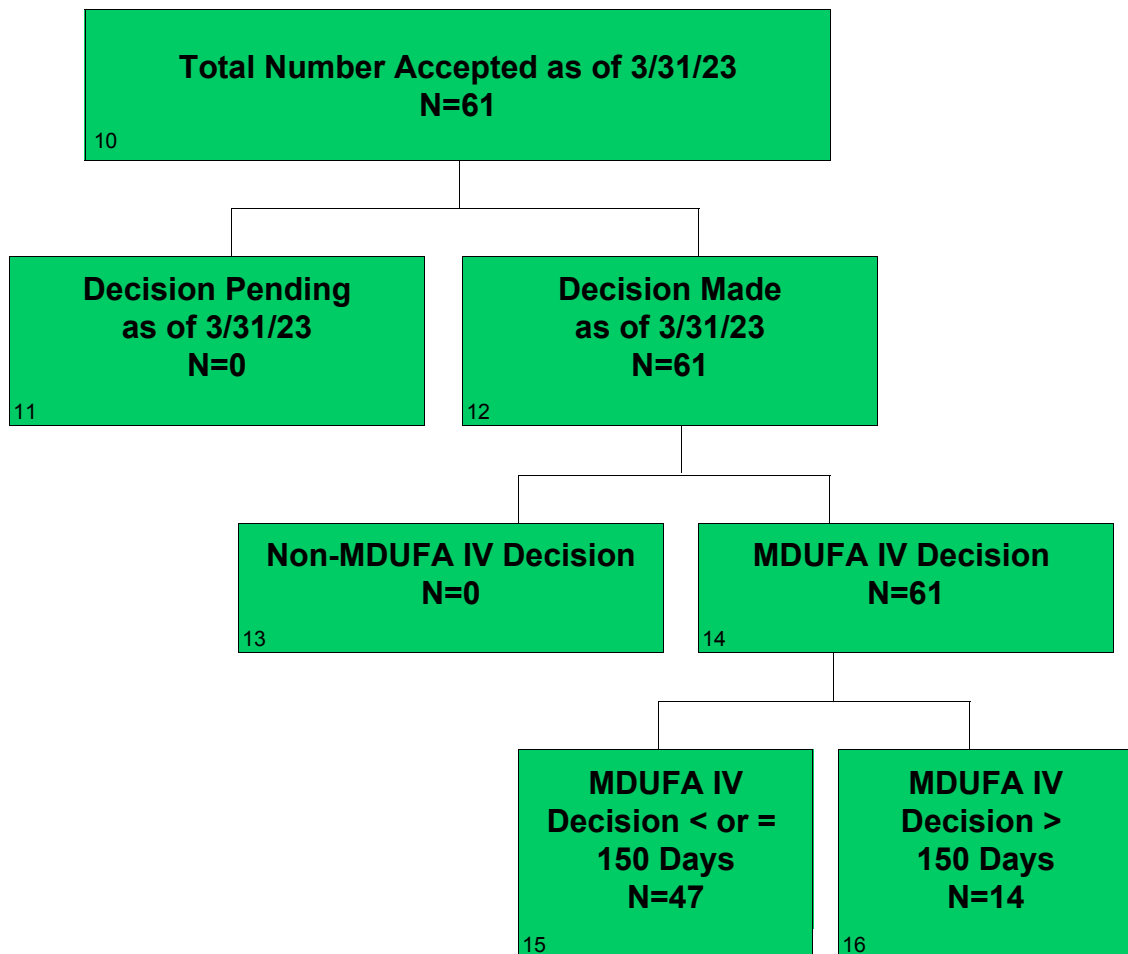


CDRH De Novo - FY 2019 as of 3/31/23

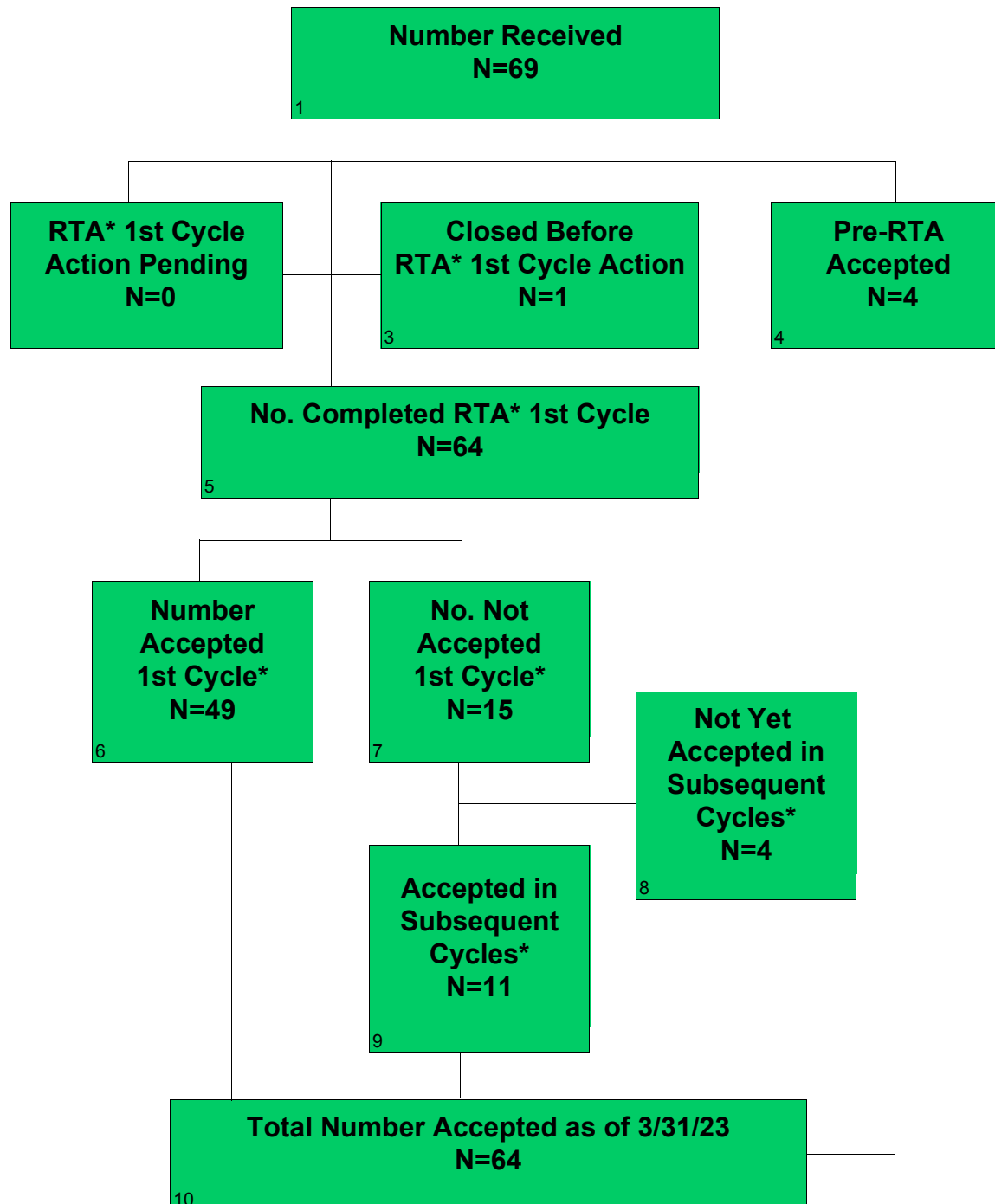


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019 as of 3/31/23 Continued

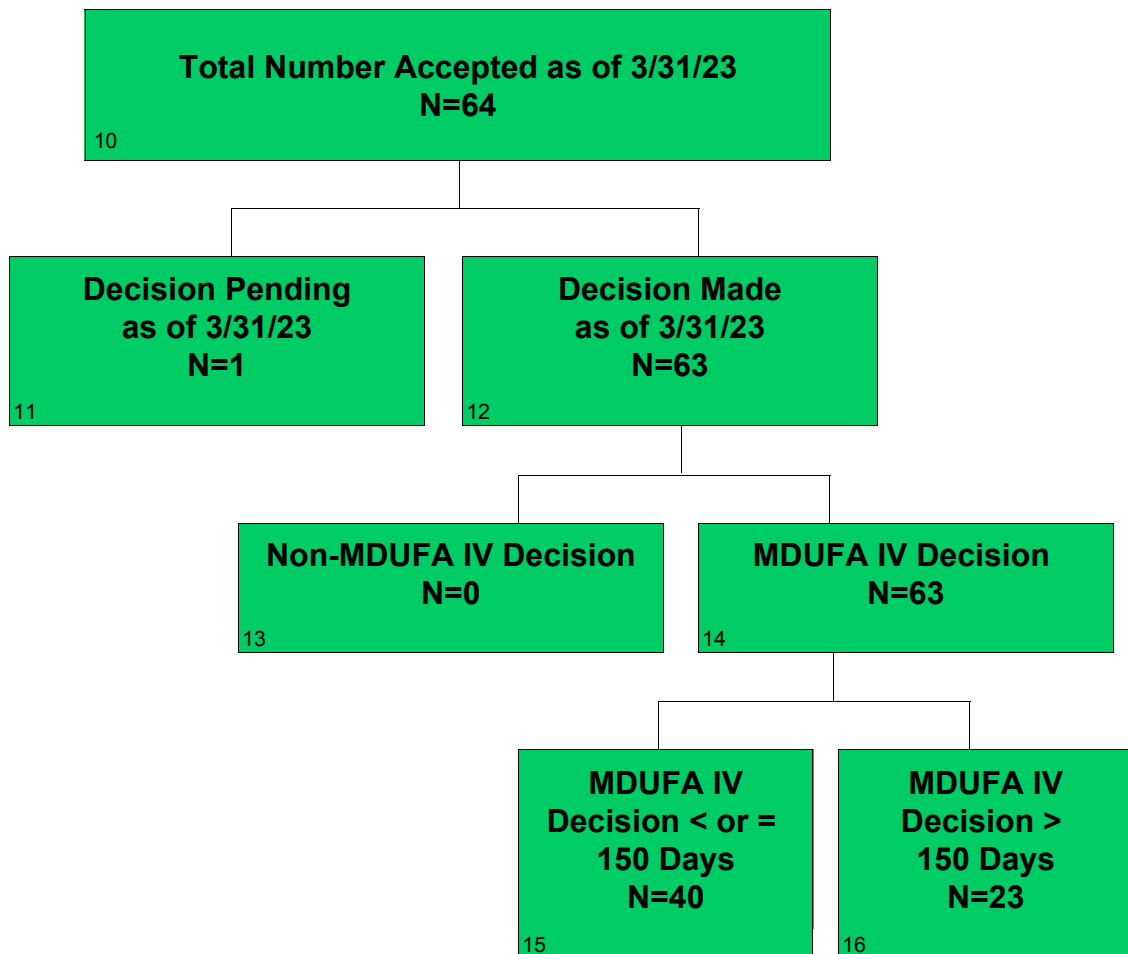


CDRH De Novo - FY 2020 as of 3/31/23

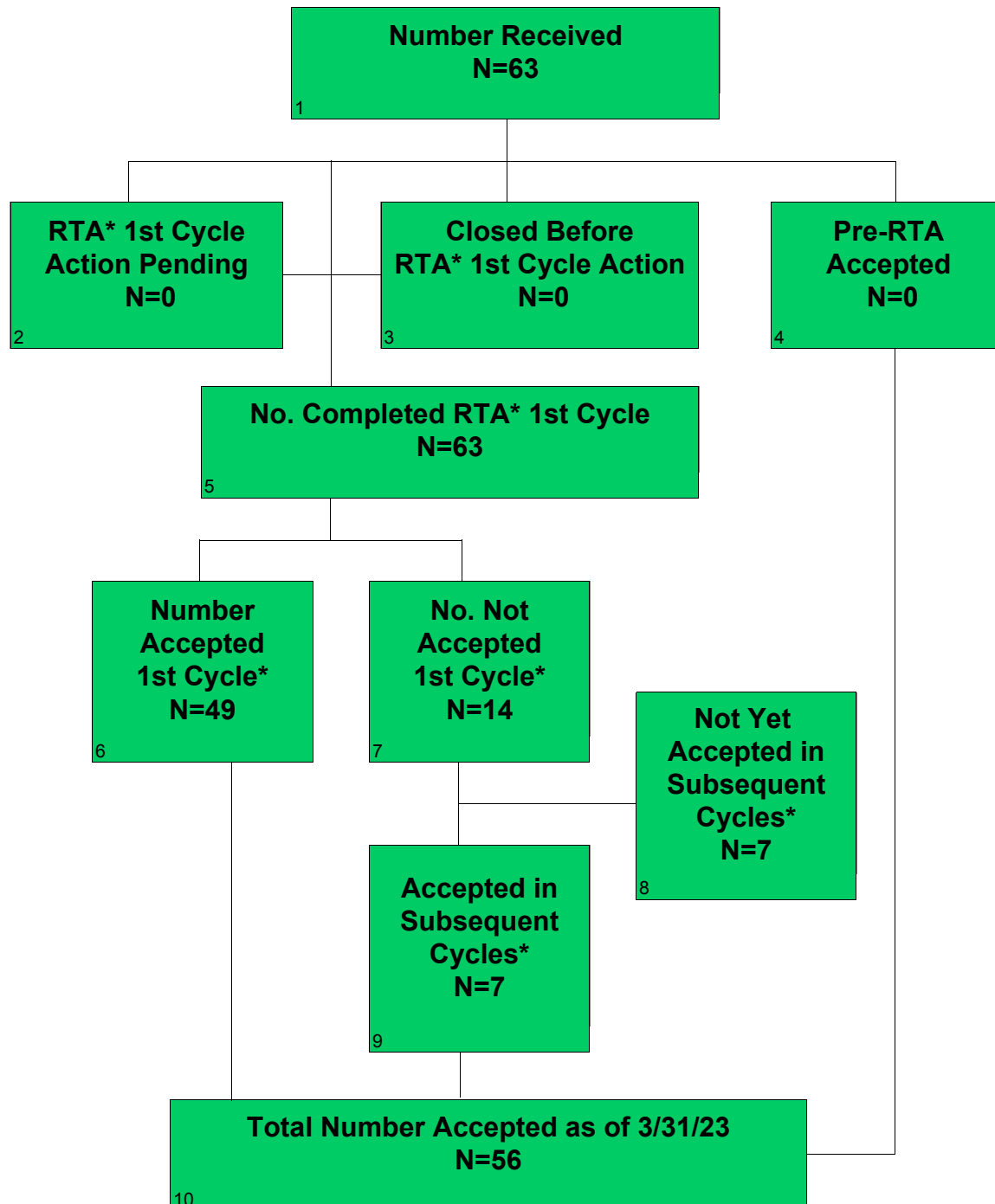


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020 as of 3/31/23 Continued

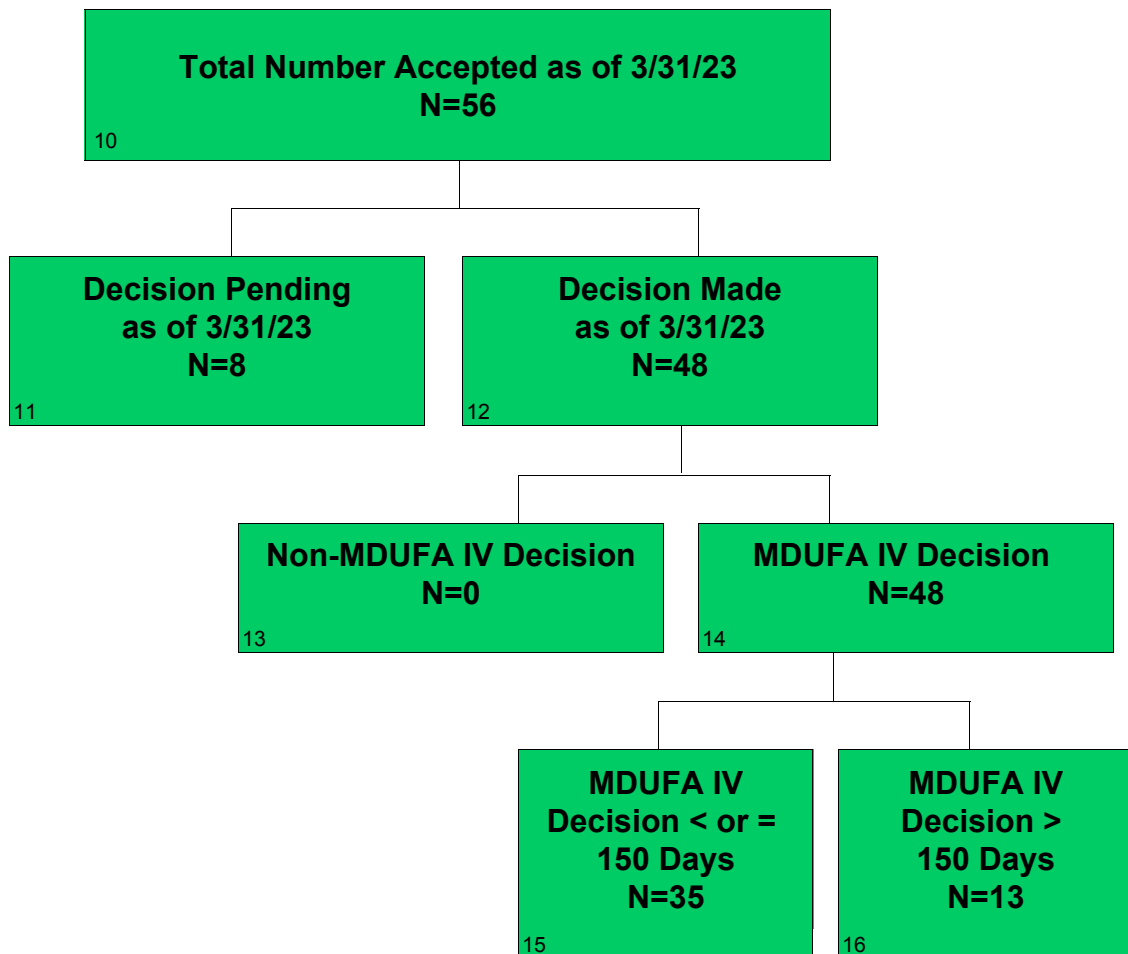


CDRH De Novo - FY 2021 as of 3/31/23

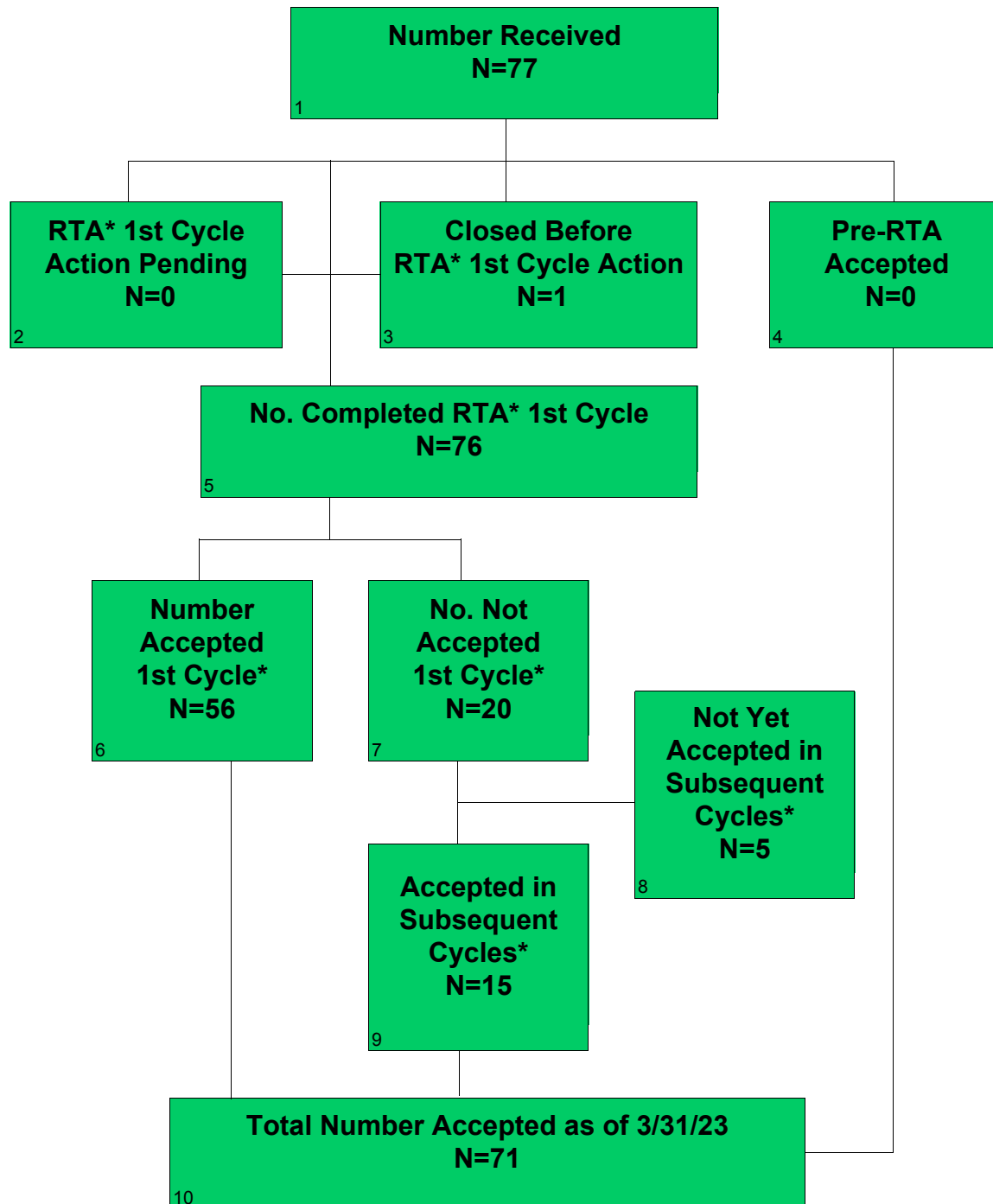


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2021 as of 3/31/23 Continued

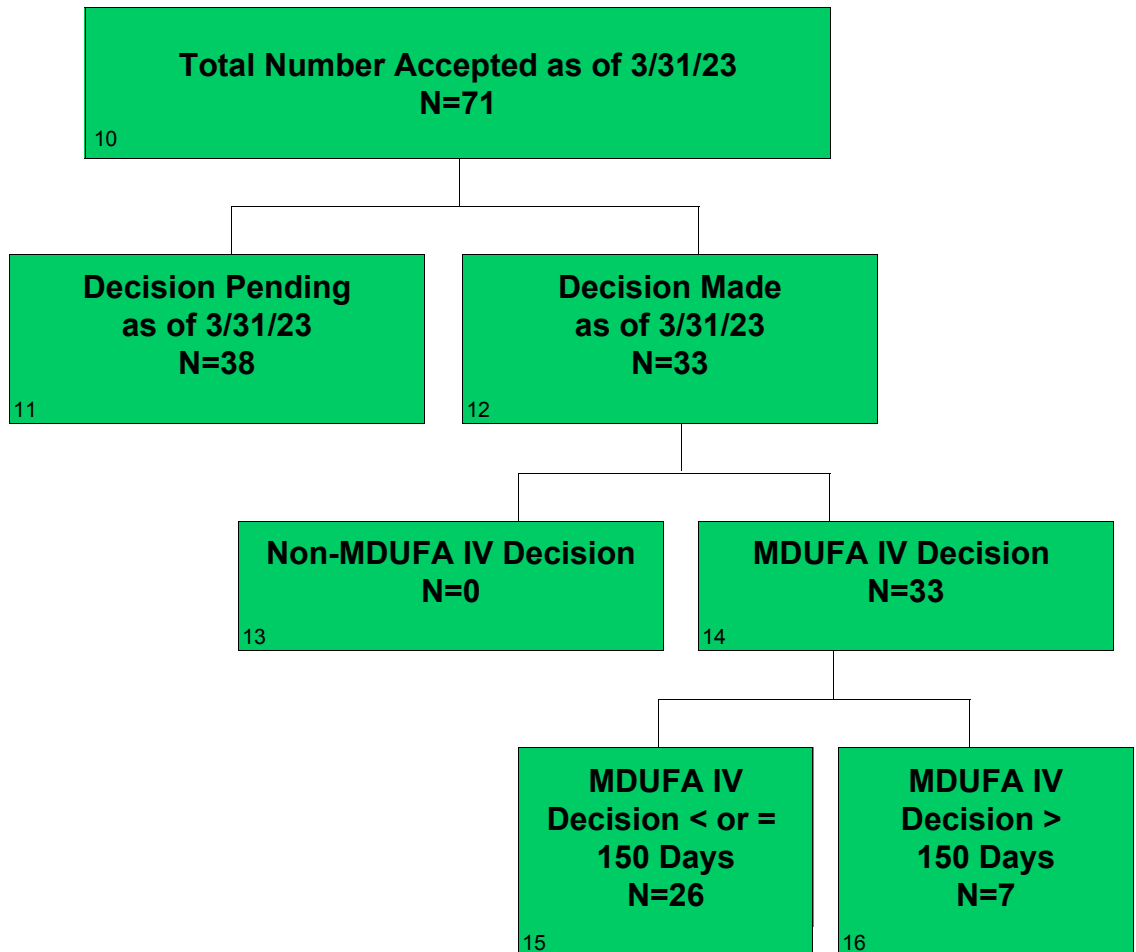


CDRH De Novo - FY 2022 as of 3/31/23



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

CDRH De Novo - FY 2022 as of 3/31/23 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	77
Closed Before RTA Action	N/A	N/A	1	0	1
Number Accepted First RTA Cycle	N/A	N/A	46	41	46
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	3	8	10
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	15	14	20
Rate of Submissions Not Accepted for Review	N/A	N/A	23.44%	22.22%	26.32%

*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 50% Within 150 FDA Days	FY 2019 55% Within 150FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	56	61	64	56	71
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	56	61	63	48	33
MDUFA IV Decisions Within 150 FDA Days	45	47	40	35	26
De Novos Pending MDUFA IV Decision	0	0	1	8	38
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	5	6
Current Performance Percent Within 150 FDA Days	80.36%	77.05%	62.50%	66.04%	66.67%

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	1.81	1.77	1.48
Number With MDUFA IV Decision	56	61	63	48	33
Average FDA Days to MDUFA IV Decision	130.13	143.57	190.14	173.13	136.52
20th Percentile FDA Days to MDUFA IV Decision	75	76	121	141	76
40th Percentile FDA Days to MDUFA IV Decision	145	130	149	149	149
60th Percentile FDA Days to MDUFA IV Decision	150	148	150	150	150
80th Percentile FDA Days to MDUFA IV Decision	150	180	228	209	164
Maximum FDA Days to MDUFA IV Decision	254	485	762	459	231
Average Industry Days to MDUFA IV Decision	110.13	117.44	183.54	202.48	101.36
20th Percentile Industry Days to MDUFA IV Decision	0	0	37	74	0
40th Percentile Industry Days to MDUFA IV Decision	89	29	140	134	62
60th Percentile Industry Days to MDUFA IV Decision	166	177	233	231	140
80th Percentile Industry Days to MDUFA IV Decision	180	204	334	358	177
Maximum Industry Days to MDUFA IV Decision	389	373	431	427	357
Average Total Days to MDUFA IV Decision	240.25	261.02	373.68	375.60	237.88
20th Percentile Total Days to MDUFA IV Decision	145	107	211	230	159
40th Percentile Total Days to MDUFA IV Decision	251	179	313	284	213
60th Percentile Total Days to MDUFA IV Decision	292	304	402	441	260
80th Percentile Total Days to MDUFA IV Decision	324	388	490	531	325
Maximum Total Days to MDUFA IV Decision	463	680	1,136	680	507

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	56	71
Number With MDUFA IV Decisions	56	61	63	48	33
Number With Granted Decisions	25	28	33	24	13
