

MDUFA IV (FY 2018-2022) Performance Report

November 16, 2023, 1:00 – 2:30 pm

Zoom

FDA MDUFA Performance — Actions through September 30, 2023

- Report on decision goals

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CDRH Performance Data ----
Actions through 30 September 2023**

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Acronyms and Abbreviations

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

Office Organizations

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

OHT2: Office of Cardiovascular Devices

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

OHT4: Office of Surgical and Infection Control Devices

OHT5: Office of Neurological and Physical Medicine Devices

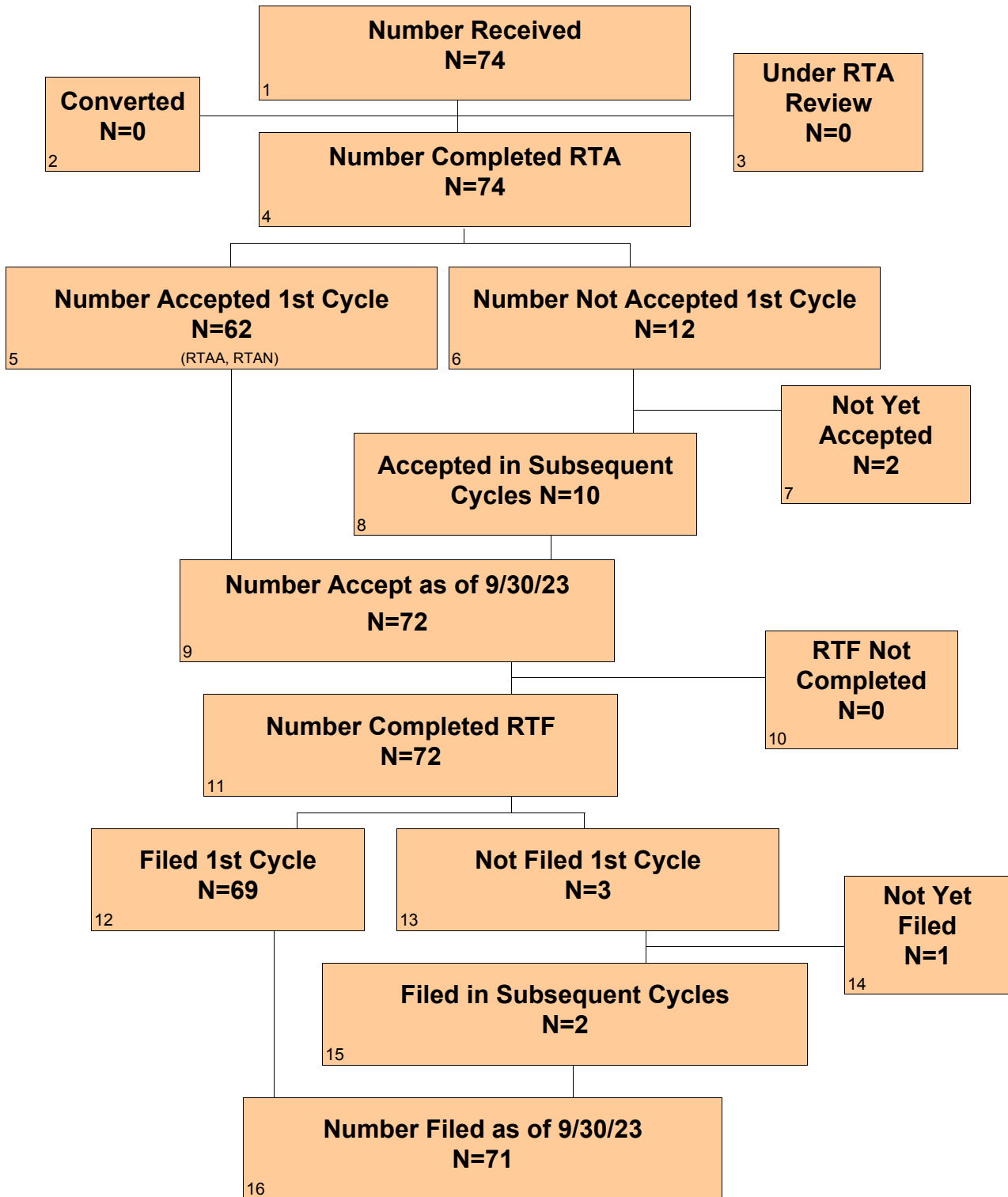
OHT6: Office of Orthopedic Devices

OHT7: Office of In Vitro Diagnostics

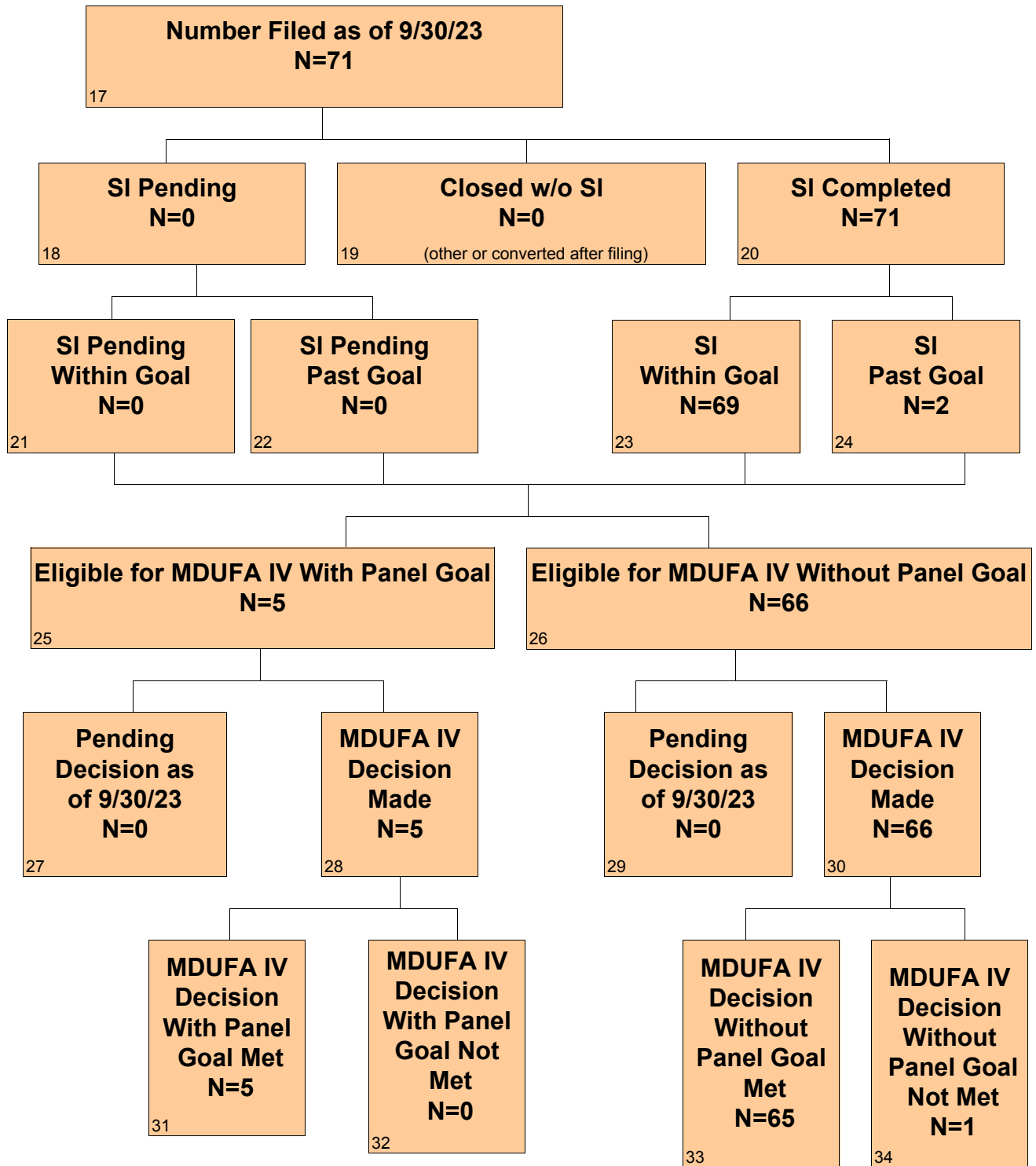
OHT8: Office of Radiological Health

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

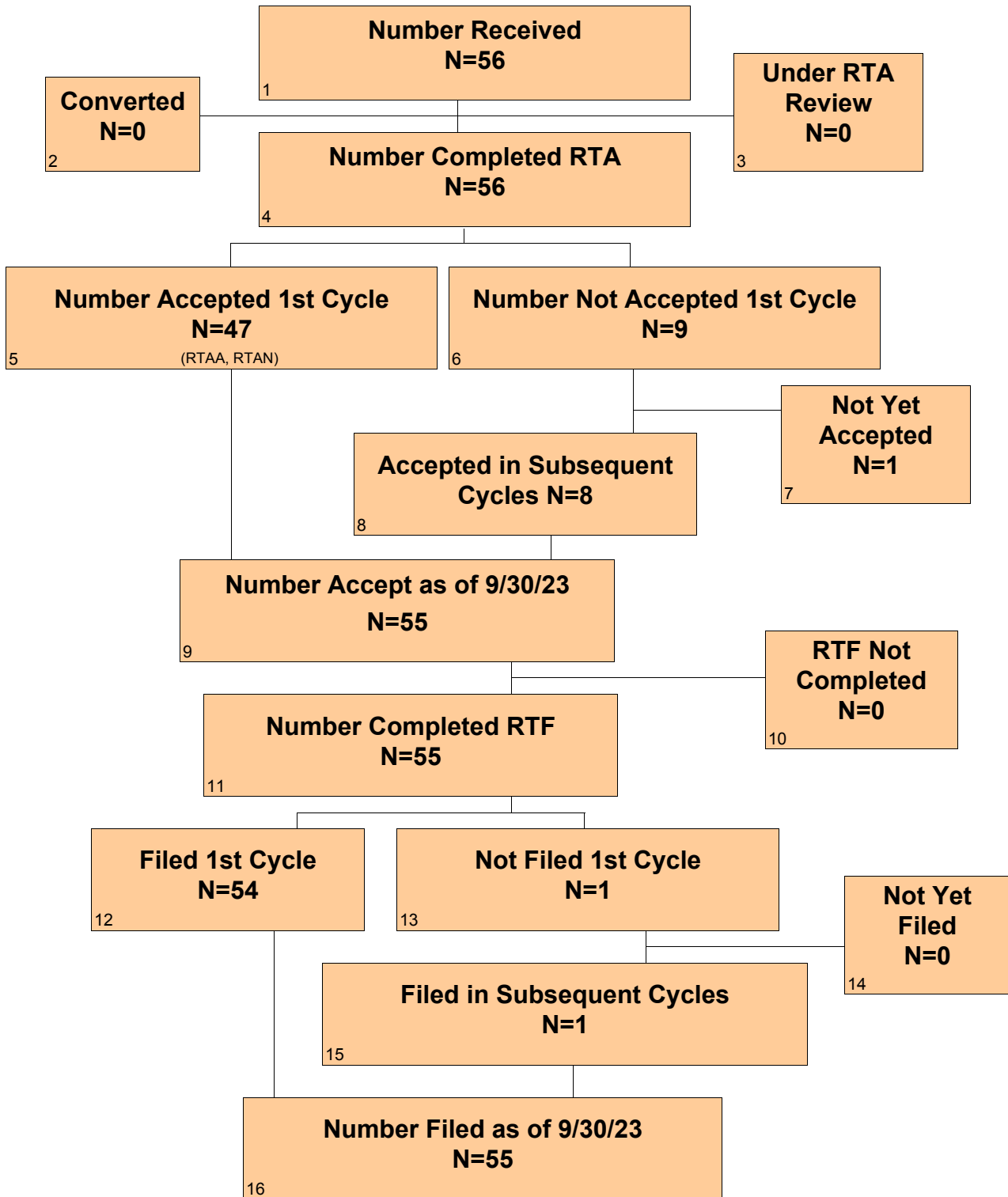
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/23



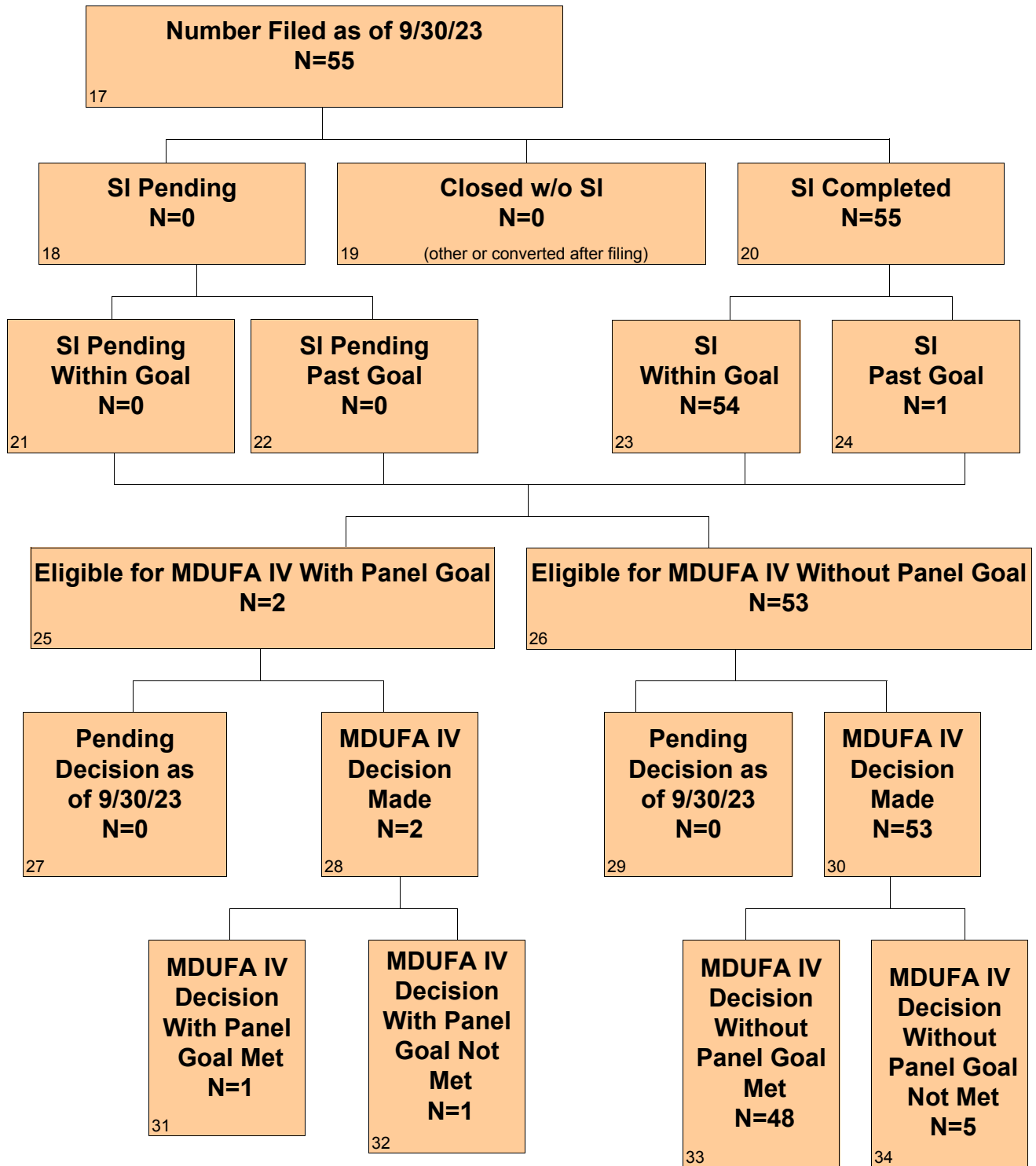
CDRH PMA Original and Panel Track Supplements - FY 2018 as of 9/30/23 Continued



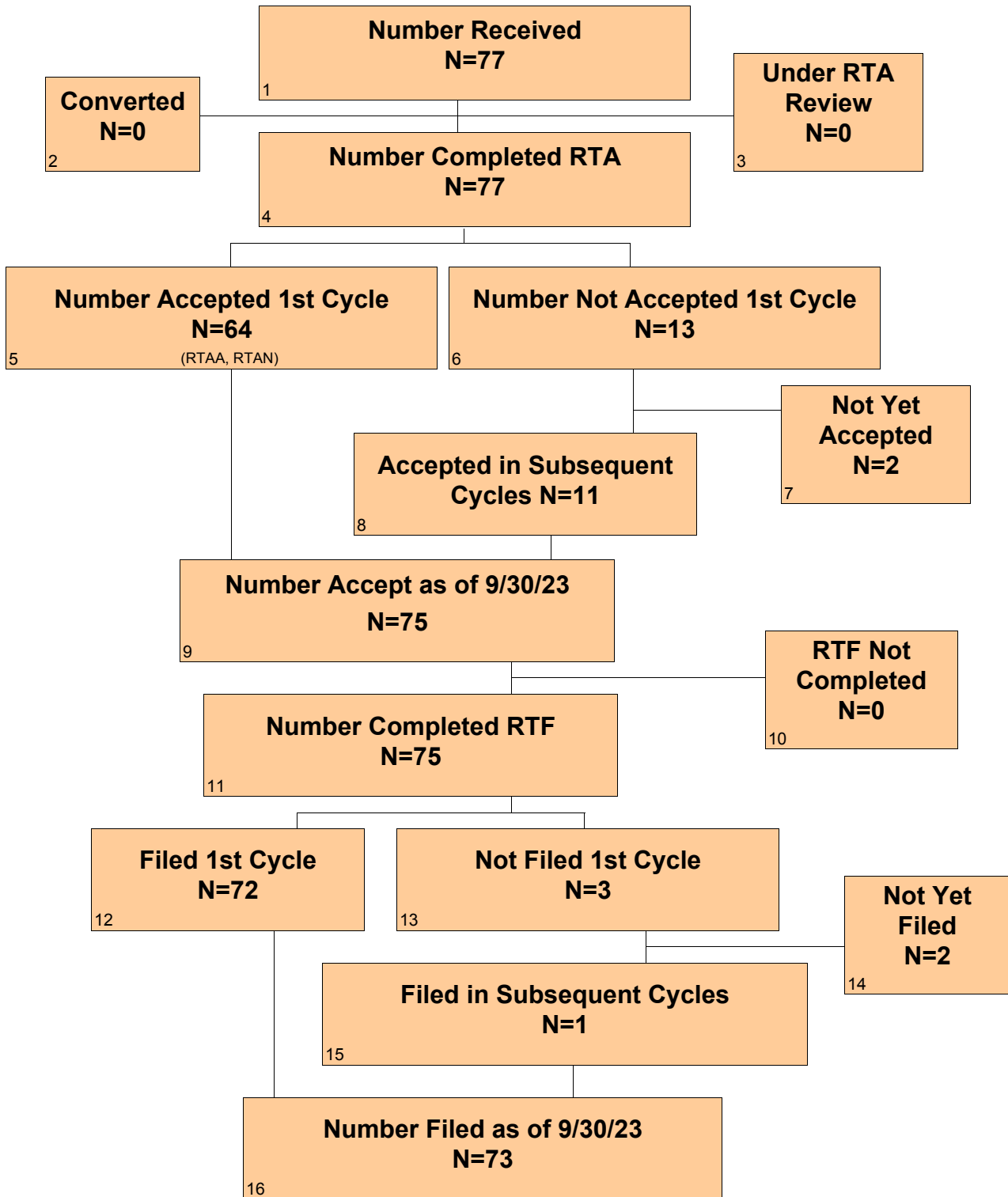
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/23



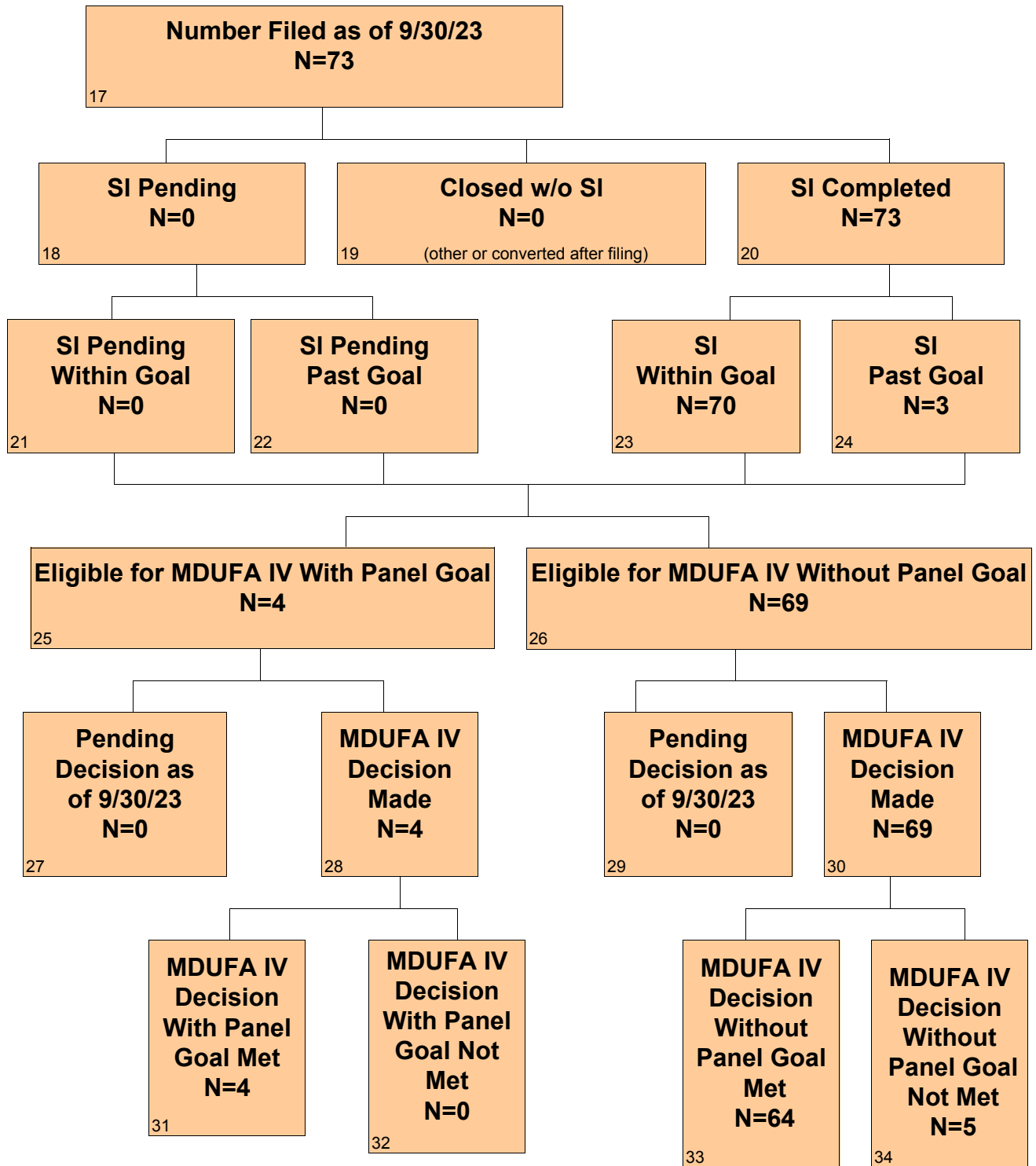
CDRH PMA Original and Panel Track Supplements - FY 2019 as of 9/30/23 Continued



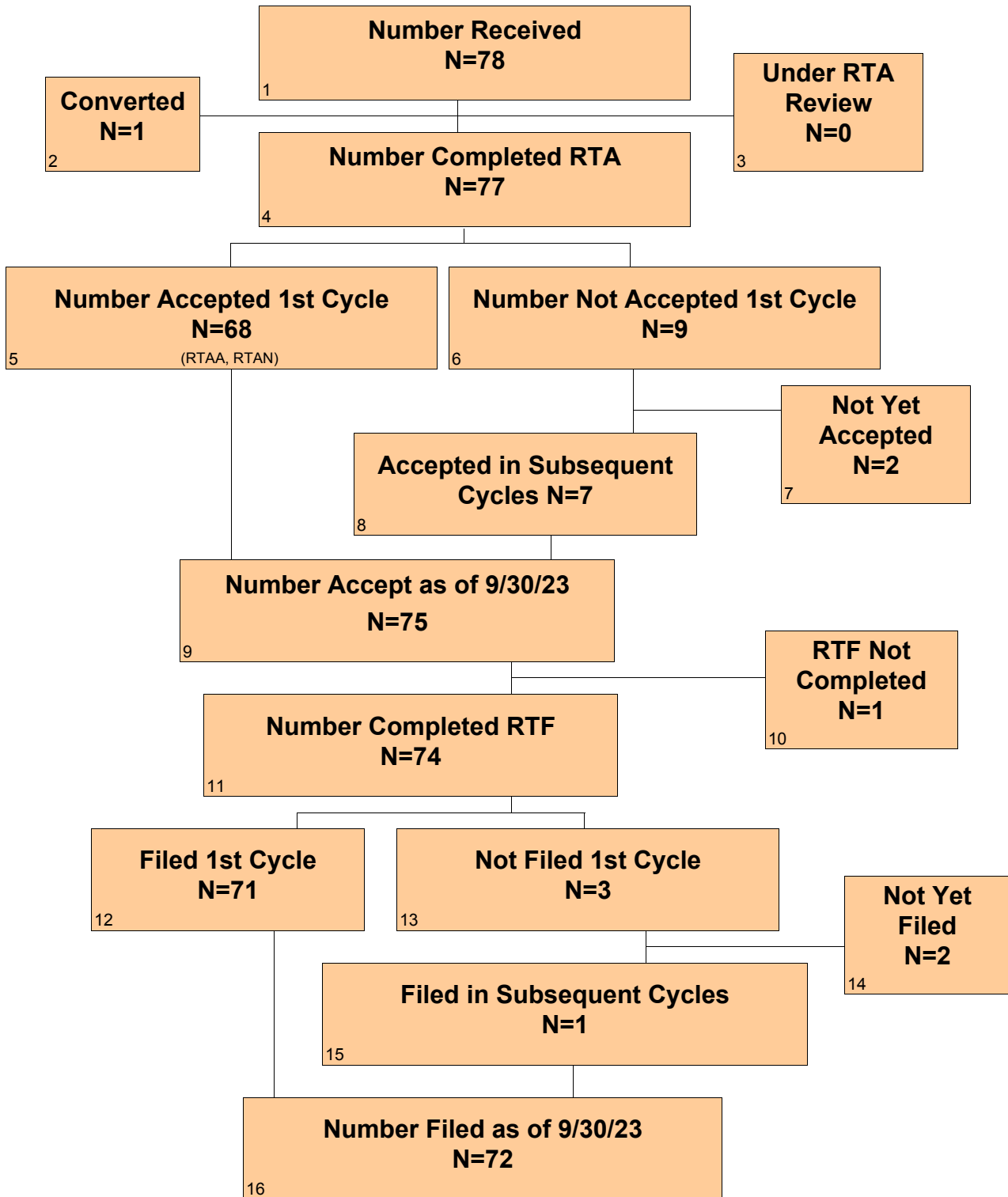
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/23



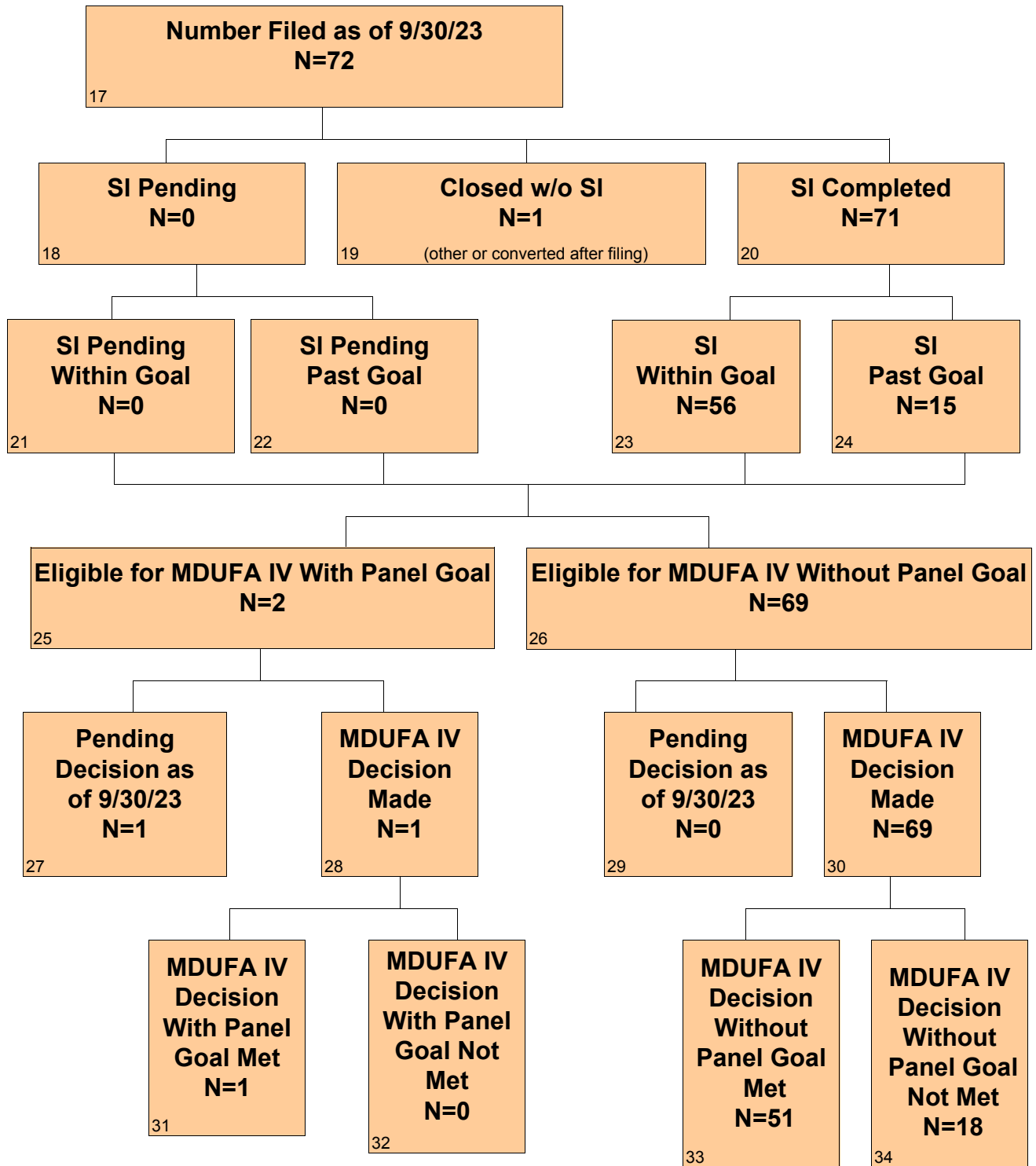
CDRH PMA Original and Panel Track Supplements - FY 2020 as of 9/30/23 Continued



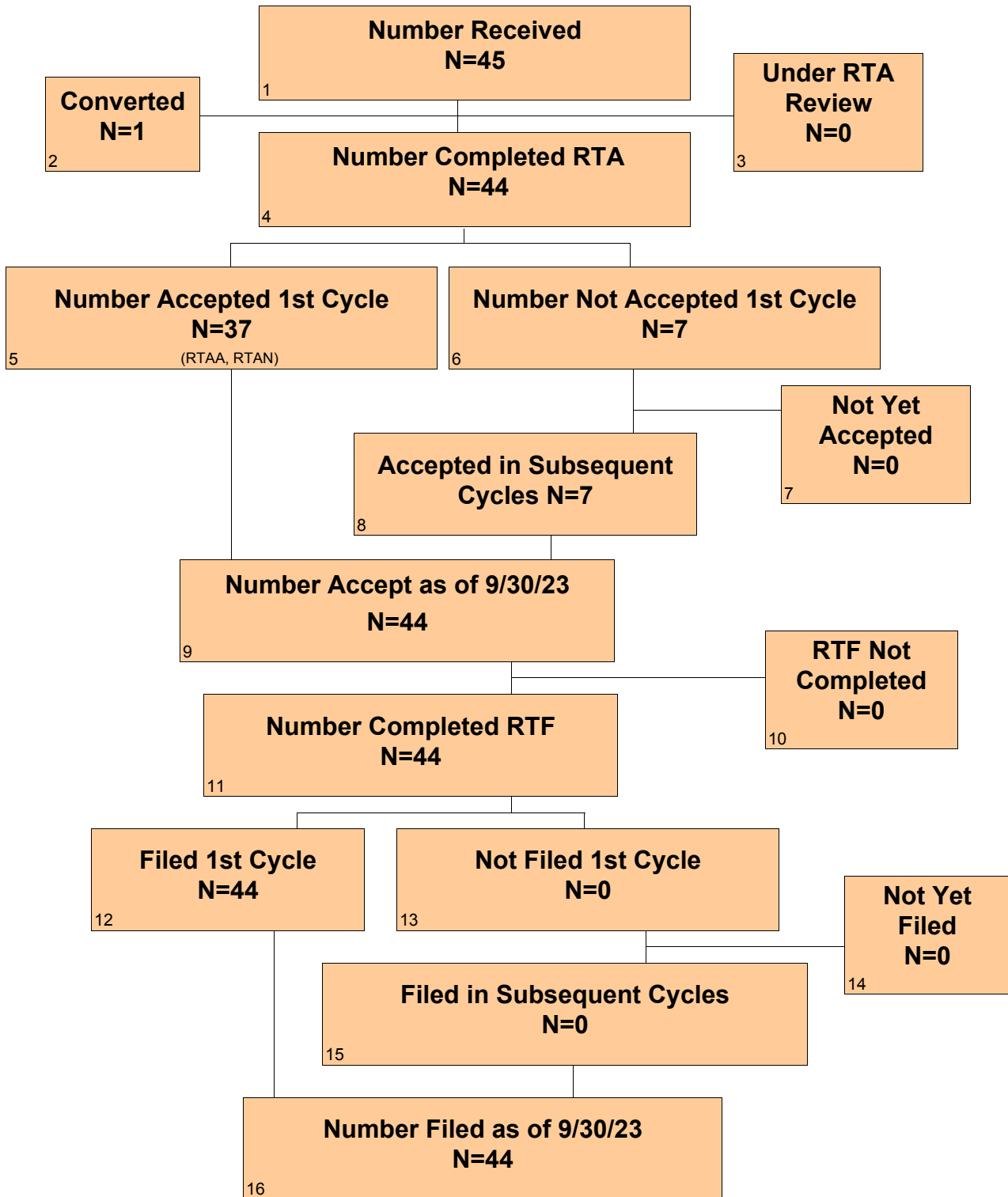
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 9/30/23



