

**Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance**  
**January 29, 2014**  
**1:00 P.M.**

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**Welcome.** *Barbara Zimmerman, CDRH-ODE.*

**Reimbursement Task Force-** Murray Sheldon, CDRH-OCD

**Guidance Development**

- FDA issued 7 medical device guidance documents during the 1st quarter of FY 2014.  
*Barbara Zimmerman, CDRH-ODE; Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIR, Philip Desjardins, CDRH-OCD.*

**FDA MDUFA Performance — Actions through December 31, 2013**

- Report on decisions goals for 1st quarter of FY 2014.
  - CDRH: *Barbara Zimmerman, CDRH.*
  - CBER: *Sheryl Kochman, CBER.*

**Qualitative Update on Finances – 1st Quarter of FY 2014**

- User fee receipts through the 1st quarter of FY 2014. *Lisa Berry, FDA-OFM.*

**CDRH Registration and Listing**

- Report on registration and listing- Dave Gartner, CDRH- OC.

**Independent Assessment**

- Progress and update- Amber Sligar, FDA-OC.

**Discussion**

- E-submission- Paul Fisher, CDRH-OCD

**Set date for next meeting, following close of Q2.** Target Date: Wednesday 4/30/14 at 10:00 am.

□□□

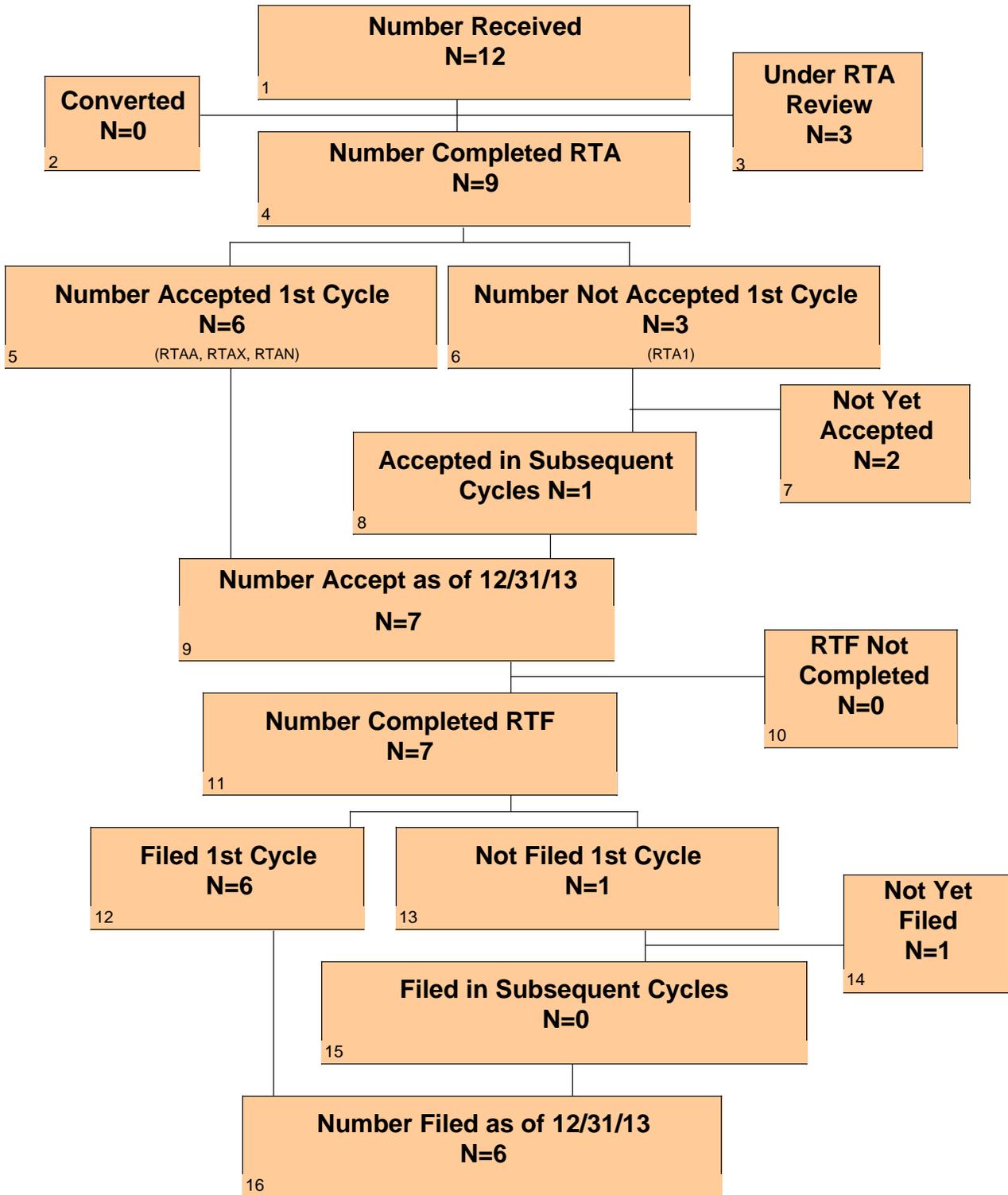
# Medical Device Guidance Documents

## Issued in FY 2014

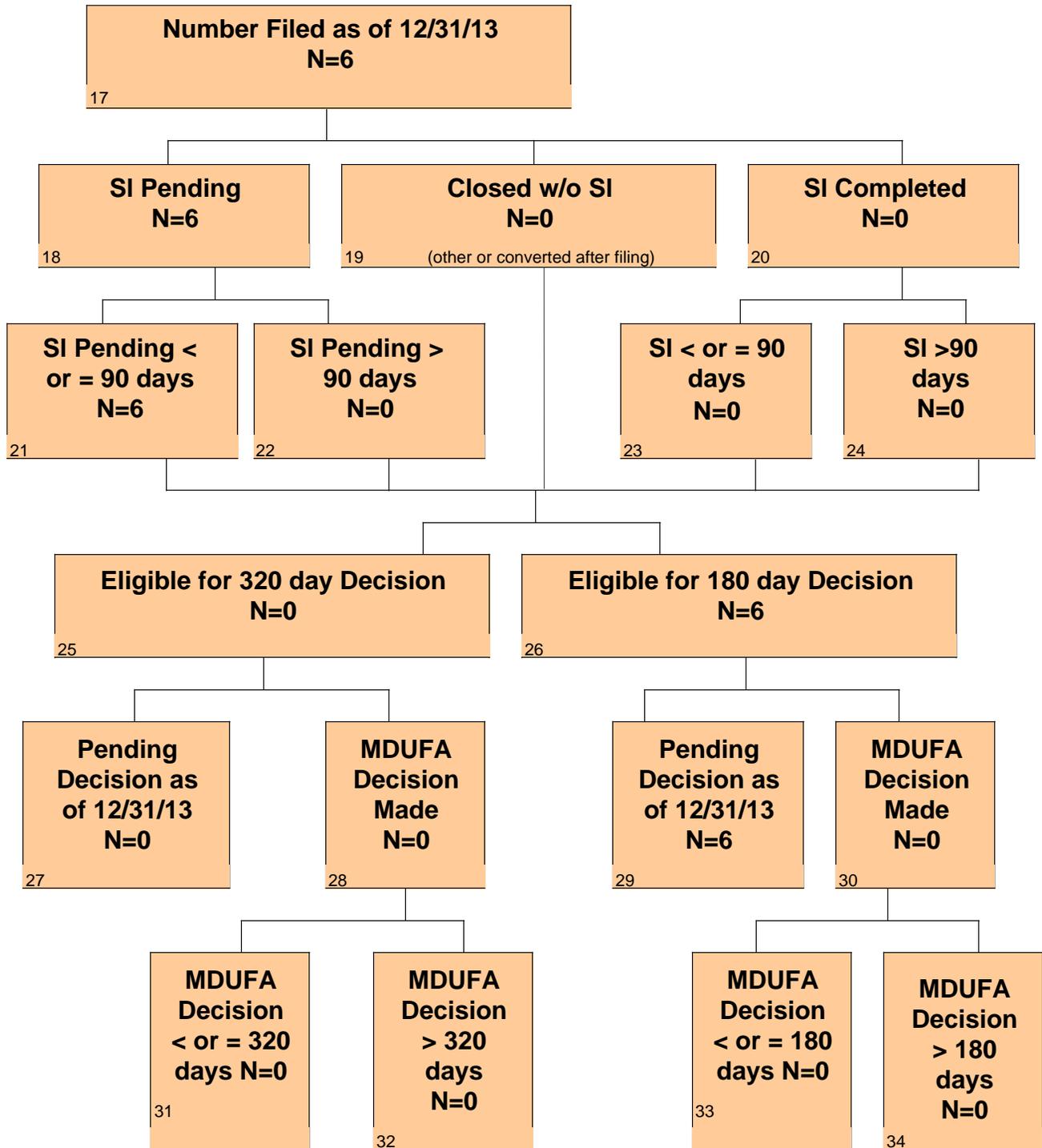
(October 1, 2012 thru December 31, 2013)