Number With Declined Decisions	15	15	16	11	8
Number of Withdrawals	10	13	9	9	10
Number Deleted	6	5	5	4	2
Rate of Granted Decisions	44.64%	45.90%	52.38%	50.00%	39.39%
Rate of Declined Decisions	26.79%	24.59%	25.40%	22.92%	24.24%
Rate of Withdrawals	17.86%	21.31%	14.29%	18.75%	30.30%
Rate of Deleted	10.71%	8.20%	7.94%	8.33%	6.06%

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	23	13	7
Mean FDA Days for Submissions that Missed the Goal	192.45	248.29	305.30	277.92	199.71
Mean Industry Days for Submissions that Missed the Goal	127.27	218.64	206.35	218.77	48.29

Table 8.6 CDRH - LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5	2	0	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	5	2	0	2
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	1
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	100.00%	40.00%	0.00%	N/A	50.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14	16	13	14
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	15	8	4
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	1	5	10
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	5	4
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	7.69%	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	12
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	10	8	6
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	6
Rate of Submissions Not Accepted for Review	N/A	N/A	16.67%	27.27%	50.00%

*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 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	8	5	13	10	10
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	8	5	13	9	5
MDUFA IV Decisions Within 150 FDA Days	5	4	10	8	4
De Novos Pending MDUFA IV Decision	0	0	0	1	5
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	62.50%	80.00%	76.92%	88.89%	80.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.63	1.80	1.85	2.00	1.20
Number With MDUFA IV Decision	8	5	13	9	5
Average FDA Days to MDUFA IV Decision	141.25	124.80	186.15	163.67	125.20
20th Percentile FDA Days to MDUFA IV Decision	110	75	74	149	75
40th Percentile FDA Days to MDUFA IV Decision	149	119	148	149	120
60th Percentile FDA Days to MDUFA IV Decision	153	148	149	150	150
80th Percentile FDA Days to MDUFA IV Decision	165	154	179	150	155
Maximum FDA Days to MDUFA IV Decision	194	180	762	281	176
Average Industry Days to MDUFA IV Decision	106.13	195.20	211.08	231.78	101.20
20th Percentile Industry Days to MDUFA IV Decision	9	185	111	105	0
40th Percentile Industry Days to MDUFA IV Decision	45	192	157	141	84
60th Percentile Industry Days to MDUFA IV Decision	75	199	276	310	157
80th Percentile Industry Days to MDUFA IV Decision	167	206	342	366	182
Maximum Industry Days to MDUFA IV Decision	389	212	374	415	184
Average Total Days to MDUFA IV Decision	247.38	320.00	397.23	395.44	226.40
20th Percentile Total Days to MDUFA IV Decision	157	268	271	255	171
40th Percentile Total Days to MDUFA IV Decision	199	304	316	289	225
60th Percentile Total Days to MDUFA IV Decision	260	336	395	467	258
80th Percentile Total Days to MDUFA IV Decision	332	360	454	549	265
Maximum Total Days to MDUFA IV Decision	463	392	1,136	623	290