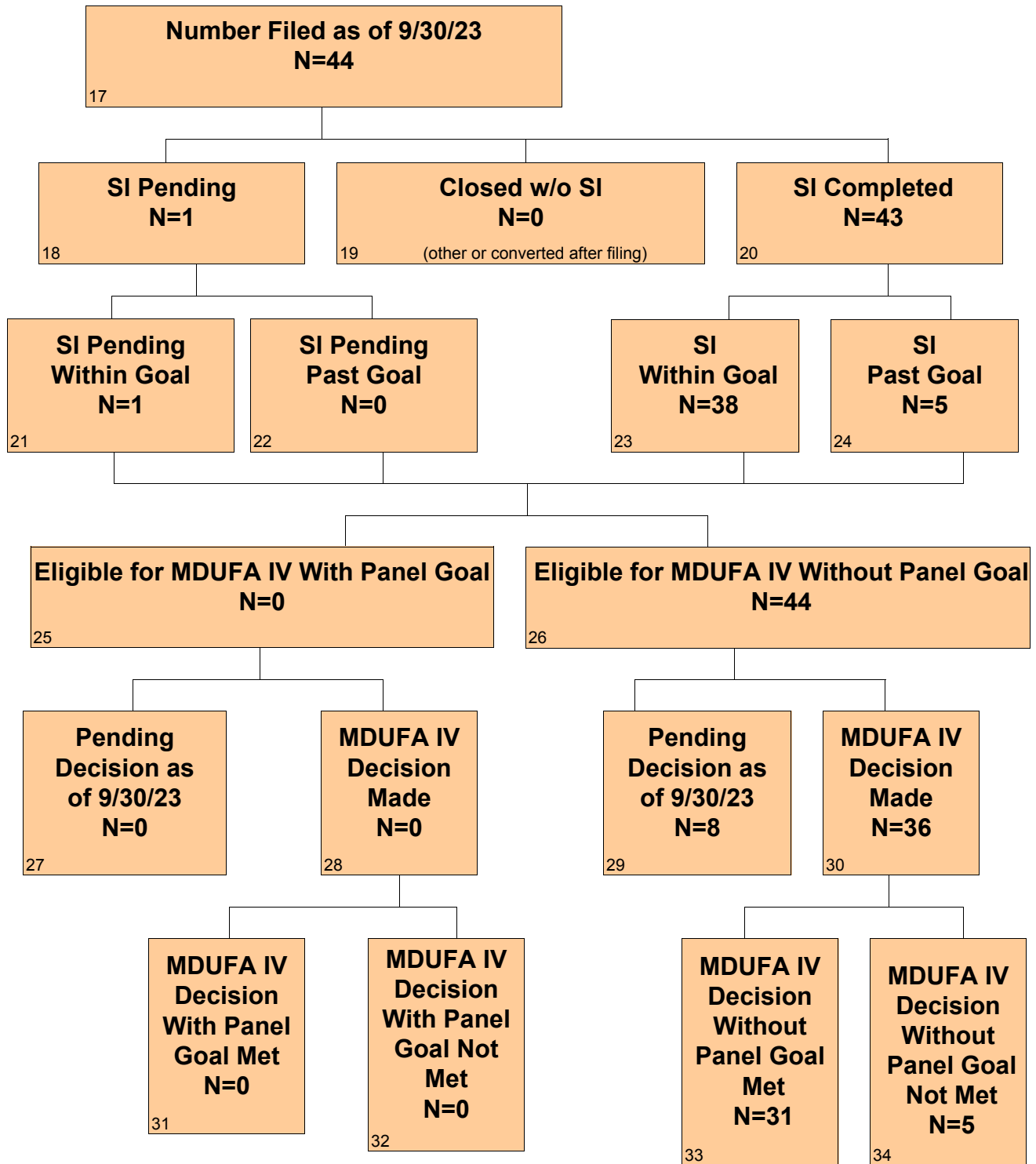
CDRH PMA Original and Panel Track Supplements - FY 2021 as of 9/30/23 Continued



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 9/30/23



CDRH PMA Original and Panel Track Supplements - FY 2022 as of 9/30/23 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	44
Number Not Filed	3	1	3	3	0
Rate of Submissions Not Filed	4.17%	1.82%	4.00%	4.05%	0.00%

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

Performance Goal

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	71	55	73	72	44
SI Goal Met	69	54	70	56	38
SI Goal Not Met	2	1	3	15	5
SI Pending Within Goal	0	0	0	0	1
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	1	0
Current SI Performance Percent Goal Met	97.18%	98.18%	95.89%	78.87%	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	43
Average Number of FDA Days to Substantive Interaction	87.03	89.95	91.74	125.73	94.81
20th Percentile FDA Days to Substantive Interaction	84	87	88	87	87
40th Percentile FDA Days to Substantive Interaction	88	88	88	89	89
60th Percentile FDA Days to Substantive Interaction	90	89	90	90	90
80th Percentile FDA Days to Substantive Interaction	90	90	90	91	90
Maximum FDA Days to Substantive Interaction	178	246	325	598	248

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	44
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	66	53	69	69	36
MDUFA IV Decision Goal Met	65	48	64	51	31
PMAs Pending MDUFA IV Decision	0	0	0	0	8
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	1
Current Performance Percent Goal Met	98.48%	90.57%	92.75%	73.91%	83.78%

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	69	69	36
Average FDA Days to MDUFA IV Decision	163.12	180.74	180.09	208.23	178.03
20th Percentile FDA Days to MDUFA IV Decision	146	147	175	172	173
40th Percentile FDA Days to MDUFA IV Decision	177	178	179	178	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	205	180
Maximum FDA Days to MDUFA IV Decision	279	338	501	648	414
Average Industry Days to MDUFA IV Decision	99.89	127.28	143.71	158.00	90.47
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	10
40th Percentile Industry Days to MDUFA IV Decision	26	31	48	47	56
60th Percentile Industry Days to MDUFA IV Decision	90	130	85	119	81
80th Percentile Industry Days to MDUFA IV Decision	163	192	252	334	133
Maximum Industry Days to MDUFA IV Decision	536	540	1,050	540	357
Average Total Days to MDUFA IV Decision	263.02	308.02	323.80	366.23	268.50
20th Percentile Total Days to MDUFA IV Decision	168	175	177	180	190
40th Percentile Total Days to MDUFA IV Decision	180	204	218	228	230
60th Percentile Total Days to MDUFA IV Decision	258	310	266	332	261
80th Percentile Total Days to MDUFA IV Decision	350	440	457	572	319
Maximum Total Days to MDUFA IV Decision	762	718	1,264	1,016	547

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	N/A
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	N/A	N/A
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	N/A
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	44
Number with MDUFA IV Decision	66	53	69	69	36
Number of Withdrawal	6	3	5	6	2
Number of Not Approvable	8	7	5	9	6
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	9.09%	5.66%	7.25%	8.70%	5.56%
Rate of Not Approvable	12.12%	13.21%	7.25%	13.04%	16.67%

**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	6
Mean FDA Days for Submissions that Missed the Goal	226.00	266.60	285.00	336.83	238.17
Mean Industry Days for Submissions that Missed the Goal	536.00	235.00	135.00	211.39	124.17

**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	N/A	795.00	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	187.00	N/A	N/A	N/A

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	12	5	6
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	12	5	6
MDUFA IV Decision Goal Met	1	4	12	3	4
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%	60.00%	66.67%

*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	14	20	9
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	19	7
MDUFA IV Decision Goal Met	15	13	12	8	6
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	100.00%	76.47%	85.71%	42.11%	75.00%

*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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	16	7	6	7	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	4
MDUFA IV Decision Goal Met	15	7	6	6	4
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%	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	4
Average FDA Days to MDUFA IV Decision	177.33	179.14	180.00	169.57	179.25
20th Percentile FDA Days to MDUFA IV Decision	176	179	180	178	179
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	67.75
20th Percentile Industry Days to MDUFA IV Decision	0	4	68	56	43
40th Percentile Industry Days to MDUFA IV Decision	52	20	81	109	52
60th Percentile Industry Days to MDUFA IV Decision	141	50	108	256	60
80th Percentile Industry Days to MDUFA IV Decision	278	148	277	351	88
Maximum Industry Days to MDUFA IV Decision	360	180	400	387	126
Average Total Days to MDUFA IV Decision	308.27	244.57	340.17	366.57	247.00
20th Percentile Total Days to MDUFA IV Decision	178	184	248	235	223
40th Percentile Total Days to MDUFA IV Decision	232	200	261	288	232
60th Percentile Total Days to MDUFA IV Decision	321	230	288	394	240
80th Percentile Total Days to MDUFA IV Decision	450	328	457	499	266
Maximum Total Days to MDUFA IV Decision	528	359	580	588	303

**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	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A
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	4
Number of Withdrawal	0	0	0	1	0
Number of Not Approvable	4	1	2	1	1
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%	25.00%

**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	N/A	N/A	N/A	201.00	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	387.00	N/A

**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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	22	14	23	19	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	22	19	11
MDUFA IV Decision Goal Met	21	12	22	19	11
PMAs Pending MDUFA IV Decision	0	0	0	0	2
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	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	22	19	11
Average FDA Days to MDUFA IV Decision	174.00	178.92	178.14	175.74	178.27
20th Percentile FDA Days to MDUFA IV Decision	161	159	176	177	178
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	171.91	99.47	77.73
20th Percentile Industry Days to MDUFA IV Decision	0	10	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	67	27	47	19
60th Percentile Industry Days to MDUFA IV Decision	45	122	67	72	74
80th Percentile Industry Days to MDUFA IV Decision	91	171	300	146	133
Maximum Industry Days to MDUFA IV Decision	162	322	1,050	393	247
Average Total Days to MDUFA IV Decision	225.48	285.92	350.05	275.21	256.00
20th Percentile Total Days to MDUFA IV Decision	168	170	177	179	180
40th Percentile Total Days to MDUFA IV Decision	180	245	207	225	199
60th Percentile Total Days to MDUFA IV Decision	229	302	246	251	254
80th Percentile Total Days to MDUFA IV Decision	324	363	479	324	311
Maximum Total Days to MDUFA IV Decision	340	501	1,227	573	427

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	N/A	N/A
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	N/A	135.00	63.00	N/A	N/A
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	N/A	N/A
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	22	19	11
Number of Withdrawal	0	0	1	0	1
Number of Not Approvable	1	1	1	2	2
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	0.00%	4.55%	0.00%	9.09%
Rate of Not Approvable	4.76%	8.33%	4.55%	10.53%	18.18%

**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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	N/A	795.00	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	187.00	N/A	N/A	N/A

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	8	3	6	4	0
Average Number of FDA Days to Substantive Interaction	99.50	139.67	89.17	88.25	N/A
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	N/A
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	N/A
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	N/A
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	N/A	319.00	N/A	N/A
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	N/A	N/A	136.00	N/A	N/A
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	N/A	455.00	N/A	N/A
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	N/A	N/A	501.00	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	335.00	N/A	N/A

**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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	2	4	5	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	2
MDUFA IV Decision Goal Met	1	1	1	0	1
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	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	2
Average FDA Days to MDUFA IV Decision	192.50	181.00	198.67	214.50	295.00
20th Percentile FDA Days to MDUFA IV Decision	172	179	189	200	224
40th Percentile FDA Days to MDUFA IV Decision	186	180	198	215	271
60th Percentile FDA Days to MDUFA IV Decision	199	182	204	223	319
80th Percentile FDA Days to MDUFA IV Decision	213	183	209	230	366
Maximum FDA Days to MDUFA IV Decision	226	184	214	237	414
Average Industry Days to MDUFA IV Decision	271.00	90.00	41.67	142.00	97.50
20th Percentile Industry Days to MDUFA IV Decision	112	49	27	83	76
40th Percentile Industry Days to MDUFA IV Decision	218	76	31	126	90
60th Percentile Industry Days to MDUFA IV Decision	324	104	40	139	105
80th Percentile Industry Days to MDUFA IV Decision	430	131	55	197	119
Maximum Industry Days to MDUFA IV Decision	536	159	69	277	133
Average Total Days to MDUFA IV Decision	463.50	271.00	240.33	356.50	392.50
20th Percentile Total Days to MDUFA IV Decision	284	231	218	297	300
40th Percentile Total Days to MDUFA IV Decision	404	258	223	328	362
60th Percentile Total Days to MDUFA IV Decision	523	284	237	332	423
80th Percentile Total Days to MDUFA IV Decision	643	311	260	405	485
Maximum Total Days to MDUFA IV Decision	762	337	283	514	547

**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	N/A	N/A	320.00	N/A	N/A
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	N/A	N/A	104.00	N/A	N/A
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	N/A	N/A	424.00	N/A	N/A
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	2
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%	50.00%

**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	414.00
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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	4	5	3	8	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	4
MDUFA IV Decision Goal Met	4	5	2	8	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%	100.00%	75.00%

**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	4
Average FDA Days to MDUFA IV Decision	180.00	188.00	132.50	175.63	181.00
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	180
60th Percentile FDA Days to MDUFA IV Decision	180	180	141	179	180
80th Percentile FDA Days to MDUFA IV Decision	180	206	158	180	182
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	80.00
20th Percentile Industry Days to MDUFA IV Decision	56	96	13	0	45
40th Percentile Industry Days to MDUFA IV Decision	134	151	26	0	76
60th Percentile Industry Days to MDUFA IV Decision	253	184	38	24	96
80th Percentile Industry Days to MDUFA IV Decision	320	224	51	336	117
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	261.00
20th Percentile Total Days to MDUFA IV Decision	236	256	158	178	227
40th Percentile Total Days to MDUFA IV Decision	314	282	162	180	256
60th Percentile Total Days to MDUFA IV Decision	433	325	167	200	276
80th Percentile Total Days to MDUFA IV Decision	500	430	171	510	297
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	N/A	N/A	320.00	N/A	N/A
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	N/A	N/A	416.00	N/A	N/A
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	N/A	N/A	736.00	N/A	N/A
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	4
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%	25.00%

**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	N/A	N/A	N/A	N/A	185.00
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	3
Number Not Filed	0	0	0	0	0
Rate of Submissions Not Filed	0.00%	0.00%	0.00%	0.00%	0.00%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	2	3	2	4	3
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	1
SI Pending Past Goal	0	0	0	0	0
Closed Without SI	0	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	100.00%

Table 1.4 OHT6 - Office of Orthopedic Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	2	3	2	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	3
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	2	3	2	4	2
MDUFA IV Decision Goal Met	2	3	2	4	2
PMAs Pending MDUFA IV Decision	0	0	0	0	1
PMAs Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	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	4	2
Average FDA Days to MDUFA IV Decision	180.00	146.33	178.50	151.25	176.50
20th Percentile FDA Days to MDUFA IV Decision	180	121	178	130	174
40th Percentile FDA Days to MDUFA IV Decision	180	156	178	161	176
60th Percentile FDA Days to MDUFA IV Decision	180	174	179	174	177
80th Percentile FDA Days to MDUFA IV Decision	180	177	179	179	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	221.75	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	69	99
60th Percentile Industry Days to MDUFA IV Decision	170	209	124	278	137
80th Percentile Industry Days to MDUFA IV Decision	226	330	166	424	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	373.00	294.50
20th Percentile Total Days to MDUFA IV Decision	237	191	219	170	239
40th Percentile Total Days to MDUFA IV Decision	293	282	261	249	276
60th Percentile Total Days to MDUFA IV Decision	350	387	303	457	313
80th Percentile Total Days to MDUFA IV Decision	406	505	345	568	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	N/A	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A	N/A
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	3
Number with MDUFA IV Decision	2	3	2	4	2
Number of Withdrawal	0	1	0	1	0
Number of Not Approvable	0	1	0	1	1
Number of Deleted	0	0	0	0	0
Rate of Withdrawal	0.00%	33.33%	0.00%	25.00%	0.00%
Rate of Not Approvable	0.00%	33.33%	0.00%	25.00%	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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	16	21	26	25	15
SI Goal Met	16	20	23	11	13
SI Goal Not Met	0	1	3	13	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	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	15
Average Number of FDA Days to Substantive Interaction	85.63	87.76	97.35	192.25	103.13
20th Percentile FDA Days to Substantive Interaction	84	87	86	88	87
40th Percentile FDA Days to Substantive Interaction	88	88	88	90	88
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	248

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	26	23	13
MDUFA IV Decision Goal Met	16	17	24	10	10
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	100.00%	80.95%	92.31%	43.48%	71.43%

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	26	23	13
Average FDA Days to MDUFA IV Decision	127.13	178.67	174.69	271.96	158.77
20th Percentile FDA Days to MDUFA IV Decision	90	134	134	113	122
40th Percentile FDA Days to MDUFA IV Decision	112	173	179	180	171
60th Percentile FDA Days to MDUFA IV Decision	146	177	180	276	180
80th Percentile FDA Days to MDUFA IV Decision	175	180	180	476	187
Maximum FDA Days to MDUFA IV Decision	180	299	406	648	197
Average Industry Days to MDUFA IV Decision	91.56	142.38	100.12	161.09	106.15
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	16
40th Percentile Industry Days to MDUFA IV Decision	0	16	22	75	54
60th Percentile Industry Days to MDUFA IV Decision	75	81	62	135	89
80th Percentile Industry Days to MDUFA IV Decision	158	325	141	312	143
Maximum Industry Days to MDUFA IV Decision	336	540	973	535	357
Average Total Days to MDUFA IV Decision	218.69	321.05	274.81	433.04	264.92
20th Percentile Total Days to MDUFA IV Decision	90	155	156	178	166
40th Percentile Total Days to MDUFA IV Decision	146	179	183	288	217
60th Percentile Total Days to MDUFA IV Decision	225	257	242	452	271
80th Percentile Total Days to MDUFA IV Decision	270	619	321	734	324
Maximum Total Days to MDUFA IV Decision	511	718	1,264	1,016	527

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	N/A	N/A	N/A	161.00	N/A
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	N/A	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	161.00	N/A
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	26	23	13
Number of Withdrawal	4	1	2	4	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%	7.69%	17.39%	7.69%
Rate of Not Approvable	12.50%	4.76%	3.85%	4.35%	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	4
Mean FDA Days for Submissions that Missed the Goal	N/A	287.25	254.00	384.92	207.50
Mean Industry Days for Submissions that Missed the Goal	N/A	288.50	124.00	219.23	151.00

Table 1.12 OHT7 - Office of In Vitro Diagnostics

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

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

**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	12	5	6
Non-MDUFA IV Decision	0	0	0	0	0
MDUFA IV Decision	1	4	12	5	6
MDUFA IV Decision Goal Met	1	4	12	3	4
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%	60.00%	66.67%

*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	14	20	9
Non-MDUFA IV Decision	0	0	0	1	0
MDUFA IV Decision	15	17	14	19	7
MDUFA IV Decision Goal Met	15	13	12	8	6
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	100.00%	76.47%	85.71%	42.11%	75.00%

*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	N/A	89.67	N/A	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	N/A	179.67	N/A	N/A
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	N/A	N/A	157.00	N/A	N/A
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	N/A	336.67	N/A	N/A
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	N/A	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A	N/A
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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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

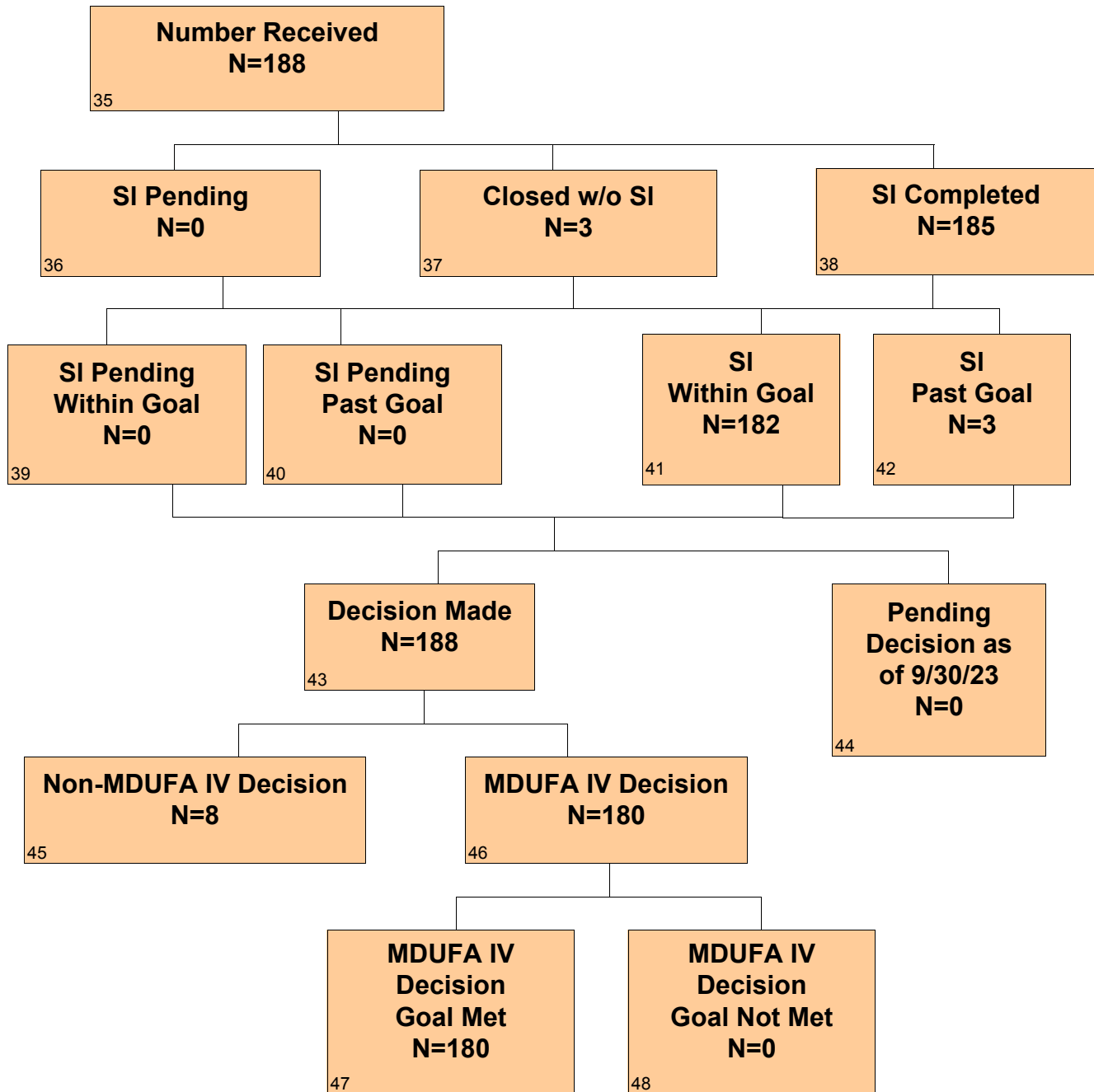
*Includes submission that went to panel

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

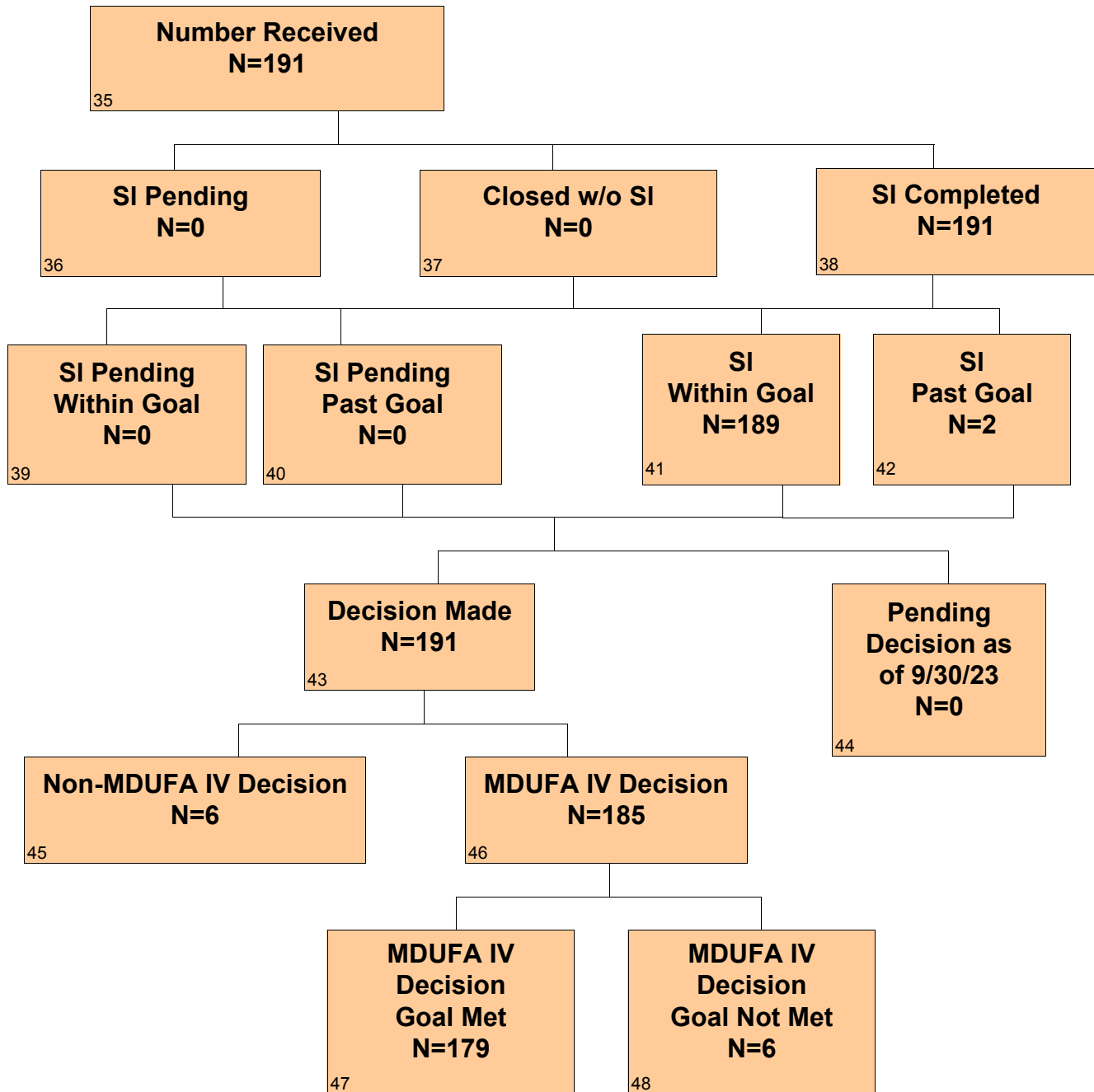
Performance Metric	FY 2018 90% Within 320 FDA Days	FY 2019 90% Within 320 FDA Days	FY 2020 90% Within 320 FDA Days	FY 2021 90% Within 320 FDA Days	FY 2022 90% Within 320 FDA Days
Number of PMAs Filed	N/A	N/A	N/A	N/A	N/A
Non-MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA IV Decision	N/A	N/A	N/A	N/A	N/A
MDUFA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

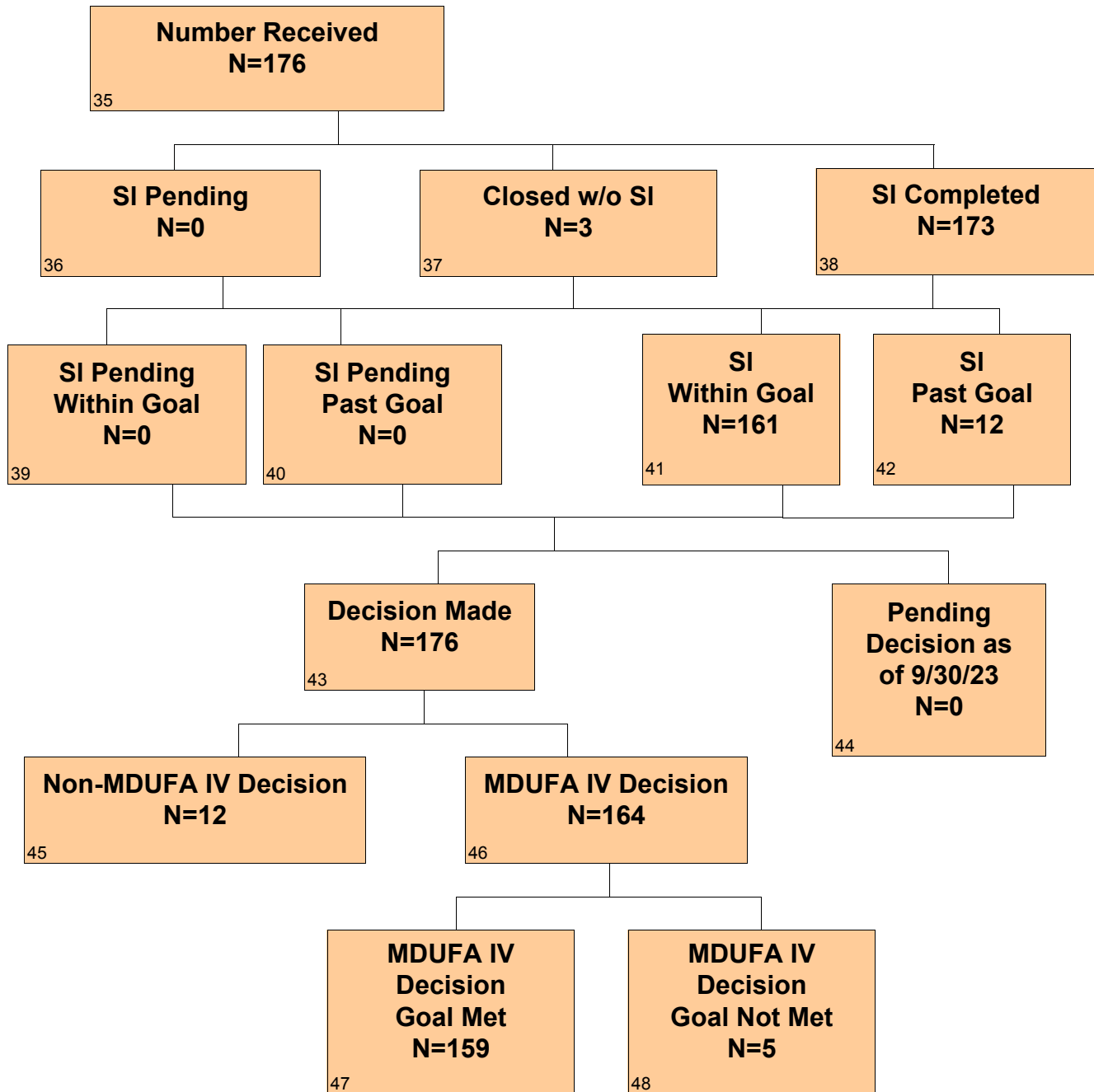
CDRH PMA 180 Day Supplements - FY 2018 as of 9/30/23



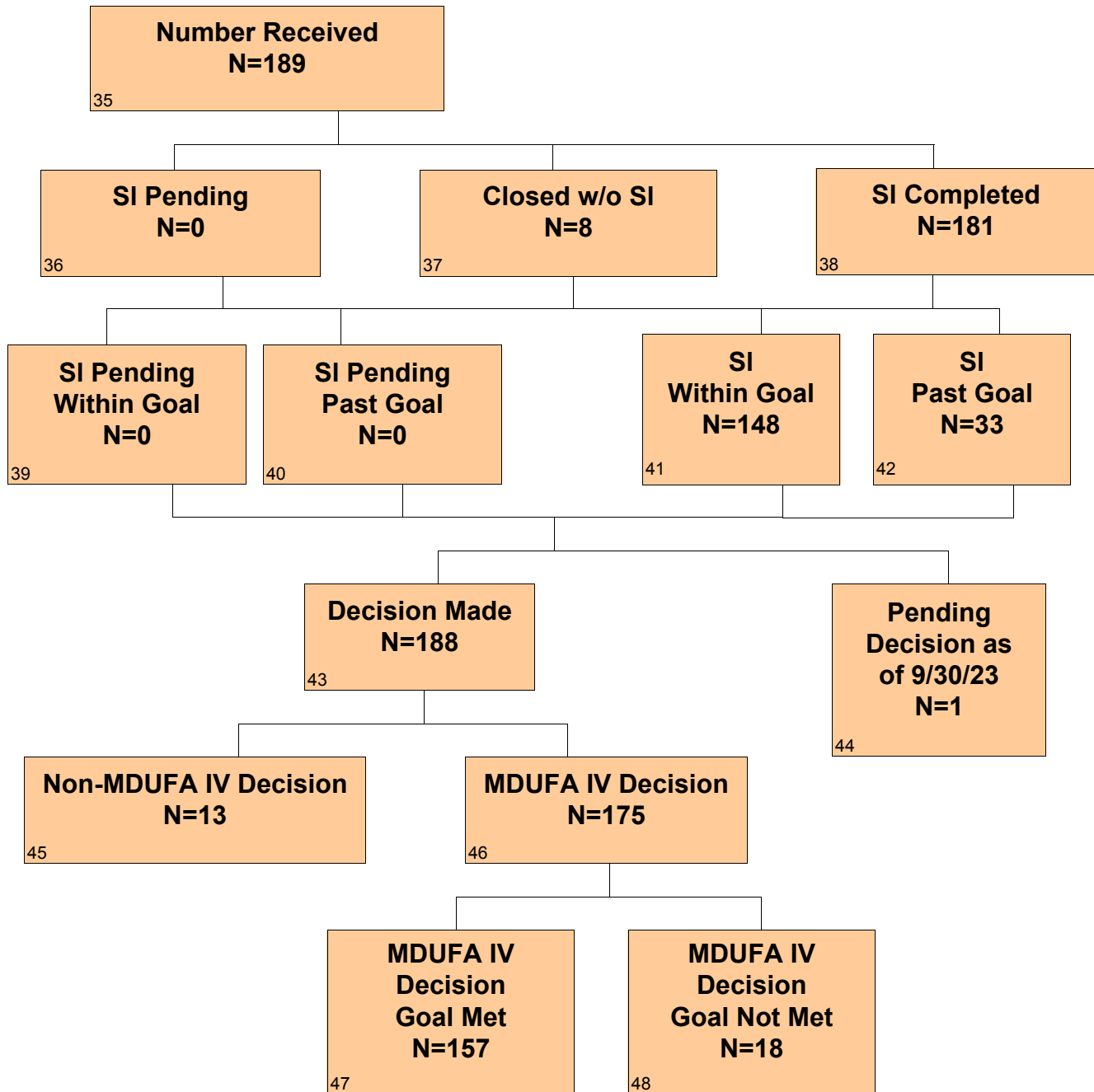
CDRH PMA 180 Day Supplements - FY 2019 as of 9/30/23



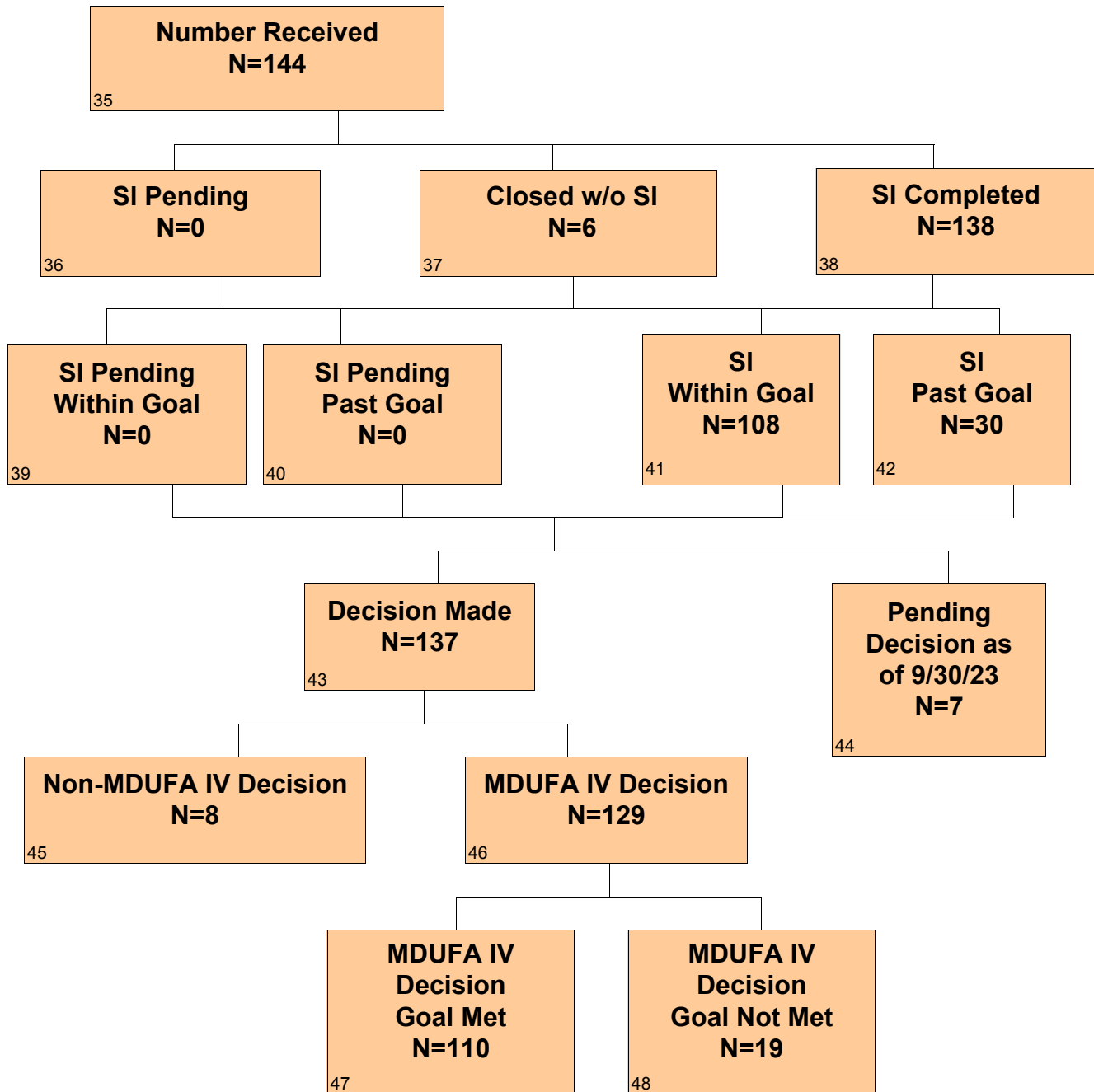
CDRH PMA 180 Day Supplements - FY 2020 as of 9/30/23