1. [Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate](#) (12/30/13)
2. [Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only - Guidance for Industry and Food and Drug Administration Staff](#) (11/25/13)
3. [Medical Device Development Tools - Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff](#) (11/14/13)
4. [Design Considerations for Pivotal Clinical Investigations for Medical Devices - Guidance for Industry, Clinical Investigators, Institutional Review Boards and Food and Drug Administration Staff](#) (11/07/13)
5. [Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff](#) (11/07/13)
6. [Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions](#) (10/10/13)
7. [Investigational Device Exemptions \(IDEs\) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human \(FIH\) Studies - Guidance for Industry and Food and Drug Administration Staff](#) (10/01/13)

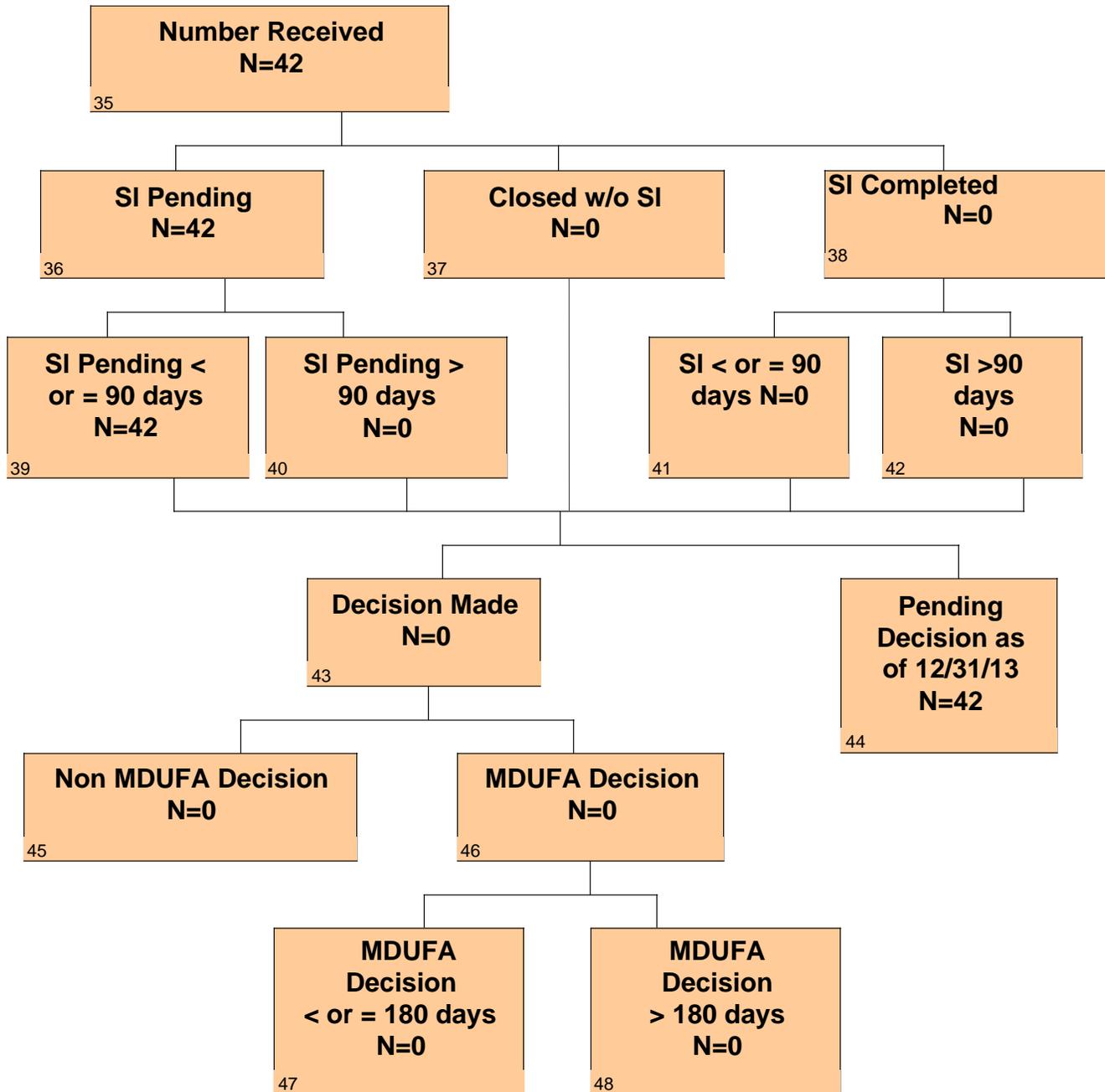
# CDRH PMA Original and Panel Track Supplements - Received FY2014 (Decisions 10/01/13-12/31/13)