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	8	5	13	10	10
Number With MDUFA IV Decisions	8	5	13	9	5
Number With Granted Decisions	5	2	6	6	2
Number With Declined Decisions	2	1	4	2	1
Number of Withdrawals	0	0	2	1	0
Number Deleted	1	2	1	0	2
Rate of Granted Decisions	62.50%	40.00%	46.15%	66.67%	40.00%
Rate of Declined Decisions	25.00%	20.00%	30.77%	22.22%	20.00%
Rate of Withdrawals	0.00%	0.00%	15.38%	11.11%	0.00%
Rate of Deleted	12.50%	40.00%	7.69%	0.00%	40.00%

**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	3	1	1
Mean FDA Days for Submissions that Missed the Goal	174.67	180.00	416.00	281.00	176.00
Mean Industry Days for Submissions that Missed the Goal	127.00	212.00	286.33	342.00	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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

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

**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	9
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	6	4	6
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	3
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 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	5	9	8	5	9
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	5	9	8	5	6
MDUFA IV Decisions Within 150 FDA Days	5	8	3	5	6
De Novos Pending MDUFA IV Decision	0	0	0	0	3
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	100.00%	88.89%	37.50%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.20	1.44	2.00	1.40	1.67
Number With MDUFA IV Decision	5	9	8	5	6
Average FDA Days to MDUFA IV Decision	74.00	144.00	200.50	102.80	124.33
20th Percentile FDA Days to MDUFA IV Decision	32	86	150	74	75
40th Percentile FDA Days to MDUFA IV Decision	58	132	162	75	149
60th Percentile FDA Days to MDUFA IV Decision	79	148	214	102	150
80th Percentile FDA Days to MDUFA IV Decision	98	150	253	144	150
Maximum FDA Days to MDUFA IV Decision	148	348	357	150	150
Average Industry Days to MDUFA IV Decision	112.40	71.11	161.75	209.20	149.83
20th Percentile Industry Days to MDUFA IV Decision	0	0	24	91	132
40th Percentile Industry Days to MDUFA IV Decision	98	6	96	148	168
60th Percentile Industry Days to MDUFA IV Decision	171	64	177	251	174
80th Percentile Industry Days to MDUFA IV Decision	188	163	279	363	180
Maximum Industry Days to MDUFA IV Decision	217	207	427	365	181
Average Total Days to MDUFA IV Decision	186.40	215.11	362.25	312.00	274.17
20th Percentile Total Days to MDUFA IV Decision	32	117	286	237	214
40th Percentile Total Days to MDUFA IV Decision	173	153	350	253	249
60th Percentile Total Days to MDUFA IV Decision	277	213	363	326	318
80th Percentile Total Days to MDUFA IV Decision	296	281	448	436	329
Maximum Total Days to MDUFA IV Decision	312	526	651	440	331

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	9
Number With MDUFA IV Decisions	5	9	8	5	6
Number With Granted Decisions	3	2	5	2	0
Number With Declined Decisions	0	5	2	0	4
Number of Withdrawals	0	1	1	1	2
Number Deleted	2	1	0	2	0
Rate of Granted Decisions	60.00%	22.22%	62.50%	40.00%	0.00%
Rate of Declined Decisions	0.00%	55.56%	25.00%	0.00%	66.67%
Rate of Withdrawals	0.00%	11.11%	12.50%	20.00%	33.33%
Rate of Deleted	40.00%	11.11%	0.00%	40.00%	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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

**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	7
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	4	5	5
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	1
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	2	1	1
Rate of Submissions Not Accepted for Review	N/A	N/A	33.33%	16.67%	14.29%

*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 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	4	11	6	6	7
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	11	6	6	5
MDUFA IV Decisions Within 150 FDA Days	3	5	4	6	5
De Novos Pending MDUFA IV Decision	0	0	0	0	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	75.00%	45.45%	66.67%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.82	1.83	2.00	1.40
Number With MDUFA IV Decision	4	11	6	6	5
Average FDA Days to MDUFA IV Decision	100.00	186.55	161.50	148.67	119.60
20th Percentile FDA Days to MDUFA IV Decision	57	148	148	147	98
40th Percentile FDA Days to MDUFA IV Decision	97	150	150	148	134
60th Percentile FDA Days to MDUFA IV Decision	135	191	150	150	148
80th Percentile FDA Days to MDUFA IV Decision	149	211	203	150	149
Maximum FDA Days to MDUFA IV Decision	151	327	243	150	150
Average Industry Days to MDUFA IV Decision	136.75	168.45	116.83	152.83	46.00
20th Percentile Industry Days to MDUFA IV Decision	100	136	21	91	0
40th Percentile Industry Days to MDUFA IV Decision	169	175	24	104	0
60th Percentile Industry Days to MDUFA IV Decision	175	177	61	135	44
80th Percentile Industry Days to MDUFA IV Decision	187	241	222	201	113
Maximum Industry Days to MDUFA IV Decision	203	338	363	355	119
Average Total Days to MDUFA IV Decision	236.75	355.00	278.33	301.50	165.60
20th Percentile Total Days to MDUFA IV Decision	179	283	209	238	126
40th Percentile Total Days to MDUFA IV Decision	293	347	213	252	149
60th Percentile Total Days to MDUFA IV Decision	312	368	267	285	180
80th Percentile Total Days to MDUFA IV Decision	321	416	372	351	233
Maximum Total Days to MDUFA IV Decision	325	617	438	502	268

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	7
Number With MDUFA IV Decisions	4	11	6	6	5
Number With Granted Decisions	0	8	3	4	3
Number With Declined Decisions	3	3	2	1	0
Number of Withdrawals	0	0	0	1	2
Number Deleted	1	0	1	0	0
Rate of Granted Decisions	0.00%	72.73%	50.00%	66.67%	60.00%
Rate of Declined Decisions	75.00%	27.27%	33.33%	16.67%	0.00%
Rate of Withdrawals	0.00%	0.00%	0.00%	16.67%	40.00%
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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

**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	7
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	3	4	3
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	1	1	0
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	3	3	4
Rate of Submissions Not Accepted for Review	N/A	N/A	42.86%	37.50%	57.14%

*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 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	5	6	7	7	6
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	5	6	7	5	0
MDUFA IV Decisions Within 150 FDA Days	3	4	3	3	0
De Novos Pending MDUFA IV Decision	0	0	0	2	6
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	2
Current Performance Percent Within 150 FDA Days	60.00%	66.67%	42.86%	60.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.80	1.50	1.57	1.60	0.00
Number With MDUFA IV Decision	5	6	7	5	0
Average FDA Days to MDUFA IV Decision	147.40	182.50	165.14	158.60	0.00
20th Percentile FDA Days to MDUFA IV Decision	133	93	113	135	0
40th Percentile FDA Days to MDUFA IV Decision	150	98	146	149	0
60th Percentile FDA Days to MDUFA IV Decision	151	107	174	169	0
80th Percentile FDA Days to MDUFA IV Decision	167	236	189	201	0
Maximum FDA Days to MDUFA IV Decision	221	485	323	215	0
Average Industry Days to MDUFA IV Decision	90.80	125.83	231.86	356.80	0.00
20th Percentile Industry Days to MDUFA IV Decision	12	0	161	341	0
40th Percentile Industry Days to MDUFA IV Decision	65	0	248	361	0
60th Percentile Industry Days to MDUFA IV Decision	124	187	267	363	0
80th Percentile Industry Days to MDUFA IV Decision	165	195	331	377	0
Maximum Industry Days to MDUFA IV Decision	179	373	365	427	0
Average Total Days to MDUFA IV Decision	238.20	308.33	397.00	515.40	0.00
20th Percentile Total Days to MDUFA IV Decision	145	93	331	478	0
40th Percentile Total Days to MDUFA IV Decision	215	107	408	500	0
60th Percentile Total Days to MDUFA IV Decision	275	285	436	530	0
80th Percentile Total Days to MDUFA IV Decision	332	609	469	564	0
Maximum Total Days to MDUFA IV Decision	400	680	668	575	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	7	6
Number With MDUFA IV Decisions	5	6	7	5	0
Number With Granted Decisions	3	1	1	1	0
Number With Declined Decisions	1	3	3	2	0
Number of Withdrawals	1	1	2	0	0
Number Deleted	0	1	1	2	0
Rate of Granted Decisions	60.00%	16.67%	14.29%	20.00%	N/A
Rate of Declined Decisions	20.00%	50.00%	42.86%	40.00%	N/A
Rate of Withdrawals	20.00%	16.67%	28.57%	0.00%	N/A
Rate of Deleted	0.00%	16.67%	14.29%	40.00%	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	2	4	2	0
Mean FDA Days for Submissions that Missed the Goal	187.00	360.50	215.50	206.50	0.00
Mean Industry Days for Submissions that Missed the Goal	170.50	284.00	246.25	317.00	0.00

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

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

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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

**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	10
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	5	7	6
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	4
Rate of Submissions Not Accepted for Review	N/A	N/A	28.57%	22.22%	40.00%

*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 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	13	6	6	7	10
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	13	6	6	7	4
MDUFA IV Decisions Within 150 FDA Days	9	6	5	6	4
De Novos Pending MDUFA IV Decision	0	0	0	0	6
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	69.23%	100.00%	83.33%	85.71%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.77	1.33	1.83	1.86	1.50
Number With MDUFA IV Decision	13	6	6	7	4
Average FDA Days to MDUFA IV Decision	153.00	113.33	138.67	155.43	113.00
20th Percentile FDA Days to MDUFA IV Decision	104	76	149	148	76
40th Percentile FDA Days to MDUFA IV Decision	148	127	149	149	92
60th Percentile FDA Days to MDUFA IV Decision	150	136	150	150	135
80th Percentile FDA Days to MDUFA IV Decision	219	149	150	150	150
Maximum FDA Days to MDUFA IV Decision	254	150	175	270	150
Average Industry Days to MDUFA IV Decision	106.08	20.17	134.67	122.86	113.00
20th Percentile Industry Days to MDUFA IV Decision	39	0	14	53	44
40th Percentile Industry Days to MDUFA IV Decision	82	0	84	69	87
60th Percentile Industry Days to MDUFA IV Decision	164	0	125	117	127
80th Percentile Industry Days to MDUFA IV Decision	174	45	169	161	179
Maximum Industry Days to MDUFA IV Decision	183	76	416	360	238
Average Total Days to MDUFA IV Decision	259.08	133.50	273.33	278.29	226.00
20th Percentile Total Days to MDUFA IV Decision	226	76	163	203	160
40th Percentile Total Days to MDUFA IV Decision	266	127	234	219	217
60th Percentile Total Days to MDUFA IV Decision	316	136	274	265	222
80th Percentile Total Days to MDUFA IV Decision	323	195	344	407	290
Maximum Total Days to MDUFA IV Decision	371	225	566	510	388

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	10
Number With MDUFA IV Decisions	13	6	6	7	4
Number With Granted Decisions	3	2	6	3	1
Number With Declined Decisions	7	0	0	3	2
Number of Withdrawals	3	4	0	1	1
Number Deleted	0	0	0	0	0
Rate of Granted Decisions	23.08%	33.33%	100.00%	42.86%	25.00%
Rate of Declined Decisions	53.85%	0.00%	0.00%	42.86%	50.00%
Rate of Withdrawals	23.08%	66.67%	0.00%	14.29%	25.00%
Rate of Deleted	0.00%	0.00%	0.00%	0.00%	0.00%

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

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

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

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

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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	4	4	5	6	7
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	5	5	6
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	1
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	0	1	0
Rate of Submissions Not Accepted for Review	N/A	N/A	0.00%	16.67%	0.00%

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

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

Performance Metric	FY 2018 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	4	4	5	6	7
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	4	4	5	6	3
MDUFA IV Decisions Within 150 FDA Days	3	3	5	4	3
De Novos Pending MDUFA IV Decision	0	0	0	0	4
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	75.00%	75.00%	100.00%	66.67%	100.00%

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	2.00
Number With MDUFA IV Decision	4	4	5	6	3
Average FDA Days to MDUFA IV Decision	133.25	144.75	147.40	165.83	145.67
20th Percentile FDA Days to MDUFA IV Decision	122	116	147	139	142
40th Percentile FDA Days to MDUFA IV Decision	148	143	150	141	147
60th Percentile FDA Days to MDUFA IV Decision	150	144	150	147	150
80th Percentile FDA Days to MDUFA IV Decision	150	173	150	204	150
Maximum FDA Days to MDUFA IV Decision	151	217	150	231	150
Average Industry Days to MDUFA IV Decision	161.00	178.50	132.60	147.83	236.67
20th Percentile Industry Days to MDUFA IV Decision	149	104	62	0	176
40th Percentile Industry Days to MDUFA IV Decision	179	175	107	74	178
60th Percentile Industry Days to MDUFA IV Decision	180	177	146	98	215
80th Percentile Industry Days to MDUFA IV Decision	180	252	179	357	286
Maximum Industry Days to MDUFA IV Decision	181	362	245	358	357
Average Total Days to MDUFA IV Decision	294.25	323.25	280.00	313.67	382.33
20th Percentile Total Days to MDUFA IV Decision	260	221	209	213	318
40th Percentile Total Days to MDUFA IV Decision	278	333	256	231	325
60th Percentile Total Days to MDUFA IV Decision	316	380	296	302	365
80th Percentile Total Days to MDUFA IV Decision	330	439	329	491	436
Maximum Total Days to MDUFA IV Decision	331	505	395	504	507

Table 8.4 OHT6 - Office of Orthopedic Devices**De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	4	4	5	6	7
Number With MDUFA IV Decisions	4	4	5	6	3
Number With Granted Decisions	1	1	3	3	2
Number With Declined Decisions	1	3	2	1	1
Number of Withdrawals	1	0	0	2	0
Number Deleted	1	0	0	0	0
Rate of Granted Decisions	25.00%	25.00%	60.00%	50.00%	66.67%
Rate of Declined Decisions	25.00%	75.00%	40.00%	16.67%	33.33%
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	2	0
Mean FDA Days for Submissions that Missed the Goal	151.00	217.00	0.00	217.50	0.00
Mean Industry Days for Submissions that Missed the Goal	180.00	178.00	0.00	49.00	0.00

Table 8.6 OHT6 - Office of Orthopedic Devices**LDT De Novo MDUFA IV Decision Metrics**

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

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	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decisions Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
De Novos Pending MDUFA IV Decision Over 150 FDA Days	N/A	N/A	N/A	N/A	N/A
Current Performance Percent Within 150 FDA Days	N/A	N/A	N/A	N/A	N/A

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	16	19	21	15	19
Closed Before RTA Action	N/A	N/A	1	0	1
Number Accepted First RTA Cycle	N/A	N/A	12	6	11
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	2	7	3
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	4
Rate of Submissions Not Accepted for Review	N/A	N/A	26.32%	13.33%	22.22%