CDRH PMA 180 Day Supplements - FY 2021 as of 9/30/23



CDRH PMA 180 Day Supplements - FY 2022 as of 9/30/23



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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days	95% SI Within 90 FDA Days
Eligible for SI	188	191	176	189	144
SI Goal Met	182	189	161	148	110
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	0
Closed Without SI	3	0	3	8	4
Current SI Performance Percent Goal Met	98.38%	98.95%	93.06%	81.77%	78.57%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days	95% SI Within 180 FDA Days
Supplements Received	188	191	176	189	144
Non-MDUFA IV Decision	8	6	12	13	8
MDUFA IV Decision	180	185	164	175	129
MDUFA IV Decision Goal Met	180	179	159	157	110
Supplements Pending MDUFA IV Decision	0	0	0	1	7
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	0
Current Performance Percent Goal Met	100.00%	96.76%	96.95%	89.20%	85.27%

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	144
Number with MDUFA IV Decision	180	185	164	175	129
Number of Not Approvable	13	10	9	13	7
Rate of Not Approvable	7.22%	5.41%	5.49%	7.43%	5.43%

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	19
Mean FDA Days for Submissions that Missed the Goal	N/A	263.33	419.00	239.15	231.84
Mean Industry Days for Submissions that Missed the Goal	N/A	69.67	99.80	72.60	91.21

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	21
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%	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	2
MDUFA IV Decision	20	36	28	14	18
MDUFA IV Decision Goal Met	20	35	28	14	18
Supplements Pending MDUFA IV Decision	0	0	0	0	1
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	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	18
Number of Not Approvable	1	1	1	2	2
Rate of Not Approvable	5.00%	2.78%	3.57%	14.29%	11.11%

**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	N/A	302.00	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	41.00	N/A	N/A	N/A

**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	41
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	0
Closed Without SI	2	0	0	8	0
Current SI Performance Percent Goal Met	98.91%	100.00%	94.29%	91.86%	80.39%

**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	9	1
MDUFA IV Decision	92	78	68	85	49
MDUFA IV Decision Goal Met	92	78	68	85	46
Supplements Pending MDUFA IV Decision	0	0	0	0	1
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	93.88%

**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	68	85	49
Number of Not Approvable	6	6	4	10	0
Rate of Not Approvable	6.52%	7.69%	5.88%	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	3
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	203.33
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	21.33

**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	N/A	N/A	N/A	233.00	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	49.00	N/A

**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	8	10	7	15	10
SI Goal Met	8	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	0
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	8	10	7	15	10
Non-MDUFA IV Decision	1	1	0	0	0
MDUFA IV Decision	7	9	7	14	10
MDUFA IV Decision Goal Met	7	5	6	9	6
Supplements Pending MDUFA IV Decision	0	0	0	1	0
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	1	0
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	8	10	7	15	10
Number with MDUFA IV Decision	7	9	7	14	10
Number of Not Approvable	0	0	0	1	1
Rate of Not Approvable	0.00%	0.00%	0.00%	7.14%	10.00%

**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	N/A	258.50	383.00	258.17	297.25
Mean Industry Days for Submissions that Missed the Goal	N/A	91.00	223.00	72.67	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	17
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	0
Closed Without SI	1	0	0	0	0
Current SI Performance Percent Goal Met	100.00%	100.00%	100.00%	95.00%	82.35%

**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	17
Non-MDUFA IV Decision	2	0	2	0	0
MDUFA IV Decision	11	16	21	20	14
MDUFA IV Decision Goal Met	11	15	21	19	12
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%	93.75%	100.00%	95.00%	85.71%

**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	17
Number with MDUFA IV Decision	11	16	21	20	14
Number of Not Approvable	2	0	1	0	3
Rate of Not Approvable	18.18%	0.00%	4.76%	0.00%	21.43%

**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	N/A	244.00	N/A	181.00	239.50
Mean Industry Days for Submissions that Missed the Goal	N/A	13.00	N/A	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	1	6	2	4	4
SI Goal Met	1	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	1
Current SI Performance Percent Goal Met	100.00%	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	1	6	2	4	4
Non-MDUFA IV Decision	0	0	1	0	1
MDUFA IV Decision	1	6	1	4	2
MDUFA IV Decision Goal Met	1	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	100.00%	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	1	6	2	4	4
Number with MDUFA IV Decision	1	6	1	4	2
Number of Not Approvable	0	0	0	0	0
Rate of Not Approvable	0.00%	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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	1	2
MDUFA IV Decision	33	23	25	21	21
MDUFA IV Decision Goal Met	33	23	21	10	11
Supplements Pending MDUFA IV Decision	0	0	0	0	1
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	84.00%	47.62%	52.38%

**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	21
Number of Not Approvable	4	1	0	0	1
Rate of Not Approvable	12.12%	4.35%	0.00%	0.00%	4.76%

**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	10
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	428.00	235.00	212.70
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	69.00	74.33	141.70

**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%

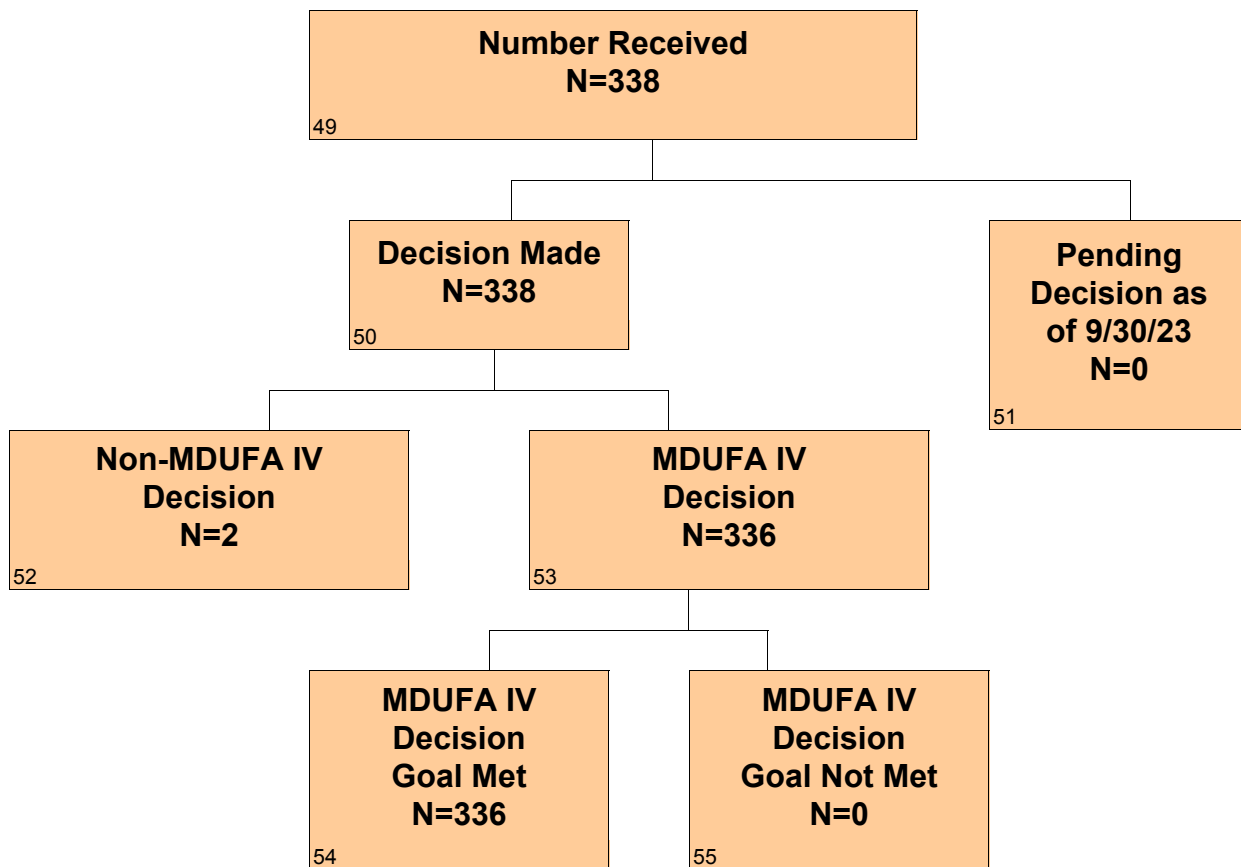
**Table 2.3 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Rate of Not Approvable**

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%

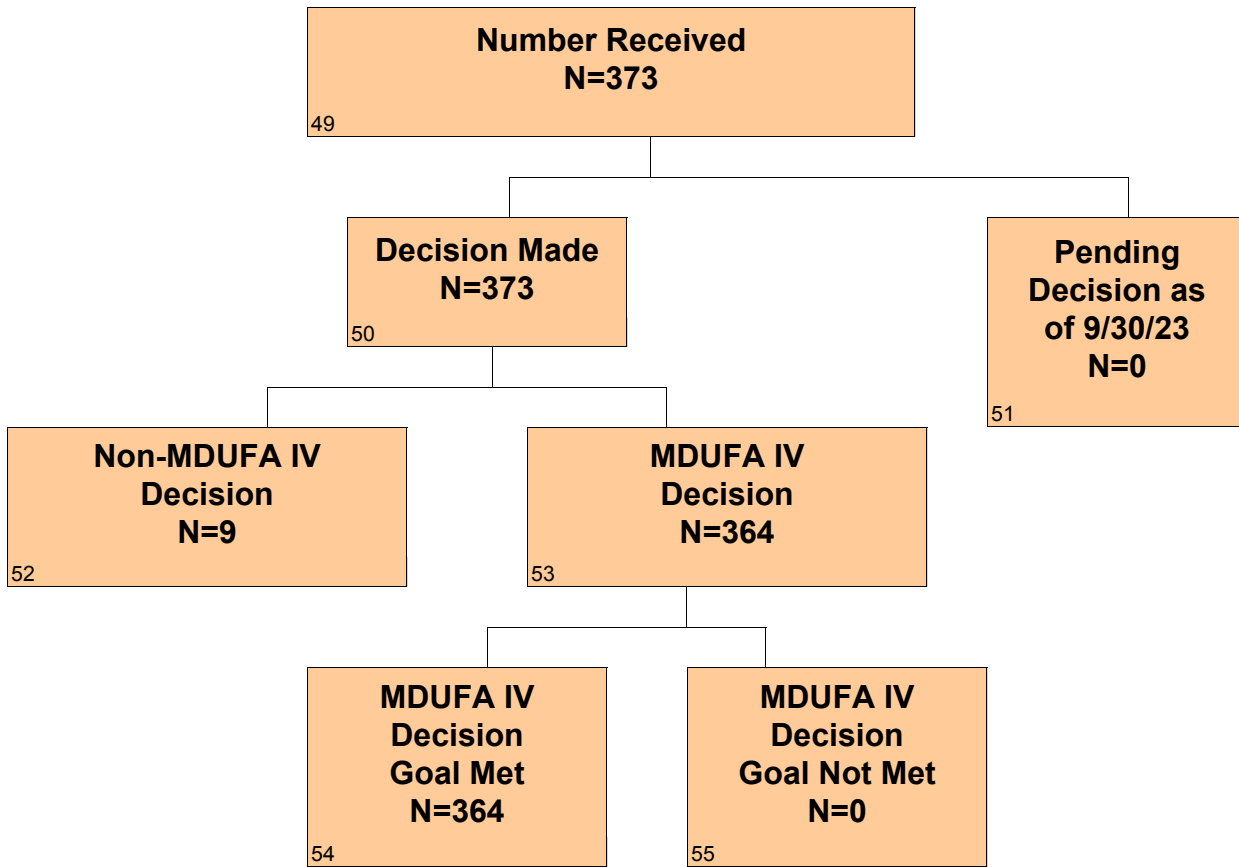
**Table 2.4 OHT8 - Office of Radiological Health
PMA 180-Day Supplements Performance Metric - Submissions Missing Performance Goal**

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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

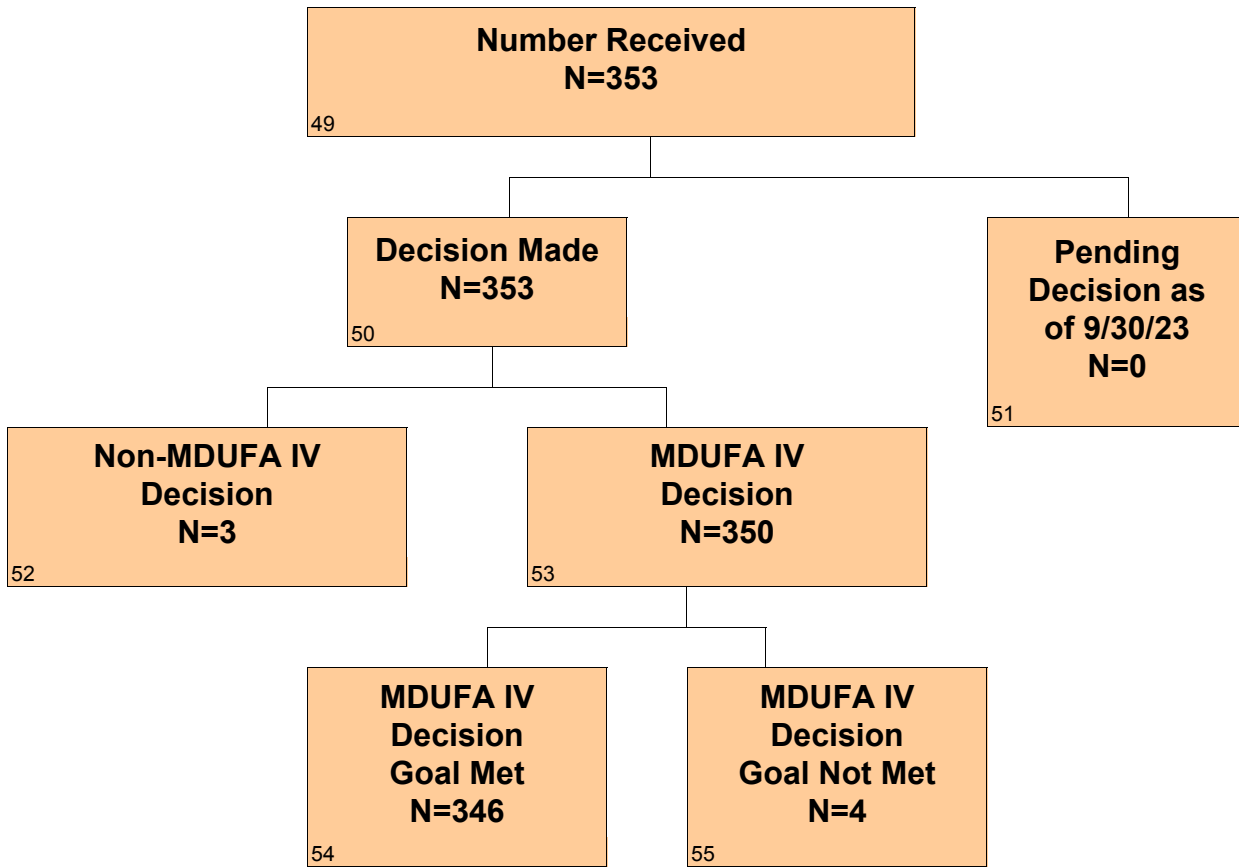
CDRH PMA Real Time Supplements - FY 2018 as of 9/30/23



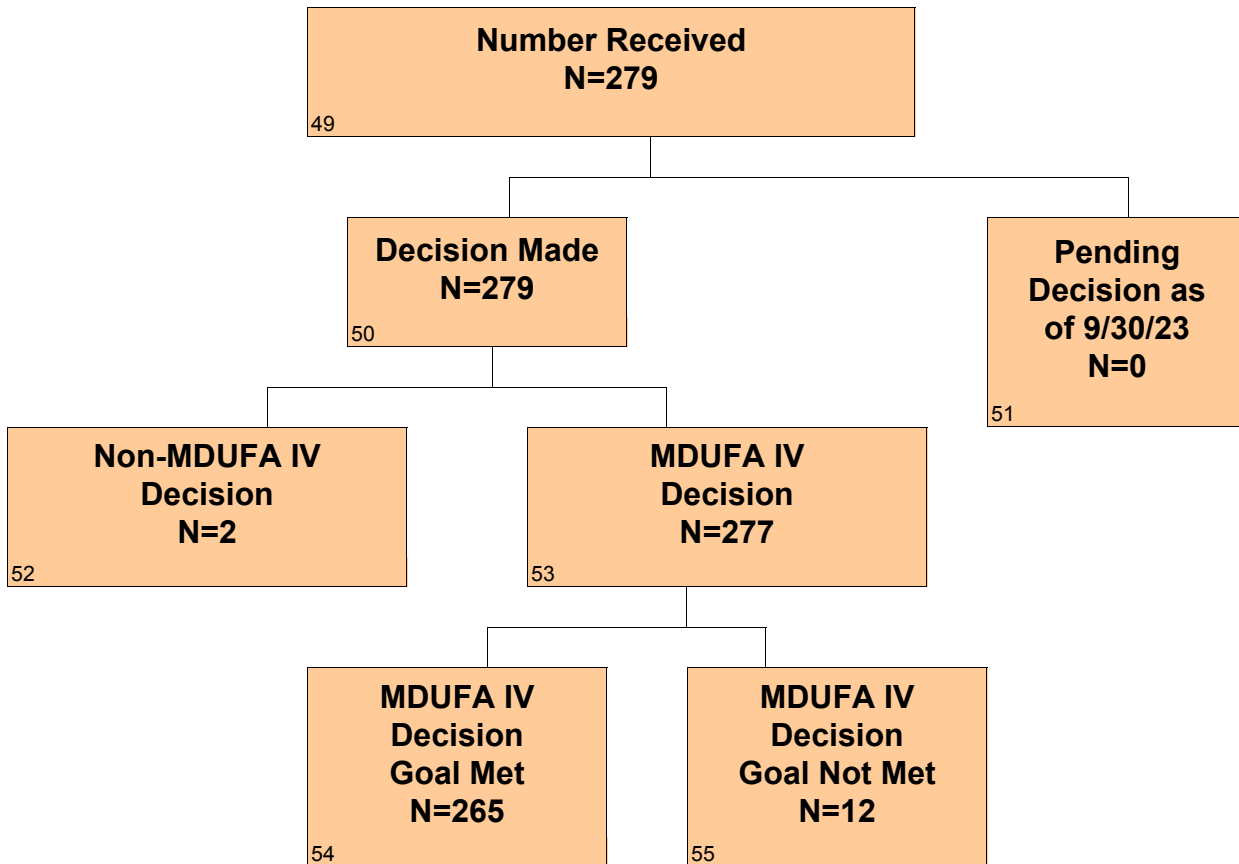
CDRH PMA Real Time Supplements - FY 2019 as of 9/30/23



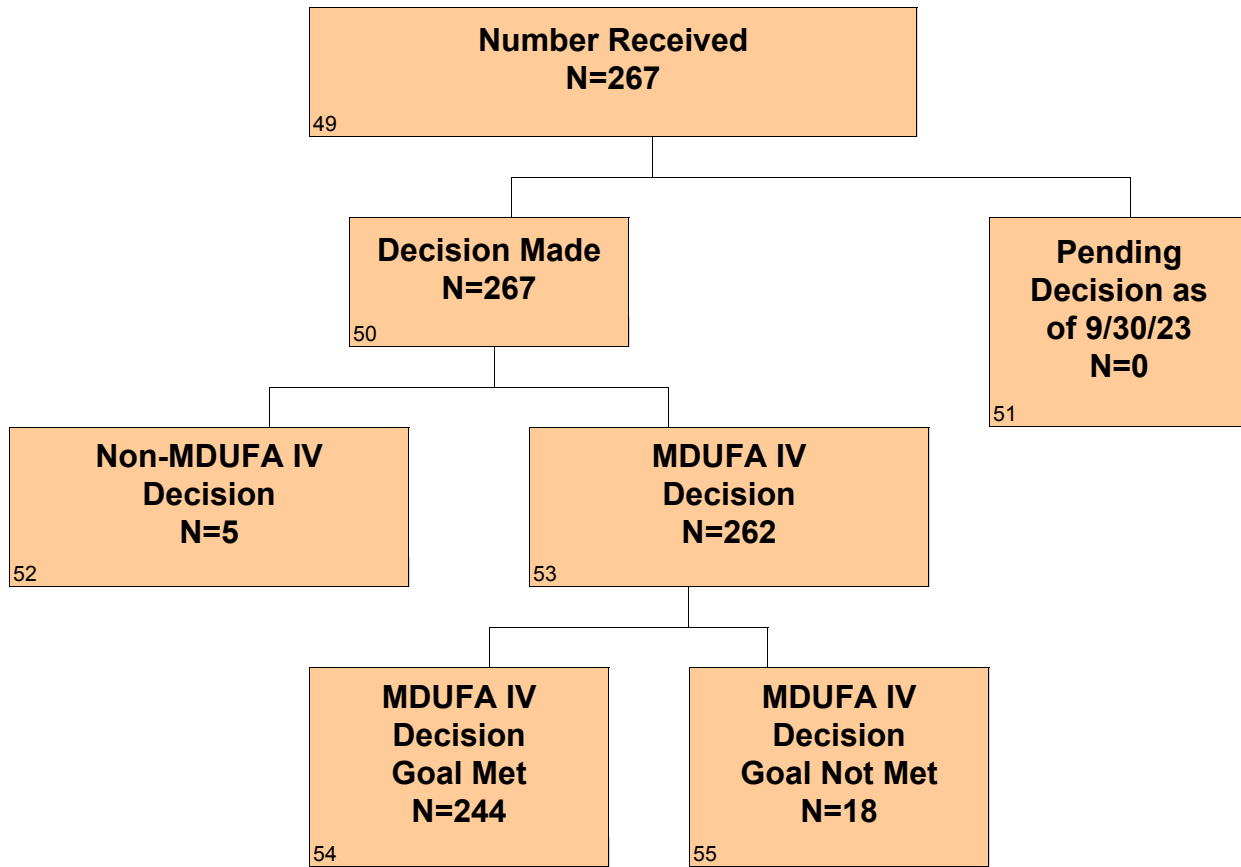
CDRH PMA Real Time Supplements - FY 2020 as of 9/30/23



CDRH PMA Real Time Supplements - FY 2021 as of 9/30/23



CDRH PMA Real Time Supplements - FY 2022 as of 9/30/23



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	279	267
Non-MDUFA IV Decision	2	9	3	2	5
MDUFA IV Decision	336	364	350	277	262
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%	95.67%	93.13%

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	279	267
Number With MDUFA IV Decision	336	364	350	277	262
Number of Not Approvable	20	29	6	10	11
Rate of Not Approvable	5.95%	7.97%	1.71%	3.61%	4.20%

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	12	18
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	98.25	198.00	141.06
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	N/A	N/A	99.00	134.00	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	12	15	12	12	6
Non-MDUFA IV Decision	1	0	0	0	0
MDUFA IV Decision	11	15	12	12	6
MDUFA IV Decision Goal Met	11	15	12	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%	83.33%	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	12	15	12	12	6
Number with MDUFA IV Decision	11	15	12	12	6
Number of Not Approvable	4	0	0	1	0
Rate of Not Approvable	36.36%	0.00%	0.00%	8.33%	0.00%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	0	0	0	2	4
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	147.00	257.00
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	18	25	10	4	9
Non-MDUFA IV Decision	0	0	0	0	1
MDUFA IV Decision	18	25	10	4	8
MDUFA IV Decision Goal Met	18	25	10	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%	75.00%	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	18	25	10	4	9
Number with MDUFA IV Decision	18	25	10	4	8
Number of Not Approvable	2	2	1	1	1
Rate of Not Approvable	11.11%	8.00%	10.00%	25.00%	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	1	0
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	N/A	322.00	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	56	48
Non-MDUFA IV Decision	1	3	0	0	1
MDUFA IV Decision	92	45	61	56	47
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%	85.71%	70.21%

**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	56	48
Number with MDUFA IV Decision	92	45	61	56	47
Number of Not Approvable	0	1	0	5	1
Rate of Not Approvable	0.00%	2.22%	0.00%	8.93%	2.13%

**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	8	14
Mean FDA Days for Submissions that Missed the Goal	N/A	N/A	98.00	203.25	107.93
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

**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	N/A	N/A	N/A	N/A	N/A
Mean Industry Days for Submissions that Missed the Goal	N/A	N/A	N/A	N/A	N/A

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2022 and September 30, 2023.

Section 5 PMA Annual General Metrics

Table 5.1 CDRH - PMAs (All Review Tracks) Annual General Metrics - PMAs Received by Type

PMA Submissions Received	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Report Submissions	0	0	0	0	0
Original PMAs (Panel) - Breakthrough Device	1	0	1	0	0
Original PMAs (No Panel) - Breakthrough Device	3	2	5	7	1
Original PMAs (Panel) - Non-Breakthrough Device	4	2	2	1	0
Original PMAs (No Panel) - Non-Breakthrough Device	38	31	40	32	21
Panel-Tracked Supplements (Panel) - Breakthrough Device	0	0	0	0	0
Panel-Tracked Supplements (No Panel) - Breakthrough Device	1	0	1	0	1
Panel-Tracked Supplements (Panel) - Non-Breakthrough Device	0	0	1	1	0
Panel-Tracked Supplements (No Panel) - Non-Breakthrough Device	27	21	27	37	22
PMA Modules	64	73	70	73	88
180-Day Supplements	188	191	176	189	144
Real-Time Supplements	338	373	353	279	267

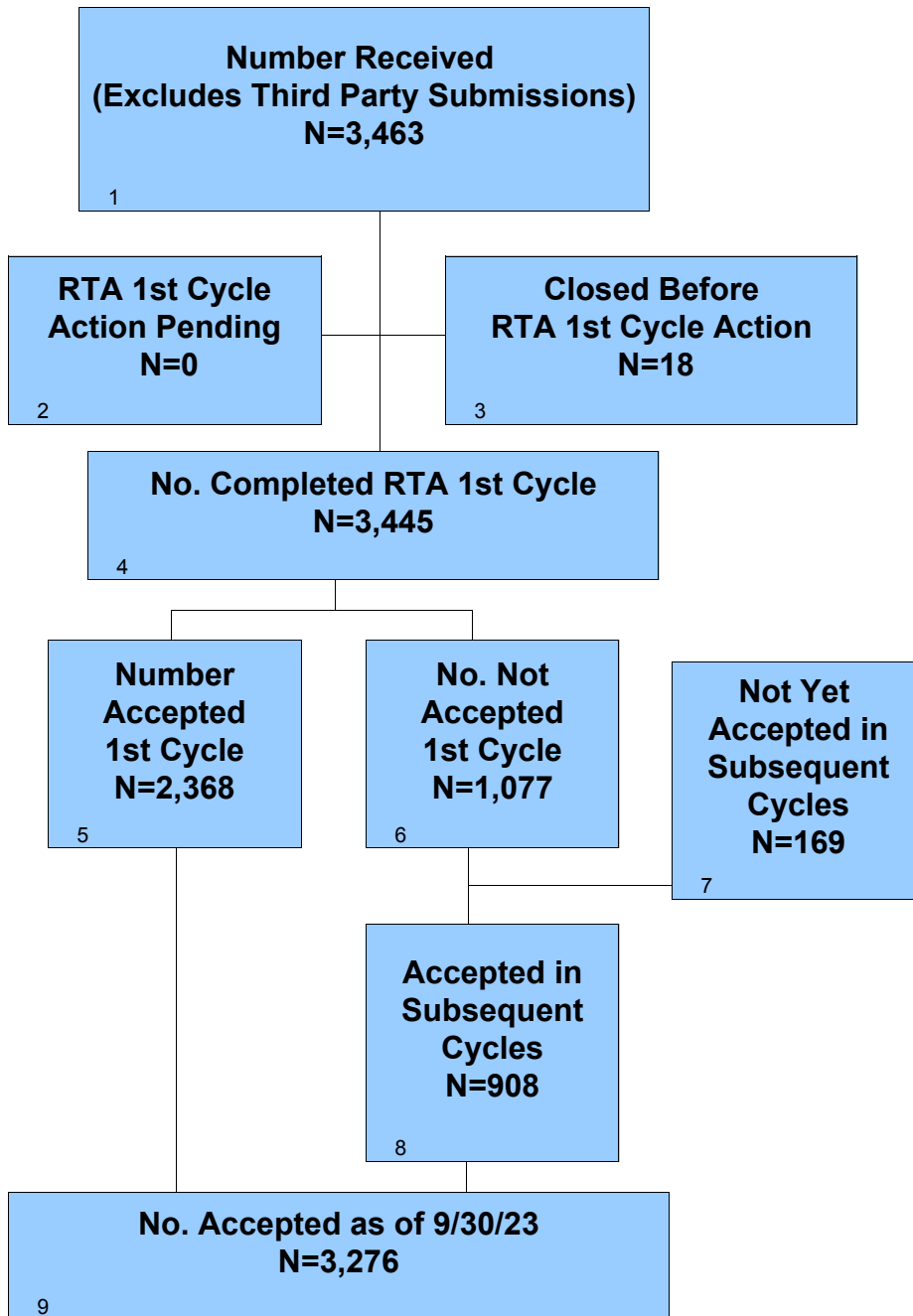
Table 5.2 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Percent Cohorts Closed

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	71	55	73	72	44
Number With a Decision (MDUFA or Non-MDUFA)	71	55	73	70	36
% of FY Closed	100.00%	100.00%	100.00%	97.22%	81.81%

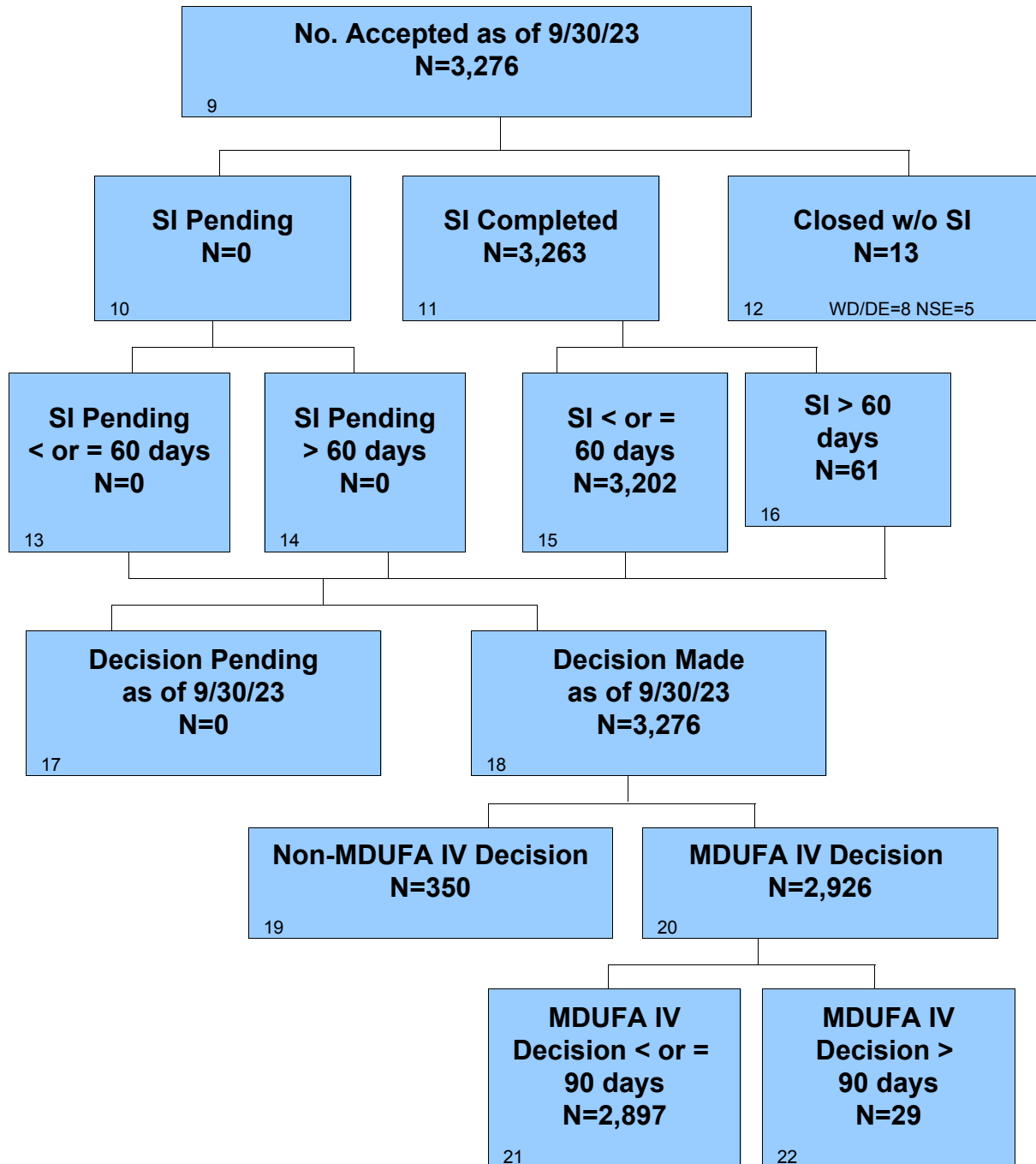
Table 5.3 CDRH - PMA Original and Panel-Track Supplements Annual Shared Outcome Goal - Three-Year Rolling Average Time to MDUFA IV Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	3 Year Cohort 320 FDA Days	3 Year Cohort 315 FDA Days	3 Year Cohort 310 FDA Days	3 Year Cohort 300 FDA Days	3 Year Cohort 290 FDA Days
Number With a MDUFA Decision	198	183	191	192	175
Number With a MDUFA Decision After Trimming the Upper and Lower 5%	180	165	173	174	159
Three-year Rolling Average Total Time to MDUFA Decision	264.04	264.42	274.92	307.36	N/A