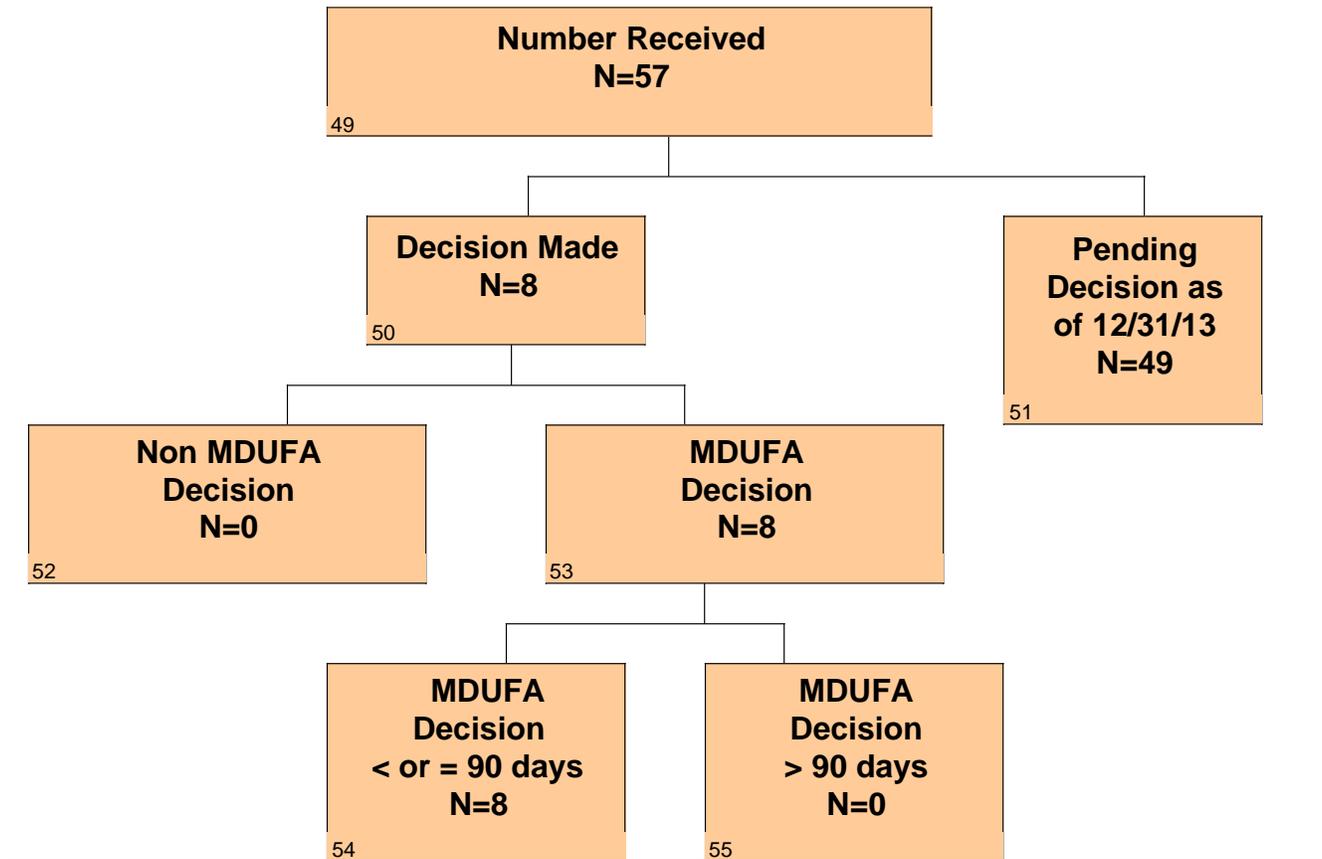
# CDRH PMA Original and Panel Track Supplements - Received FY2014 (Decisions 10/01/13-12/31/13) Con't