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

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

Performance Metric	FY 2018 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	16	19	18	13	16
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	16	19	17	8	6
MDUFA IV Decisions Within 150 FDA Days	16	16	9	1	1
De Novos Pending MDUFA IV Decision	0	0	1	5	10
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	5	4
Current Performance Percent Within 150 FDA Days	100.00%	84.21%	50.00%	7.69%	10.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.50	1.58	1.71	1.75	1.17
Number With MDUFA IV Decision	16	19	17	8	6
Average FDA Days to MDUFA IV Decision	126.25	120.16	241.94	291.75	188.83
20th Percentile FDA Days to MDUFA IV Decision	109	71	118	209	173
40th Percentile FDA Days to MDUFA IV Decision	132	118	148	220	189
60th Percentile FDA Days to MDUFA IV Decision	147	148	223	306	210
80th Percentile FDA Days to MDUFA IV Decision	150	150	395	419	210
Maximum FDA Days to MDUFA IV Decision	150	243	584	459	231
Average Industry Days to MDUFA IV Decision	108.25	110.00	198.24	200.50	43.33
20th Percentile Industry Days to MDUFA IV Decision	0	0	76	92	0
40th Percentile Industry Days to MDUFA IV Decision	121	0	182	173	0
60th Percentile Industry Days to MDUFA IV Decision	175	176	237	240	34
80th Percentile Industry Days to MDUFA IV Decision	180	222	317	322	56
Maximum Industry Days to MDUFA IV Decision	189	276	431	358	170
Average Total Days to MDUFA IV Decision	234.50	230.16	440.18	492.25	232.17
20th Percentile Total Days to MDUFA IV Decision	145	90	228	369	176
40th Percentile Total Days to MDUFA IV Decision	236	150	415	532	189
60th Percentile Total Days to MDUFA IV Decision	281	295	470	581	210
80th Percentile Total Days to MDUFA IV Decision	313	340	577	622	265
Maximum Total Days to MDUFA IV Decision	327	509	928	680	380

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	16	19	18	13	16
Number With MDUFA IV Decisions	16	19	17	8	6
Number With Granted Decisions	9	11	8	5	2
Number With Declined Decisions	1	0	3	1	0
Number of Withdrawals	5	7	4	2	4
Number Deleted	1	1	2	0	0
Rate of Granted Decisions	56.25%	57.89%	47.06%	62.50%	33.33%
Rate of Declined Decisions	6.25%	0.00%	17.65%	12.50%	0.00%
Rate of Withdrawals	31.25%	36.84%	23.53%	25.00%	66.67%
Rate of Deleted	6.25%	5.26%	11.76%	0.00%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	3	8	7	5
Mean FDA Days for Submissions that Missed the Goal	0.00	209.33	382.50	316.29	202.60
Mean Industry Days for Submissions that Missed the Goal	0.00	217.67	231.13	229.14	40.80

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	1	5	2	0	2
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	5	2	0	2
MDUFA IV Decisions Within 150 FDA Days	1	2	0	0	1
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	100.00%	40.00%	0.00%	N/A	50.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	15	14	16	13	14
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	15	14	15	8	4
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	0
De Novos Pending MDUFA IV Decision	0	0	1	5	10
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	1	5	4
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	7.69%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	1	1	1	2	6
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	1	2	3
Number Without a RTA Review and > 15 Days Since Date Received	N/A	N/A	0	0	2
Number Without a RTA Review and <= 15 Days Since Date Received	N/A	N/A	0	0	0
Number Not Accepted	N/A	N/A	0	0	1
Rate of Submissions Not Accepted for Review	N/A	N/A	0.00%	0.00%	16.67%

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

**Table 8.2 OHT8 - Office of Radiological Health
De Novo MDUFA IV Decision Performance Goals**

Performance Metric	FY 2018 50% Within 150 FDA Days	FY 2019 55% Within 150 FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	1	1	1	2	6
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	1	1	1	2	4
MDUFA IV Decisions Within 150 FDA Days	1	1	1	2	3
De Novos Pending MDUFA IV Decision	0	0	0	0	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	100.00%	100.00%	75.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Average Review Cycles	1.00	2.00	2.00	1.50	1.75
Number With MDUFA IV Decision	1	1	1	2	4
Average FDA Days to MDUFA IV Decision	108.00	149.00	148.00	110.50	128.25
20th Percentile FDA Days to MDUFA IV Decision	108	149	148	87	90
40th Percentile FDA Days to MDUFA IV Decision	108	149	148	103	142
60th Percentile FDA Days to MDUFA IV Decision	108	149	148	118	147
80th Percentile FDA Days to MDUFA IV Decision	108	149	148	134	173
Maximum FDA Days to MDUFA IV Decision	108	149	148	149	209
Average Industry Days to MDUFA IV Decision	0.00	15.00	360.00	267.50	72.00
20th Percentile Industry Days to MDUFA IV Decision	0	15	360	213	0
40th Percentile Industry Days to MDUFA IV Decision	0	15	360	249	27
60th Percentile Industry Days to MDUFA IV Decision	0	15	360	286	107
80th Percentile Industry Days to MDUFA IV Decision	0	15	360	322	142
Maximum Industry Days to MDUFA IV Decision	0	15	360	358	154
Average Total Days to MDUFA IV Decision	108.00	164.00	508.00	378.00	200.25
20th Percentile Total Days to MDUFA IV Decision	108	164	508	347	95
40th Percentile Total Days to MDUFA IV Decision	108	164	508	368	178
60th Percentile Total Days to MDUFA IV Decision	108	164	508	388	265
80th Percentile Total Days to MDUFA IV Decision	108	164	508	409	314
Maximum Total Days to MDUFA IV Decision	108	164	508	430	343

Table 8.4 OHT8 - Office of Radiological Health**De Novo Performance Metrics - Rate of Grant, Decline, Withdrawal and Delete Decisions**

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

Table 8.5 OHT8 - Office of Radiological Health**De Novo Performance Metrics-Submissions Missing Performance Goals**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	0	1
Mean FDA Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	209.00
Mean Industry Days for Submissions that Missed the Goal	0.00	0.00	0.00	0.00	134.00

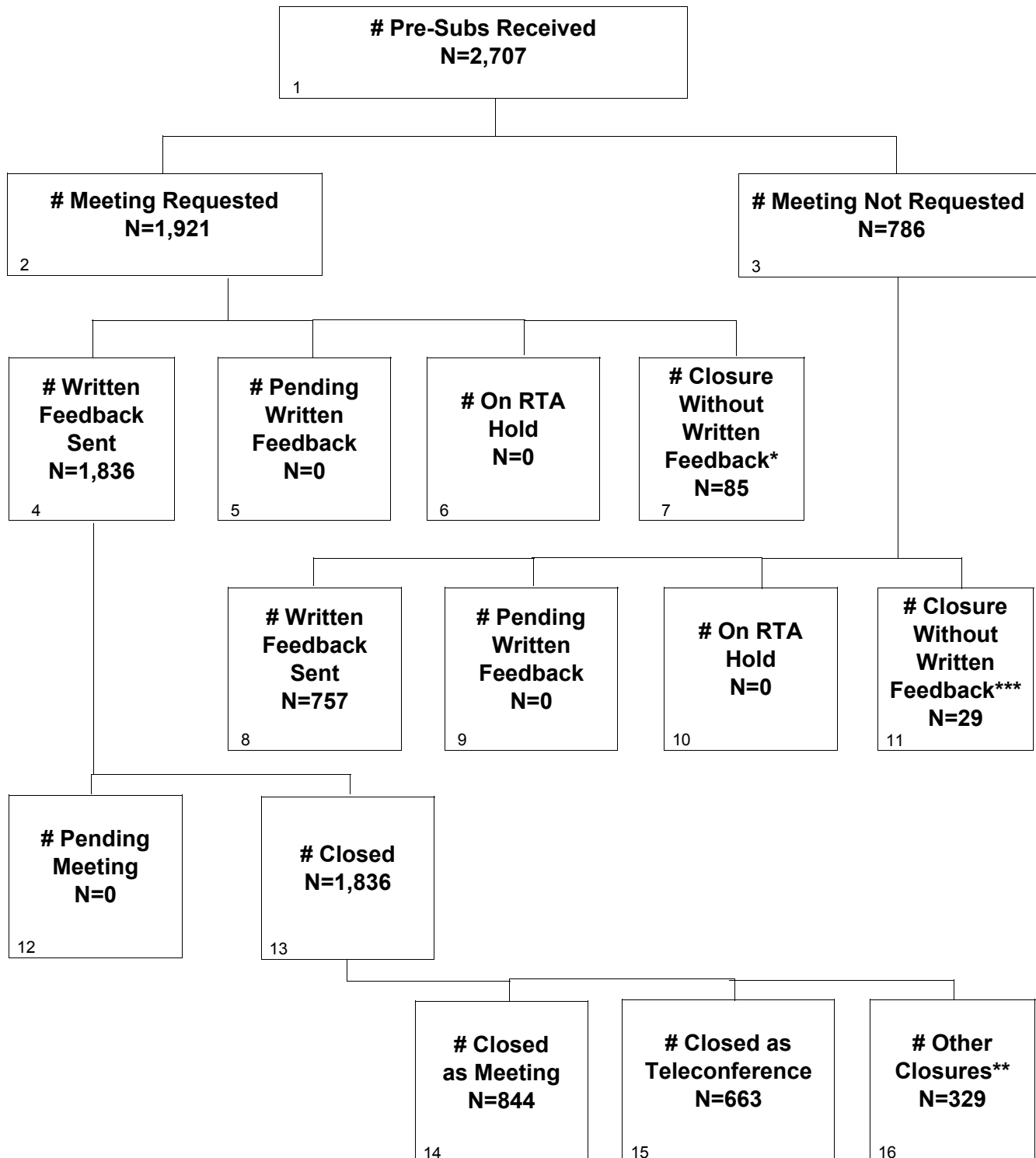
Table 8.6 OHT8 - Office of Radiological Health**LDT De Novo MDUFA IV Decision Metrics**

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

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

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

CDRH Pre-Sub - FY 2018 as of 3/31/23



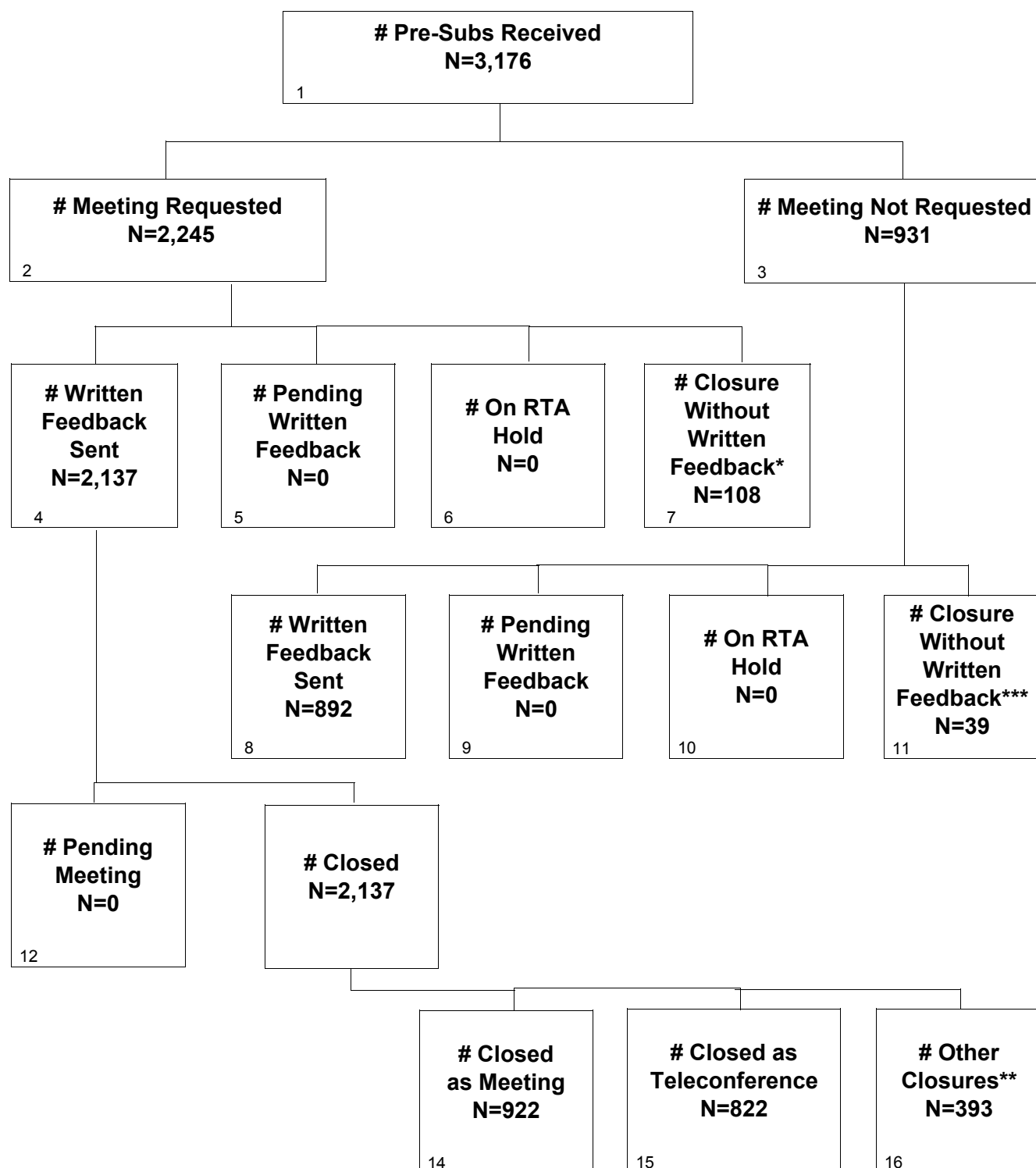
* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