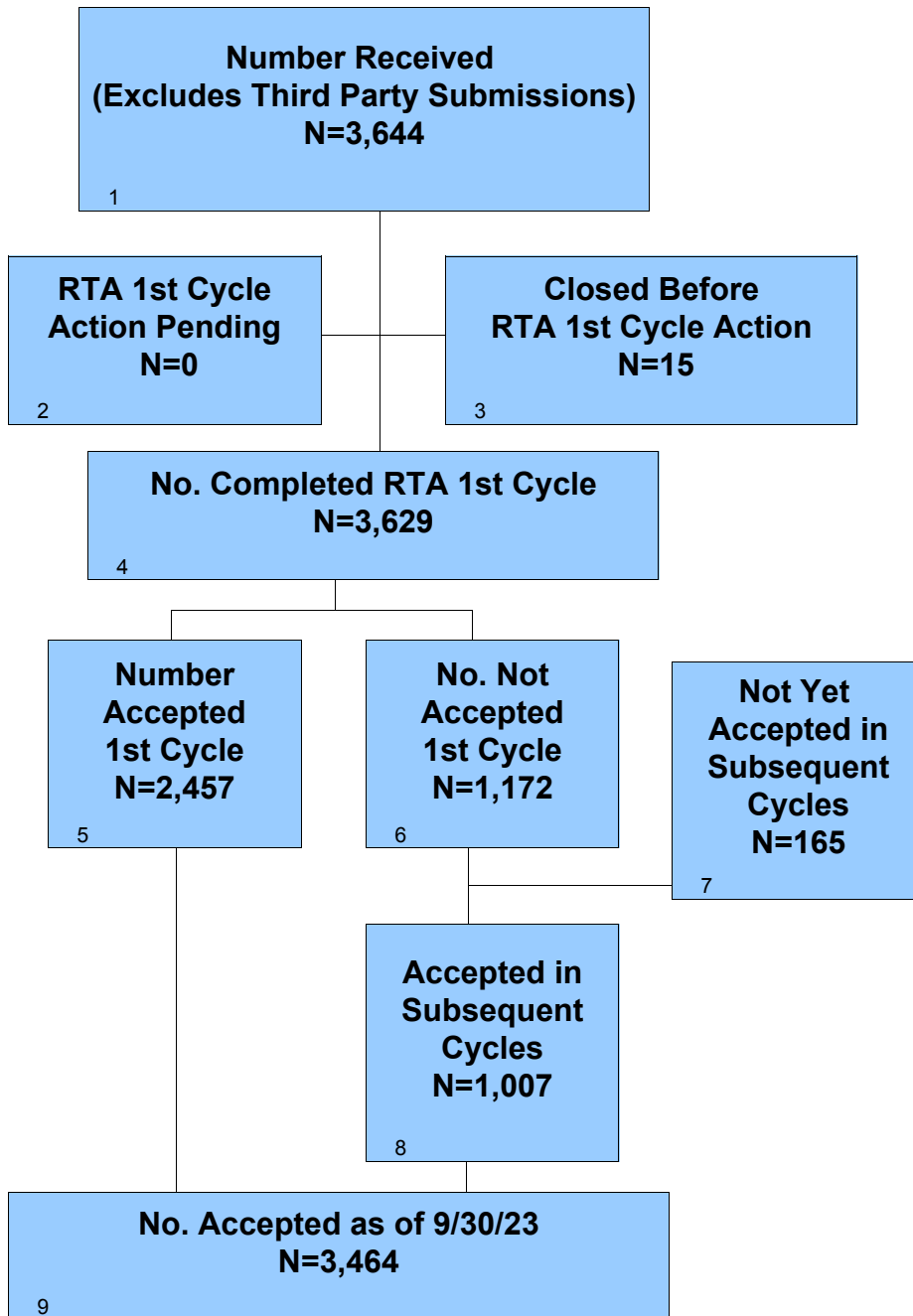
CDRH 510(k)s - FY 2018 as of 9/30/23



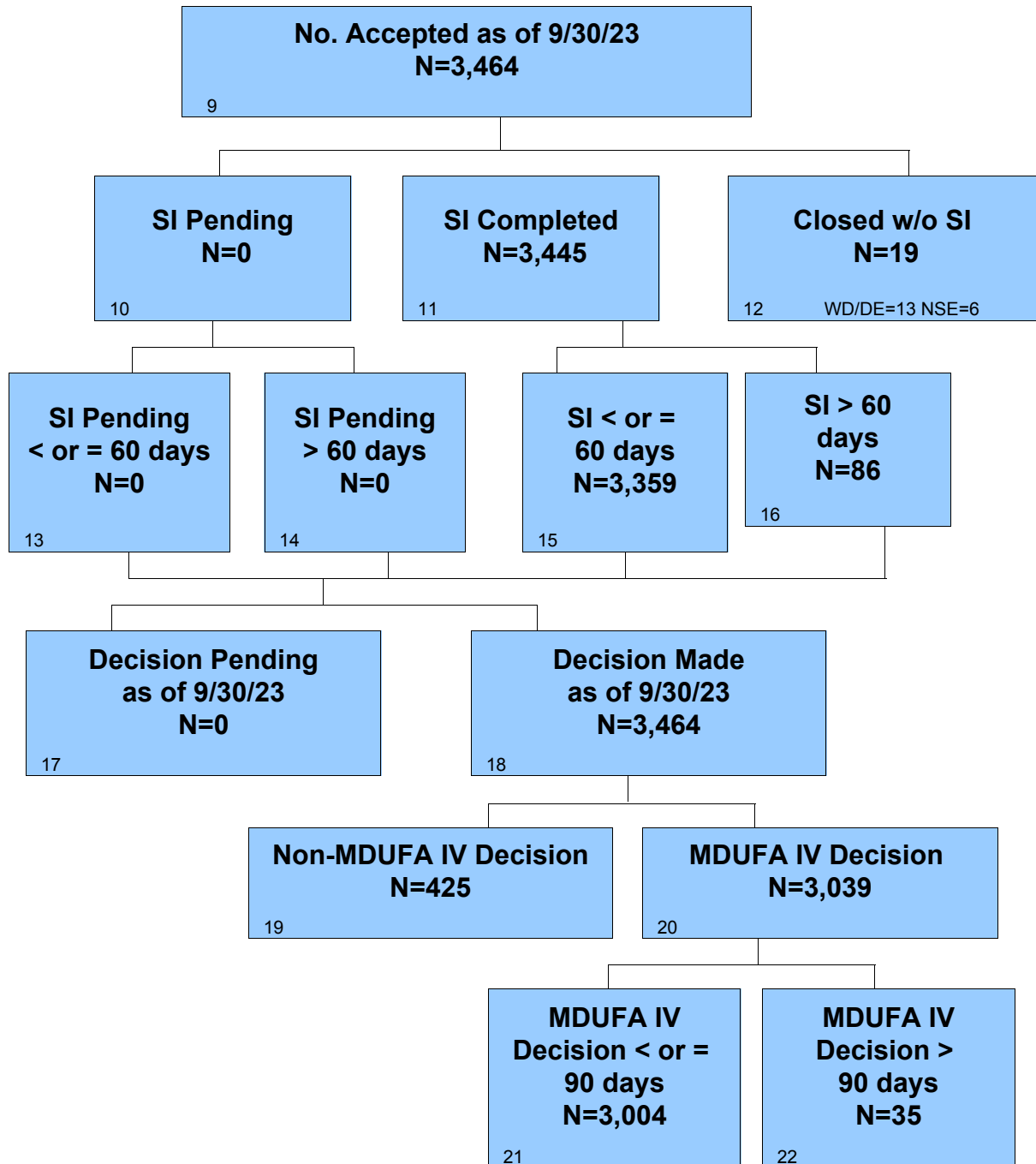
CDRH 510(k)s - FY 2018 as of 9/30/23 Continued



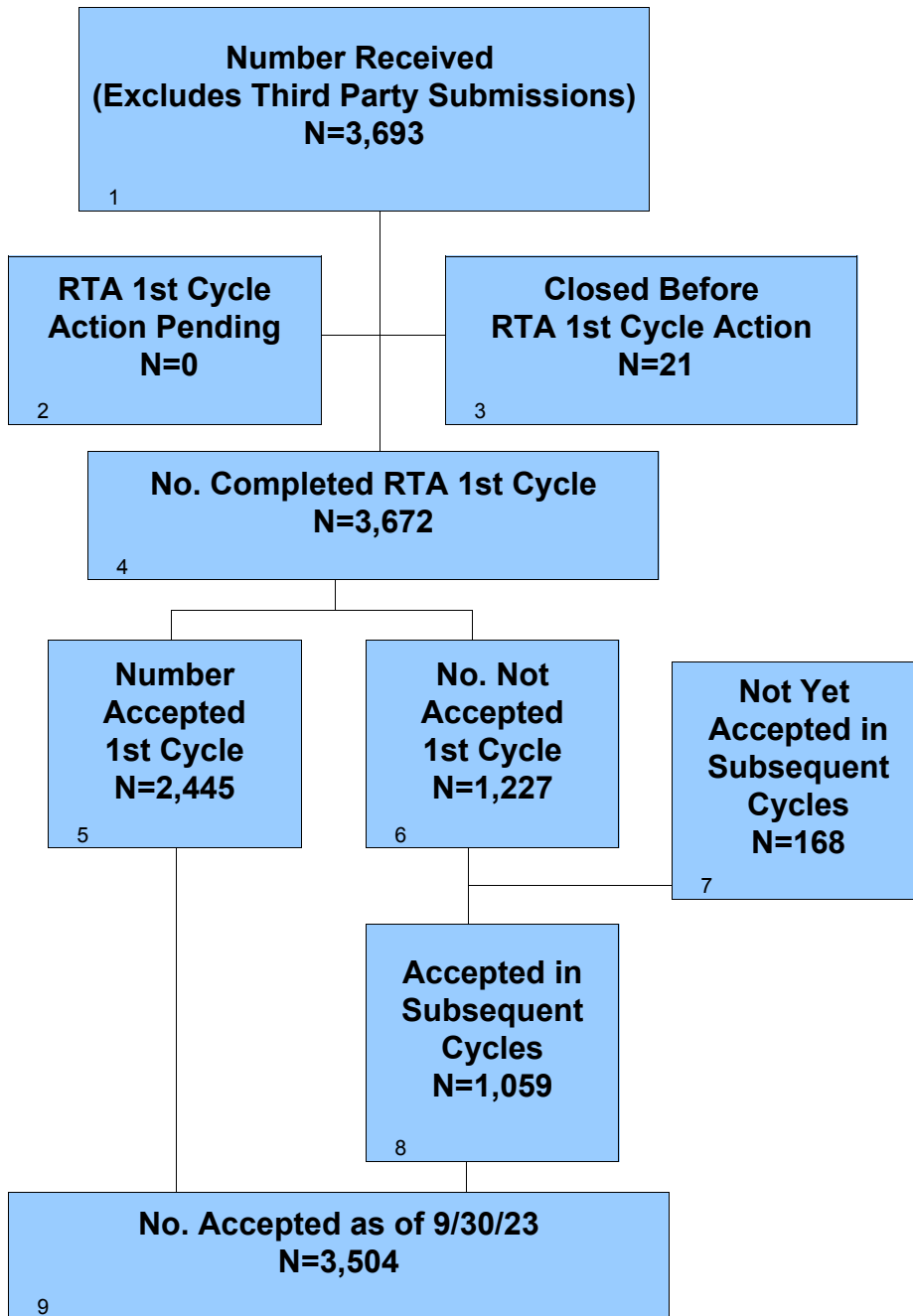
CDRH 510(k)s - FY 2019 as of 9/30/23



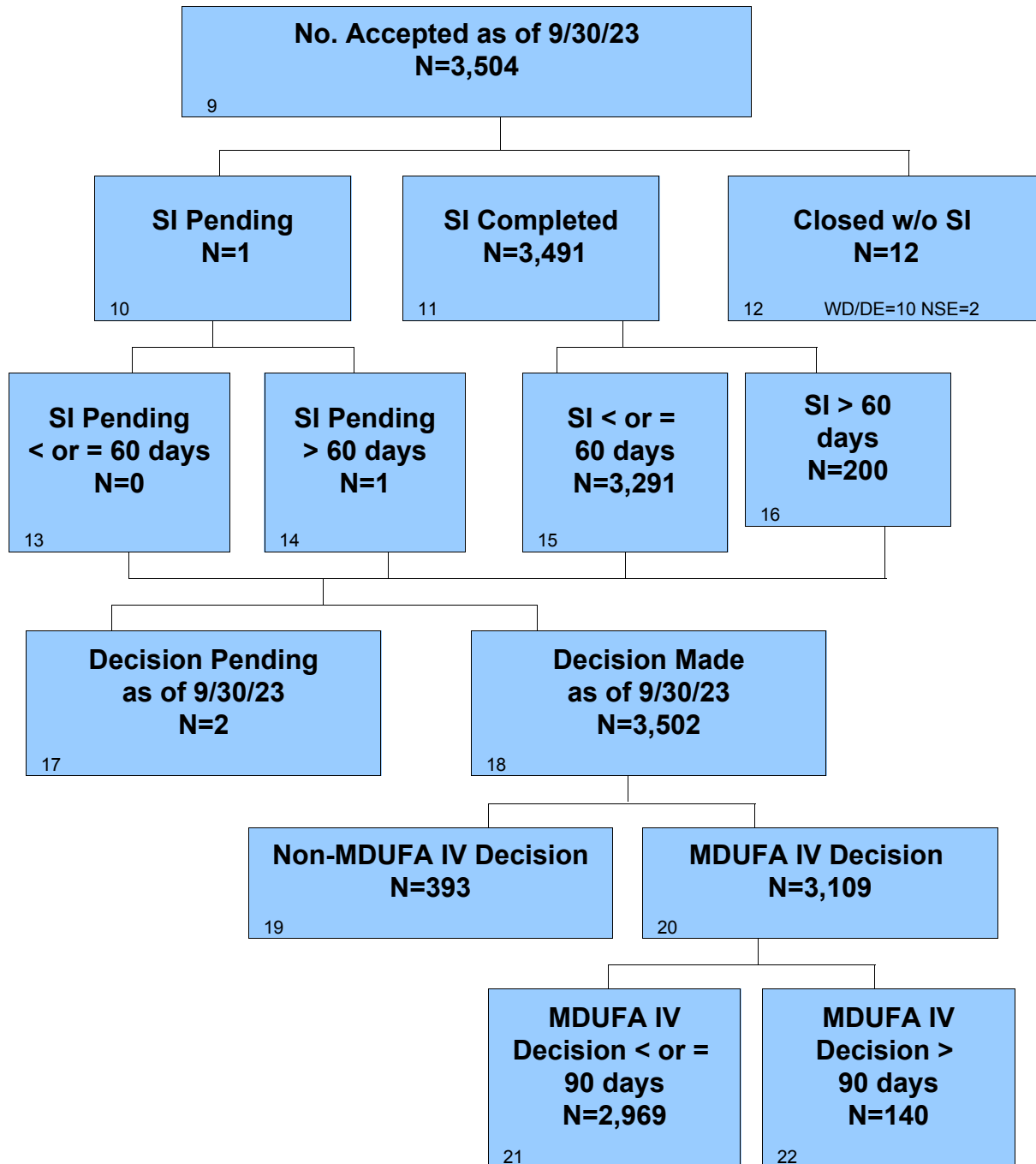
CDRH 510(k)s - FY 2019 as of 9/30/23 Continued



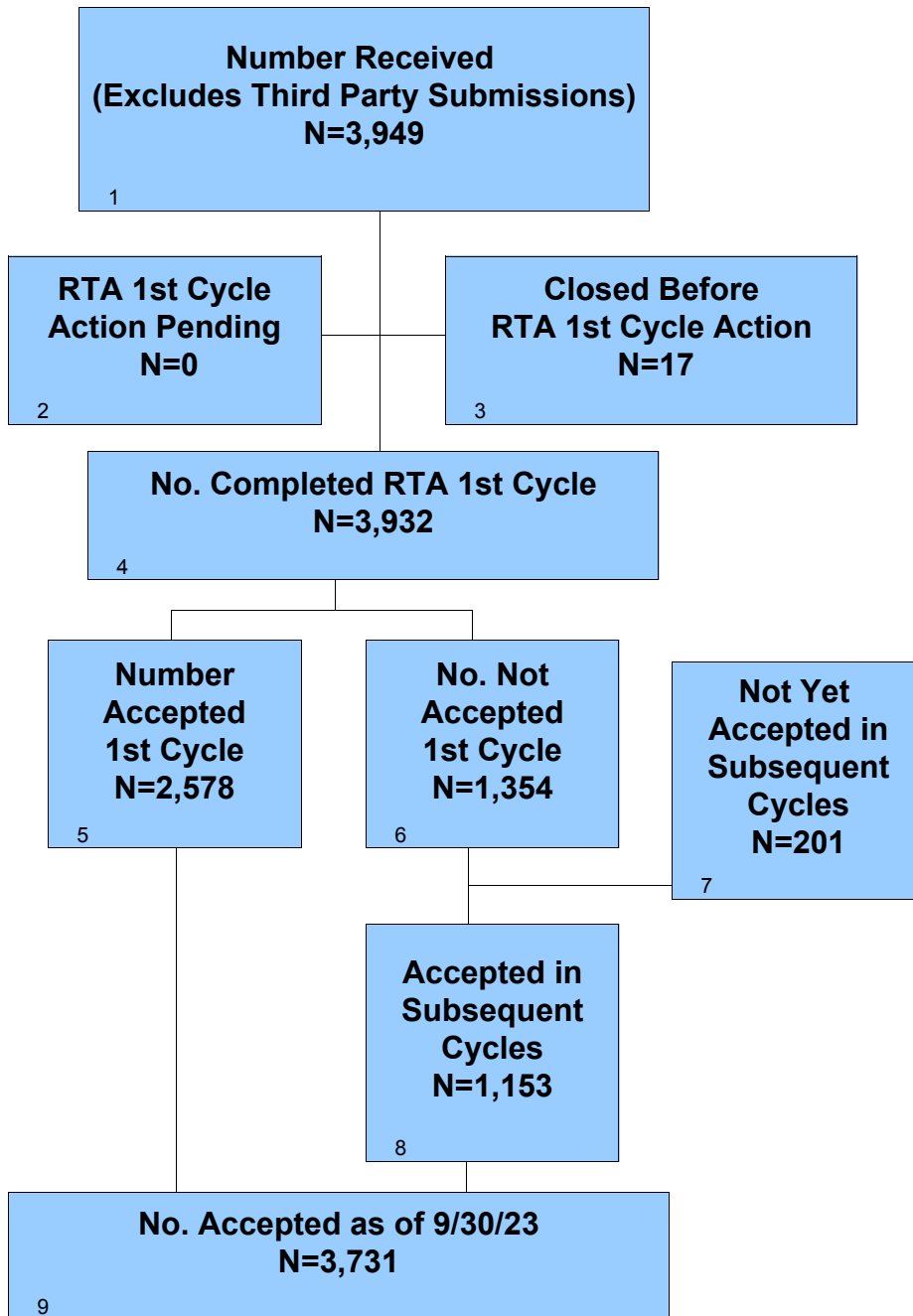
CDRH 510(k)s - FY 2020 as of 9/30/23



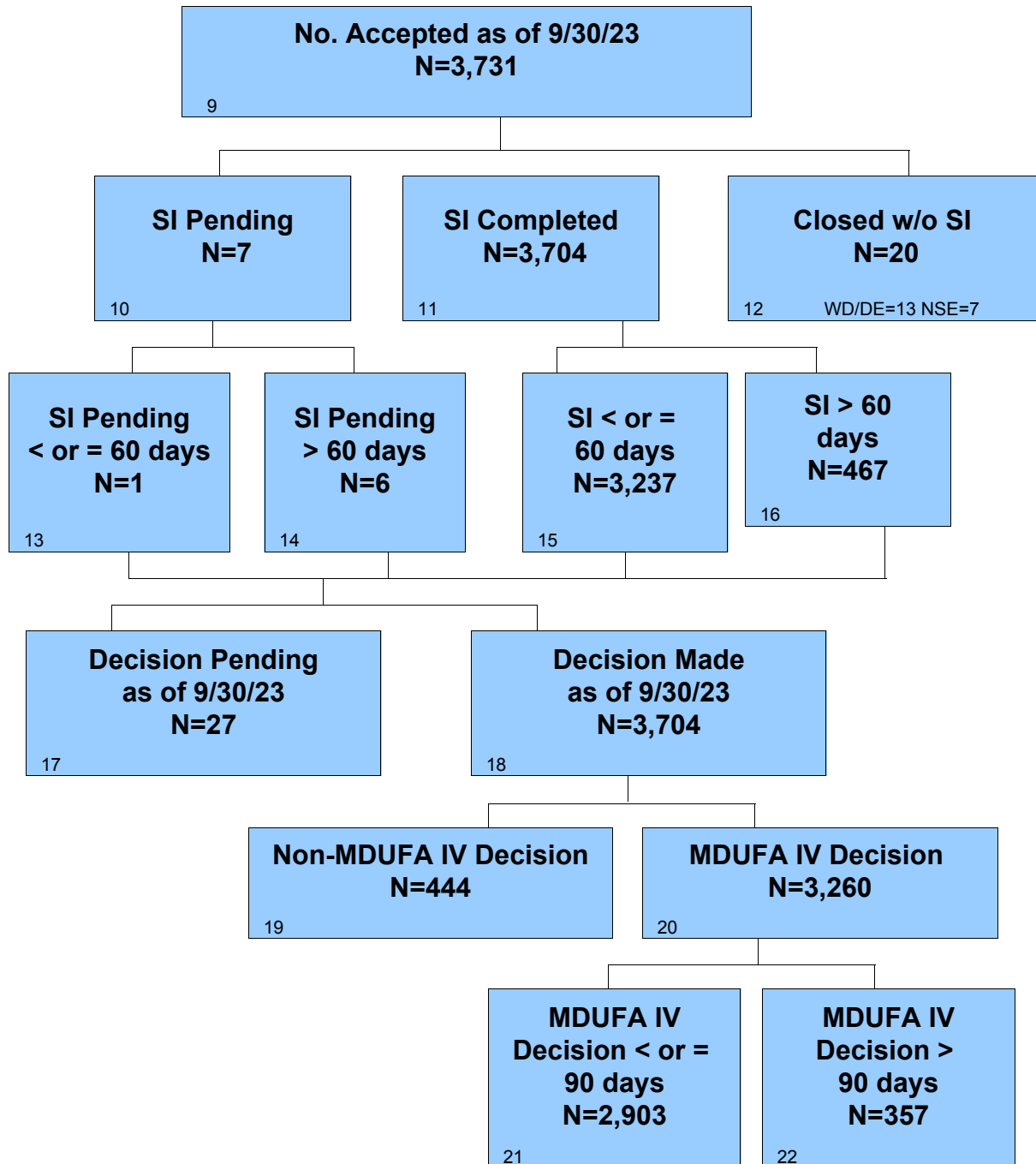
CDRH 510(k)s - FY 2020 as of 9/30/23 Continued



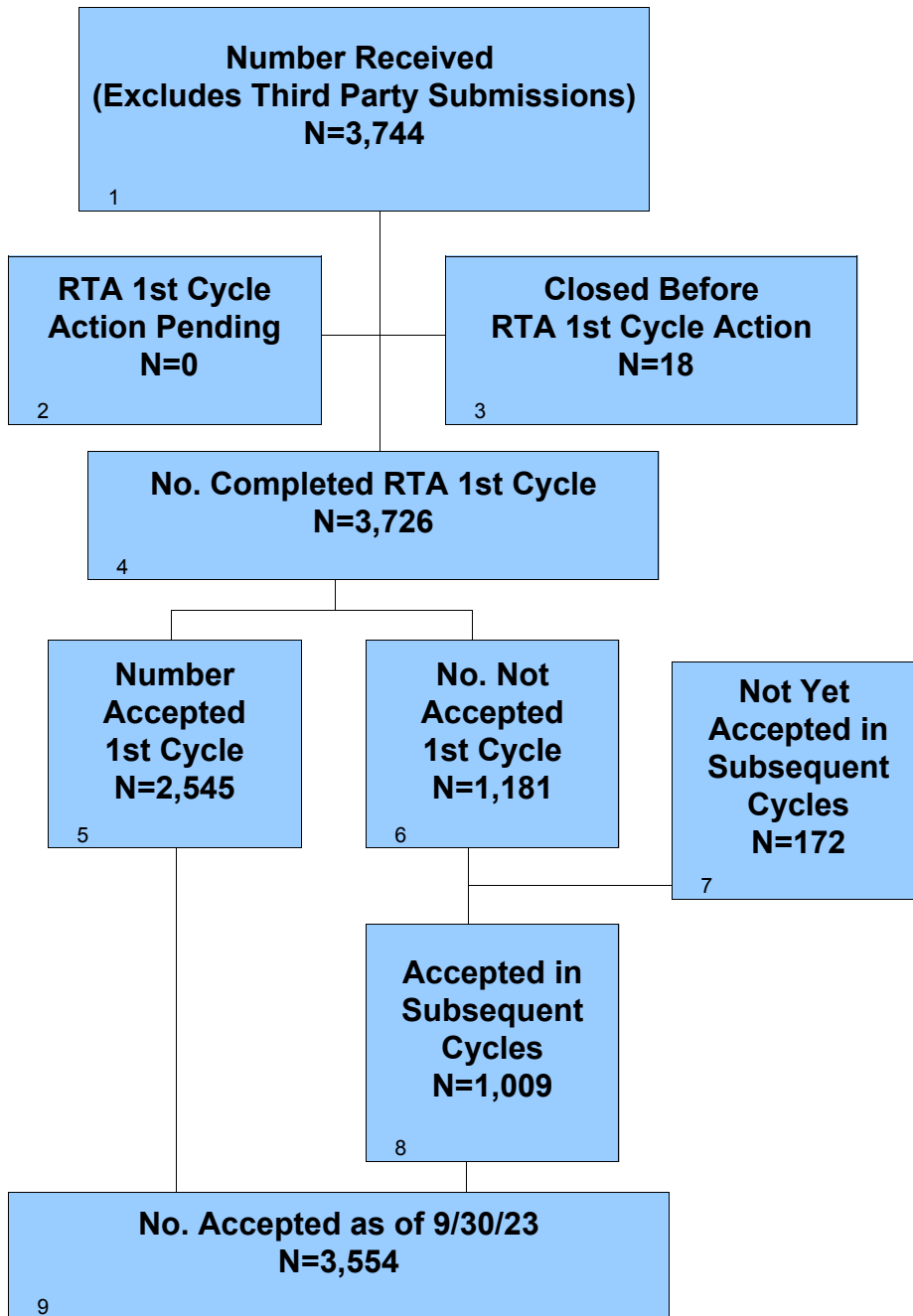
CDRH 510(k)s - FY 2021 as of 9/30/23



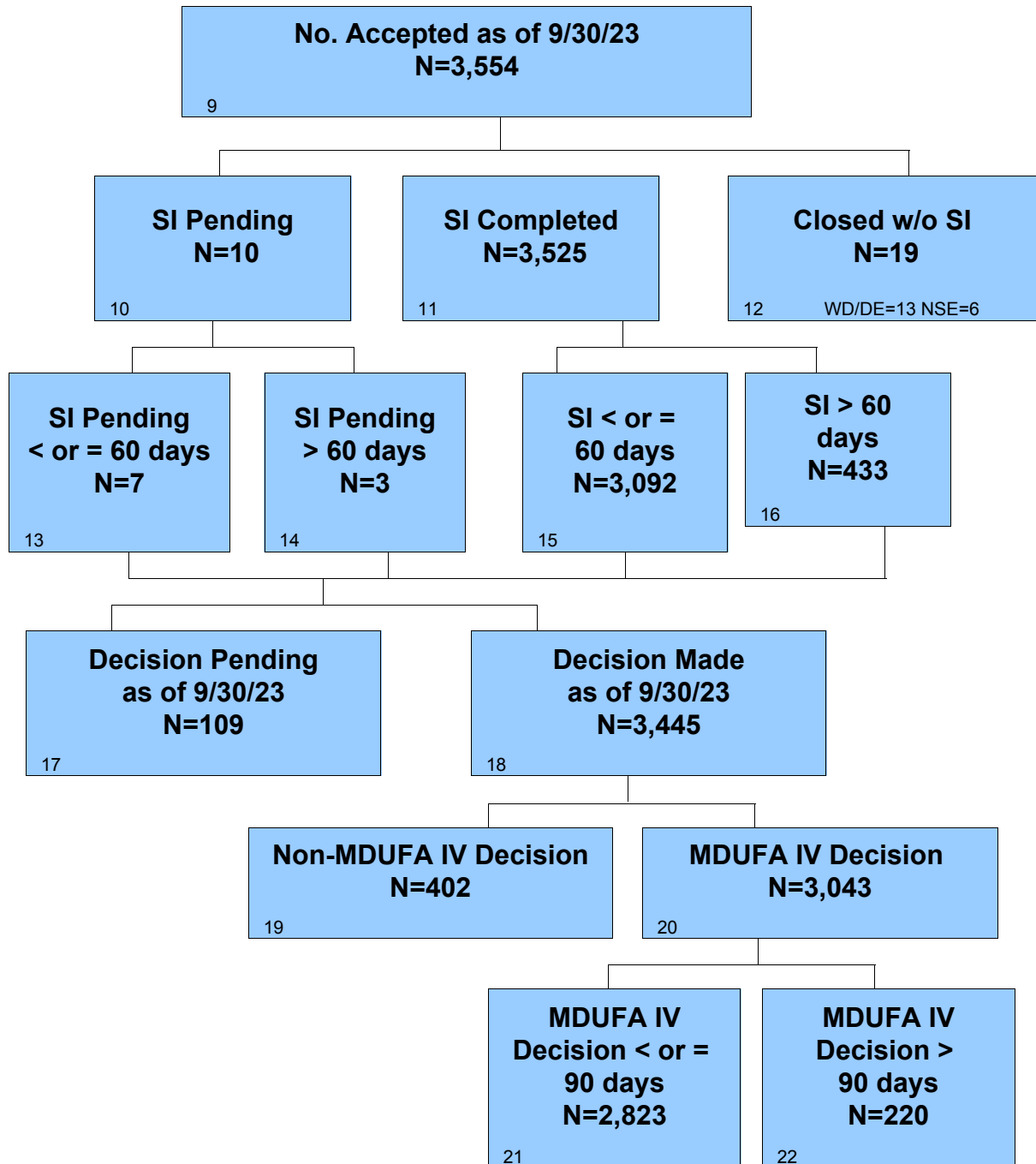
CDRH 510(k)s - FY 2021 as of 9/30/23 Continued



CDRH 510(k)s - FY 2022 as of 9/30/23



CDRH 510(k)s - FY 2022 as of 9/30/23 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	3,949	3,744
Closed Before RTA Action or TS	18	15	21	17	18
Number Accepted	2,353	2,403	2,396	2,358	2,169
Number Without a RTA Review and > 15 Days Since Date Received	15	54	49	220	376
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	1,354	1,181
Rate of Submissions Not Accepted for Review	31.26%	32.30%	33.42%	34.44%	31.70%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	3,276	3,464	3,504	3,731	3,554
Deleted or Withdrawn Prior to SI	8	13	10	13	13
SI Within 60 FDA Days	3,202	3,359	3,291	3,237	3,092
SI Over 60 FDA Days	61	86	200	467	433
SI Pending Within 60 FDA Days	0	0	0	1	7
SI Pending Over 60 FDA Days	0	0	1	6	3
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%	87.09%	87.49%

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	3,704	3,525
Average Number of FDA Days to Substantive Interaction	51.04	51.42	55.02	59.60	58.82
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	381	431

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	3,731	3,554
Non-MDUFA IV Decision	350	425	393	444	402
MDUFA IV Decision (SE/NSE)	2,926	3,039	3,109	3,260	3,043
MDUFA IV Decision Within 90 FDA Days	2,897	3,004	2,969	2,903	2,823
510(k)s Pending MDUFA IV Decision	0	0	2	27	109
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	2	22	43
Current Performance Percent Within 90 FDA Days	99.01%	98.85%	95.44%	88.45%	91.48%

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	1.65	1.67	1.65
Number With MDUFA IV Decision	2,926	3,039	3,109	3,260	3,043
Average Number of FDA Days to MDUFA IV Decision	72.62	73.55	79.92	84.63	82.93
20th Percentile FDA Days to MDUFA IV Decision	54	55	55	58	58
40th Percentile FDA Days to MDUFA IV Decision	79	82	84	86	85
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	831	576	426
Average Number of Industry Days to MDUFA IV Decision	54.69	60.40	70.86	78.63	67.95
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	5	0	5	14	10
60th Percentile Industry Days to MDUFA IV Decision	44	49	54	66	59
80th Percentile Industry Days to MDUFA IV Decision	127	139	147	158	149
Maximum Industry Days to MDUFA IV Decision	563	507	834	613	471
Average Number of Total Days to MDUFA IV Decision	127.31	133.95	150.78	163.26	150.88
20th Percentile Total Days to MDUFA IV Decision	57	57	57	60	59
40th Percentile Total Days to MDUFA IV Decision	89	90	90	100	97
60th Percentile Total Days to MDUFA IV Decision	128	133	140	158	152
80th Percentile Total Days to MDUFA IV Decision	212	224	240	253	244
Maximum Total Days to MDUFA IV Decision	783	871	1,282	912	695

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	3,731	3,554
Number With MDUFA IV Decision	2,926	3,039	3,109	3,260	3,043
Number of SE Decision	2,809	2,924	3,004	3,114	2,924
Number of NSE Decision	117	115	105	146	119
Number of Withdrawal	185	213	214	247	245
Number of Deleted	156	194	175	194	153
Rate of SE Decision	96.00%	96.22%	96.62%	95.52%	96.09%
Rate of NSE Decision	4.00%	3.78%	3.38%	4.48%	3.91%
Rate of Withdrawal	5.65%	6.15%	6.11%	6.62%	6.89%
Rate of Deleted	4.76%	5.60%	4.99%	5.20%	4.31%

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	140	357	220
Mean FDA Days for Submissions that Missed the Goal	111.38	140.80	238.37	170.42	194.15
Mean Industry Days for Submissions that Missed the Goal	136.24	201.94	180.37	110.55	97.65

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	3
MDUFA IV Decision Within 90 FDA Days	1	1	2	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	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	45	38
MDUFA IV Decision (SE/NSE)	231	241	200	146	159
MDUFA IV Decision Within 90 FDA Days	230	237	122	13	15
510(k)s Pending MDUFA IV Decision	0	0	1	4	23
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	4	22
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	60.70%	8.67%	8.29%

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	594
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	335
Rate of Submissions Not Accepted for Review	62.25%	63.01%	56.34%	59.10%	56.59%

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

Substantive Interaction (SI) Goal	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	494	551	506	493	542
Deleted or Withdrawn Prior to SI	2	6	0	0	0
SI Within 60 FDA Days	477	490	415	421	446
SI Over 60 FDA Days	14	54	90	71	89
SI Pending Within 60 FDA Days	0	0	0	0	6
SI Pending Over 60 FDA Days	0	0	1	1	1
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%	85.40%	83.21%

**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	535
Average Number of FDA Days to Substantive Interaction	55.63	56.04	55.38	55.98	57.29
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	236

**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	493	542
Non-MDUFA IV Decision	74	85	66	77	77
MDUFA IV Decision (SE/NSE)	420	466	439	410	434
MDUFA IV Decision Within 90 FDA Days	417	464	435	403	425
510(k)s Pending MDUFA IV Decision	0	0	1	6	31
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	6	5
Current Performance Percent Within 90 FDA Days	99.29%	99.57%	98.86%	96.88%	96.81%

**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	1.73	1.75
Number With MDUFA IV Decision	420	466	439	410	434
Average Number of FDA Days to MDUFA IV Decision	81.05	82.40	79.92	81.55	81.61
20th Percentile FDA Days to MDUFA IV Decision	77	84	76	76	81
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	272	119
Average Number of Industry Days to MDUFA IV Decision	65.45	68.89	72.39	94.99	87.40
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	18	20	17	28	28
60th Percentile Industry Days to MDUFA IV Decision	63	67	64	92	102
80th Percentile Industry Days to MDUFA IV Decision	152	154	152	175	173
Maximum Industry Days to MDUFA IV Decision	389	356	497	583	471
Average Number of Total Days to MDUFA IV Decision	146.51	151.28	152.30	176.54	169.01
20th Percentile Total Days to MDUFA IV Decision	79	88	84	82	86
40th Percentile Total Days to MDUFA IV Decision	103	106	99	116	114
60th Percentile Total Days to MDUFA IV Decision	148	154	150	179	190
80th Percentile Total Days to MDUFA IV Decision	241	242	241	261	263
Maximum Total Days to MDUFA IV Decision	479	446	585	731	559

**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	493	542
Number With MDUFA IV Decision	420	466	439	410	434
Number of SE Decision	402	443	423	391	412
Number of NSE Decision	18	23	16	19	22
Number of Withdrawal	35	48	35	52	46
Number of Deleted	39	34	31	23	31
Rate of SE Decision	95.71%	95.06%	96.36%	95.37%	94.93%
Rate of NSE Decision	4.29%	4.94%	3.64%	4.63%	5.07%
Rate of Withdrawal	7.09%	8.71%	6.92%	10.55%	8.49%
Rate of Deleted	7.89%	6.17%	6.13%	4.67%	5.72%

**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	7	9
Mean FDA Days for Submissions that Missed the Goal	115.33	133.50	101.25	164.86	101.00
Mean Industry Days for Submissions that Missed the Goal	107.67	258.00	167.75	393.57	241.67

**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	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 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	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 6.1 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	383	354
Closed Before RTA Action	4	2	1	2	0
Number Accepted	237	266	281	273	243
Number Without a RTA Review and > 15 Days Since Date Received	2	10	4	17	32
Number Without a RTA Review and <= 15 Days Since Date Received	0	0	0	0	0
Number Not Accepted	114	100	90	91	79
Rate of Submissions Not Accepted for Review	32.29%	26.60%	24.00%	23.88%	22.32%

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	374	343
Deleted or Withdrawn Prior to SI	4	0	1	1	7
SI Within 60 FDA Days	324	358	354	353	325
SI Over 60 FDA Days	13	8	12	18	9
SI Pending Within 60 FDA Days	0	0	0	0	0
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%	94.64%	96.73%