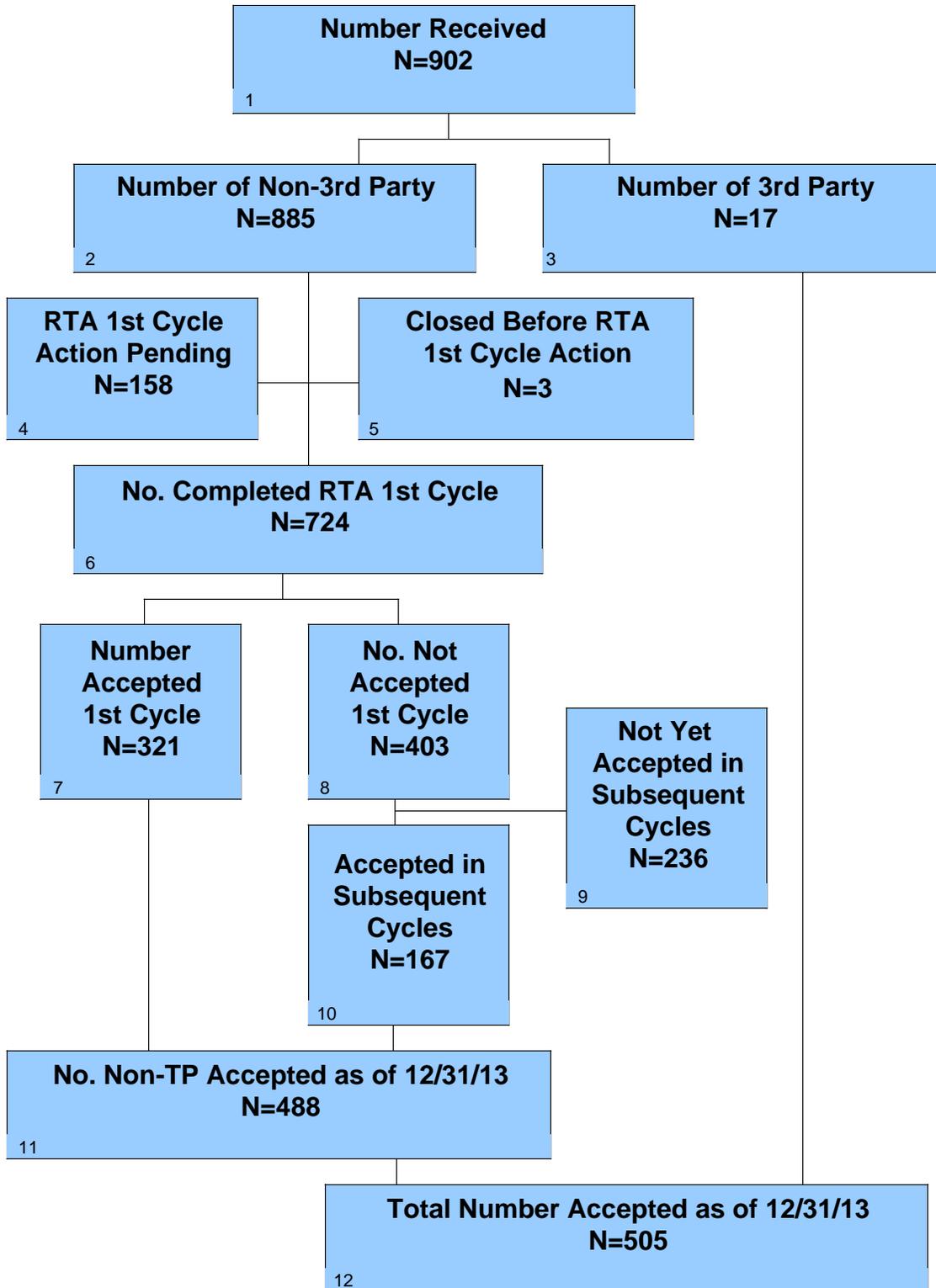
# CDRH PMA 180 Day Supplements - Received FY2014 (Decisions 10/01/13-12/31/13)