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

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

CDRH Pre-Sub - FY 2019

as of 3/31/23



* 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 3/31/23



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

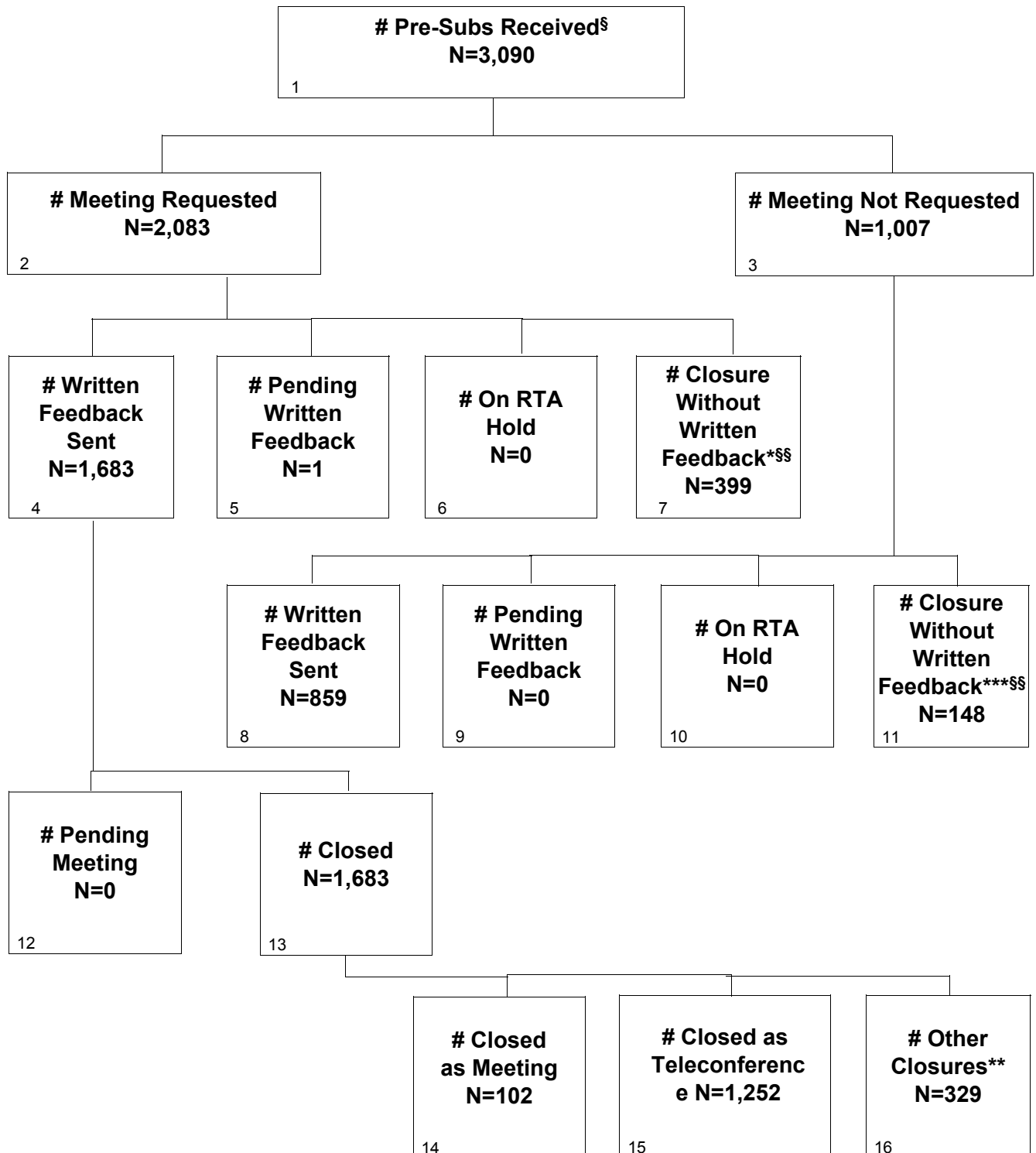
** Closures include CNLR, CNLF, CCOV, JTRX, JPND, DELE & WTDR

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

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

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

CDRH Pre-Sub - FY 2021 as of 3/31/23



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

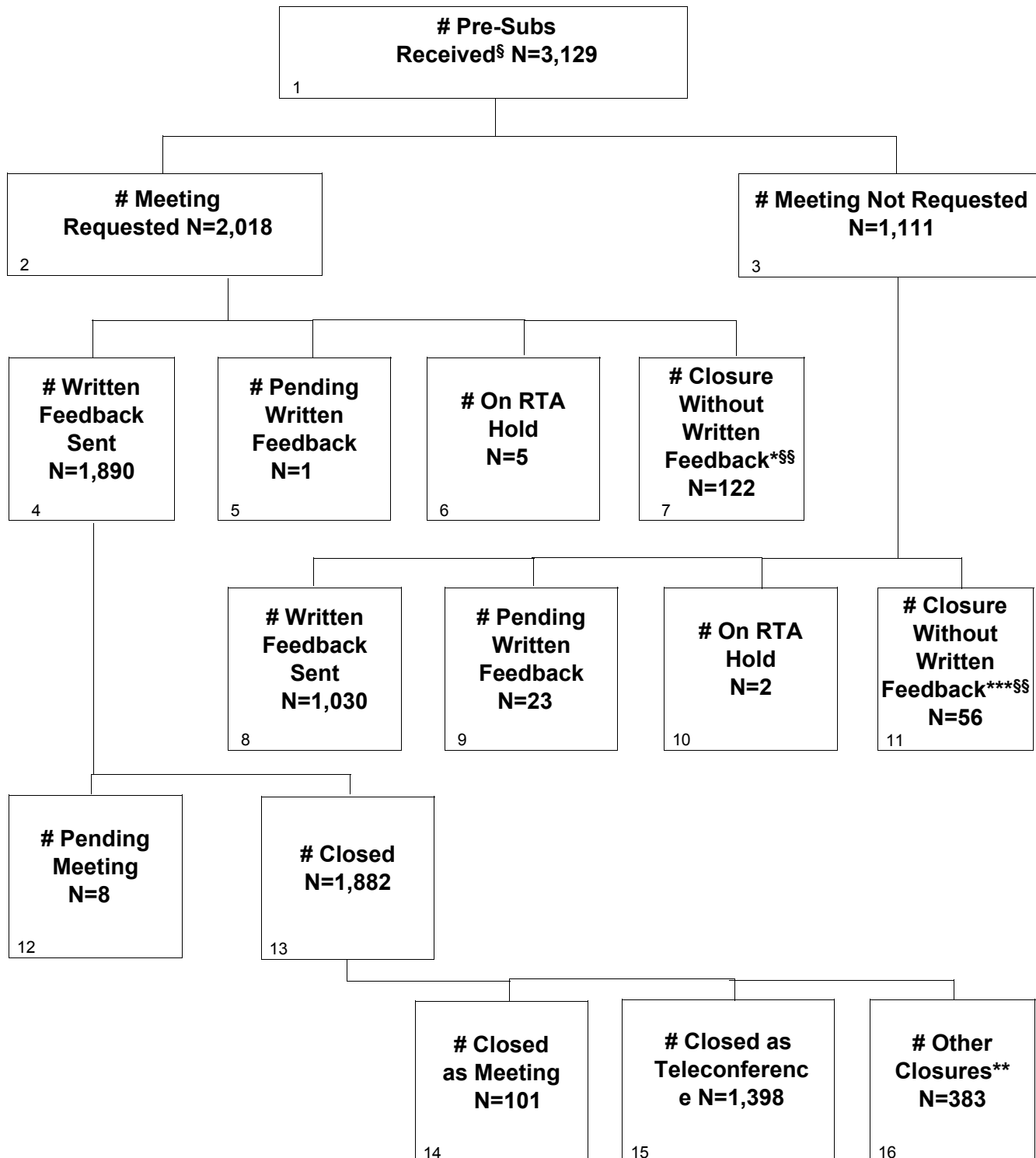
** Closures include CCOV, CNLR, CNLF, JTRX, JPND, DELE & WTDR

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

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

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

CDRH Pre-Sub - FY 2022 as of 3/31/23



* 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.

Section 9 Pre-Sub Center Level Metrics

Table 9.1 CDRH - Pre-Sub Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	2,707	3,176	3,306	3,090	3,129
Closed Before RTA Action**	27	41	109	388	64
Number Accepted First RTA Cycle**	2,565	3,004	3,035	2,449	2,728
Number Without a RTA Review and > 15 Days Since Date Received**	49	71	121	224	295
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	66	60	41	29	42
Rate of Submissions Not Accepted for Review	2.46%	1.91%	1.28%	1.07%	1.37%

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

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

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

Performance Metric	MDUFA IV Goal (# of Submissions Received During FY with Written Feedback Provided by Day 70 or 5 Days Prior to Meeting)				
	FY 2018 ≥ 1530 Submissions	FY 2019 ≥ 1645 Submissions	FY 2020 ≥ 1765 Submissions	FY 2021 ≥ 1880 Submissions	FY 2022 ≥ 1950 Submissions
Written Feedback Sent	2,594	3,029	3,021	2,542	2,921
Written Feedback Provided Within MDUFA IV Goal	2,439	2,848	2,652	2,022	2,239

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	2,594	3,029	3,021	2,542	2,921
Average FDA Days to Written Feedback	58.86	60.22	63.54	69.16	69.27
20th Percentile FDA Days to Written Feedback	49	49	52	52	55
40th Percentile FDA Days to Written Feedback	59	60	62	63	64
60th Percentile FDA Days to Written Feedback	65	65	66	67	69
80th Percentile FDA Days to Written Feedback	69	70	70	70	71
Maximum FDA Days to Written Feedback	172	950	925	685	441

*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	91	150
Average Days to Scheduling for Meetings Scheduled After Day 30	35.59	36.62	43.33	57.26	54.52

*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	1,728	1,354	1,499
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,113	1,111	892	984
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	483	560	540	419	460
Meeting Minutes Not Submitted and >15 Days Since Meeting	53	71	77	43	55
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	64.43%	63.82%	64.29%	65.88%	65.64%

*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	390	430	401	386
Closed Before RTA Action**	0	6	5	8	1
Number Accepted First RTA Cycle**	284	360	407	376	356
Number Without a RTA Review and > 15 Days Since Date Received**	8	9	10	13	22
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	27	15	8	4	7
Rate of Submissions Not Accepted for Review	8.46%	3.91%	1.88%	1.02%	1.82%

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

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

**Table 9.2 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	360	402	380	377
Written Feedback Provided Within MDUFA IV Goal	256	315	280	225	226

*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	360	402	380	377
Average FDA Days to Written Feedback	64.18	64.07	73.30	75.42	75.24
20th Percentile FDA Days to Written Feedback	56	57	62	63	63
40th Percentile FDA Days to Written Feedback	64	65	66	67	68
60th Percentile FDA Days to Written Feedback	69	69	70	70	70
80th Percentile FDA Days to Written Feedback	70	70	74	81	82
Maximum FDA Days to Written Feedback	168	119	389	685	280

*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	20	32
Average Days to Scheduling for Meetings Scheduled After Day 30	44.75	34.00	42.40	100.75	63.03

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	183	224	243	224	207
Meeting Minutes Submitted Within 15 Days of Meeting	126	151	152	145	124
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	50	68	80	75	72
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	5	11	4	11
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	68.85%	67.41%	62.55%	64.73%	59.90%

*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	673	773	670
Closed Before RTA Action**	6	7	4	7	1
Number Accepted First RTA Cycle**	506	555	647	738	642
Number Without a RTA Review and > 15 Days Since Date Received**	12	14	13	24	22
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	6	6	9	4	5
Rate of Submissions Not Accepted for Review	1.15%	1.04%	1.35%	0.52%	0.75%

*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	659	746	655
Written Feedback Provided Within MDUFA IV Goal	482	535	609	676	604

*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	659	746	655
Average FDA Days to Written Feedback	53.02	55.51	56.16	58.80	59.11
20th Percentile FDA Days to Written Feedback	39	44	44	45	47
40th Percentile FDA Days to Written Feedback	50	53	55	57	58
60th Percentile FDA Days to Written Feedback	59	63	63	64	65
80th Percentile FDA Days to Written Feedback	67	69	69	69	69
Maximum FDA Days to Written Feedback	91	115	143	222	294

*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	11
Average Days to Scheduling for Meetings Scheduled After Day 30	32.13	39.89	38.75	41.00	47.18

*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	337
Meeting Minutes Submitted Within 15 Days of Meeting	183	199	212	248	226
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	119	105	123	126	100
Meeting Minutes Not Submitted and >15 Days Since Meeting	11	20	22	11	11
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	58.47%	61.42%	59.38%	64.42%	67.06%

*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	383	400	378	373
Closed Before RTA Action**	5	7	11	31	1
Number Accepted First RTA Cycle**	307	360	376	326	339
Number Without a RTA Review and > 15 Days Since Date Received**	11	7	4	16	24
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	11	9	9	5	9
Rate of Submissions Not Accepted for Review	3.34%	2.39%	2.31%	1.44%	2.42%

*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	356	372	336	356
Written Feedback Provided Within MDUFA IV Goal	300	345	352	294	329

*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	356	372	336	356
Average FDA Days to Written Feedback	60.53	63.35	61.36	65.67	63.89
20th Percentile FDA Days to Written Feedback	53	53	51	58	59
40th Percentile FDA Days to Written Feedback	61	61	61	64	64
60th Percentile FDA Days to Written Feedback	65	66	66	67	67
80th Percentile FDA Days to Written Feedback	69	69	70	70	70
Maximum FDA Days to Written Feedback	156	950	168	204	242

*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	13
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	36.88	36.00	52.11	57.23

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	178	204	220	197	191
Meeting Minutes Submitted Within 15 Days of Meeting	112	125	156	141	134
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	64	73	61	52	52
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3	4	5
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.92%	61.27%	70.91%	71.57%	70.16%

*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	273	335	313	305
Closed Before RTA Action**	4	5	21	117	1
Number Accepted First RTA Cycle**	234	248	302	164	281
Number Without a RTA Review and > 15 Days Since Date Received**	6	11	7	29	17
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	7	9	5	3	6
Rate of Submissions Not Accepted for Review	2.83%	3.36%	1.59%	1.53%	1.97%

*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	251	298	179	286
Written Feedback Provided Within MDUFA IV Goal	215	219	262	118	202

*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	251	298	179	286
Average FDA Days to Written Feedback	60.70	62.57	63.10	72.40	67.38
20th Percentile FDA Days to Written Feedback	52	55	56	55	55
40th Percentile FDA Days to Written Feedback	59	63	62	64	64
60th Percentile FDA Days to Written Feedback	65	66	66	69	68
80th Percentile FDA Days to Written Feedback	69	70	70	80	75
Maximum FDA Days to Written Feedback	121	106	268	413	285

*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	27
Average Days to Scheduling for Meetings Scheduled After Day 30	33.25	34.25	42.80	42.84	52.63

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	124	141	178	96	161
Meeting Minutes Submitted Within 15 Days of Meeting	92	95	117	69	103
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	26	41	49	23	49
Meeting Minutes Not Submitted and >15 Days Since Meeting	6	5	12	4	9
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	74.19%	67.38%	65.73%	71.88%	63.98%

*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	310	342	358
Closed Before RTA Action**	3	2	2	2	4
Number Accepted First RTA Cycle**	232	253	287	317	329
Number Without a RTA Review and > 15 Days Since Date Received**	7	10	16	15	17
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	7	12	5	8	8
Rate of Submissions Not Accepted for Review	2.85%	4.36%	1.62%	2.35%	2.26%

*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 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	300	329	337
Written Feedback Provided Within MDUFA IV Goal	202	219	186	216	217

*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	300	329	337
Average FDA Days to Written Feedback	64.73	72.86	83.45	86.88	79.28
20th Percentile FDA Days to Written Feedback	58	63	65	64	64
40th Percentile FDA Days to Written Feedback	65	68	70	69	68
60th Percentile FDA Days to Written Feedback	69	70	70	70	70
80th Percentile FDA Days to Written Feedback	70	70	84	88	81
Maximum FDA Days to Written Feedback	172	397	925	591	441

*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	26
Average Days to Scheduling for Meetings Scheduled After Day 30	34.20	33.00	37.50	38.50	41.42

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

Table 9.5 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	178	174	206
Meeting Minutes Submitted Within 15 Days of Meeting	99	103	108	107	123
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	50	59	63	57	75
Meeting Minutes Not Submitted and >15 Days Since Meeting	7	12	7	10	8
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	63.46%	59.20%	60.67%	61.49%	59.71%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	133	173	179	241	263
Closed Before RTA Action**	1	3	1	2	1
Number Accepted First RTA Cycle**	127	162	168	230	252
Number Without a RTA Review and > 15 Days Since Date Received**	5	6	7	6	6
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	0	2	3	3	4
Rate of Submissions Not Accepted for Review	0.00%	1.18%	1.69%	1.26%	1.53%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	167	173	227	256
Written Feedback Provided Within MDUFA IV Goal	115	154	169	224	251