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	371	334
Average Number of FDA Days to Substantive Interaction	49.74	50.76	51.63	51.34	51.56
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	374	343
Non-MDUFA IV Decision	32	52	33	43	57
MDUFA IV Decision (SE/NSE)	309	314	335	331	283
MDUFA IV Decision Within 90 FDA Days	303	303	320	321	276
510(k)s Pending MDUFA IV Decision	0	0	0	0	3
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	1
Current Performance Percent Within 90 FDA Days	98.06%	96.50%	95.52%	96.98%	97.18%

**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	1.83
Number With MDUFA IV Decision	309	314	335	331	283
Average Number of FDA Days to MDUFA IV Decision	71.68	71.37	75.07	74.18	75.58
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	86
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	90
Maximum FDA Days to MDUFA IV Decision	159	117	245	293	119
Average Number of Industry Days to MDUFA IV Decision	64.80	66.25	89.59	103.13	86.67
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	36
60th Percentile Industry Days to MDUFA IV Decision	65	68	81	102	94
80th Percentile Industry Days to MDUFA IV Decision	146	140	159	177	168
Maximum Industry Days to MDUFA IV Decision	292	359	607	516	389
Average Number of Total Days to MDUFA IV Decision	136.48	137.61	164.65	177.31	162.25
20th Percentile Total Days to MDUFA IV Decision	55	51	56	58	64
40th Percentile Total Days to MDUFA IV Decision	102	98	118	123	118
60th Percentile Total Days to MDUFA IV Decision	150	148	166	190	180
80th Percentile Total Days to MDUFA IV Decision	228	227	250	265	256
Maximum Total Days to MDUFA IV Decision	370	447	707	608	508

Table 6.6 OHT2 - Office of Cardiovascular Devices

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
510(k) Accepted	341	366	368	374	343
Number With MDUFA IV Decision	309	314	335	331	283
Number of SE Decision	291	289	308	285	254
Number of NSE Decision	18	25	27	46	29
Number of Withdrawal	20	31	21	28	36
Number of Deleted	10	20	12	15	20
Rate of SE Decision	94.17%	92.04%	91.94%	86.10%	89.75%
Rate of NSE Decision	5.83%	7.96%	8.06%	13.90%	10.25%
Rate of Withdrawal	5.87%	8.47%	5.71%	7.49%	10.50%
Rate of Deleted	2.93%	5.46%	3.26%	4.01%	5.83%

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	10	7
Mean FDA Days for Submissions that Missed the Goal	107.17	99.82	110.13	117.50	99.00
Mean Industry Days for Submissions that Missed the Goal	131.50	159.09	261.60	285.30	181.29

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	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 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	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 6.1 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	442
Closed Before RTA Action	3	4	4	6	2
Number Accepted	334	350	287	292	261
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	137
Rate of Submissions Not Accepted for Review	25.66%	24.74%	33.72%	39.04%	31.14%

**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	471	429
Deleted or Withdrawn Prior to SI	0	1	1	2	0
SI Within 60 FDA Days	427	448	404	436	410
SI Over 60 FDA Days	6	4	13	25	19
SI Pending Within 60 FDA Days	0	0	0	1	0
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%	93.16%	95.57%

**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	461	429
Average Number of FDA Days to Substantive Interaction	51.10	52.60	53.39	54.15	55.36
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	471	429
Non-MDUFA IV Decision	50	77	59	53	55
MDUFA IV Decision (SE/NSE)	386	377	359	409	361
MDUFA IV Decision Within 90 FDA Days	382	372	349	400	359
510(k)s Pending MDUFA IV Decision	0	0	0	9	13
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	6	0
Current Performance Percent Within 90 FDA Days	98.96%	98.67%	97.21%	96.39%	99.45%

**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	1.84	1.77
Number With MDUFA IV Decision	386	377	359	409	361
Average Number of FDA Days to MDUFA IV Decision	75.68	78.18	78.93	81.19	80.34
20th Percentile FDA Days to MDUFA IV Decision	58	60	67	83	80
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	106.91	89.39
20th Percentile Industry Days to MDUFA IV Decision	0	5	0	5	0
40th Percentile Industry Days to MDUFA IV Decision	29	53	55	63	42
60th Percentile Industry Days to MDUFA IV Decision	94	118	128	119	93
80th Percentile Industry Days to MDUFA IV Decision	165	174	179	173	170
Maximum Industry Days to MDUFA IV Decision	214	444	834	525	364
Average Number of Total Days to MDUFA IV Decision	150.61	173.83	187.01	188.10	169.73
20th Percentile Total Days to MDUFA IV Decision	64	87	87	90	88
40th Percentile Total Days to MDUFA IV Decision	113	140	139	150	131
60th Percentile Total Days to MDUFA IV Decision	177	205	216	208	181
80th Percentile Total Days to MDUFA IV Decision	248	261	266	263	256
Maximum Total Days to MDUFA IV Decision	304	540	990	615	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	471	429
Number With MDUFA IV Decision	386	377	359	409	361
Number of SE Decision	361	354	337	375	339
Number of NSE Decision	25	23	22	34	22
Number of Withdrawal	20	31	28	24	29
Number of Deleted	30	44	30	29	26
Rate of SE Decision	93.52%	93.90%	93.87%	91.69%	93.91%
Rate of NSE Decision	6.48%	6.10%	6.13%	8.31%	6.09%
Rate of Withdrawal	4.59%	6.83%	6.70%	5.10%	6.76%
Rate of Deleted	6.88%	9.69%	7.18%	6.16%	6.06%

**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	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 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	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 6.1 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	1,015	747
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	376	241
Rate of Submissions Not Accepted for Review	32.00%	33.94%	36.87%	37.19%	32.31%

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	938	706
Deleted or Withdrawn Prior to SI	0	3	2	3	1
SI Within 60 FDA Days	512	543	626	756	599
SI Over 60 FDA Days	4	12	25	179	104
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	1	1	0	1
Current SI Performance Percent Within 60 FDA Days	99.22%	97.66%	96.01%	80.86%	85.09%

**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	935	703
Average Number of FDA Days to Substantive Interaction	52.60	52.19	53.97	58.85	57.29
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	364	431

**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	938	706
Non-MDUFA IV Decision	68	74	85	123	66
MDUFA IV Decision (SE/NSE)	448	485	569	807	615
MDUFA IV Decision Within 90 FDA Days	440	480	538	612	565
510(k)s Pending MDUFA IV Decision	0	0	0	8	25
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	6	13
Current Performance Percent Within 90 FDA Days	98.21%	98.97%	94.55%	75.28%	89.97%

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	1.57
Number With MDUFA IV Decision	448	485	569	807	615
Average Number of FDA Days to MDUFA IV Decision	73.88	73.19	78.90	86.61	78.08
20th Percentile FDA Days to MDUFA IV Decision	57	55	59	74	56
40th Percentile FDA Days to MDUFA IV Decision	79	81	84	87	82
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	831	440	408
Average Number of Industry Days to MDUFA IV Decision	48.98	55.75	67.69	66.82	50.03
20th Percentile Industry Days to MDUFA IV Decision	0	0	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	0	11	9	0
60th Percentile Industry Days to MDUFA IV Decision	31	41	63	51	29
80th Percentile Industry Days to MDUFA IV Decision	110	129	142	131	106
Maximum Industry Days to MDUFA IV Decision	563	507	419	535	446
Average Number of Total Days to MDUFA IV Decision	122.86	128.95	146.58	153.43	128.12
20th Percentile Total Days to MDUFA IV Decision	59	57	60	83	57
40th Percentile Total Days to MDUFA IV Decision	88	88	92	98	88
60th Percentile Total Days to MDUFA IV Decision	110	125	147	142	117
80th Percentile Total Days to MDUFA IV Decision	193	211	229	224	193
Maximum Total Days to MDUFA IV Decision	783	623	1,120	638	656

**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	938	706
Number With MDUFA IV Decision	448	485	569	807	615
Number of SE Decision	436	471	556	791	610
Number of NSE Decision	12	14	13	16	5
Number of Withdrawal	36	37	37	48	41
Number of Deleted	31	35	47	74	24
Rate of SE Decision	97.32%	97.11%	97.72%	98.02%	99.19%
Rate of NSE Decision	2.68%	2.89%	2.28%	1.98%	0.81%
Rate of Withdrawal	6.98%	6.62%	5.66%	5.12%	5.81%
Rate of Deleted	6.01%	6.26%	7.19%	7.89%	3.40%

**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	31	195	50
Mean FDA Days for Submissions that Missed the Goal	119.50	120.00	143.26	117.37	142.42
Mean Industry Days for Submissions that Missed the Goal	168.63	207.40	159.06	86.57	87.02

**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	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 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	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 6.1 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	288
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	126
Rate of Submissions Not Accepted for Review	41.63%	40.88%	55.43%	48.00%	44.06%

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	260
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	232	257	231	256	253
SI Over 60 FDA Days	4	3	9	2	7
SI Pending Within 60 FDA Days	0	0	0	0	0
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%	97.31%

**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	260
Average Number of FDA Days to Substantive Interaction	53.91	54.53	53.39	53.68	55.07
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	89

**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	260
Non-MDUFA IV Decision	30	31	17	32	22
MDUFA IV Decision (SE/NSE)	206	229	223	226	227
MDUFA IV Decision Within 90 FDA Days	201	222	223	224	222
510(k)s Pending MDUFA IV Decision	0	0	0	0	11
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	1
Current Performance Percent Within 90 FDA Days	97.57%	96.94%	100.00%	99.12%	97.37%

**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	1.48	1.62	1.69
Number With MDUFA IV Decision	206	229	223	226	227
Average Number of FDA Days to MDUFA IV Decision	76.47	80.32	75.83	76.86	79.17
20th Percentile FDA Days to MDUFA IV Decision	60	69	62	58	60
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	163	176
Average Number of Industry Days to MDUFA IV Decision	42.60	55.79	63.68	76.24	68.38
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	17
60th Percentile Industry Days to MDUFA IV Decision	38	39	28	69	60
80th Percentile Industry Days to MDUFA IV Decision	84	129	130	164	142
Maximum Industry Days to MDUFA IV Decision	187	391	360	361	430
Average Number of Total Days to MDUFA IV Decision	119.07	136.10	139.51	153.10	147.56
20th Percentile Total Days to MDUFA IV Decision	61	83	62	65	80
40th Percentile Total Days to MDUFA IV Decision	89	90	89	90	102
60th Percentile Total Days to MDUFA IV Decision	117	125	114	152	149
80th Percentile Total Days to MDUFA IV Decision	171	219	216	255	230
Maximum Total Days to MDUFA IV Decision	346	543	449	451	520

**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	260
Number With MDUFA IV Decision	206	229	223	226	227
Number of SE Decision	198	222	212	213	210
Number of NSE Decision	8	7	11	13	17
Number of Withdrawal	17	16	13	18	12
Number of Deleted	10	14	4	14	9
Rate of SE Decision	96.12%	96.94%	95.07%	94.25%	92.51%
Rate of NSE Decision	3.88%	3.06%	4.93%	5.75%	7.49%
Rate of Withdrawal	7.20%	6.15%	5.42%	6.98%	4.62%
Rate of Deleted	4.24%	5.38%	1.67%	5.43%	3.46%

**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	2	5
Mean FDA Days for Submissions that Missed the Goal	111.40	119.43	0.00	147.00	110.40
Mean Industry Days for Submissions that Missed the Goal	80.60	110.29	0.00	191.00	104.40

**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	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 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	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 6.1 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	603
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	164
Rate of Submissions Not Accepted for Review	22.85%	21.59%	23.35%	23.44%	27.29%

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	582
Deleted or Withdrawn Prior to SI	0	2	3	1	2
SI Within 60 FDA Days	575	617	635	560	576
SI Over 60 FDA Days	19	3	1	1	0
SI Pending Within 60 FDA Days	0	0	0	0	0
SI Pending Over 60 FDA Days	0	0	0	0	1
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%	99.31%

**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	576
Average Number of FDA Days to Substantive Interaction	50.43	49.80	49.84	50.33	52.15
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	582
Non-MDUFA IV Decision	40	47	61	43	52
MDUFA IV Decision (SE/NSE)	554	575	578	519	528
MDUFA IV Decision Within 90 FDA Days	552	574	578	518	528
510(k)s Pending MDUFA IV Decision	0	0	0	0	2
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	0	0	1
Current Performance Percent Within 90 FDA Days	99.64%	99.83%	100.00%	99.81%	99.81%

**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	1.53
Number With MDUFA IV Decision	554	575	578	519	528
Average Number of FDA Days to MDUFA IV Decision	71.36	70.57	66.99	66.63	69.35
20th Percentile FDA Days to MDUFA IV Decision	52	51	37	44	51
40th Percentile FDA Days to MDUFA IV Decision	74	76	60	60	68
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	59.82	54.54
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	33	33
80th Percentile Industry Days to MDUFA IV Decision	103	103	99	111	131
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	126.46	123.89
20th Percentile Total Days to MDUFA IV Decision	57	56	38	48	54
40th Percentile Total Days to MDUFA IV Decision	86	87	67	64	80
60th Percentile Total Days to MDUFA IV Decision	115	111	103	111	116
80th Percentile Total Days to MDUFA IV Decision	189	185	184	199	213
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	582
Number With MDUFA IV Decision	554	575	578	519	528
Number of SE Decision	540	563	574	515	518
Number of NSE Decision	14	12	4	4	10
Number of Withdrawal	24	28	38	31	35
Number of Deleted	16	19	23	12	16
Rate of SE Decision	97.47%	97.91%	99.31%	99.23%	98.11%
Rate of NSE Decision	2.53%	2.09%	0.69%	0.77%	1.89%
Rate of Withdrawal	4.04%	4.50%	5.95%	5.52%	6.01%
Rate of Deleted	2.69%	3.05%	3.60%	2.14%	2.75%

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	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 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	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 6.1 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	241
Closed Before RTA Action	3	3	3	1	7
Number Accepted	245	237	191	56	121
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%	12.82%

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	16
SI Over 60 FDA Days	1	2	50	171	205
SI Pending Within 60 FDA Days	0	0	0	0	0
SI Pending Over 60 FDA Days	0	0	0	0	0
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%	7.24%

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	221
Average Number of FDA Days to Substantive Interaction	50.56	49.13	93.22	162.30	127.28
20th Percentile FDA Days to Substantive Interaction	44	30	45	116	101
40th Percentile FDA Days to Substantive Interaction	54	53	58	128	119
60th Percentile FDA Days to Substantive Interaction	58	58	60	170	120
80th Percentile FDA Days to Substantive Interaction	59	60	60	238	133
Maximum FDA Days to Substantive Interaction	61	61	496	381	402

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	46	38
MDUFA IV Decision (SE/NSE)	232	242	204	146	162
MDUFA IV Decision Within 90 FDA Days	231	238	124	13	15
510(k)s Pending MDUFA IV Decision	0	0	1	4	23
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	4	22
Current Performance Percent Within 90 FDA Days	99.57%	98.35%	60.49%	8.67%	8.15%

**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	1.58	1.58	1.57
Number With MDUFA IV Decision	232	242	204	146	162
Average Number of FDA Days to MDUFA IV Decision	72.98	71.48	165.82	237.41	209.87
20th Percentile FDA Days to MDUFA IV Decision	53	31	56	143	135
40th Percentile FDA Days to MDUFA IV Decision	84	60	87	211	203
60th Percentile FDA Days to MDUFA IV Decision	88	87	90	268	214
80th Percentile FDA Days to MDUFA IV Decision	90	90	310	324	286
Maximum FDA Days to MDUFA IV Decision	93	655	673	576	426
Average Number of Industry Days to MDUFA IV Decision	58.27	46.80	85.63	101.28	81.41
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	81	119	86
80th Percentile Industry Days to MDUFA IV Decision	145	129	164	189	174
Maximum Industry Days to MDUFA IV Decision	231	448	638	375	362
Average Number of Total Days to MDUFA IV Decision	131.25	118.28	251.45	338.69	291.28
20th Percentile Total Days to MDUFA IV Decision	55	31	58	148	158
40th Percentile Total Days to MDUFA IV Decision	88	67	91	237	210
60th Percentile Total Days to MDUFA IV Decision	134	90	238	381	330
80th Percentile Total Days to MDUFA IV Decision	235	194	476	511	436
Maximum Total Days to MDUFA IV Decision	321	871	1,282	912	695

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	204	146	162
Number of SE Decision	221	234	197	142	158
Number of NSE Decision	11	8	7	4	4
Number of Withdrawal	26	14	29	32	24
Number of Deleted	15	23	22	14	14
Rate of SE Decision	95.26%	96.69%	96.57%	97.26%	97.53%
Rate of NSE Decision	4.74%	3.31%	3.43%	2.74%	2.47%
Rate of Withdrawal	9.49%	5.02%	11.28%	16.33%	10.76%
Rate of Deleted	5.47%	8.24%	8.56%	7.14%	6.28%

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	80	133	147
Mean FDA Days for Submissions that Missed the Goal	93.00	370.00	321.99	255.14	226.19
Mean Industry Days for Submissions that Missed the Goal	202.00	268.00	159.60	110.48	89.05

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	3
MDUFA IV Decision Within 90 FDA Days	1	1	2	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	100.00%	100.00%	50.00%	#DIV/0!	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	45	38
MDUFA IV Decision (SE/NSE)	231	241	200	146	159
MDUFA IV Decision Within 90 FDA Days	230	237	122	13	15
510(k)s Pending MDUFA IV Decision	0	0	1	4	23
510(k)s Pending MDUFA IV Decision Over 90 FDA Days	0	0	1	4	22
Current Performance Percent Within 90 FDA Days	99.57%	98.34%	60.70%	8.67%	8.29%

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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	385	373	422	439	469
Deleted or Withdrawn Prior to SI	1	0	0	0	1
SI Within 60 FDA Days	384	373	422	436	467
SI Over 60 FDA Days	0	0	0	0	0
SI Pending Within 60 FDA Days	0	0	0	0	0
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%	99.79%

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	467
Average Number of FDA Days to Substantive Interaction	43.70	44.96	46.49	48.76	49.15
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	FY 2019	FY 2020	FY 2021	FY 2022
	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days	95% Within 90 FDA Days
510(k)s Accepted	385	373	422	439	469
Non-MDUFA IV Decision	14	22	20	27	35
MDUFA IV Decision (SE/NSE)	371	351	402	412	433
MDUFA IV Decision Within 90 FDA Days	371	351	402	412	433
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	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	1.57	1.59
Number With MDUFA IV Decision	371	351	402	412	433
Average Number of FDA Days to MDUFA IV Decision	58.72	61.13	63.56	68.43	69.15
20th Percentile FDA Days to MDUFA IV Decision	30	28	29	48	50
40th Percentile FDA Days to MDUFA IV Decision	55	58	60	71	71
60th Percentile FDA Days to MDUFA IV Decision	73	77	82	86	86
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	54.67	54.86
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	35	46
80th Percentile Industry Days to MDUFA IV Decision	56	81	87	105	114
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	123.10	124.01
20th Percentile Total Days to MDUFA IV Decision	30	28	29	48	51
40th Percentile Total Days to MDUFA IV Decision	58	59	63	80	86
60th Percentile Total Days to MDUFA IV Decision	93	103	114	118	132
80th Percentile Total Days to MDUFA IV Decision	138	165	167	193	199
Maximum Total Days to MDUFA IV Decision	270	416	447	700	448

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	412	433
Number of SE Decision	360	348	397	402	423
Number of NSE Decision	11	3	5	10	10
Number of Withdrawal	7	8	13	14	22
Number of Deleted	5	5	6	13	13
Rate of SE Decision	97.04%	99.15%	98.76%	97.57%	97.69%
Rate of NSE Decision	2.96%	0.85%	1.24%	2.43%	2.31%
Rate of Withdrawal	1.82%	2.14%	3.08%	3.19%	4.69%
Rate of Deleted	1.30%	1.34%	1.42%	2.96%	2.77%

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	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 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	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

Section 7 510(k) Annual General Metrics

Table 7.1 CDRH - 510(k) Annual General Metrics - 510(k)s Received by Type

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	3,351	3,542	3,589	3,821	3,631
Number of Traditional Submissions	2,789	2,907	2,912	3,201	3,107
Number of Special Submissions	419	493	517	449	396
Number of Abbreviated Submissions	68	64	75	81	51
Average Number of Days to Accept/Refuse to Accept	10.58	11.20	11.43	11.80	11.75
Number of Third Party Submissions	75	78	85	90	77

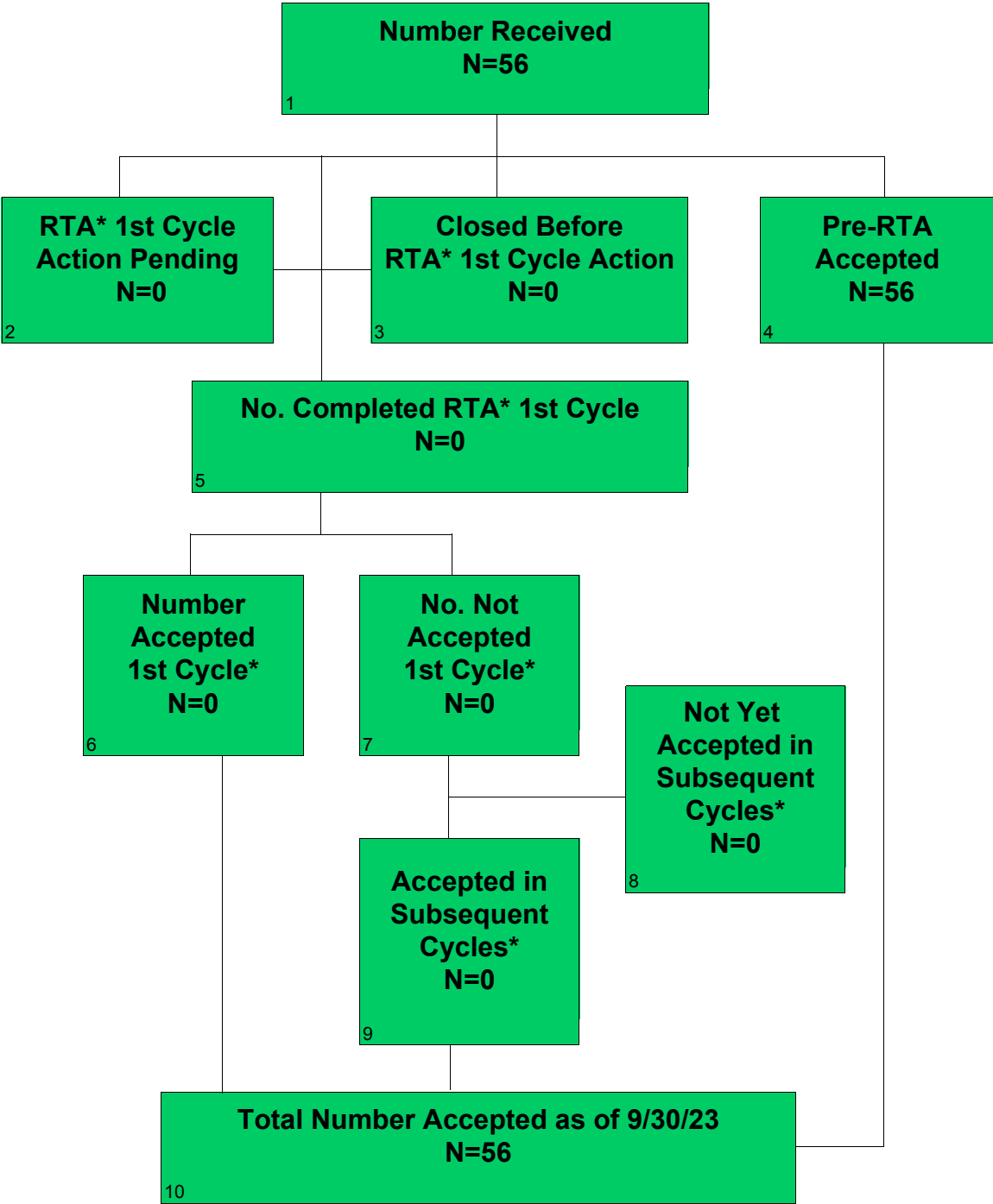
Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal

Performance Metrics	FY 2018 124 Days	FY 2019 120 Days	FY 2020 116 Days	FY 2021 112 Days	FY 2022 108 Days
Number Accepted	3,351	3,542	3,589	3,821	3,631
Currently Under Review	0	0	2	27	110
Number With Non-MDUFA IV Decision	355	432	400	462	408
Number With MDUFA IV Decision	2,996	3,110	3,187	3,332	3,113
Percent of Cohort Closed	100.00%	100.00%	99.94%	99.20%	96.59%
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	2,878	2,984	3,061	3,199	2,995
Average Total Time to MDUFA IV Decision	125.92	132.10	148.64	161	148

Table 7.3 CDRH - 510(k) Third Party Performance

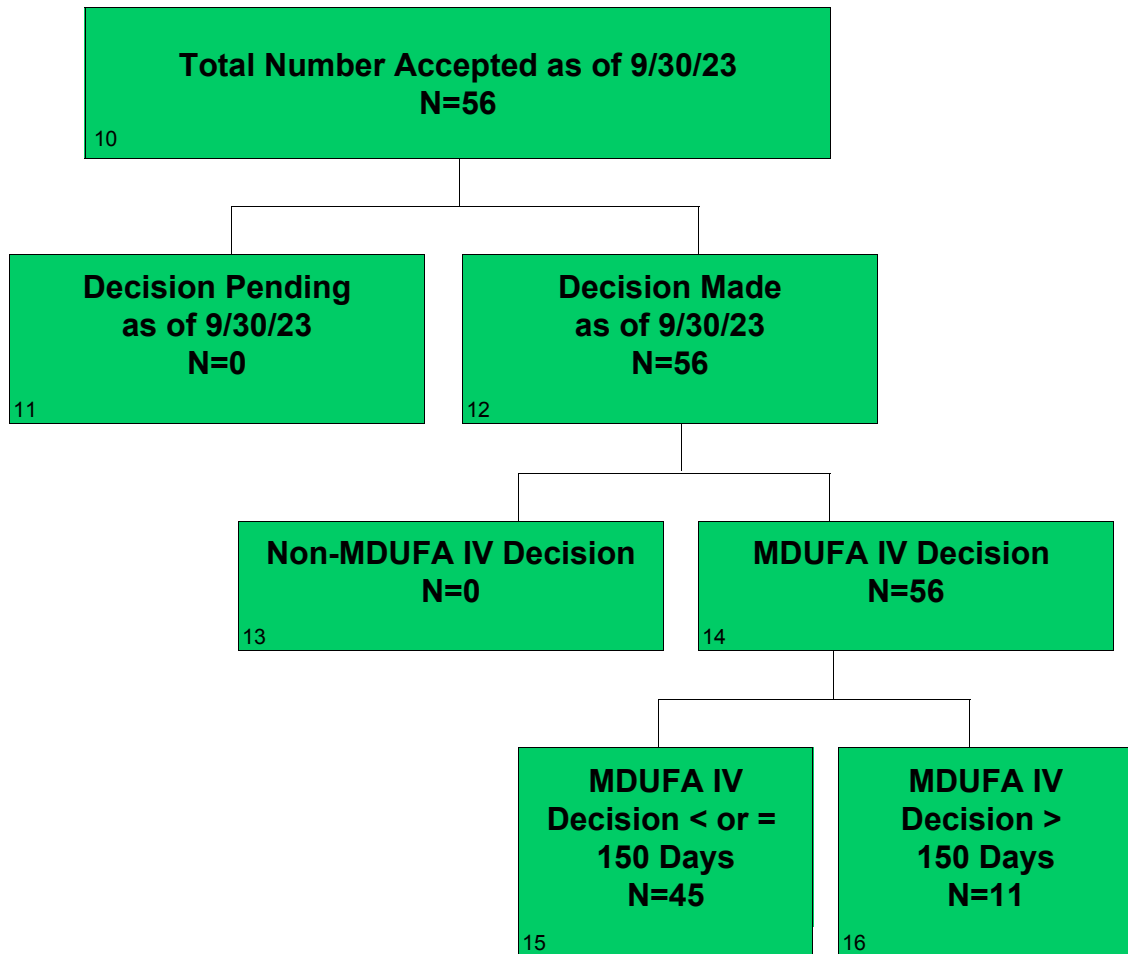
Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Third Party Submissions	75	78	85	90	77
90th Percentile FDA Days to MDUFA IV Decision	55.40	52.00	33.10	46.70	56.20

CDRH De Novo - FY 2018 as of 9/30/23

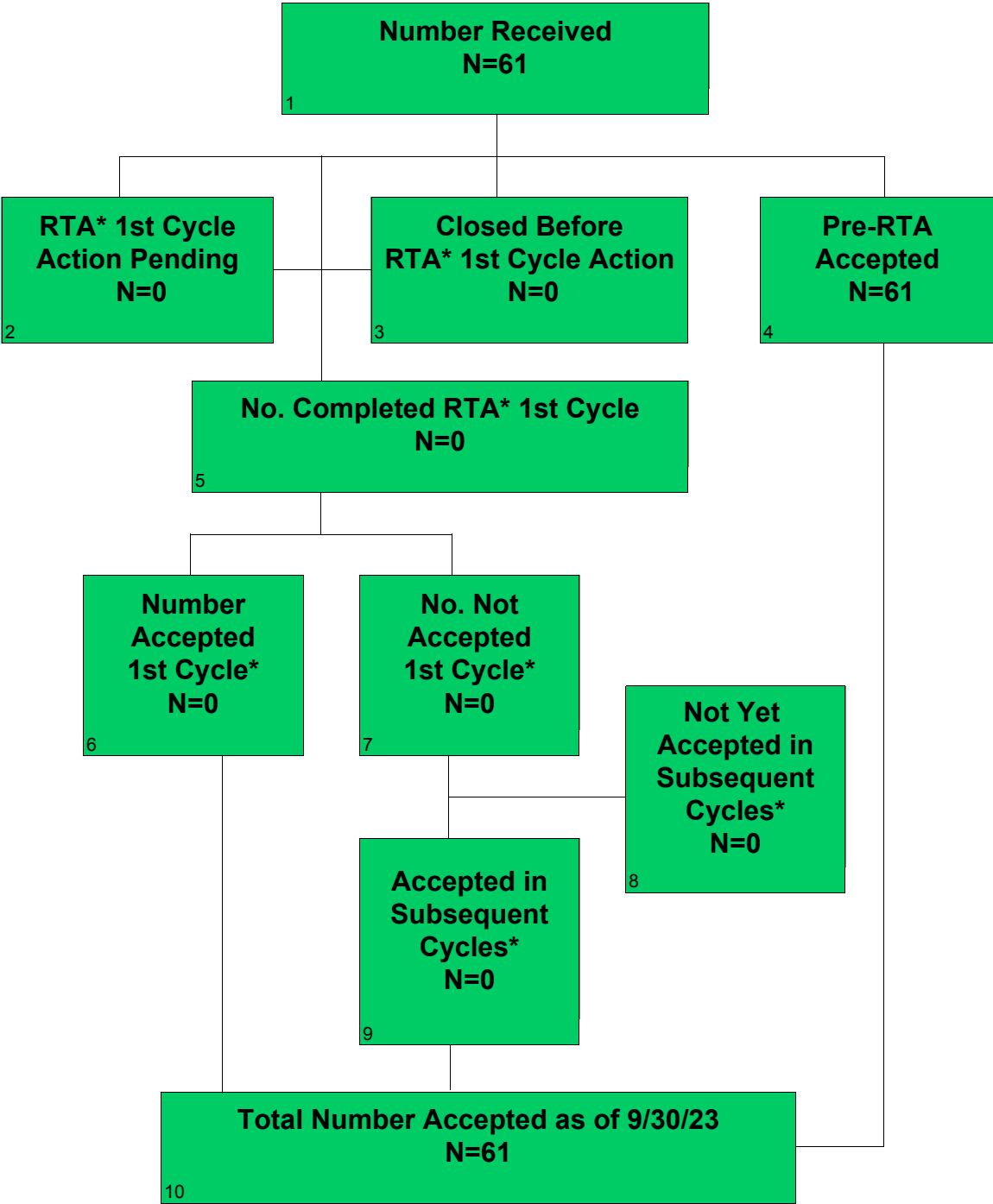


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2018 as of 9/30/23 Continued

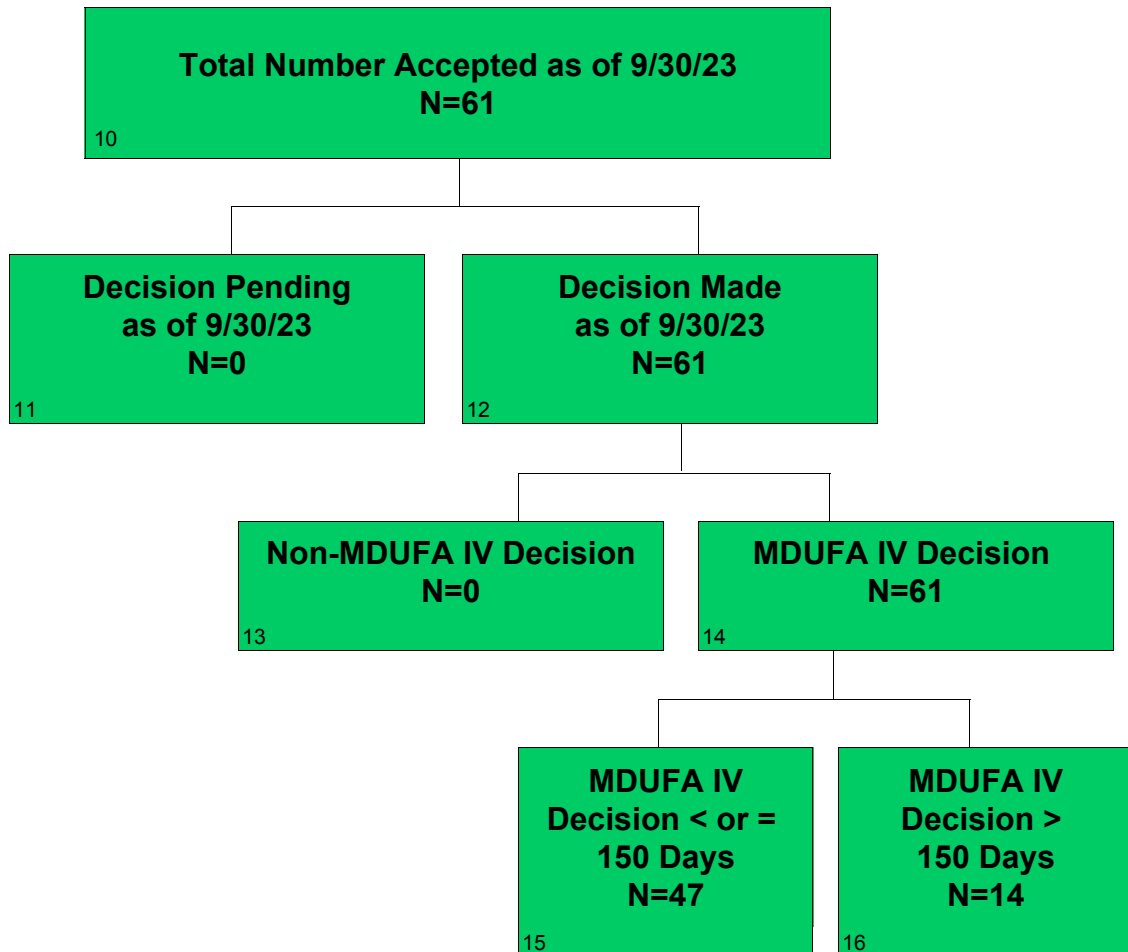


CDRH De Novo - FY 2019 as of 9/30/23

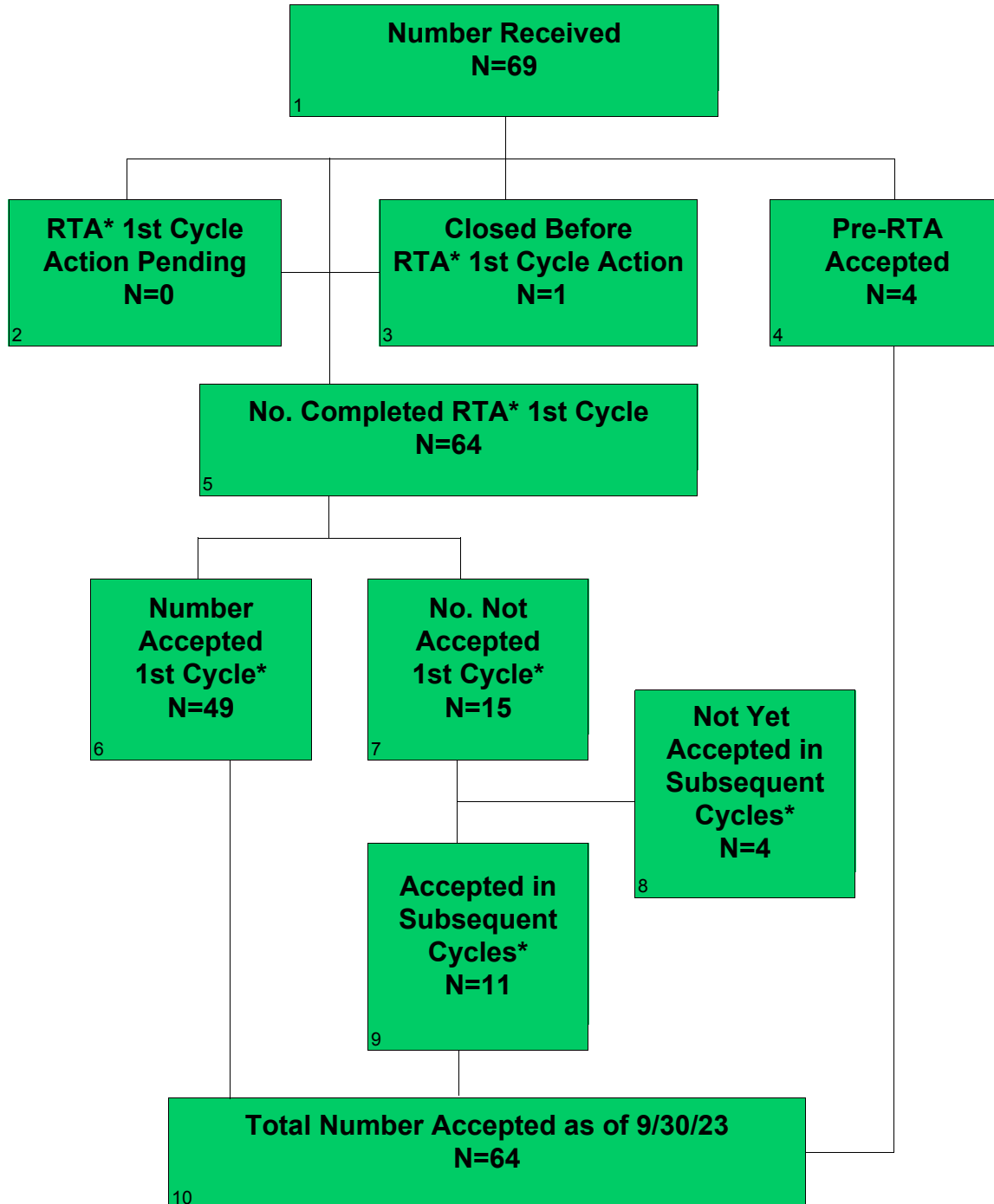


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2019 as of 9/30/23 Continued