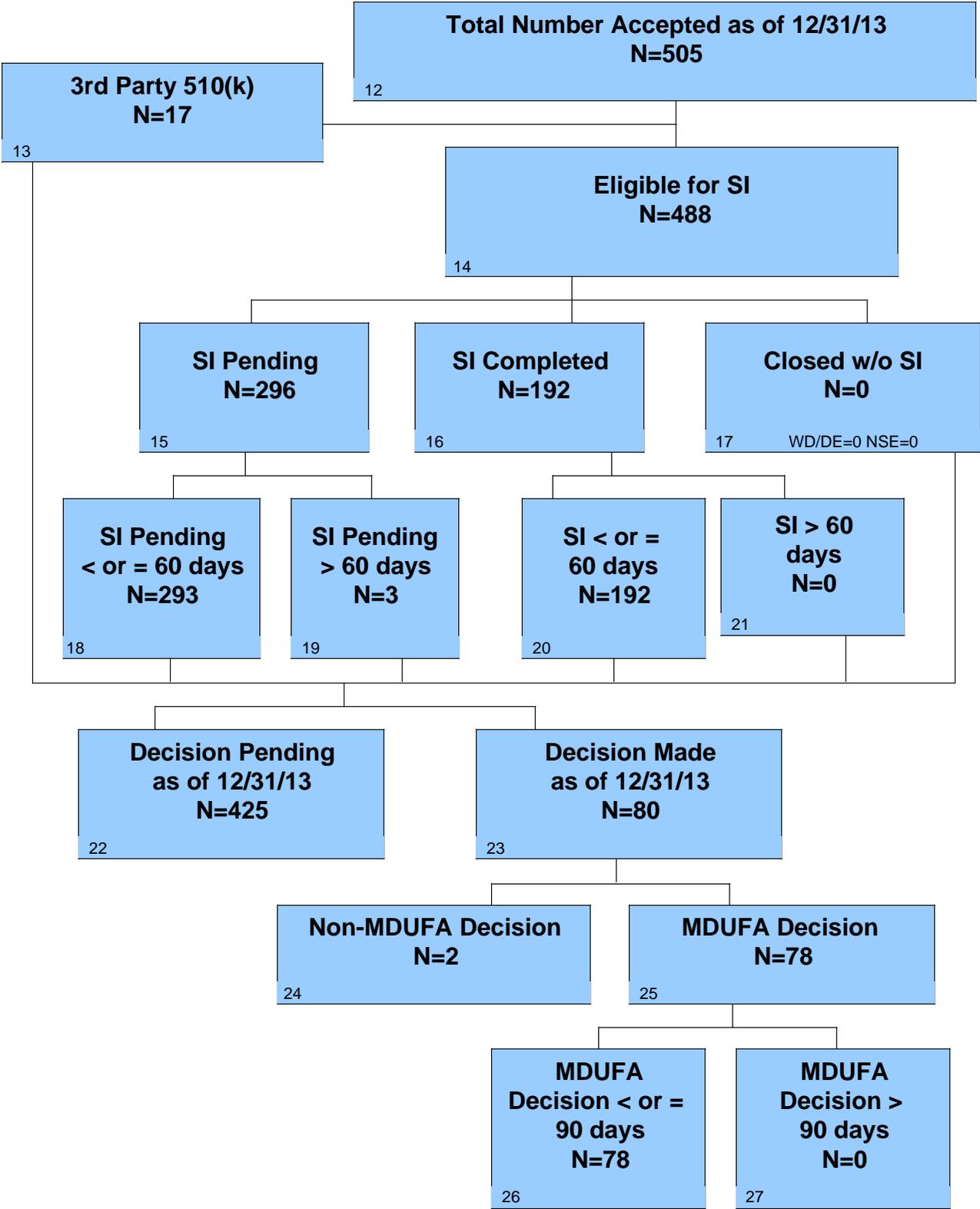
# CDRH PMA Real Time Supplements - Received FY2014 (Decisions 10/01/13-12/31/13)