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	129	167	173	227	256
Average FDA Days to Written Feedback	61.91	61.18	62.34	58.92	57.84
20th Percentile FDA Days to Written Feedback	52	55	57	45	45
40th Percentile FDA Days to Written Feedback	62	62	63	60	58
60th Percentile FDA Days to Written Feedback	67	66	69	65	64
80th Percentile FDA Days to Written Feedback	70	70	70	70	69
Maximum FDA Days to Written Feedback	106	92	105	78	101

*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	4
Average Days to Scheduling for Meetings Scheduled After Day 30	33.00	43.75	0.00	31.00	34.75

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

Table 9.5 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	122
Meeting Minutes Submitted Within 15 Days of Meeting	55	53	61	63	90
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	19	29	15	35	27
Meeting Minutes Not Submitted and >15 Days Since Meeting	3	5	3	2	5
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	71.43%	60.92%	77.22%	63.00%	73.77%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	759	906	766	434	533
Closed Before RTA Action**	7	7	61	221	51
Number Accepted First RTA Cycle**	749	885	645	99	297
Number Without a RTA Review and > 15 Days Since Date Received**	0	12	60	113	184
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	3	2	0	1	1
Rate of Submissions Not Accepted for Review	0.40%	0.22%	0.00%	0.47%	0.21%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	746	891	610	140	422
Written Feedback Provided Within MDUFA IV Goal	743	881	590	64	179

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	746	891	610	140	422
Average FDA Days to Written Feedback	58.34	57.48	59.87	105.03	90.19
20th Percentile FDA Days to Written Feedback	49	46	51	52	63
40th Percentile FDA Days to Written Feedback	59	58	60	69	70
60th Percentile FDA Days to Written Feedback	64	64	65	93	81
80th Percentile FDA Days to Written Feedback	69	69	69	133	112
Maximum FDA Days to Written Feedback	85	307	142	588	347

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	5	4	6	4	34
Average Days to Scheduling for Meetings Scheduled After Day 30	34.40	35.50	53.50	95.25	62.26

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	390	475	334	27	107
Meeting Minutes Submitted Within 15 Days of Meeting	239	310	213	18	65
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	134	150	109	6	39
Meeting Minutes Not Submitted and >15 Days Since Meeting	17	15	12	3	3
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	61.28%	65.26%	63.77%	66.67%	60.75%

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	132	192	213	208	241
Closed Before RTA Action**	1	4	4	0	4
Number Accepted First RTA Cycle**	126	181	203	199	232
Number Without a RTA Review and > 15 Days Since Date Received**	0	2	4	8	3
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	5	5	2	1	2
Rate of Submissions Not Accepted for Review	3.82%	2.66%	0.96%	0.48%	0.84%

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

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

**Table 9.2 OHT8 - Office of Radiological Health
MDUFA IV Pre-Sub Performance Goals***

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	181	207	205	232
Written Feedback Provided Within MDUFA IV Goal	126	180	204	205	231

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	127	181	207	205	232
Average FDA Days to Written Feedback	51.53	52.29	55.62	56.54	58.90
20th Percentile FDA Days to Written Feedback	43	39	48	49	51
40th Percentile FDA Days to Written Feedback	49	52	55	56	58
60th Percentile FDA Days to Written Feedback	56	57	59	61	63
80th Percentile FDA Days to Written Feedback	61	65	65	65	66
Maximum FDA Days to Written Feedback	70	70	190	70	72

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

Table 9.4 OHT8 - Office of Radiological Health
MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	1	1	0	1	3
Average Days to Scheduling for Meetings Scheduled After Day 30	31.00	36.00	0.00	34.00	48.00

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

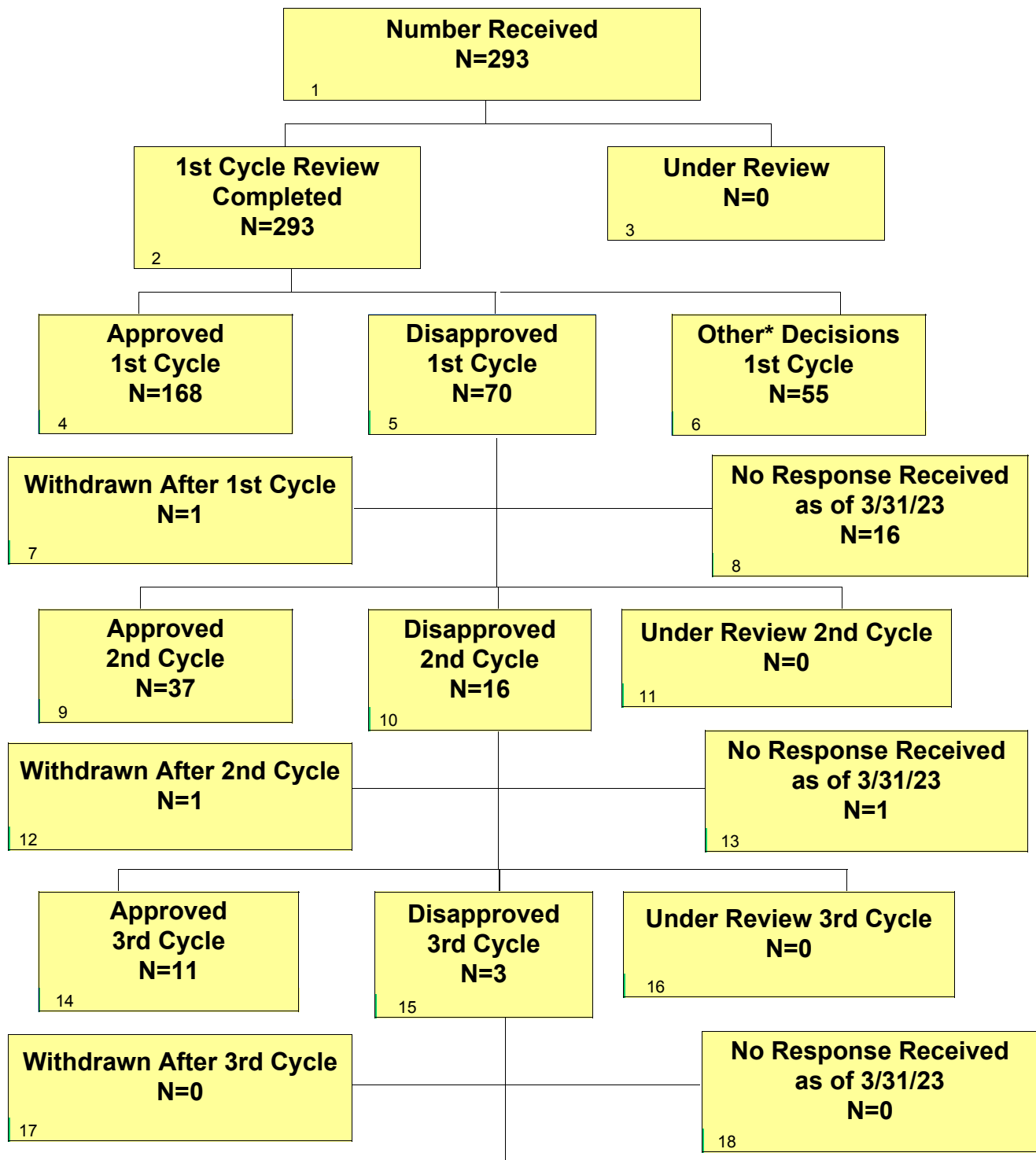
Table 9.5 OHT8 - Office of Radiological Health

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	86	115	139	151	168
Meeting Minutes Submitted Within 15 Days of Meeting	65	77	92	101	119
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	21	35	40	45	46
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	3	7	5	3
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	75.58%	66.96%	66.19%	66.89%	70.83%