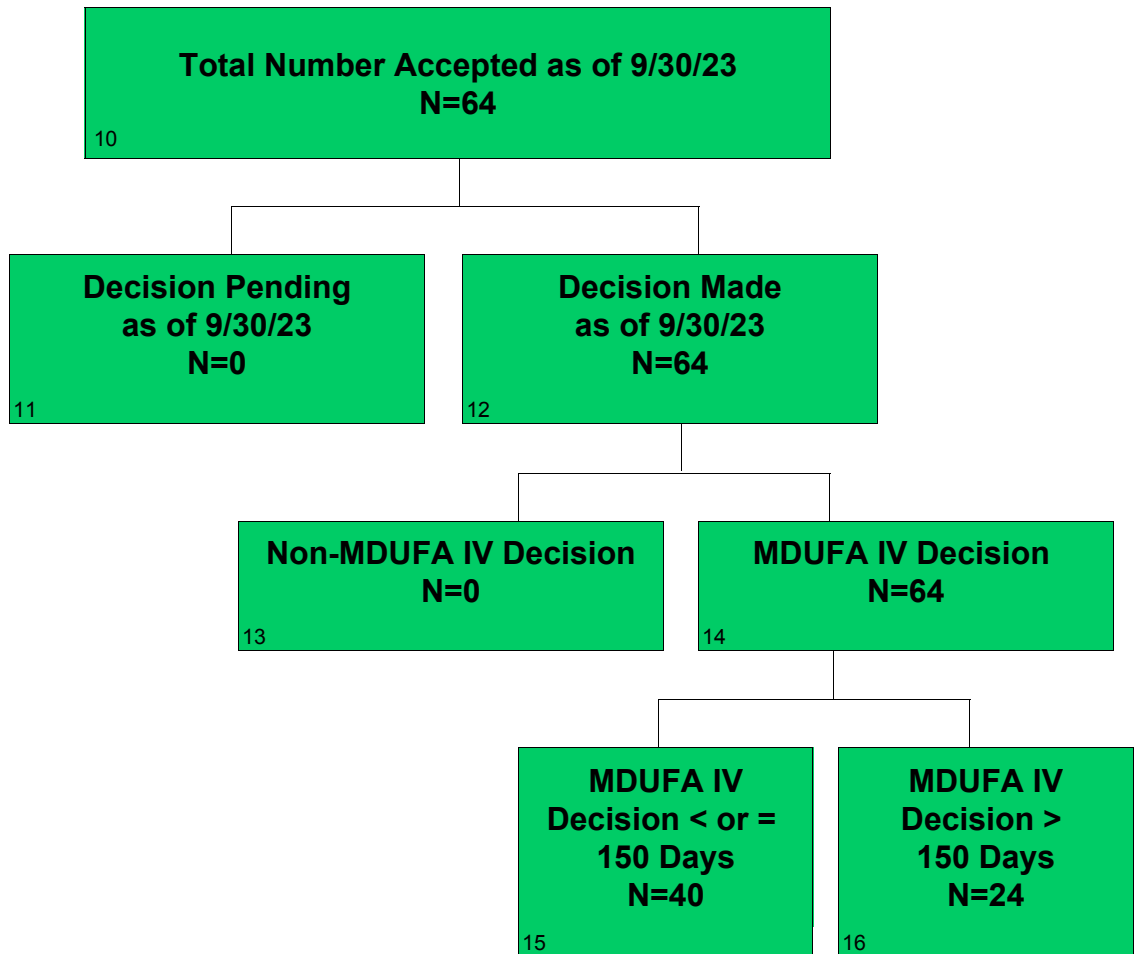


CDRH De Novo - FY 2020 as of 9/30/23

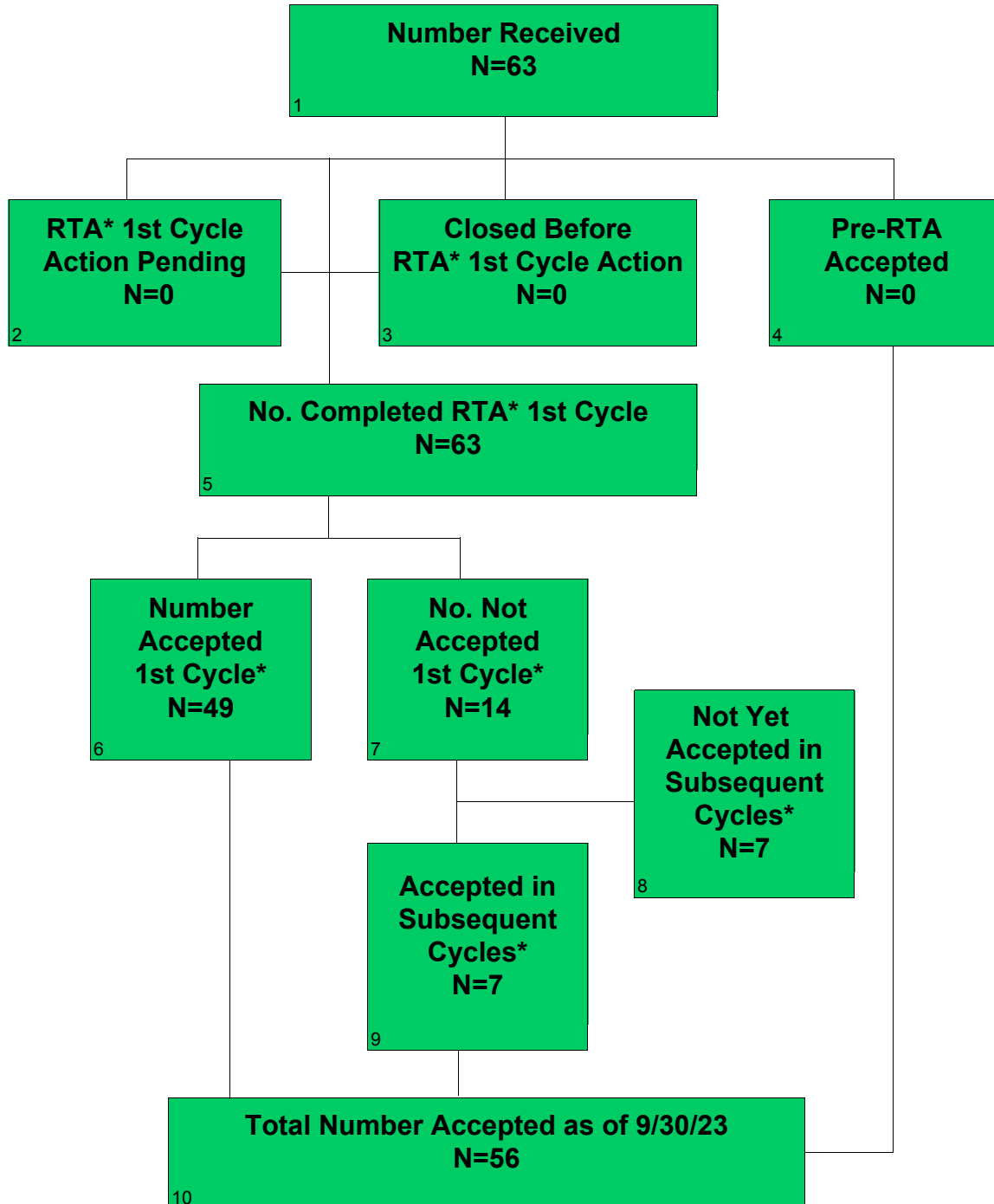


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2020 as of 9/30/23 Continued

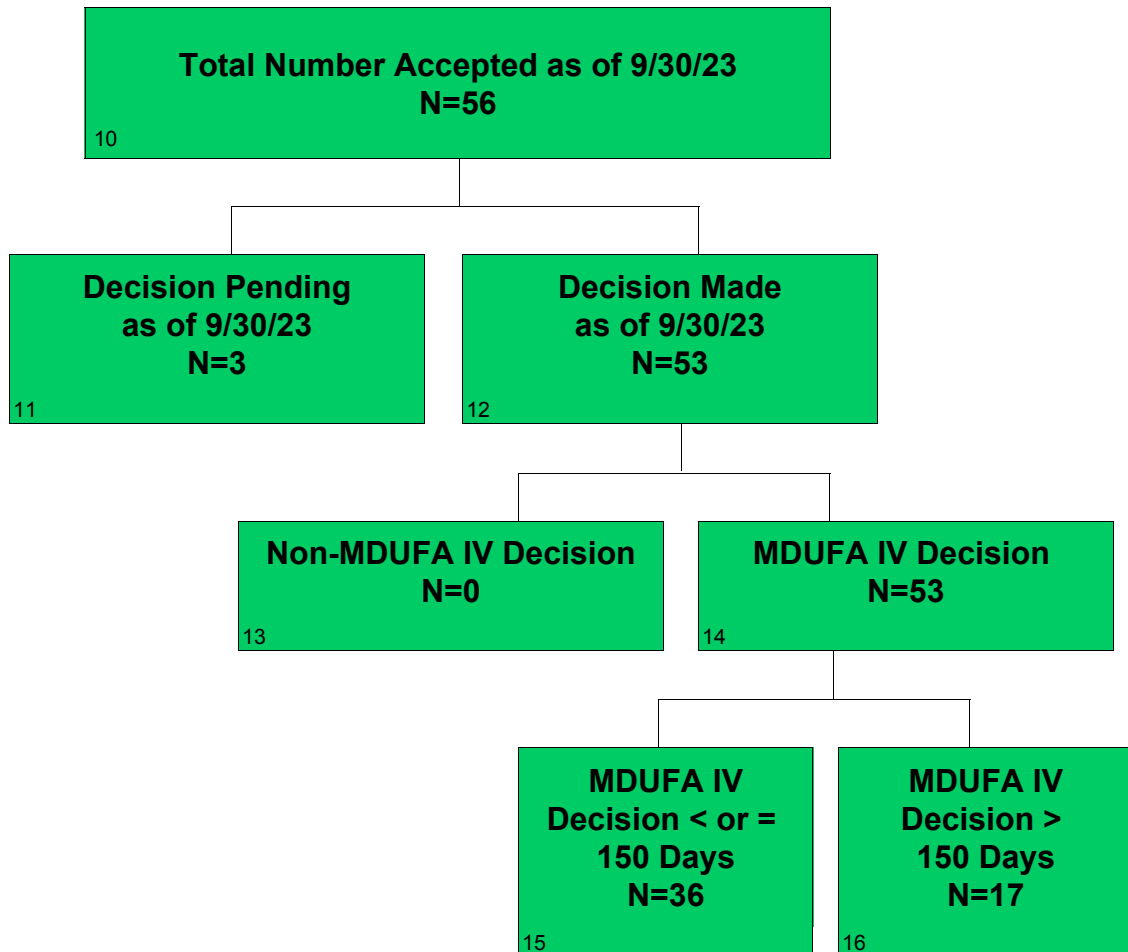


CDRH De Novo - FY 2021 as of 9/30/23

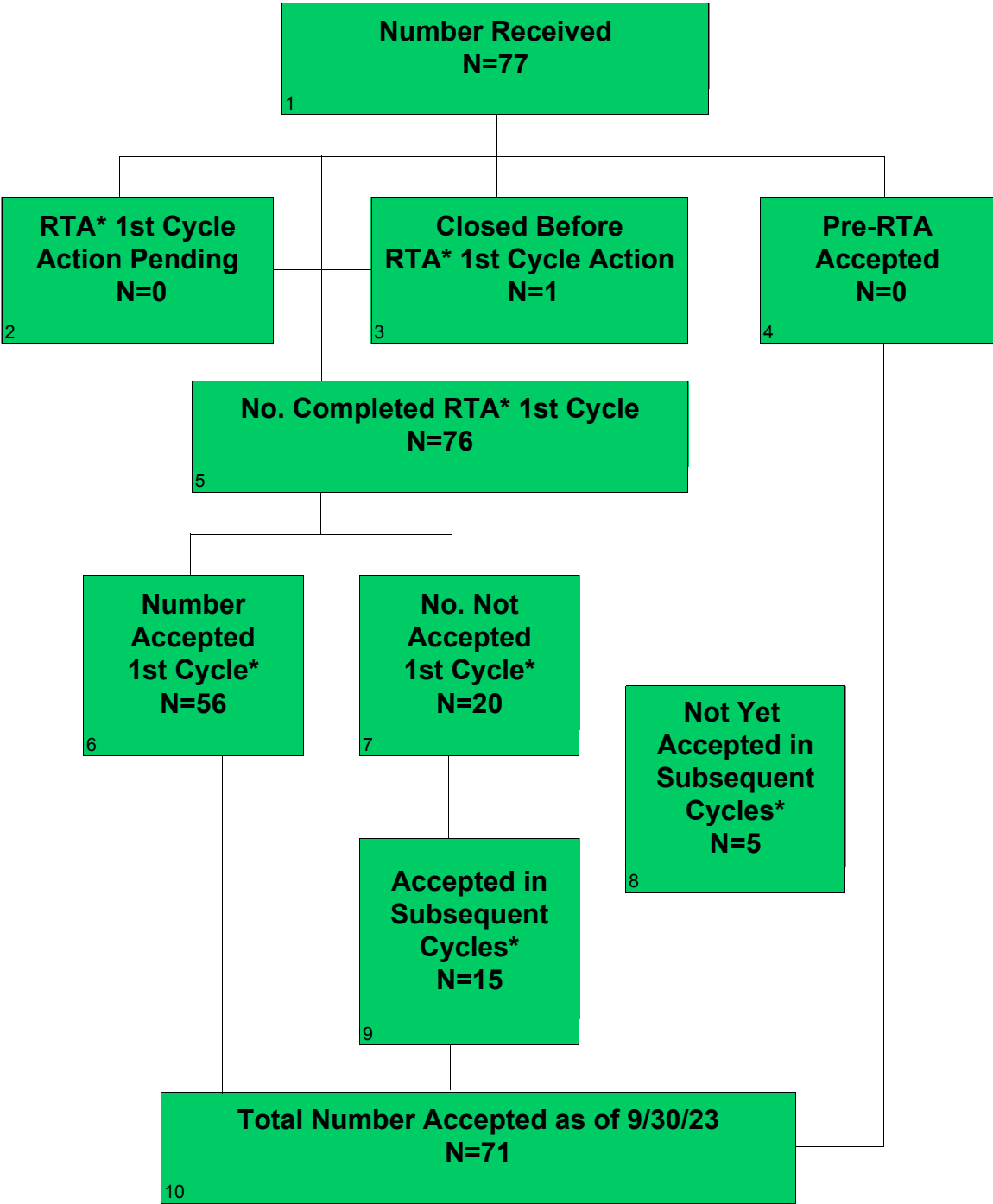


*RTA was implemented on November 8, 2019, thus RTA metrics include only De Novos received on or after November 8, 2019. All other metrics include De Novos received on or after October 1, 2017.

CDRH De Novo - FY 2021 as of 9/30/23 Continued

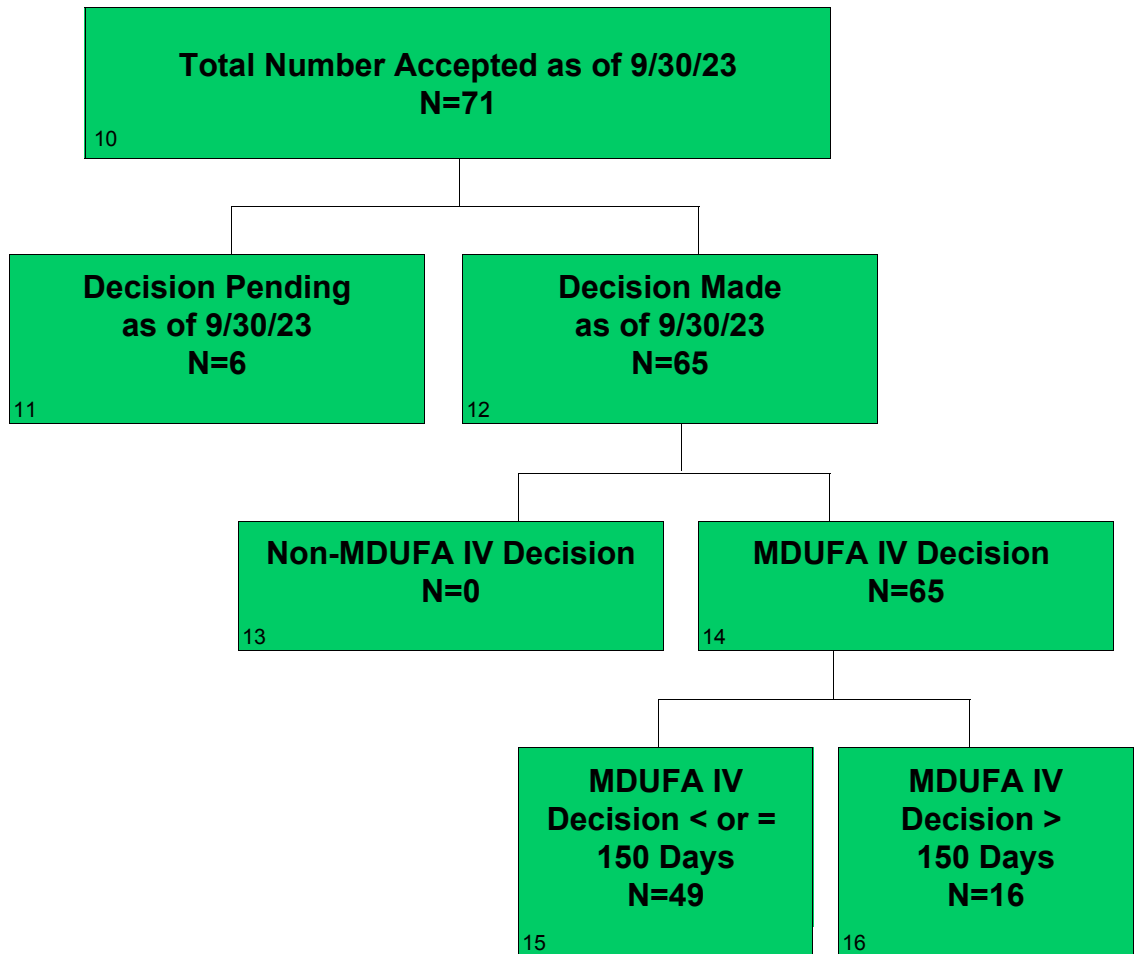


CDRH De Novo - FY 2022 as of 9/30/23



*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 9/30/23 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	64	53	65
MDUFA IV Decisions Within 150 FDA Days	45	47	40	36	49
De Novos Pending MDUFA IV Decision	0	0	0	3	6
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	3	3
Current Performance Percent Within 150 FDA Days	80.36%	77.05%	62.50%	64.29%	72.06%

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	1.81	1.66
Number With MDUFA IV Decision	56	61	64	53	65
Average FDA Days to MDUFA IV Decision	130.13	143.57	196.77	182.34	151.54
20th Percentile FDA Days to MDUFA IV Decision	75	76	123	143	119
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	236	220	179
Maximum FDA Days to MDUFA IV Decision	254	485	762	552	342
Average Industry Days to MDUFA IV Decision	110.13	117.44	186.77	215.81	158.60
20th Percentile Industry Days to MDUFA IV Decision	0	0	44	77	58
40th Percentile Industry Days to MDUFA IV Decision	89	29	142	149	152
60th Percentile Industry Days to MDUFA IV Decision	166	177	236	319	178
80th Percentile Industry Days to MDUFA IV Decision	180	204	341	359	195
Maximum Industry Days to MDUFA IV Decision	389	373	431	508	460
Average Total Days to MDUFA IV Decision	240.25	261.02	383.53	398.15	310.14
20th Percentile Total Days to MDUFA IV Decision	145	107	211	232	210
40th Percentile Total Days to MDUFA IV Decision	251	179	314	299	281
60th Percentile Total Days to MDUFA IV Decision	292	304	402	487	328
80th Percentile Total Days to MDUFA IV Decision	324	388	494	563	389
Maximum Total Days to MDUFA IV Decision	463	680	1,136	912	707

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	64	53	65
Number With Granted Decisions	25	28	34	27	25
Number With Declined Decisions	15	15	16	12	20
Number of Withdrawals	10	13	9	10	14
Number Deleted	6	5	5	4	6
Rate of Granted Decisions	44.64%	45.90%	53.13%	50.94%	38.46%
Rate of Declined Decisions	26.79%	24.59%	25.00%	22.64%	30.77%
Rate of Withdrawals	17.86%	21.31%	14.06%	18.87%	21.54%
Rate of Deleted	10.71%	8.20%	7.81%	7.55%	9.23%

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	24	17	16
Mean FDA Days for Submissions that Missed the Goal	192.45	248.29	318.17	283.35	225.50
Mean Industry Days for Submissions that Missed the Goal	127.27	218.64	214.00	238.53	145.38

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	16	11	13
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	2
De Novos Pending MDUFA IV Decision	0	0	0	2	1
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	2	1
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	7.69%	14.29%

Table 8.8 CDRH - De Novo Annual General Metrics*

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted First RTA Cycle	56	61	64	56	71
Average Number of Days to Accept / Refuse to Accept*	N/A	N/A	11.61	12.68	12.27

*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.

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	10	10
MDUFA IV Decisions Within 150 FDA Days	5	4	10	9	9
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	62.50%	80.00%	76.92%	90.00%	90.00%

**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	2.10	1.40
Number With MDUFA IV Decision	8	5	13	10	10
Average FDA Days to MDUFA IV Decision	141.25	124.80	186.15	162.30	123.00
20th Percentile FDA Days to MDUFA IV Decision	110	75	74	149	75
40th Percentile FDA Days to MDUFA IV Decision	149	119	148	150	121
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	150
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	259.40	192.70
20th Percentile Industry Days to MDUFA IV Decision	9	185	111	113	112
40th Percentile Industry Days to MDUFA IV Decision	45	192	157	160	176
60th Percentile Industry Days to MDUFA IV Decision	75	199	276	346	183
80th Percentile Industry Days to MDUFA IV Decision	167	206	342	393	343
Maximum Industry Days to MDUFA IV Decision	389	212	374	508	369
Average Total Days to MDUFA IV Decision	247.38	320.00	397.23	421.70	315.70
20th Percentile Total Days to MDUFA IV Decision	157	268	271	262	241
40th Percentile Total Days to MDUFA IV Decision	199	304	316	307	278
60th Percentile Total Days to MDUFA IV Decision	260	336	395	516	326
80th Percentile Total Days to MDUFA IV Decision	332	360	454	577	439
Maximum Total Days to MDUFA IV Decision	463	392	1,136	658	487

**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	10	10
Number With Granted Decisions	5	2	6	6	3
Number With Declined Decisions	2	1	4	3	3
Number of Withdrawals	0	0	2	1	0
Number Deleted	1	2	1	0	4
Rate of Granted Decisions	62.50%	40.00%	46.15%	60.00%	30.00%
Rate of Declined Decisions	25.00%	20.00%	30.77%	30.00%	30.00%
Rate of Withdrawals	0.00%	0.00%	15.38%	10.00%	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	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 OHT1 - Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Device
Conventional IVD (non-LDT) De Novo MDUFA IV Decision Metrics**

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	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	9
MDUFA IV Decisions Within 150 FDA Days	5	8	3	5	9
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%	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	1.78
Number With MDUFA IV Decision	5	9	8	5	9
Average FDA Days to MDUFA IV Decision	74.00	144.00	200.50	102.80	124.44
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	185.67
20th Percentile Industry Days to MDUFA IV Decision	0	0	24	91	154
40th Percentile Industry Days to MDUFA IV Decision	98	6	96	148	175
60th Percentile Industry Days to MDUFA IV Decision	171	64	177	251	181
80th Percentile Industry Days to MDUFA IV Decision	188	163	279	363	201
Maximum Industry Days to MDUFA IV Decision	217	207	427	365	362
Average Total Days to MDUFA IV Decision	186.40	215.11	362.25	312.00	310.11
20th Percentile Total Days to MDUFA IV Decision	32	117	286	237	235
40th Percentile Total Days to MDUFA IV Decision	173	153	350	253	270
60th Percentile Total Days to MDUFA IV Decision	277	213	363	326	327
80th Percentile Total Days to MDUFA IV Decision	296	281	448	436	349
Maximum Total Days to MDUFA IV Decision	312	526	651	440	512

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	9
Number With Granted Decisions	3	2	5	2	0
Number With Declined Decisions	0	5	2	0	6
Number of Withdrawals	0	1	1	1	2
Number Deleted	2	1	0	2	1
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%	22.22%
Rate of Deleted	40.00%	11.11%	0.00%	40.00%	11.11%

Table 8.5 OHT2 - Office of Cardiovascular Devices

De Novo Performance Metrics-Submissions Missing Performance Goals

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

Table 8.6 OHT2 - Office of Cardiovascular Devices

LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	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	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 8.1 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	7
MDUFA IV Decisions Within 150 FDA Days	3	5	4	6	7
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	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	1.57
Number With MDUFA IV Decision	4	11	6	6	7
Average FDA Days to MDUFA IV Decision	100.00	186.55	161.50	148.67	127.86
20th Percentile FDA Days to MDUFA IV Decision	57	148	148	147	120
40th Percentile FDA Days to MDUFA IV Decision	97	150	150	148	147
60th Percentile FDA Days to MDUFA IV Decision	135	191	150	150	149
80th Percentile FDA Days to MDUFA IV Decision	149	211	203	150	150
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	84.14
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	44
60th Percentile Industry Days to MDUFA IV Decision	175	177	61	135	116
80th Percentile Industry Days to MDUFA IV Decision	187	241	222	201	167
Maximum Industry Days to MDUFA IV Decision	203	338	363	355	180
Average Total Days to MDUFA IV Decision	236.75	355.00	278.33	301.50	212.00
20th Percentile Total Days to MDUFA IV Decision	179	283	209	238	148
40th Percentile Total Days to MDUFA IV Decision	293	347	213	252	180
60th Percentile Total Days to MDUFA IV Decision	312	368	267	285	250
80th Percentile Total Days to MDUFA IV Decision	321	416	372	351	314
Maximum Total Days to MDUFA IV Decision	325	617	438	502	330

**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	7
Number With Granted Decisions	0	8	3	4	4
Number With Declined Decisions	3	3	2	1	1
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%	57.14%
Rate of Declined Decisions	75.00%	27.27%	33.33%	16.67%	14.29%
Rate of Withdrawals	0.00%	0.00%	0.00%	16.67%	28.57%
Rate of Deleted	25.00%	0.00%	16.67%	0.00%	0.00%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	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	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 8.1 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	6	4
MDUFA IV Decisions Within 150 FDA Days	3	4	3	3	3
De Novos Pending MDUFA IV Decision	0	0	0	1	2
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	1	1
Current Performance Percent Within 150 FDA Days	60.00%	66.67%	42.86%	42.86%	60.00%

**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	1.67	1.75
Number With MDUFA IV Decision	5	6	7	6	4
Average FDA Days to MDUFA IV Decision	147.40	182.50	165.14	160.33	188.00
20th Percentile FDA Days to MDUFA IV Decision	133	93	113	148	134
40th Percentile FDA Days to MDUFA IV Decision	150	98	146	150	147
60th Percentile FDA Days to MDUFA IV Decision	151	107	174	169	148
80th Percentile FDA Days to MDUFA IV Decision	167	236	189	198	226
Maximum FDA Days to MDUFA IV Decision	221	485	323	215	342
Average Industry Days to MDUFA IV Decision	90.80	125.83	231.86	322.50	214.00
20th Percentile Industry Days to MDUFA IV Decision	12	0	161	271	166
40th Percentile Industry Days to MDUFA IV Decision	65	0	248	359	179
60th Percentile Industry Days to MDUFA IV Decision	124	187	267	363	180
80th Percentile Industry Days to MDUFA IV Decision	165	195	331	364	248
Maximum Industry Days to MDUFA IV Decision	179	373	365	427	349
Average Total Days to MDUFA IV Decision	238.20	308.33	397.00	482.83	402.00
20th Percentile Total Days to MDUFA IV Decision	145	93	331	446	328
40th Percentile Total Days to MDUFA IV Decision	215	107	408	486	357
60th Percentile Total Days to MDUFA IV Decision	275	285	436	509	437
80th Percentile Total Days to MDUFA IV Decision	332	609	469	561	474
Maximum Total Days to MDUFA IV Decision	400	680	668	575	490

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	6	4
Number With Granted Decisions	3	1	1	1	2
Number With Declined Decisions	1	3	3	2	1
Number of Withdrawals	1	1	2	1	1
Number Deleted	0	1	1	2	0
Rate of Granted Decisions	60.00%	16.67%	14.29%	16.67%	50.00%
Rate of Declined Decisions	20.00%	50.00%	42.86%	33.33%	25.00%
Rate of Withdrawals	20.00%	16.67%	28.57%	16.67%	25.00%
Rate of Deleted	0.00%	16.67%	14.29%	33.33%	0.00%

Table 8.5 OHT4 - Office of Surgical and Infection Control Devices

De Novo Performance Metrics-Submissions Missing Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	2	2	4	3	1
Mean FDA Days for Submissions that Missed the Goal	187.00	360.50	215.50	194.00	342.00
Mean Industry Days for Submissions that Missed the Goal	170.50	284.00	246.25	261.67	148.00

Table 8.6 OHT4 - Office of Surgical and Infection Control Devices

LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	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	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 8.1 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	9
MDUFA IV Decisions Within 150 FDA Days	9	6	5	6	9
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	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	1.78
Number With MDUFA IV Decision	13	6	6	7	9
Average FDA Days to MDUFA IV Decision	153.00	113.33	138.67	155.43	133.33
20th Percentile FDA Days to MDUFA IV Decision	104	76	149	148	120
40th Percentile FDA Days to MDUFA IV Decision	148	127	149	149	149
60th Percentile FDA Days to MDUFA IV Decision	150	136	150	150	150
80th Percentile FDA Days to MDUFA IV Decision	219	149	150	150	150
Maximum FDA Days to MDUFA IV Decision	254	150	175	270	150
Average Industry Days to MDUFA IV Decision	106.08	20.17	134.67	122.86	124.78
20th Percentile Industry Days to MDUFA IV Decision	39	0	14	53	68
40th Percentile Industry Days to MDUFA IV Decision	82	0	84	69	98
60th Percentile Industry Days to MDUFA IV Decision	164	0	125	117	134
80th Percentile Industry Days to MDUFA IV Decision	174	45	169	161	199
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	258.11
20th Percentile Total Days to MDUFA IV Decision	226	76	163	203	212
40th Percentile Total Days to MDUFA IV Decision	266	127	234	219	228
60th Percentile Total Days to MDUFA IV Decision	316	136	274	265	258
80th Percentile Total Days to MDUFA IV Decision	323	195	344	407	348
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	9
Number With Granted Decisions	3	2	6	3	2
Number With Declined Decisions	7	0	0	3	6
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%	22.22%
Rate of Declined Decisions	53.85%	0.00%	0.00%	42.86%	66.67%
Rate of Withdrawals	23.08%	66.67%	0.00%	14.29%	11.11%
Rate of Deleted	0.00%	0.00%	0.00%	0.00%	0.00%

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

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

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	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	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 8.1 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	5
MDUFA IV Decisions Within 150 FDA Days	3	3	5	4	4
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	1
Current Performance Percent Within 150 FDA Days	75.00%	75.00%	100.00%	66.67%	66.67%

**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	5
Average FDA Days to MDUFA IV Decision	133.25	144.75	147.40	165.83	159.20
20th Percentile FDA Days to MDUFA IV Decision	122	116	147	139	147
40th Percentile FDA Days to MDUFA IV Decision	148	143	150	141	150
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	162
Maximum FDA Days to MDUFA IV Decision	151	217	150	231	209
Average Industry Days to MDUFA IV Decision	161.00	178.50	132.60	147.83	210.20
20th Percentile Industry Days to MDUFA IV Decision	149	104	62	0	171
40th Percentile Industry Days to MDUFA IV Decision	179	175	107	74	177
60th Percentile Industry Days to MDUFA IV Decision	180	177	146	98	181
80th Percentile Industry Days to MDUFA IV Decision	180	252	179	357	218
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	369.40
20th Percentile Total Days to MDUFA IV Decision	260	221	209	213	310
40th Percentile Total Days to MDUFA IV Decision	278	333	256	231	322
60th Percentile Total Days to MDUFA IV Decision	316	380	296	302	354
80th Percentile Total Days to MDUFA IV Decision	330	439	329	491	415
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	5
Number With Granted Decisions	1	1	3	3	3
Number With Declined Decisions	1	3	2	1	2
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%	60.00%
Rate of Declined Decisions	25.00%	75.00%	40.00%	16.67%	40.00%
Rate of Withdrawals	25.00%	0.00%	0.00%	33.33%	0.00%
Rate of Deleted	25.00%	0.00%	0.00%	0.00%	0.00%

Table 8.5 OHT6 - Office of Orthopedic Devices

De Novo Performance Metrics-Submissions Missing Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Submissions that Missed the Goal	1	1	0	2	1
Mean FDA Days for Submissions that Missed the Goal	151.00	217.00	0.00	217.50	209.00
Mean Industry Days for Submissions that Missed the Goal	180.00	178.00	0.00	49.00	183.00