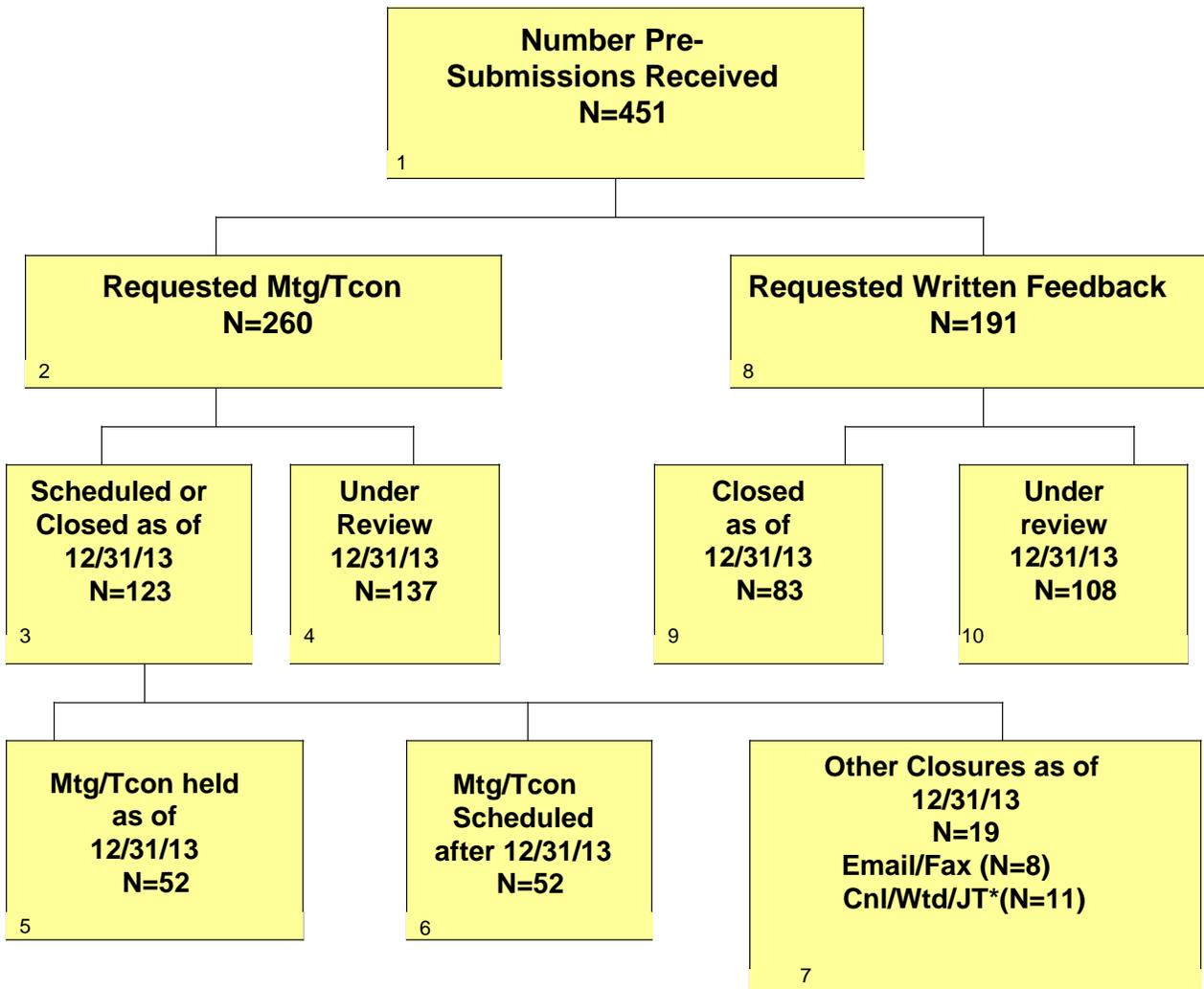
# CDRH 510(k)s – Received FY2014 (Decisions 10/1/13 - 12/31/13)