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

CDRH IDEs - FY 2018

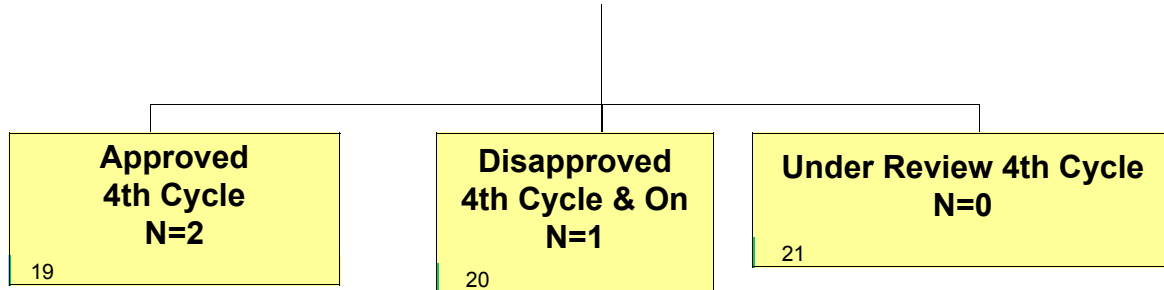
as of 3/31/23



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

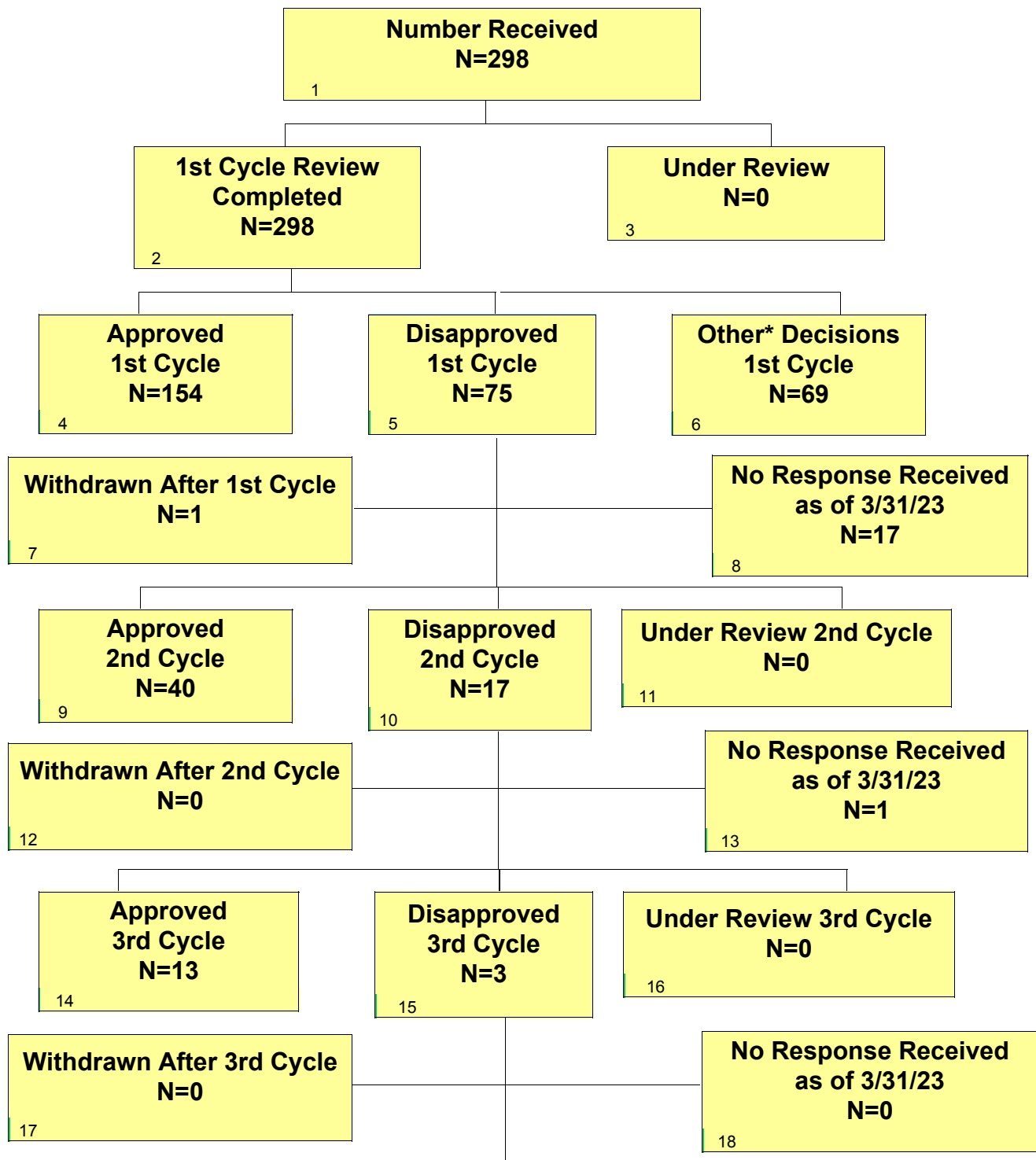
CDRH IDEs - FY 2018

as of 3/31/23



CDRH IDEs - FY 2019

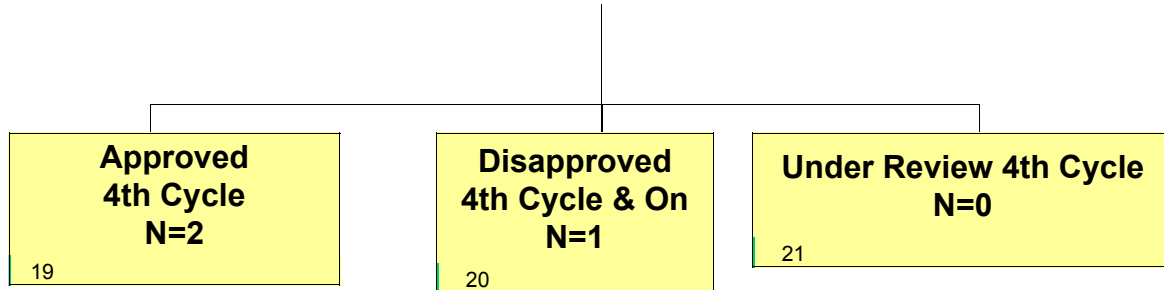
as of 3/31/23



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

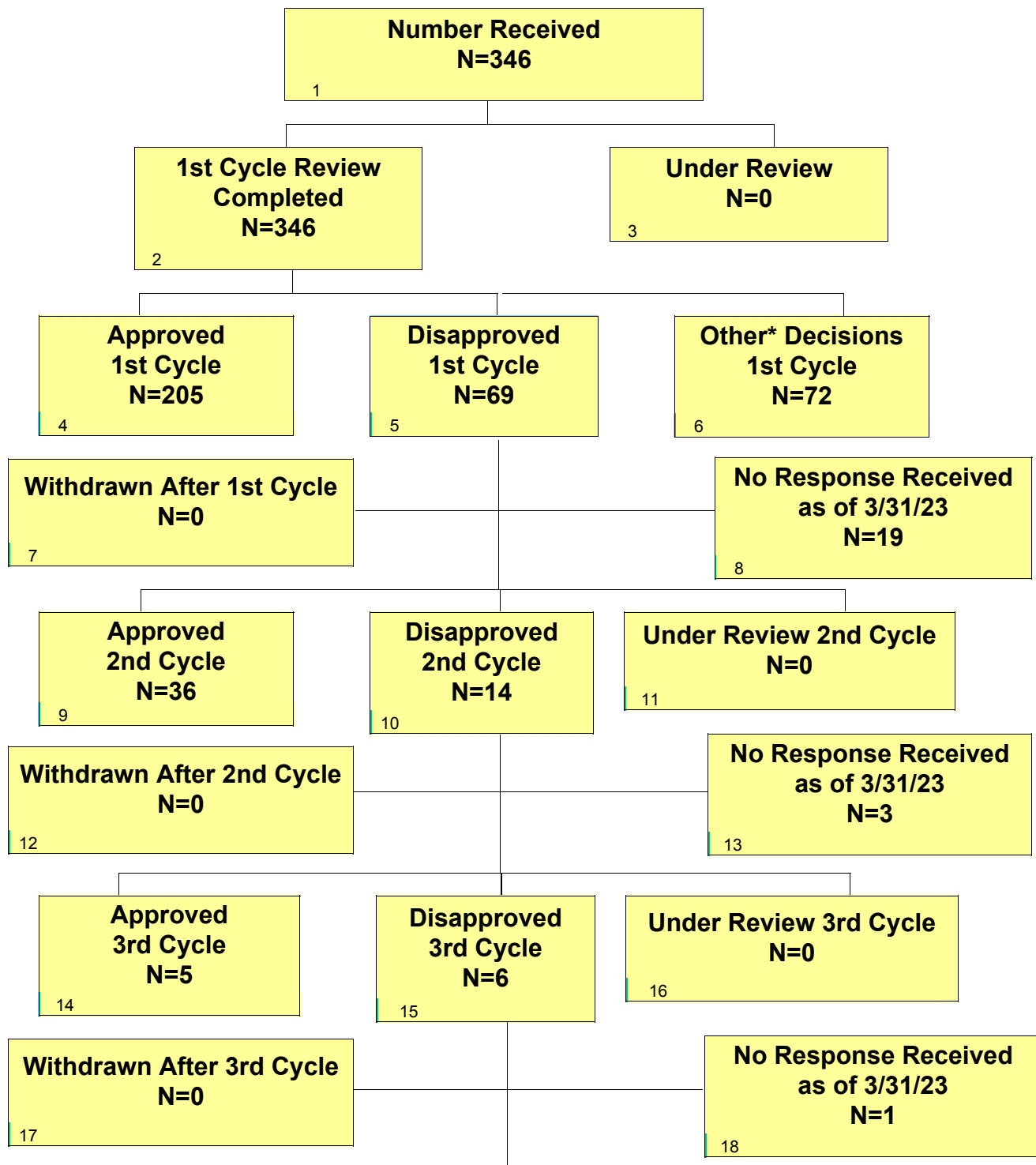
CDRH IDEs - FY 2019

as of 3/31/23



CDRH IDEs - FY 2020

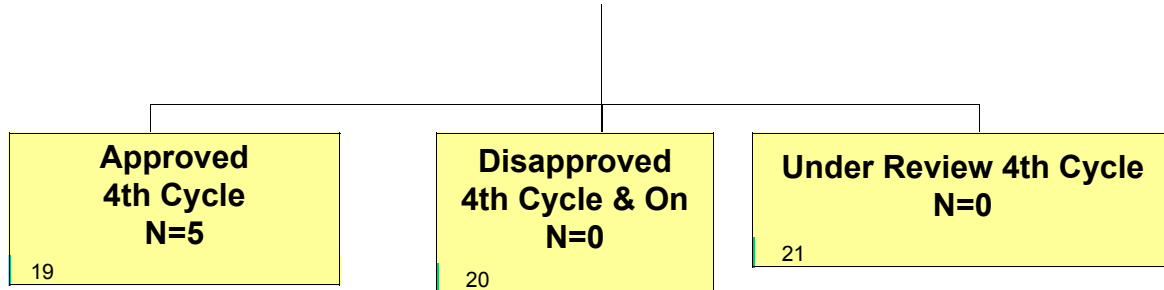
as of 3/31/23



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

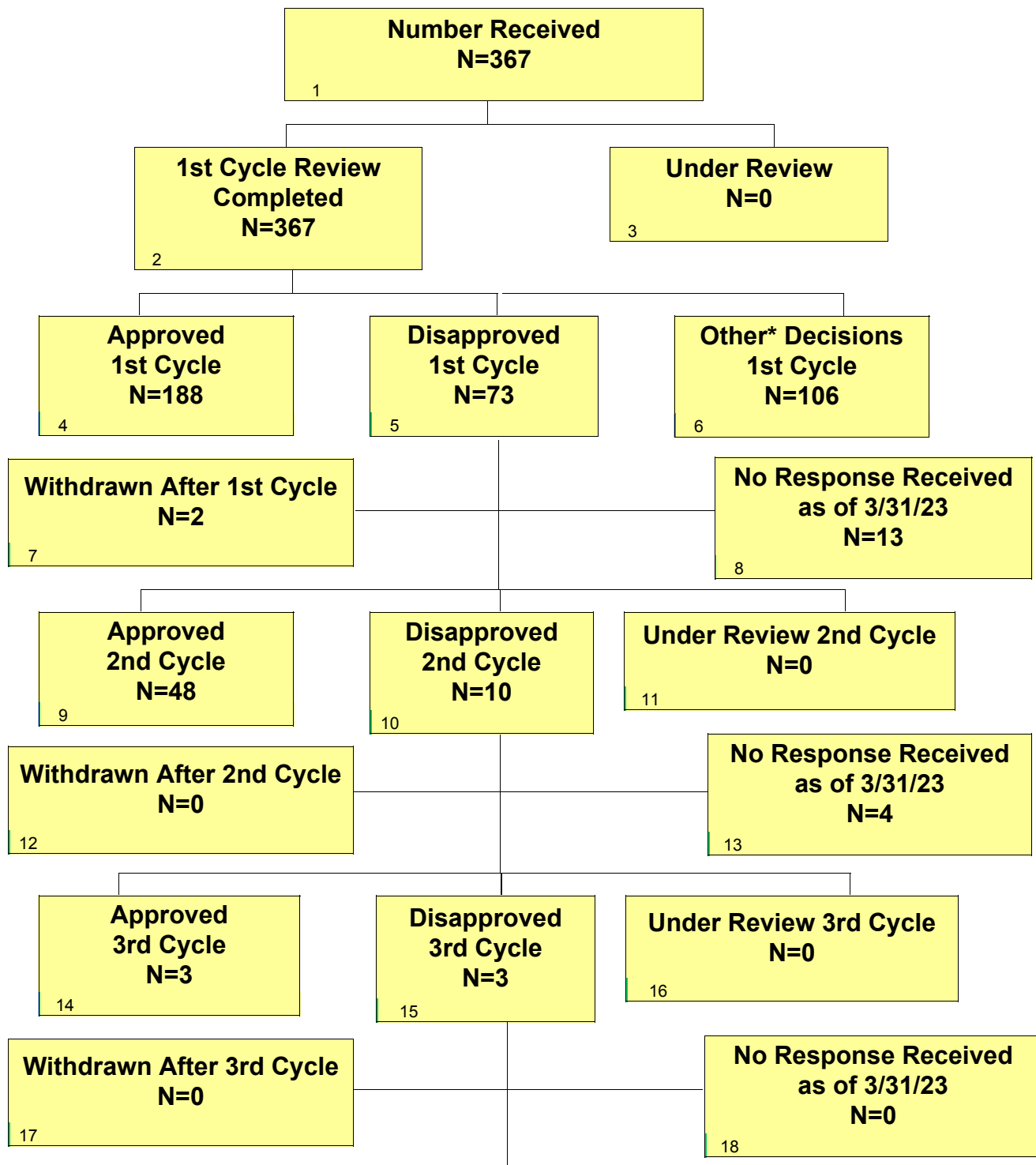
CDRH IDEs - FY 2020

as of 3/31/23



CDRH IDEs - FY 2021

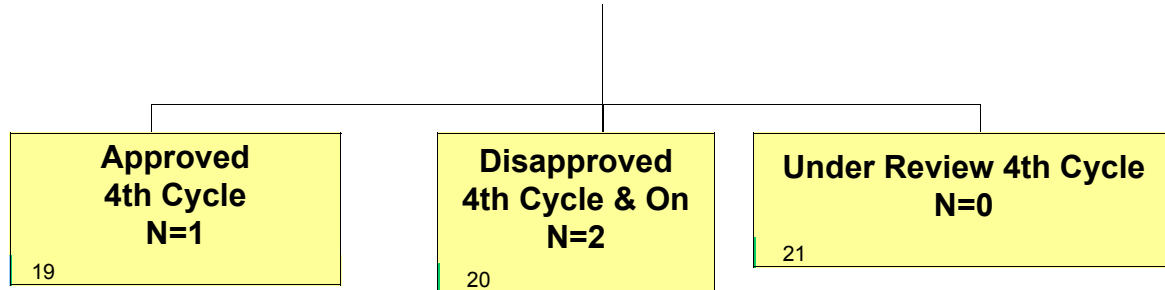
as of 3/31/23



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

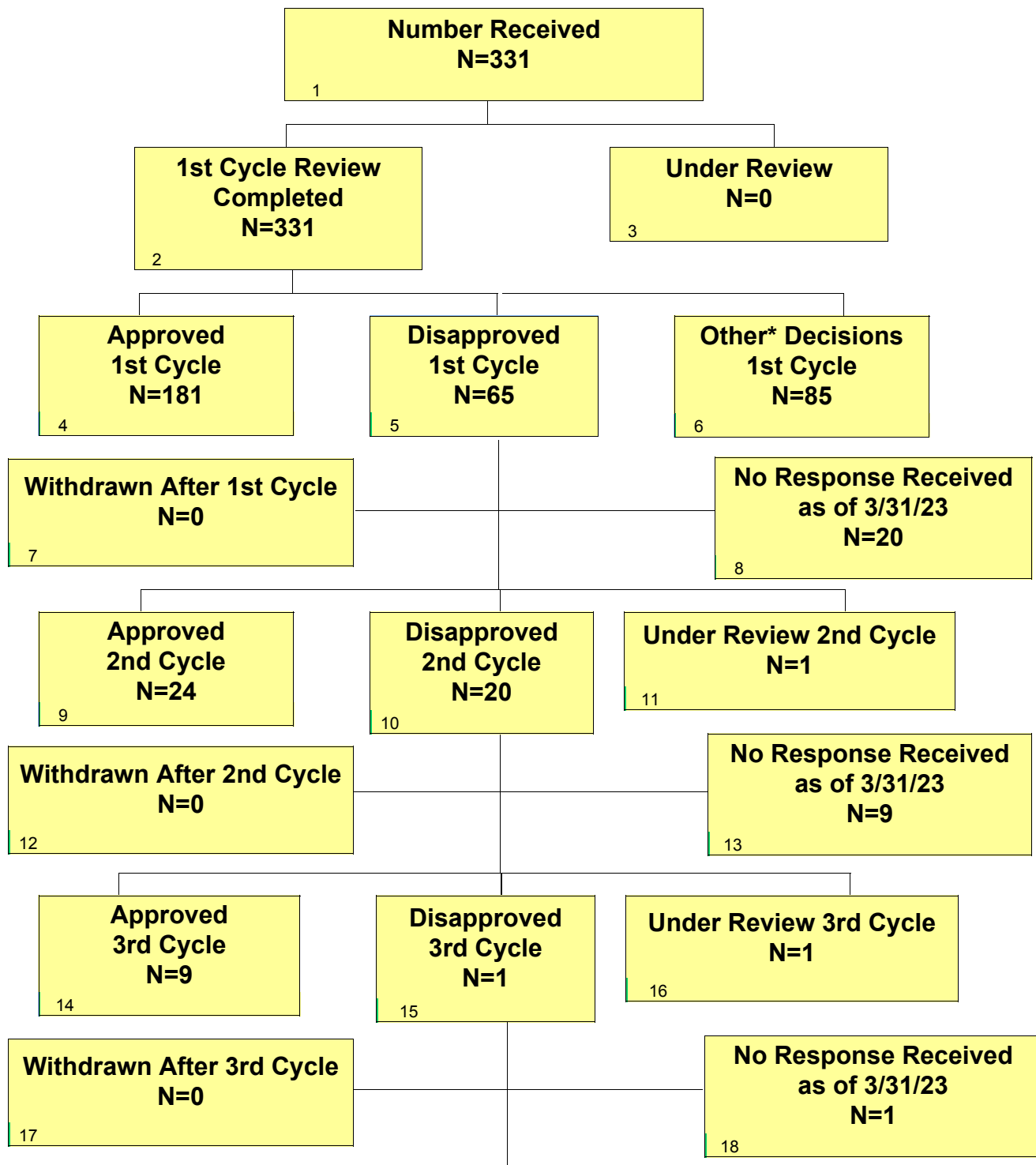
CDRH IDEs - FY 2021

as of 3/31/23



CDRH IDEs - FY 2022

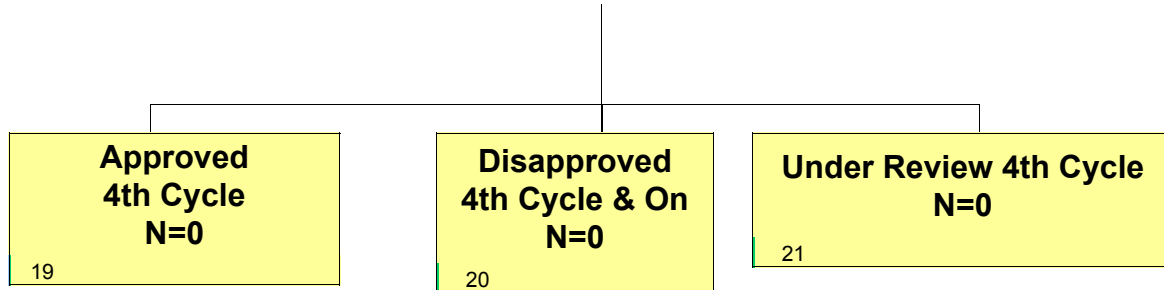
as of 3/31/23



* Other decisions include withdrawn (N=16), withdrawn and converted (N=49), RTA (N=0), nonsignificant risk device (N=10), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=7), Basic Physiological Research (N=0).

CDRH IDEs - FY 2022

as of 3/31/23



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	331
Average Number of Cycles to IDE Approval or Conditional Approval	1.32	1.34	1.24	1.29	1.20
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.34	0.24	0.29	0.20

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	31
Average Number of Cycles to IDE Approval or Conditional Approval	1.41	1.36	1.32	1.45	1.33
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.36	0.32	0.45	0.33

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	79
Average Number of Cycles to IDE Approval or Conditional Approval	1.58	1.43	1.45	1.63	1.56
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.43	0.45	0.63	0.56

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	40
Average Number of Cycles to IDE Approval or Conditional Approval	1.60	1.50	1.45	1.41	1.04
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.60	0.50	0.45	0.41	0.04

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	38
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.11	1.15	1.08
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.11	0.15	0.08

Table 10.1 OHT5 - Office of Neurological and Physical Medicine Devices
IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	62	70	66	59	59
Average Number of Cycles to IDE Approval or Conditional Approval	1.16	1.47	1.17	1.14	1.11
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.17	0.14	0.11

Table 10.1 OHT6 - Office of Orthopedic Devices
IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	16	11	17	19	11
Average Number of Cycles to IDE Approval or Conditional Approval	1.18	1.20	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.18	0.20	0.00	0.00	0.00

Table 10.1 OHT7 - Office of In Vitro Diagnostics
IDE MDUFA IV Decision Performance Goal

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of IDEs Received	44	43	53	76	64
Average Number of Cycles to IDE Approval or Conditional Approval	1.00	1.03	1.00	1.00	1.00
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.00	0.03	0.00	0.00	0.00

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

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

Section 11 CLIA Waiver Annual Metrics

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

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

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

Appendix A Variable Definitions

Section 1 PMA Originals and Panel Track Supplements

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

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year.
2	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 GrantedDeclined, Withdrawn or Deleted).
3	MDUFA IV Decisions	Number of submissions accepted (line 1) and closed with a MDUFA IV decision (GrantedDeclined, 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 Missed 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 PercentWithin 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.