Table 8.6 OHT6 - Office of Orthopedic Devices

LDT De Novo MDUFA IV Decision Metrics

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	0	0
Current Performance Percent Within 150 FDA Days	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	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 8.1 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	18	11	15
MDUFA IV Decisions Within 150 FDA Days	16	16	9	1	3
De Novos Pending MDUFA IV Decision	0	0	0	2	1
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	2	1
Current Performance Percent Within 150 FDA Days	100.00%	84.21%	50.00%	7.69%	18.75%

**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	1.72	1.82	1.53
Number With MDUFA IV Decision	16	19	18	11	15
Average FDA Days to MDUFA IV Decision	126.25	120.16	262.61	306.27	203.00
20th Percentile FDA Days to MDUFA IV Decision	109	71	121	210	158
40th Percentile FDA Days to MDUFA IV Decision	132	118	149	241	199
60th Percentile FDA Days to MDUFA IV Decision	147	148	245	280	216
80th Percentile FDA Days to MDUFA IV Decision	150	150	441	425	234
Maximum FDA Days to MDUFA IV Decision	150	243	614	552	302
Average Industry Days to MDUFA IV Decision	108.25	110.00	208.89	242.18	164.20
20th Percentile Industry Days to MDUFA IV Decision	0	0	81	168	27
40th Percentile Industry Days to MDUFA IV Decision	121	0	193	221	126
60th Percentile Industry Days to MDUFA IV Decision	175	176	241	325	175
80th Percentile Industry Days to MDUFA IV Decision	180	222	347	350	276
Maximum Industry Days to MDUFA IV Decision	189	276	431	360	460
Average Total Days to MDUFA IV Decision	234.50	230.16	471.50	548.45	367.20
20th Percentile Total Days to MDUFA IV Decision	145	90	247	527	206
40th Percentile Total Days to MDUFA IV Decision	236	150	428	577	300
60th Percentile Total Days to MDUFA IV Decision	281	295	492	592	380
80th Percentile Total Days to MDUFA IV Decision	313	340	639	638	502
Maximum Total Days to MDUFA IV Decision	327	509	1,004	912	707

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	18	11	15
Number With Granted Decisions	9	11	9	8	7
Number With Declined Decisions	1	0	3	1	0
Number of Withdrawals	5	7	4	2	7
Number Deleted	1	1	2	0	1
Rate of Granted Decisions	56.25%	57.89%	50.00%	72.73%	46.67%
Rate of Declined Decisions	6.25%	0.00%	16.67%	9.09%	0.00%
Rate of Withdrawals	31.25%	36.84%	22.22%	18.18%	46.67%
Rate of Deleted	6.25%	5.26%	11.11%	0.00%	6.67%

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	9	10	12
Mean FDA Days for Submissions that Missed the Goal	0.00	209.33	408.22	324.90	222.67
Mean Industry Days for Submissions that Missed the Goal	0.00	217.67	248.78	266.40	155.08

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	16	11	13
MDUFA IV Decisions Within 150 FDA Days	15	14	9	1	2
De Novos Pending MDUFA IV Decision	0	0	0	2	1
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0	2	1
Current Performance Percent Within 150 FDA Days	100.00%	100.00%	56.25%	7.69%	14.29%

**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	6
MDUFA IV Decisions Within 150 FDA Days	1	1	1	2	5
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%	100.00%	100.00%	100.00%	83.33%

**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	1.83
Number With MDUFA IV Decision	1	1	1	2	6
Average FDA Days to MDUFA IV Decision	108.00	149.00	148.00	110.50	135.33
20th Percentile FDA Days to MDUFA IV Decision	108	149	148	87	140
40th Percentile FDA Days to MDUFA IV Decision	108	149	148	103	149
60th Percentile FDA Days to MDUFA IV Decision	108	149	148	118	149
80th Percentile FDA Days to MDUFA IV Decision	108	149	148	134	150
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	104.83
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	134
60th Percentile Industry Days to MDUFA IV Decision	0	15	360	286	154
80th Percentile Industry Days to MDUFA IV Decision	0	15	360	322	162
Maximum Industry Days to MDUFA IV Decision	0	15	360	358	179
Average Total Days to MDUFA IV Decision	108.00	164.00	508.00	378.00	240.17
20th Percentile Total Days to MDUFA IV Decision	108	164	508	347	149
40th Percentile Total Days to MDUFA IV Decision	108	164	508	368	294
60th Percentile Total Days to MDUFA IV Decision	108	164	508	388	312
80th Percentile Total Days to MDUFA IV Decision	108	164	508	409	328
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	6
Number With Granted Decisions	1	1	1	0	4
Number With Declined Decisions	0	0	0	1	1
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%	66.67%
Rate of Declined Decisions	0.00%	0.00%	0.00%	50.00%	16.67%
Rate of Withdrawals	0.00%	0.00%	0.00%	50.00%	16.67%
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

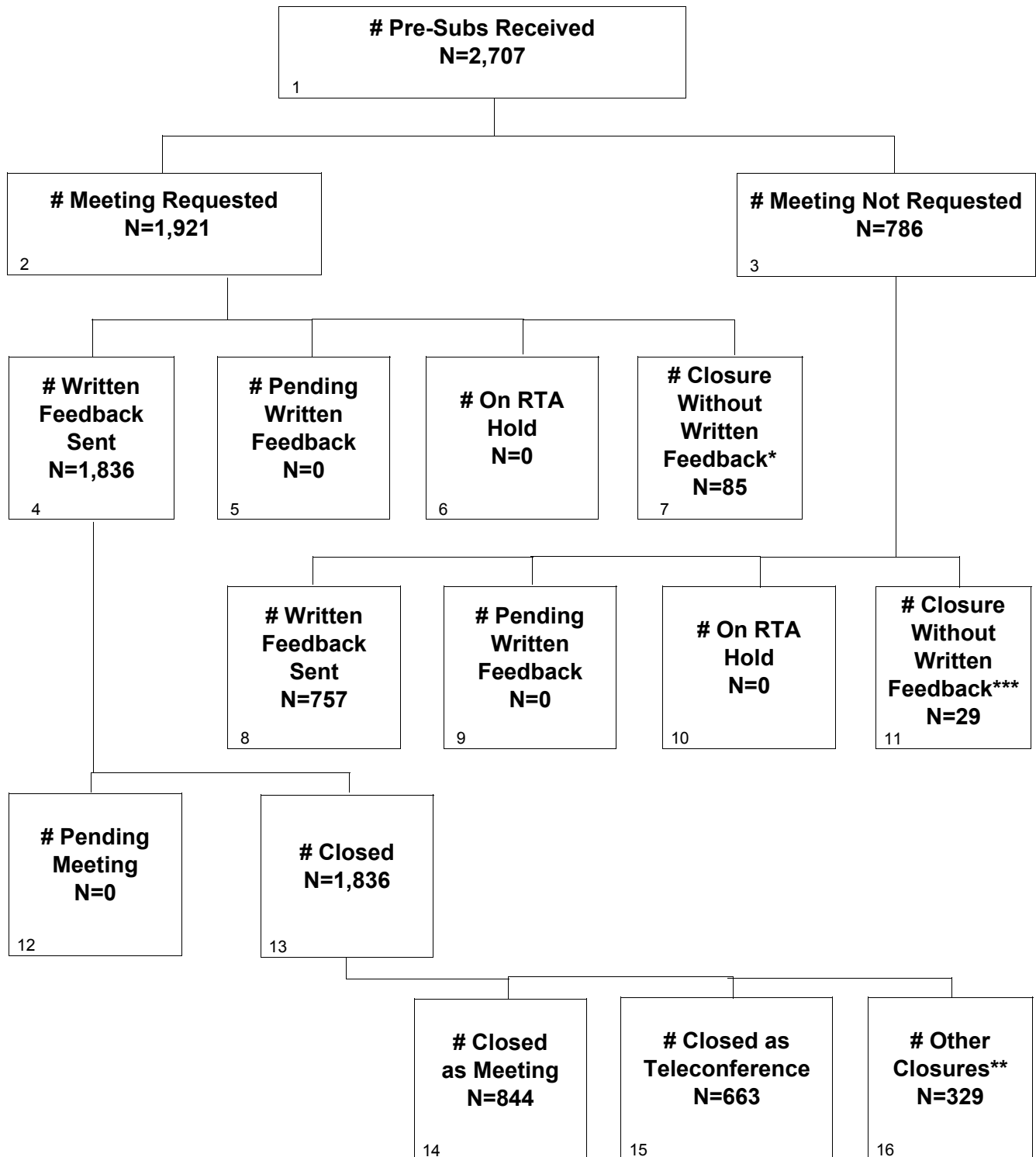
Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
De Novos Accepted	0	0	0	0	0
Non-MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions	0	0	0	0	0
MDUFA IV Decisions Within 150 FDA Days	0	0	0	0	0
De Novos Pending MDUFA IV Decision	0	0	0	0	0
De Novos Pending MDUFA IV Decision Over 150 FDA Days	0	0	0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

Table 8.7 OHT8 - Office of Radiological Health

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

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

CDRH Pre-Sub - FY 2018 as of 9/30/23

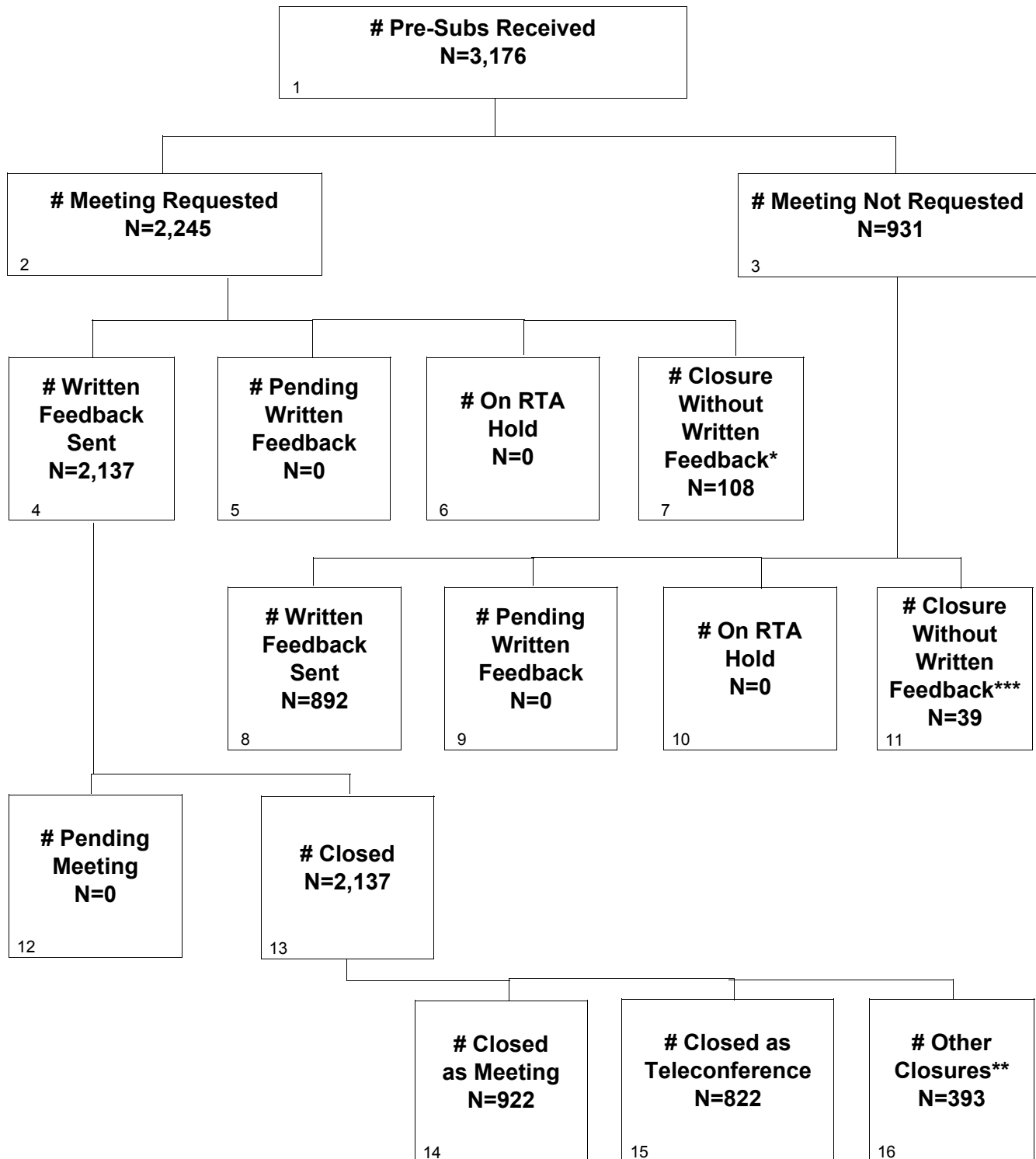


* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

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

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

CDRH Pre-Sub - FY 2019 as of 9/30/23

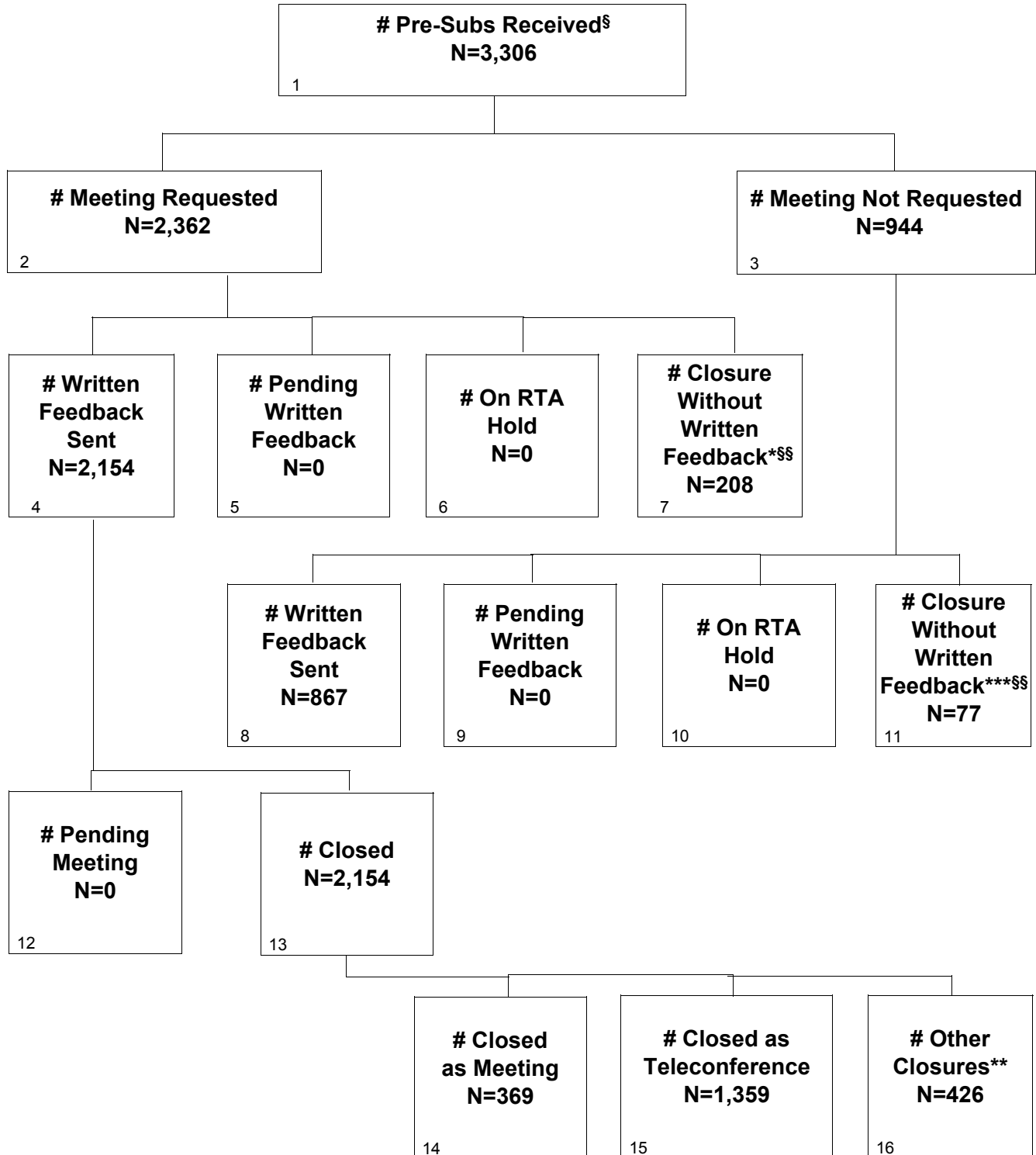


* Closures include TCON, MTNG, CNLR, CNLF, JTRX, JPND, DELE & WTDR

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

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

CDRH Pre-Sub - FY 2020 as of 9/30/23



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

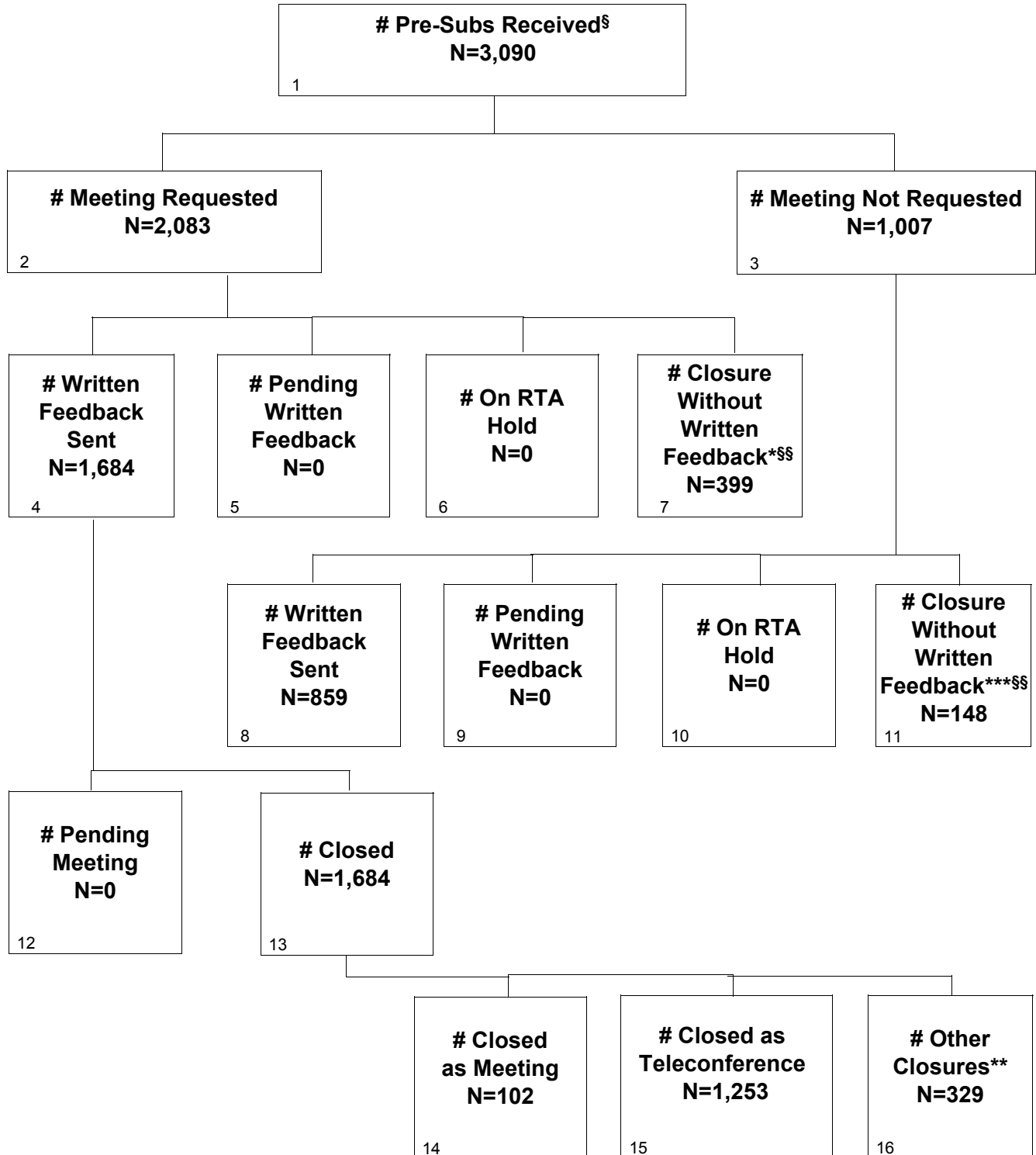
** Closures include CNLR, CNLF, CCOV, JTRX, JPND, DELE & WTDR

*** 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 9/30/23



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

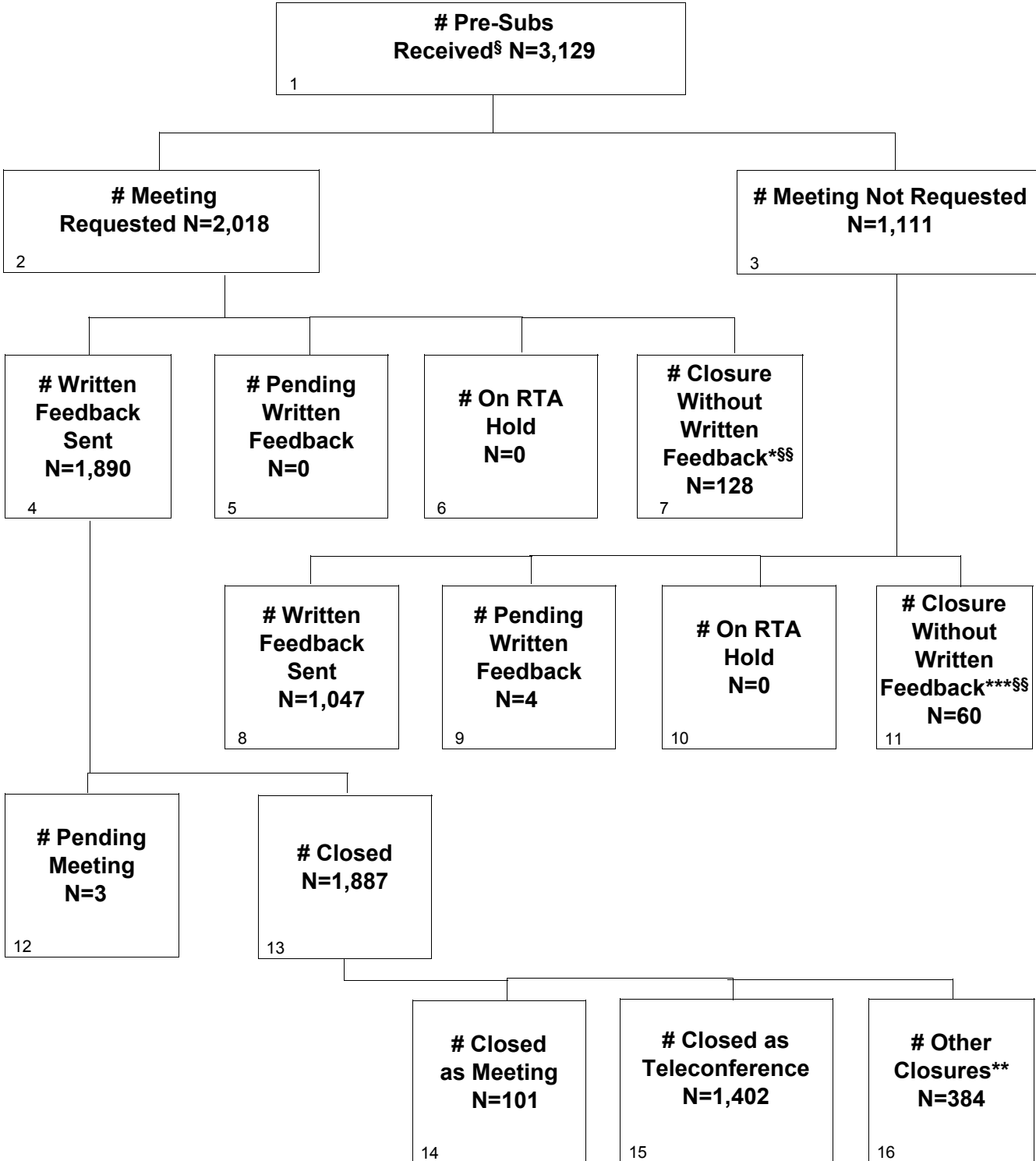
** Closures include CCOV, CNLR, CNLF, JTRX, JPND, DELE & WTDR

*** 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 9/30/23



* 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	2,543	2,938
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	2,543	2,938
Average FDA Days to Written Feedback	58.86	60.22	63.54	69.47	70.66
20th Percentile FDA Days to Written Feedback	49	49	52	52	56
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	856	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	1,355	1,503
Meeting Minutes Submitted Within 15 Days of Meeting	971	1,113	1,111	893	986
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	462
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%	65.90%	65.60%

*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	381	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	381	377
Average FDA Days to Written Feedback	64.18	64.07	73.30	77.47	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	82	82
Maximum FDA Days to Written Feedback	168	119	389	856	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	225	211
Meeting Minutes Submitted Within 15 Days of Meeting	126	151	152	146	126
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	74
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%	64.89%	59.72%

*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	579	672	773	670
Closed Before RTA Action**	6	7	4	7	1
Number Accepted First RTA Cycle**	506	552	646	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%	1.05%	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	560	658	746	655
Written Feedback Provided Within MDUFA IV Goal	482	532	608	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	560	658	746	655
Average FDA Days to Written Feedback	53.02	55.46	56.14	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	62	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	321	356	385	337
Meeting Minutes Submitted Within 15 Days of Meeting	183	197	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	104	122	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%	61.37%	59.55%	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	402	378	373
Closed Before RTA Action**	5	7	11	31	1
Number Accepted First RTA Cycle**	307	360	378	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%	2.30%	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	373	336	0
Written Feedback Provided Within MDUFA IV Goal	300	345	353	294	0

*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	373	336	0
Average FDA Days to Written Feedback	60.53	63.35	61.37	65.67	0.00
20th Percentile FDA Days to Written Feedback	53	53	51	58	0
40th Percentile FDA Days to Written Feedback	61	61	61	64	0
60th Percentile FDA Days to Written Feedback	65	66	66	67	0
80th Percentile FDA Days to Written Feedback	69	69	70	70	0
Maximum FDA Days to Written Feedback	156	950	168	204	0

*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	0
Average Days to Scheduling for Meetings Scheduled After Day 30	32.00	36.88	36.00	52.11	0.00

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

**Table 9.5 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	221	197	0
Meeting Minutes Submitted Within 15 Days of Meeting	112	125	157	141	0
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	0
Meeting Minutes Not Submitted and >15 Days Since Meeting	2	6	3	4	0
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	62.92%	61.27%	71.04%	71.57%	N/A

*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	276	335	313	305
Closed Before RTA Action**	4	5	21	117	1
Number Accepted First RTA Cycle**	234	251	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%	3.32%	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	254	298	179	286
Written Feedback Provided Within MDUFA IV Goal	215	222	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	254	298	179	286
Average FDA Days to Written Feedback	60.70	62.60	63.09	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	144	178	96	161
Meeting Minutes Submitted Within 15 Days of Meeting	92	97	116	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	42	50	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%	67.36%	65.17%	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	339
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	339
Average FDA Days to Written Feedback	64.73	72.86	83.45	86.88	80.80
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	83
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	765	434	533
Closed Before RTA Action**	7	7	61	221	51
Number Accepted First RTA Cycle**	749	885	644	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	437
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	437
Average FDA Days to Written Feedback	58.34	57.48	59.87	105.03	97.55
20th Percentile FDA Days to Written Feedback	49	46	51	52	64
40th Percentile FDA Days to Written Feedback	59	58	60	69	70
60th Percentile FDA Days to Written Feedback	64	64	65	93	84
80th Percentile FDA Days to Written Feedback	69	69	69	133	115
Maximum FDA Days to Written Feedback	85	307	142	588	435

*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

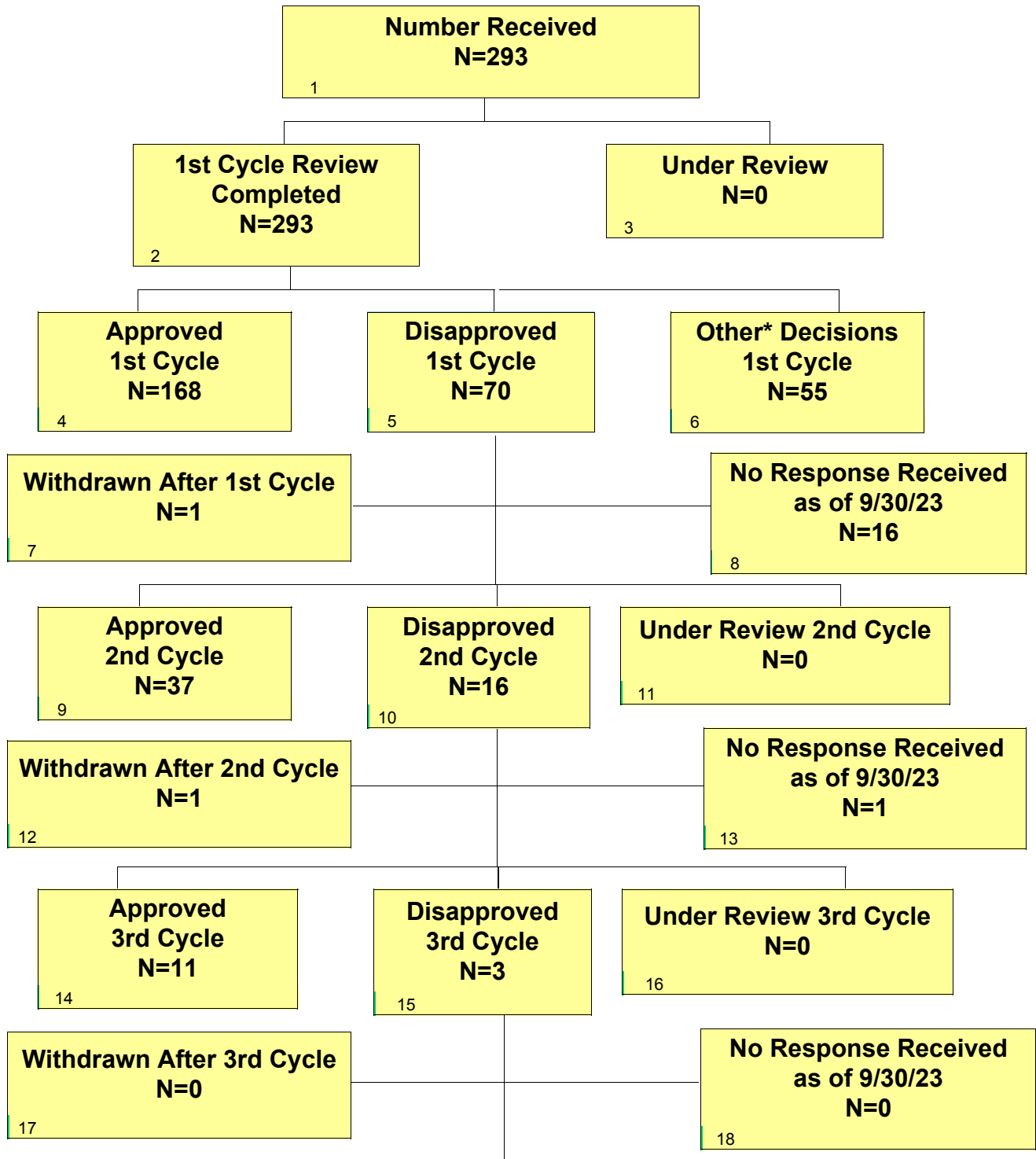
*Excludes data from Q-Submissions re-submitted after being closed without feedback due to reallocation of resources to COVID-19 activities.

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.

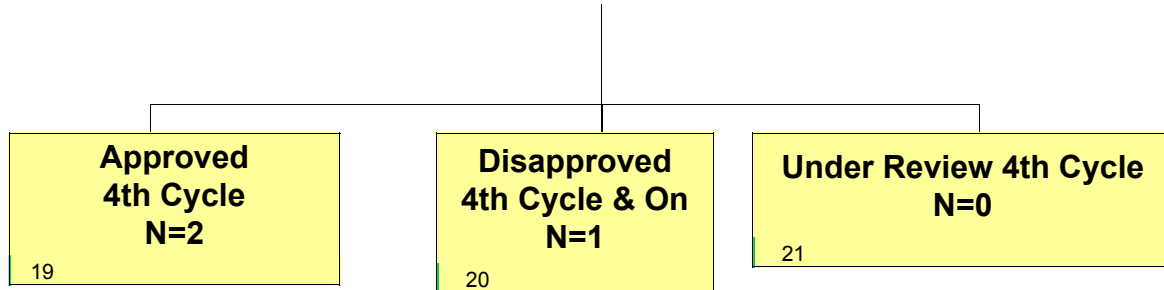
CDRH IDEs - FY 2018 as of 9/30/23



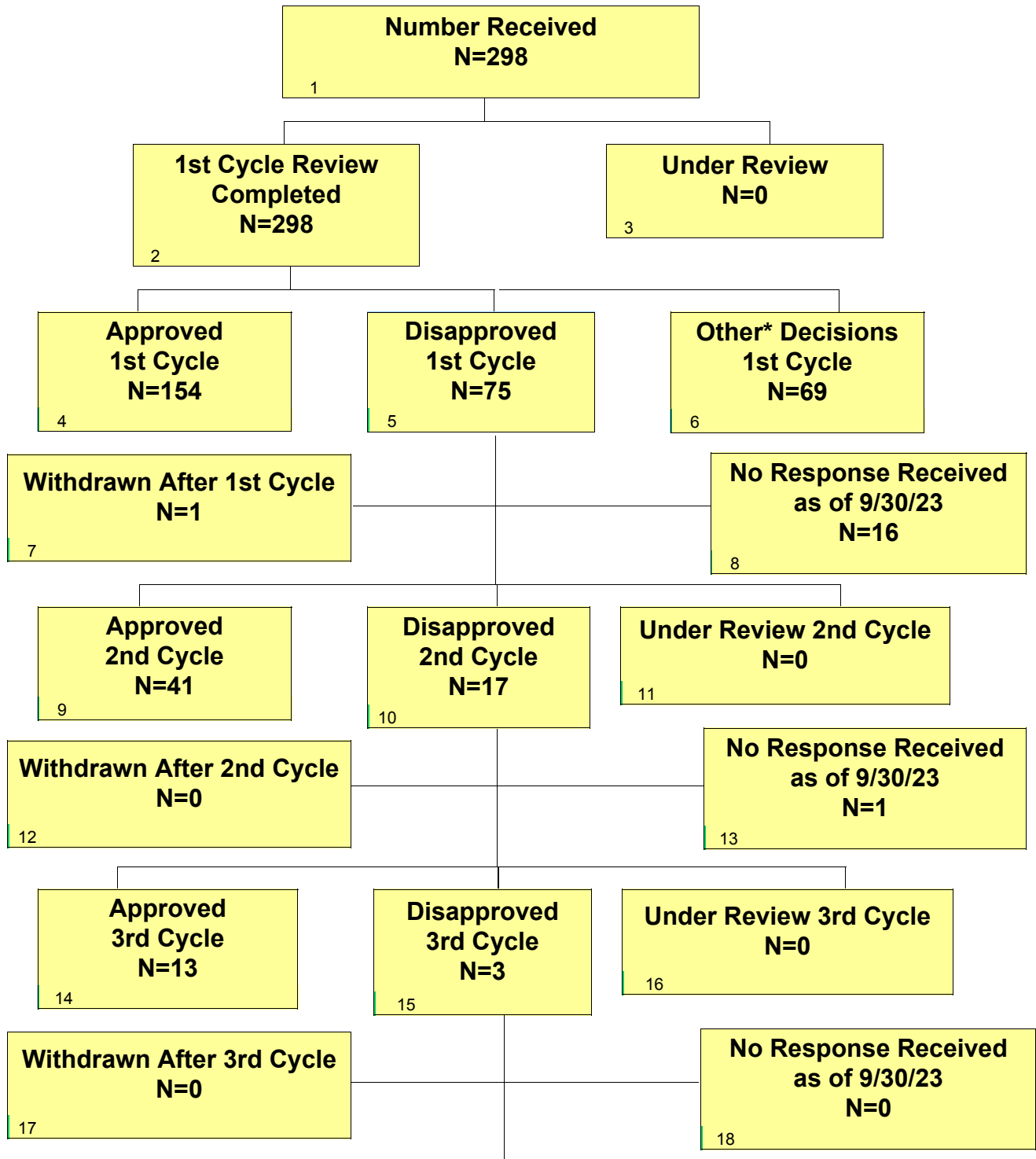
* Other decisions include withdrawn (N=10), withdrawn and converted (N=31), RTA (N=0), nonsignificant risk device (N=11), exempt (N=1), product jurisdiction pending (N=0), or product jurisdiction transferred (N=2), Basic Physiological Research (N=0).

CDRH IDEs - FY 2018

as of 9/30/23

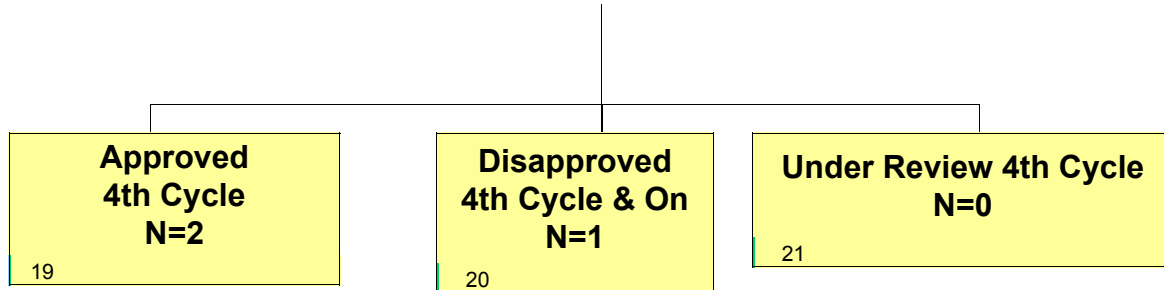


CDRH IDEs - FY 2019 as of 9/30/23

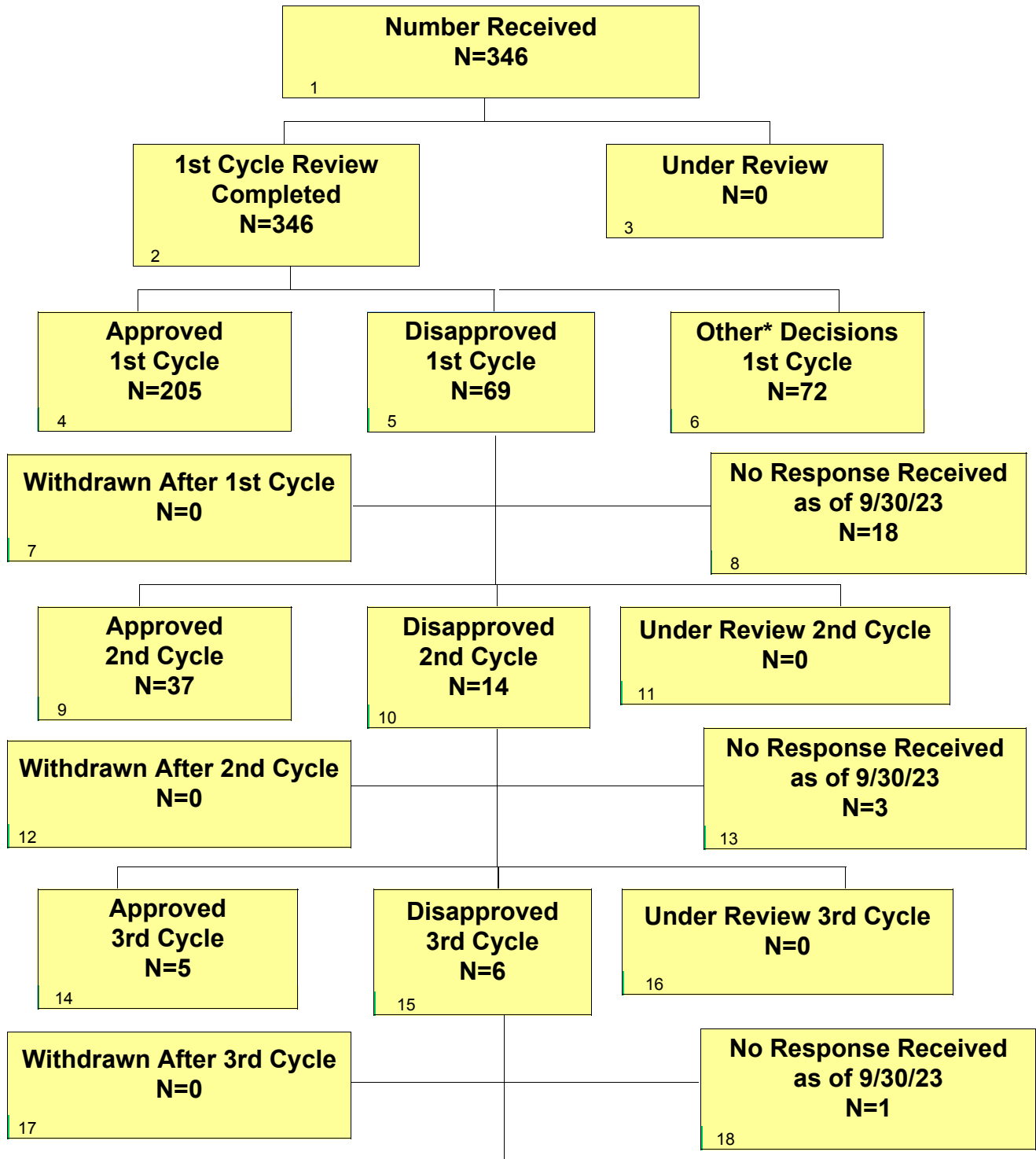


* Other decisions include withdrawn (N=8), withdrawn and converted (N=40), RTA (N=0), nonsignificant risk device (N=13), exempt (N=1), product jurisdiction pending (N=2), or product jurisdiction transferred (N=5), Basic Physiological Research (N=0).

CDRH IDEs - FY 2019 as of 9/30/23

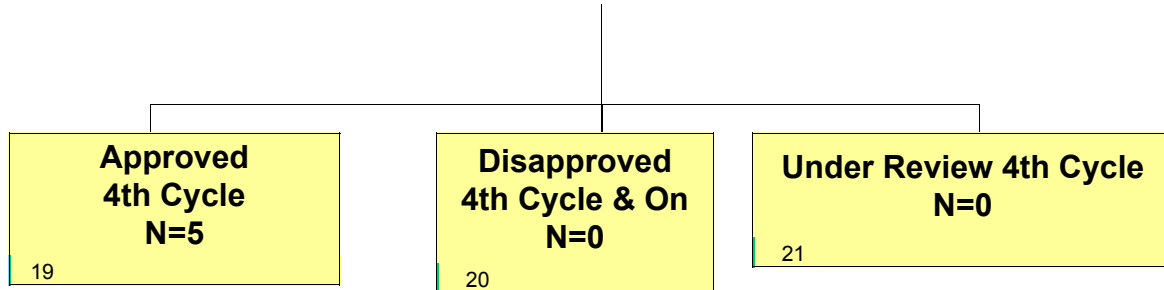


CDRH IDEs - FY 2020 as of 9/30/23

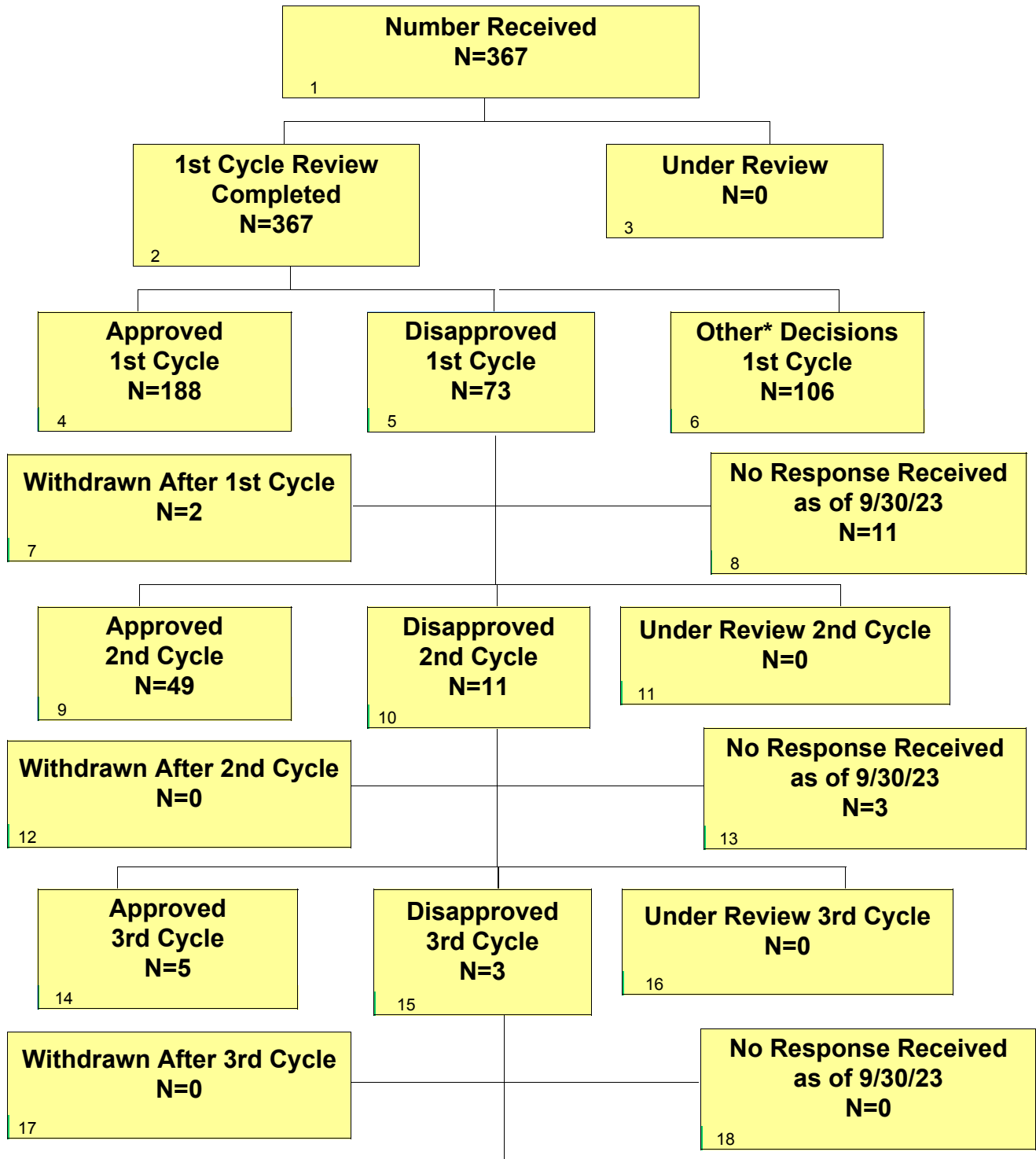


* Other decisions include withdrawn (N=12), withdrawn and converted (N=37), RTA (N=0), nonsignificant risk device (N=15), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=4), Basic Physiological Research (N=0).

CDRH IDEs - FY 2020 as of 9/30/23

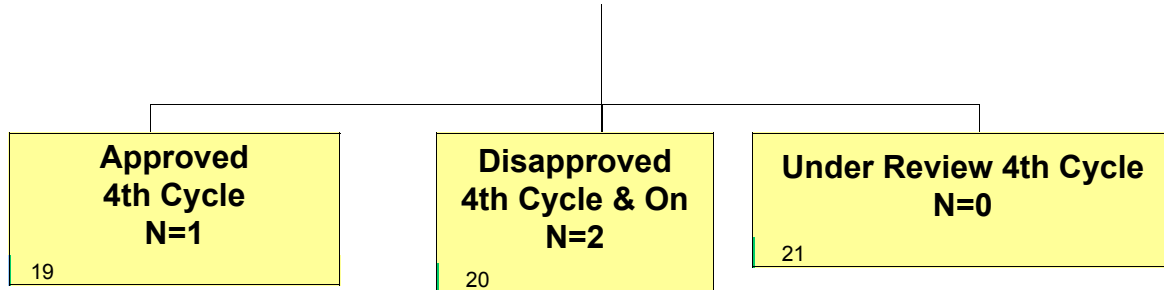


CDRH IDEs - FY 2021 as of 9/30/23

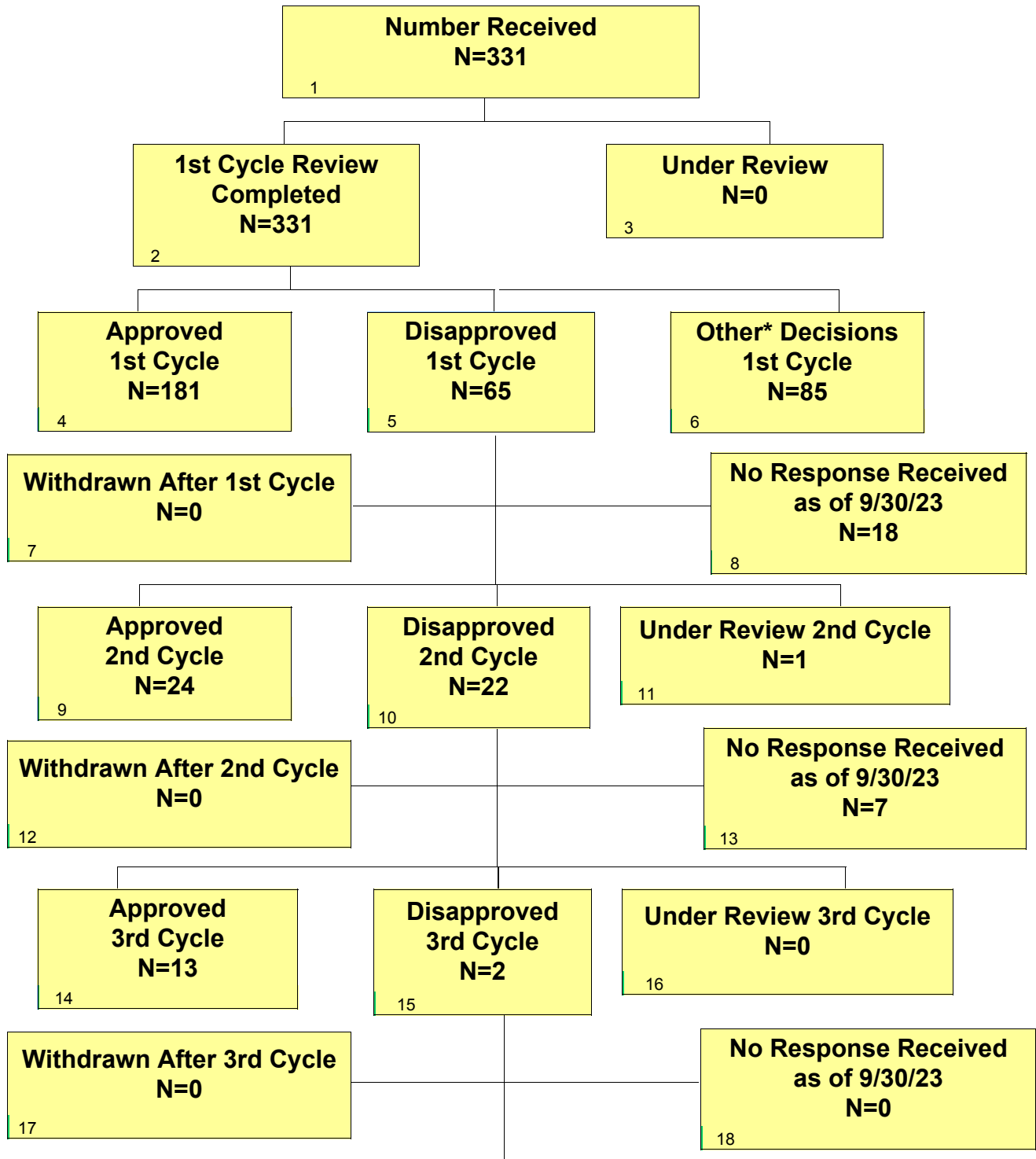


* Other decisions include withdrawn (N=26), withdrawn and converted (N=56), RTA (N=0), nonsignificant risk device (N=17), exempt (N=3), product jurisdiction pending (N=1), or product jurisdiction transferred (N=3), Basic Physiological Research (N=0).

CDRH IDEs - FY 2021 as of 9/30/23

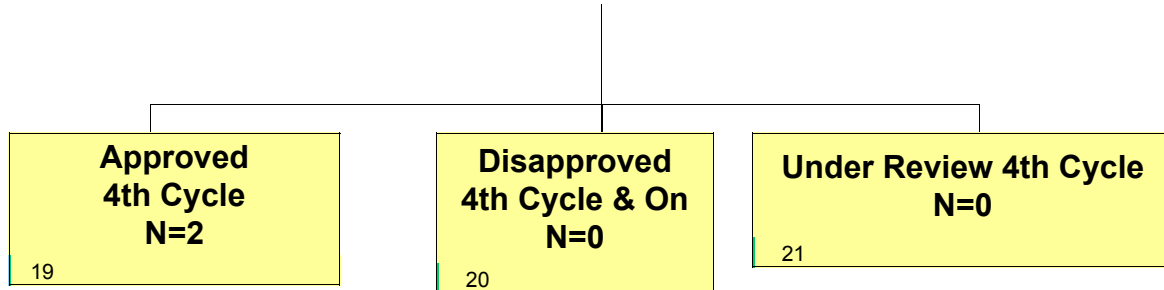


CDRH IDEs - FY 2022 as of 9/30/23



* 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 9/30/23



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	1.37	1.25	1.31	1.25
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.32	0.37	0.25	0.31	0.25

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	1.41
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.41	0.36	0.32	0.45	0.41

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	1.55	1.45	1.66	1.70
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.58	0.55	0.45	0.66	0.70

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	1.47	1.45	1.04
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.60	0.50	0.47	0.45	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	37
Average Number of Cycles to IDE Approval or Conditional Approval	1.29	1.21	1.11	1.15	1.09
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.29	0.21	0.11	0.15	0.09

**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	1.16
Average Number of Amendments Prior to IDE Approval or Conditional Approval	0.16	0.47	0.17	0.14	0.16

**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	12
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

Table 11.1 CDRH – CLIA Waiver Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	4	8 (12)	1	3 (4)	1 (5)
Withdrawn prior to SI	0	1 (1)	0	0 (0)	0 (0)
SI within 90 FDA days	4	7 (11)	0	0 (0)	0 (0)
SI over 90 FDA days	0	0 (0)	0	3 (3)	0 (3)
SI pending within 90 FDA days	0	0 (0)	0	0 (0)	0 (0)
SI pending over 90 FDA days	0	0 (0)	0	0 (0)	0 (0)
Denial without SI	0	0 (0)	1	0 (1)	1 (2)
Current SI Performance Percent within 90 FDA days	N/A*	100.00%	N/A*	N/A*	N/A*

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	4	7	0	3	0
Average number of FDA days to Substantive Interaction	59.50	59.86	0.00	177.67	0.00
20th Percentile FDA days to Substantive Interaction	39	49	0	145	0
40th Percentile FDA days to Substantive Interaction	48	55	0	180	0
60th Percentile FDA days to Substantive Interaction	67	65	0	203	0
80th Percentile FDA days to Substantive Interaction	79	84	0	214	0
Maximum FDA days to Substantive Interaction	88	90	0	225	0

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days	90% Within 150 FDA Days
Eligible for MDUFA IV Decisions	4	8 (12)	1	3 (4)	1 (5)
Non-MDUFA IV Decisions	0	1 (1)	0	0 (0)	0 (0)
MDUFA IV Decisions	4	8 (12)	1	3 (4)	1 (5)
MDUFA IV Decisions within 150 FDA Days	4	7 (11)	0	1 (1)	1 (2)
CLIA Waiver Applications pending MDUFA IV Decision	0	0 (0)	0	0 (0)	0 (0)
CLIA Waiver Applications pending MDUFA IV Decision over 150 FDA days	0	0 (0)	0	0 (0)	0 (0)
Current Performance Percent within 150 FDA Days	N/A*	91.67%	N/A*	N/A*	N/A*

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 11.4 CDRH – CLIA Waiver with Panel Review MDUFA Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decisions	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 320 FDA Days	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0	0	0
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*	N/A*	N/A*

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA decision	4	8	1	3	1
Average FDA days to MDUFA IV decision	119.50	82.25	462.00	331.33	120.00
20th Percentile FDA days to MDUFA IV decision	102	47	462	226	120
40th Percentile FDA days to MDUFA IV decision	143	50	462	341	120
60th Percentile FDA days to MDUFA IV decision	145	64	462	416	120
80th Percentile FDA days to MDUFA IV decision	147	80	462	450	120
Maximum FDA days to MDUFA IV decision	148	281	462	484	120
Average Industry days to MDUFA IV decision	150.50	145.38	0.00	178.00	0.00
20th Percentile Industry days to MDUFA IV decision	86	0	0	71	0
40th Percentile Industry days to MDUFA IV decision	151	138	0	142	0
60th Percentile Industry days to MDUFA IV decision	173	180	0	213	0
80th Percentile Industry days to MDUFA IV decision	219	180	0	285	0
Maximum Industry days to MDUFA IV decision	278	450	0	357	0
Average Total days to MDUFA IV decision	270.00	227.63	462.00	509.33	120.00
20th Percentile Total days to MDUFA IV decision	192	55	462	331	120
40th Percentile Total days to MDUFA IV decision	236	167	462	551	120
60th Percentile Total days to MDUFA IV decision	276	228	462	680	120
80th Percentile Total days to MDUFA IV decision	342	260	462	718	120
Maximum Total days to MDUFA IV decision	420	731	462	756	120

Table 11.6 CDRH – CLIA Waiver (with Panel Review) Time to MDUFA Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA 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

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

Table 12.1 CDRH – DUAL (510(k) and CLIA Waiver) Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days	90% SI within 90 FDA days
Eligible for SI	11	5	6 (11)	4	10 (14)
Withdrawn prior to SI	0	0	0	0	0 (0)
SI within 90 FDA days	11	5	6 (11)	0	0 (0)
SI over 90 FDA days	0	0	0	4	9 (13)
SI pending within 90 FDA days	0	0	0	0	0 (0)
SI pending over 90 FDA days	0	0	0	0	1 (1)
Denial without SI	0	0	0	0	0 (0)
Current SI Performance Percent within 90 FDA days*	100.00%	N/A*	100.00%	N/A*	0.00%

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.2 CDRH –DUAL (510(k) and CLIA Waiver)Substantive Interaction Metrics – Time to Substantive Interaction

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Substantive Interactions	11	5	6	4	9
Average number of FDA days to Substantive Interaction	85.18	86.60	85.00	269.75	289.44
20th Percentile FDA days to Substantive Interaction	84	87	82	213	179
40th Percentile FDA days to Substantive Interaction	87	88	86	299	211
60th Percentile FDA days to Substantive Interaction	87	88	88	313	237
80th Percentile FDA days to Substantive Interaction	88	88	90	341	471
Maximum FDA days to Substantive Interaction	90	88	90	375	511

Table 12.3 CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) MDUFA Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days	90% Within 180 FDA Days
Eligible for MDUFA IV Decision	11	5	6 (11)	4	10 (14)
Non-MDUFA IV Decisions	0	1	0 (1)	0	0 (0)
MDUFA IV Decisions	11	5	6 (11)	4	5 (9)
MDUFA IV Decisions within 180 FDA Days	11	4	4 (8)	1	0 (1)
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0 (0)	0	5 (5)
CLIA Waiver Applications pending MDUFA IV Decision over 180 FDA days	0	0	0 (0)	0	5 (5)
Current Performance Percent within 180 FDA Days*	100.00%	N/A*	72.73%	N/A*	7.14%

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.4 CDRH – DUAL (510(k) and CLIA Waiver) (with panel review) MDUFA Decision Performance Goals

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days	90% Within 320 FDA Days
Eligible for MDUFA IV Decision	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 with in 320 FDA Days	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision	0	0	0	0	0
CLIA Waiver Applications pending MDUFA IV Decision over 320 FDA days	0	0	0	0	0
Current Performance Percent within 320 FDA Days	N/A*	N/A*	N/A*	N/A*	N/A*

* MDUFA Cohort for this fiscal year is insufficient to form a cohort (> 10) to calculate performance. Per agreement in the MDUFA IV commitment letter, performance for this goal will be calculated once a combined MDUFA Cohort of at least 10 submissions is achieved.

Table 12.5 CDRH – DUAL (510(k) and CLIA Waiver) (without Panel Review) Time to MDUFA Decision

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number with MDUFA IV decision	11	5	6	4	5
Average FDA days to MDUFA IV decision	139.64	142.60	200.17	352.50	251.80
20th Percentile FDA days to MDUFA IV decision	87	88	82	293	216
40th Percentile FDA days to MDUFA IV decision	140	137	148	428	230
60th Percentile FDA days to MDUFA IV decision	176	173	180	432	254
80th Percentile FDA days to MDUFA IV decision	180	180	285	443	284
Maximum FDA days to MDUFA IV decision	180	190	432	458	317
Average Industry days to MDUFA IV decision	42.18	142.20	252.33	218.75	178.00
20th Percentile Industry days to MDUFA IV decision	0	69	144	175	100
40th Percentile Industry days to MDUFA IV decision	0	139	266	178	142
60th Percentile Industry days to MDUFA IV decision	0	177	355	180	170
80th Percentile Industry days to MDUFA IV decision	110	198	373	246	211
Maximum Industry days to MDUFA IV decision	180	270	376	346	360
Average Total days to MDUFA IV decision	181.82	284.80	452.50	571.25	429.80
20th Percentile Total days to MDUFA IV decision	87	243	226	470	371
40th Percentile Total days to MDUFA IV decision	155	263	450	611	395
60th Percentile Total days to MDUFA IV decision	177	302	521	631	406
80th Percentile Total days to MDUFA IV decision	270	353	551	692	458
Maximum Total days to MDUFA IV decision	354	358	787	773	636

Table 12.6 CDRH – DUAL (510(k) and CLIA Waiver) (with Panel Review) Time to MDUFA 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

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 MDUFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 De Novo MDUFA IV Performance

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8 Annual Metrics for De Novo Requests

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

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

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

Section 9 Pre-Submissions

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

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

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

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

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

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

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

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

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

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

Section 10 IDE Performance Metrics

Table 10.1 IDE Performance Metrics

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

Section 11 CLIA Waiver Annual Metrics

Table 11.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Quarterly Update on
Medical Device Performance Goals
---- MDUFA IV CBER Performance Data ----
Actions through 30 Sep 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 5 PMA Annual Metrics and Goals

Table 5.1 CBER – PMAs (All Review Tracks) Annual General Metrics – PMAs Received by Type

PMA Submissions Received	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Report Submissions	0	0	0	0	0
Original PMAs (Panel) – Priority	0	0	0	0	0
Original PMAs (No Panel) – Priority	0	0	0	0	0
Original PMAs (Panel) – Non-Priority	0	0	0	0	0
Original PMAs (No Panel) – Non-Priority	3	3	2	0	1
Panel-Tracked Supplements (Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (No Panel) – Priority	0	0	0	0	0
Panel-Tracked Supplements (Panel) – Non-Priority	0	0	0	0	0
Panel-Tracked Supplements (No Panel) – Non-Priority	0	0	1	1	1
PMA Modules	7	1	0	0	0
180-Day Supplements	8	5	8	7	7
Real-Time Supplements	3	2	5	9	9

Table 5.2 CBER – PMA Originals and Panel Tracked Supplements Annual Shared Outcome Goal – Percent Cohorts Closed

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Filed	2	3	3	1	1
Number with a decision (MDUFA or Non-MDUFA)	2	3	3	1	1
% of FY closed	100.00%	100.00%	100.00%	100.00%	100.00%

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	6
MDUFA IV Decision Goal Met	8	5	8	3	5
Supplements Pending MDUFA IV Decision	0	0	0	0	1
Supplements Pending MDUFA IV Decision Past Goal	0	0	0	0	0
Current Performance Percent Goal Met	100.00%	100.00%	100.00%	100.00%	83.33%

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	6
Number of Not Approvable	0	0	1	0	1
Rate of Not Approvable	0.00%	0.00%	12.50%	0.00%	16.67%

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	FY 2019	FY 2020	FY 2021	FY 2022
	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days	95% SI Within 60 FDA Days
Eligible for SI	49	51	44	40	37
Deleted or Withdrawn Prior to SI	0	0	0	0	0
SI Within 60 FDA Days	49	51	43	40	37
SI Over 60 FDA Days	0	0	1	0	0
SI Pending Within 60 FDA Days	0	0	0	0	0
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	37
Average Number of FDA Days to Substantive Interaction	50.60	45.27	48.98	53.63	51.51
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	4
MDUFA IV Decision (SE/NSE)	43	46	37	33	32
MDUFA IV Decision Within 90 FDA Days	43	46	37	33	32
510(k)s Pending MDUFA IV Decision	0	0	0	6	1
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	1.47
Number With MDUFA IV Decision	43	46	37	33	32
Average Number of FDA Days to MDUFA IV Decision	75.58	67.48	64.08	74.79	72.34
20th Percentile FDA Days to MDUFA IV Decision	65	28	30	66	38
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	88
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	58.38
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	46
80th Percentile Industry Days to MDUFA IV Decision	59	179	29	128	118
Maximum Industry Days to MDUFA IV Decision	178	389	199	366	357
Average Number of Total Days to MDUFA IV Decision	100.84	143.24	81.05	127.70	130.72
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	86
60th Percentile Total Days to MDUFA IV Decision	90	141	82	90	103
80th Percentile Total Days to MDUFA IV Decision	147	269	105	215	200
Maximum Total Days to MDUFA IV Decision	268	463	287	450	446

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	32
Number of SE Decision	43	43	35	33	27
Number of NSE Decision	0	3	2	0	5
Number of Withdrawal	2	4	4	1	2
Number of Deleted	3	1	3	0	2
Rate of SE Decision	100.00%	93.48%	94.59%	100.00%	84.38%
Rate of NSE Decision	0.00%	6.52%	5.41%	0.00%	15.63%
Rate of Withdrawal	4.08%	7.84%	9.09%	2.50%	5.41%
Rate of Deleted	6.12%	1.96%	6.82%	0.00%	5.41%

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 7 510(k) Annual General Metrics

Table 7.1 CBER - 510(k) Annual General Metrics - 510(k)s Received by Type

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number Accepted	49	51	44	40	37
Number of Traditional Submissions	41	35	34	35	30
Number of Special Submissions	8	16	10	5	7
Number of Abbreviated Submissions	0	0	0	0	0
Average Number of Days to Accept/Refuse to Accept	12.69	12.57	12.57	12.08	12.19
Number of Third Party Submissions	0	0	0	0	0

Table 7.2 CBER - 510(k) Annual Shared Outcome Goal

Performance Metrics	FY 2018 124 Days	FY 2019 120 Days	FY 2020 116 Days	FY 2021 112 Days	FY 2022 108 Days
Number Accepted	49	51	44	40	37
Currently Under Review	0	0	0	6	1
Number With Non-MDUFA IV Decision	6	5	7	1	4
Number With MDUFA IV Decision	43	46	37	33	32
Percent of Cohort Closed	100.00%	100.00%	100.00%	84.62%	96.97%
Number With MDUFA IV Decision After Trimming the Upper and Lower 2%	41	44	35	31	30
Average Total Time to MDUFA IV Decision	100.84	143.24	81.05	127.70	130.72

Table 7.3 CBER - 510(k) Third Party Performance

Performance Metrics	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Third Party Submissions	0	0	0	0	0
90th Percentile FDA Days to MDUFA IV Decision	0.00	0.00	0.00	0.00	0.00

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 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 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	2	0	0	1
Number With MDUFA IV Decision	0	1	0	0	1
Average FDA Days to MDUFA IV Decision	0.00	150.00	0.00	0.00	150.00
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	81.00	0.00	0.00	0.00
20th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
40th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
60th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
80th Percentile Industry Days to MDUFA IV Decision	0	81	0	0	0
Maximum Industry Days to MDUFA IV Decision	0	81	0	0	0
Average Total Days to MDUFA IV Decision	0.00	231.00	0.00	0.00	150.00
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	46
Number Without a RTA Review and > 15 Days Since Date Received**	1	3	1	3	3
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%

*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 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	44

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

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
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

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

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
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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	18
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	0
Percent of Submissions With Meetings for Which Industry Provided Minutes Within 15 Days	78.57%	90.91%	96.30%	80.49%	81.82%

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

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard BLAs Filed	14	4	0	2	1
Number of Standard BLA First Actions less than or equal to 10 months	14	4	0	2	1
Number of Standard BLA First Actions greater than 10 months	0	0	0	0	0
Number of Standard BLAs Pending	0	0	0	0	0
Number of Priority BLA Filed	0	0	0	0	0
Number of Priority BLA First Actions less than or equal to 6 months	0	0	0	0	0
Number of Priority BLA First Actions greater than 6 months	0	0	0	0	0
Number of Priority BLAs Pending	0	0	0	0	0

BLA Efficacy Supplements
CBER – Annual General Metric Report for BLA Efficacy Supplements

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard Efficacy Supplements Filed	8	2	0	0	0
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	8	2	0	0	0
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0	0	0	0
Number of Standard Efficacy Supplements Pending	0	0	0	0	0
Number of Priority Efficacy Supplements Filed	0	0	0	0	0
Number of Priority Efficacy Supplements First Actions less than or equal to 6 months	0	0	0	0	0
Number of Priority Efficacy Supplements First Actions greater than 6 months	0	0	0	0	0
Number of Priority Efficacy Supplements Pending	0	0	0	0	0

BLA Prior Approval Manufacturing Supplements
CBER – Annual General Metric Report for BLA PAS Supplements

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Standard PAS Supplements Filed	94	54	92	52	48
Number of Standard PAS Supplements First Actions less than or equal to 4months	94	53	92	52	48
Number of Standard PAS Supplements First Actions greater than 4 months	0	1	0	0	0
Number of Standard PAS Supplements Pending	0	0	0	0	0

BLA/BLA Resubmissions
CBER – Annual General Metric Report for BLA/BLA Resubmissions

Performance Metric	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Number of Class 1 Resubmissions Received	1	17	0	0	0
Number of Class 1 Resubmission Actions less than or equal to 2 months	1	17	0	0	0
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0	0	0	0
Number of Class 1 Resbumssions Pending	0	0	0	0	0
Number of Class 2 Resubmissions Received	7	0	1	0	2
Number of Class 2 Resubmission Actions less than or equal to 6 months	7	0	1	0	2
Number of Class 2 Resubmission Actions greater than 6 months	0	0	0	0	0
Number of Class 2 Resubmissions Pending	0	0	0	0	0

Shared Outcome Goals (FY 2018 Through FY 2022)

FDA has two shared outcome goals each fiscal year, one for Original PMAs and Panel-Track Supplements and one for 510(k)s. FDA committed to report the average TTD within a closed cohort based on the methodology prescribed in the MDUFA IV commitment letter. A PMA cohort is considered closed when 95 percent of applications have reached a decision. A 510(k) cohort is considered closed when 99 percent of accepted submissions have reached a decision. Both the 510(k) and PMA cohorts include submissions reviewed in CDRH and CBER.

FDA's performance in the MDUFA IV shared outcome goals (as well as whether the goal was met or missed) as of September 30th of the applicable fiscal year, is shown in **bold** text in the table below. The FY 2020 PMA cohort met the decision threshold to calculate the average TTD and FDA met the goal. The FY 2021 PMA and FY 2021 510(k) cohorts met the decision threshold to calculate the average TTD and FDA missed these goals. The FY 2022 PMA and FY 2022 510(k) cohorts have not met the decision threshold to calculate the average TTD. FDA will report the average TTD for these goals in future reports once these cohorts have met the decision threshold.

MDUFA IV's Shared Outcome Goals

Submission Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Original PMAs and Panel-Track PMA Supplements					
TTD Goal (Days)	320	315	310	300	290
TTD Performance (Days)	272 (MET)	267 (MET)	277 (MET)	305 (MISSED)	*
510(k) Premarket Notifications					
TTD Goal (Days)	124	120	116	112	108
TTD Performance (Days)	123 (MET)	128 (MISSED)	139 (MISSED)	141 (MISSED)	*

* As of September 30, 2023, the fiscal year cohort had not met the decision threshold to calculate performance results.