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CBER Performance Data ----
Actions through 31Mar 2023**

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	3	3	1	2
Closed Before RTA Action	0	0	0	0	0
Number with Accepted RTA Review	1	2	3	1	1
Number Without a RTA Review and > 15 Days Since Date Received	0	0	0	0	0
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted for Filing Review	2	1	0	0	1
Rate of Submissions Not Accepted for Filing Review	66.67%	33.33%	0.00%	0.00%	50.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	3	3	1	2
Number Accepted	1	2	3	1	1
Completed RTF	3	3	3	1	2
Number Not Filed	1	0	0	0	1
Rate of Submissions Not Filed	33.33%	0.00%	0.00%	0.00%	50.00%

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

Performance Goal

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	2	3	3	1	1
SI Goal Met	2	3	2	1	1
SI Goal Not Met	0	0	1	0	0
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	66.67%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	3	3	1	1
Average Number of FDA Days to Substantive Interaction	69.00	85.33	91.33	86.00	85.00
20th Percentile FDA Days to Substantive Interaction	50	82	81	86	85
40th Percentile FDA Days to Substantive Interaction	50	84	89	86	85
60th Percentile FDA Days to Substantive Interaction	88	84	89	86	85
80th Percentile FDA Days to Substantive Interaction	88	90	104	86	85
Maximum FDA Days to Substantive Interaction	88	90	104	86	85

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

Performance Metric	FY 2018 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 90% Within 180 FDA Days
Number of PMAs Filed	2	3	3	1	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	2	3	3	1	1
MDUFA IV Decision Goal Met	2	3	3	1	1
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%	100.00%

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

Performance Metric	FY 2018 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 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	1
Average FDA Days to MDUFA IV Decision	164.50	162.33	164.67	177.00	123.00
20th Percentile FDA Days to MDUFA IV Decision	156	140	150	177	123
40th Percentile FDA Days to MDUFA IV Decision	156	171	169	177	123
60th Percentile FDA Days to MDUFA IV Decision	173	171	169	177	123
80th Percentile FDA Days to MDUFA IV Decision	173	176	175	177	123
Maximum FDA Days to MDUFA IV Decision	173	176	175	177	123
Average Industry Days to MDUFA IV Decision	319.50	161.00	55.33	0.00	70.00
20th Percentile Industry Days to MDUFA IV Decision	105	56	166	0	70
40th Percentile Industry Days to MDUFA IV Decision	105	177	166	0	70
60th Percentile Industry Days to MDUFA IV Decision	534	177	166	0	70
80th Percentile Industry Days to MDUFA IV Decision	534	250	166	0	70
Maximum Industry Days to MDUFA IV Decision	534	250	166	0	70
Average Total Days to MDUFA IV Decision	484.00	323.33	220.00	177.00	193.00
20th Percentile Total Days to MDUFA IV Decision	261	196	150	177	193
40th Percentile Total Days to MDUFA IV Decision	261	348	169	177	193
60th Percentile Total Days to MDUFA IV Decision	707	348	169	177	193
80th Percentile Total Days to MDUFA IV Decision	707	426	341	177	193
Maximum Total Days to MDUFA IV Decision	707	426	341	177	193

Table 1.8 CBER - PMA Original and Panel-Track Supplements (with Panel Review)

Performance Metric - Time to MDUFA IV Decision

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

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

Performance Metric - Rates of Withdrawal, Not Approvable and Deleted

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	3	1	1
Number with MDUFA IV Decision	2	3	3	1	1
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	0%	0%	0%	0%	0%
Rate of Not Approvable	50.00%	33.33%	0%	0%	0%

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 90% Within 180 FDA Days	FY 2019 90% Within 180 FDA Days	FY 2020 90% Within 180 FDA Days	FY 2021 90% Within 180 FDA Days	FY 2022 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 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 90% Within 320 FDA Days
Number of PMAs Filed	1	2	2	0	1
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	2	2	0	1
MDUFA IV Decision Goal Met	1	2	2	0	1
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%	#DIV/0!	100.00%

*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 95% SI Within 90 FDA Days	FY 2019 95% SI Within 90 FDA Days	FY 2020 95% SI Within 90 FDA Days	FY 2021 95% SI Within 90 FDA Days	FY 2022 95% SI Within 90 FDA Days
Eligible for SI	8	5	8	7	7
SI Goal Met	8	5	8	4	6
SI Goal Not Met	0	0	0	0	1
SI Pending Within Goal	0	0	0	0	0
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	3	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	85.71%

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

Performance Metric	FY 2018 95% SI Within 180 FDA Days	FY 2019 95% SI Within 180 FDA Days	FY 2020 95% SI Within 180 FDA Days	FY 2021 95% SI Within 180 FDA Days	FY 2022 95% SI Within 180 FDA Days
Supplements Received	8	5	8	7	7
Non-MDUFA IV Decision	0	0	0	4	0
MDUFA IV Decision	8	5	8	3	5
MDUFA IV Decision Goal Met	8	5	8	3	5
Supplements Pending MDUFA IV Decision	0	0	0	0	2
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	8	5	8	7	7
Number with MDUFA IV Decision	8	5	8	3	5
Number of Not Approvable	0	0	1	0	0
Rate of Not Approvable	0.00%	0.00%	12.50%	0.00%	0.00%

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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
Supplements Received	3	2	5	9	9
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	3	2	5	9	9
MDUFA IV Decision Goal Met	3	2	5	9	9
Supplements Pending MDUFA IV Decision	0	0	0	0	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	3	2	5	9	9
Number With MDUFA IV Decision	3	2	5	9	9
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.00%	0.00%	0.00%	0.00%	0.00%

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

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

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

Table 6.1 CBER - 510(k) Acceptance Review Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	53	54	50	45	37
Closed Before RTA Action	0	0	1	1	0
Number Accepted	40	38	34	36	31
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	6
Rate of Submissions Not Accepted for Review	20.75%	27.78%	28.57%	11.36%	16.22%

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

Substantive Interaction (SI) Goal	FY 2018 95% SI Within 60 FDA Days	FY 2019 95% SI Within 60 FDA Days	FY 2020 95% SI Within 60 FDA Days	FY 2021 95% SI Within 60 FDA Days	FY 2022 95% SI Within 60 FDA Days
Eligible for SI	49	51	44	40	36
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	49	51	43	40	36
SI Over 60 FDA Days	0	0	1	0	0
SI Pending Within 60 FDA Days	0	0	0	0	1
SI Pending Over 60 FDA Days	0	0	0	0	0
510(k)s NSE Without SI	0	0	0	0	0
Current SI Performance Percent Within 60 FDA Days	100.00%	100.00%	97.73%	100.00%	100.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interaction	49	51	44	40	36
Average Number of FDA Days to Substantive Interaction	50.60	45.27	48.98	53.63	51.28
20th Percentile FDA Days to Substantive Interaction	43	21	21	56	48
40th Percentile FDA Days to Substantive Interaction	57	53	55	58	56
60th Percentile FDA Days to Substantive Interaction	59	58	59	59	59
80th Percentile FDA Days to Substantive Interaction	60	60	60	60	60
Maximum FDA Days to Substantive Interaction	60	60	64	60	60

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	49	51	44	40	37
Non-MDUFA IV Decision	6	5	7	1	3
MDUFA IV Decision (SE/NSE)	43	46	37	33	31
MDUFA IV Decision Within 90 FDA Days	43	46	37	33	31
510(k)s Pending MDUFA IV Decision	0	0	0	6	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%

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	1.36	1.45
Number With MDUFA IV Decision	43	46	37	33	31
Average Number of FDA Days to MDUFA IV Decision	75.58	67.48	64.08	74.79	71.81
20th Percentile FDA Days to MDUFA IV Decision	65	28	30	66	30
40th Percentile FDA Days to MDUFA IV Decision	85	77	65	81	83
60th Percentile FDA Days to MDUFA IV Decision	88	87	82	87	87
80th Percentile FDA Days to MDUFA IV Decision	90	89	88	90	89
Maximum FDA Days to MDUFA IV Decision	90	206	90	96	90
Average Number of Industry Days to MDUFA IV Decision	25.26	75.76	16.95	52.91	48.74
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	78	0	0	20
80th Percentile Industry Days to MDUFA IV Decision	59	179	29	128	115
Maximum Industry Days to MDUFA IV Decision	178	389	199	366	179
Average Number of Total Days to MDUFA IV Decision	100.84	143.24	81.05	127.70	120.55
20th Percentile Total Days to MDUFA IV Decision	76	59	30	66	79
40th Percentile Total Days to MDUFA IV Decision	86	87	65	81	85
60th Percentile Total Days to MDUFA IV Decision	90	141	82	90	92
80th Percentile Total Days to MDUFA IV Decision	147	269	105	215	190
Maximum Total Days to MDUFA IV Decision	268	463	287	450	269

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	37
Number With MDUFA IV Decision	43	46	37	33	31
Number of SE Decision	43	43	35	33	26
Number of NSE Decision	0	3	2	0	5
Number of Withdrawal	2	4	4	1	2
Number of Deleted	3	1	3	0	1
Rate of SE Decision	100.00%	93.48%	94.59%	100.00%	83.87%
Rate of NSE Decision	0.00%	6.52%	5.41%	0.00%	16.13%
Rate of Withdrawal	4.08%	7.84%	9.09%	2.50%	5.41%
Rate of Deleted	6.12%	1.96%	6.82%	0.00%	2.70%

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

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

Performance Metric	FY 2018 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 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 95% Within 90 FDA Days	FY 2019 95% Within 90 FDA Days	FY 2020 95% Within 90 FDA Days	FY 2021 95% Within 90 FDA Days	FY 2022 95% Within 90 FDA Days
510(k)s Accepted	15	17	7	19	14
Non-MDUFA IV Decision	0	1	0	0	0
MDUFA IV Decision (SE/NSE)	15	16	7	14	14
MDUFA IV Decision Within 90 FDA Days	15	16	7	14	14
510(k)s Pending MDUFA IV Decision	0	0	0	5	0
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	0
Current Performance Percent Within 90 FDA Days	100.00%	100.00%	100.00%	100.00%	100.00%

Section 8 De Novo Center Level Metrics

Table 8.1 CBER - De Novo Acceptance Review Decision*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Received	0	1	0	0	3
Closed Before RTA Action	N/A	N/A	0	0	0
Number Accepted First RTA Cycle	N/A	N/A	0	0	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	0	0	1
Rate of Submissions Not Accepted for Review	N/A	N/A	0.00%	0.00%	33.33%

* 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 50% Within 150 FDA Days	FY 2019 55% Within 150FDA Days	FY 2020 60% Within 150 FDA Days	FY 2021 65% Within 150 FDA Days	FY 2022 70% Within 150 FDA Days
De Novos Accepted	0	1	0	0	3
Non-MDUFA IV Decisions	0	0	0	0	1
MDUFA IV Decisions	0	1	0	0	1
MDUFA IV Decisions Within 150 FDA Days	0	1	0	0	1
De Novos Pending MDUFA IV Decision	0	0	0	0	1
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	N/A	100.00%	N/A	N/A	100.00%

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	1
Number With MDUFA IV Decision	0	1	0	0	1
Average FDA Days to MDUFA IV Decision	0.00	150	0.00	0.00	150
20th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	150
40th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	150
60th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	150
80th Percentile FDA Days to MDUFA IV Decision	0	150	0	0	150
Maximum FDA Days to MDUFA IV Decision	0	150	0	0	150
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	150
20th Percentile Total Days to MDUFA IV Decision	0	231	0	0	150
40th Percentile Total Days to MDUFA IV Decision	0	231	0	0	150
60th Percentile Total Days to MDUFA IV Decision	0	231	0	0	150
80th Percentile Total Days to MDUFA IV Decision	0	231	0	0	150
Maximum Total Days to MDUFA IV Decision	0	231	0	0	150

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	3
Number With MDUFA IV Decisions	0	1	0	0	2
Number With Granted Decisions	0	1	0	0	1
Number With Declined Decisions	0	0	0	0	0
Number of Withdrawals	0	0	0	0	0
Number Deleted	0	0	0	0	1
Rate of Granted Decisions	N/A	100.00%	N/A	N/A	50.00%
Rate of Declined Decisions	N/A	0	N/A	N/A	0
Rate of Withdrawals	N/A	0	N/A	N/A	0
Rate of Deleted	N/A	0	N/A	N/A	0.5

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	1
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	1	0	0	1
MDUFA IV Decisions Within 150 FDA Days	0	1	0	0	1
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	N/A	100.00%	N/A	N/A	100.00%

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	82	51
Closed Before RTA Action	5	3	10	7	1
Number Accepted First RTA Cycle	69	70	65	72	48
Number Without a RTA Review and > 15 Days Since Date Received	1	3	1	3	1
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	1	1	1	0	1
Rate of Submissions Not Accepted for Review	1.41%	1.35%	1.49%	0.00%	2.00%

*Updated to include Breakthrough Interactions within the report

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 ≥ 1530 Submissions	FY 2019 ≥ 1645 Submissions	FY 2020 ≥ 1765 Submissions	FY 2021 ≥ 1880 Submissions	FY 2022 ≥ 1950 Submissions
Written Feedback Sent	70	74	68	72	49
Written Feedback Provided Within MDUFA IV Goal	68	71	63	68	46

*Due to resource limitations related to COVID-19 activities, some Pre-Subs were reviewed with a delayed timeline which may have resulted in missed MDUFA goals

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Written Feedback Sent	70	74	68	72	49
Average FDA Days to Written Feedback	57.86	61.00	56.70	62.20	59.18
20th Percentile FDA Days to Written Feedback	47	55	48	54	51.0
40th Percentile FDA Days to Written Feedback	58	60	58	62	60
60th Percentile FDA Days to Written Feedback	64	63	64	64	63.8
80th Percentile FDA Days to Written Feedback	67	68	68	66	69
Maximum FDA Days to Written Feedback	72	75	77	156	80

*Due to resource limitations related to COVID-19 activities, some Pre-Subs were reviewed with a delayed timeline which may have resulted in missed MDUFA goals

Table 9.4 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Scheduling

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meetings Not Scheduled By Day 30	0	0	0	0	0
Average Days to Scheduling for Meetings Scheduled After Day 30	0.00	0.00	0.00	0.00	0.00

Table 9.5 CBER - MDUFA IV Pre-Sub Performance Metrics - Meeting Minutes

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Meeting Held	42	33	27	41	22
Meeting Minutes Submitted Within 15 Days of Meeting	33	30	26	33	17
Meeting Minutes Not Submitted and <= 15 Days Since Meeting Date	0	0	0	0	0
Meeting Minutes Past 15 Days of Meeting	9	2	1	6	4
Meeting Minutes Not Submitted and >15 Days Since Meeting	0	1	0	2	1
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	90.91%	96.30%	80.49%	77.27%

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	19
Average Number of Cycles to IDE Approval or Conditional Approval	1.25	1.63	1.07	1.29	1.17
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.25	0.63	0.07	0.29	0.17

BLA

CBER – Annual General Metric Report for BLAs

****Annual Metrics and Goals will be reported in the Annual Report****