# CDRH 510(k)s – Received FY2014 (Decisions 10/1/13 - 12/31/13) Con't

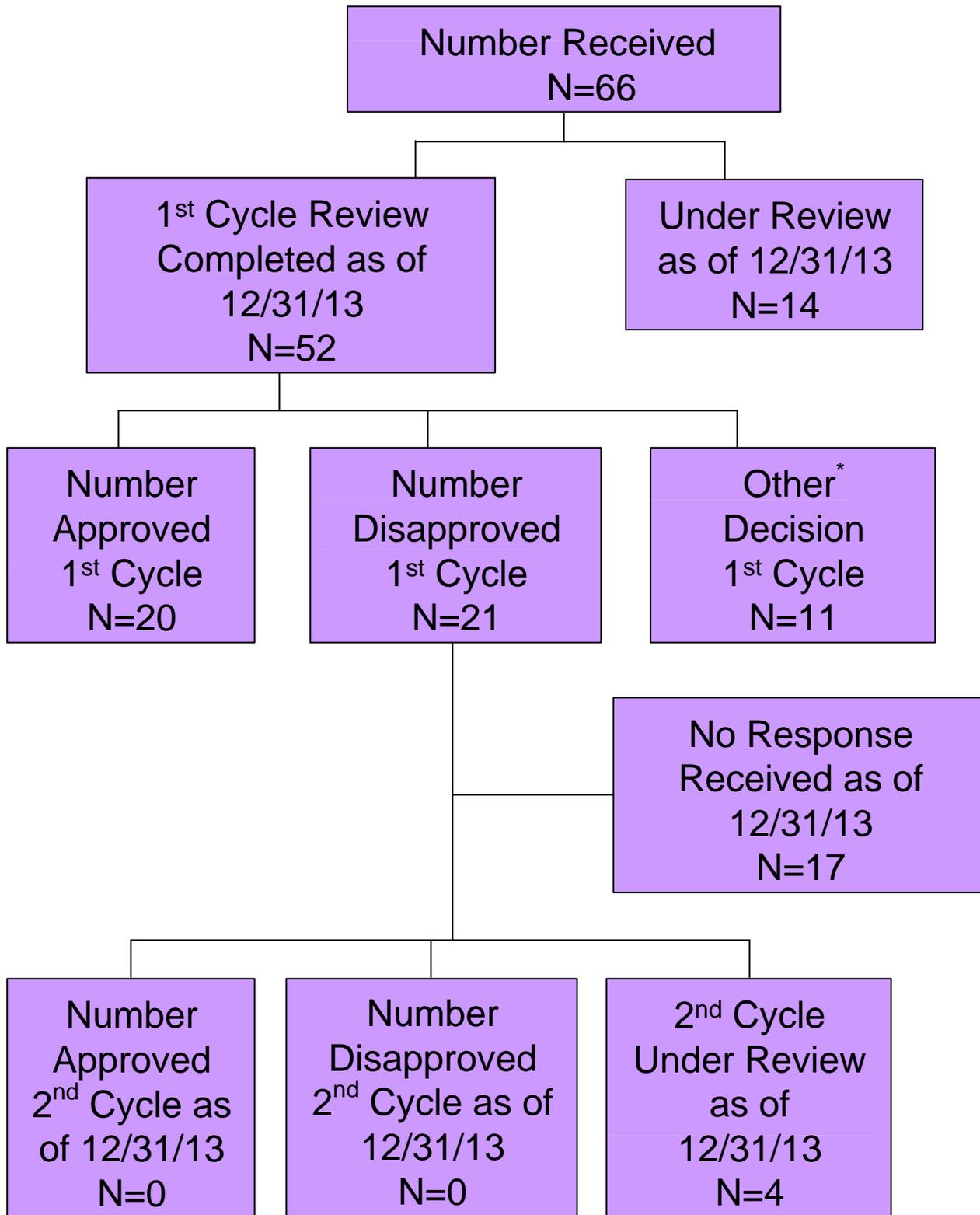


# CDRH Pre-Submissions – Received FY2014 (Decisions 10/1/13 - 12/31/13)



\*Cnl = Meeting/Tcon cancelled; Wtd = Submission Withdrawn; JT = Jurisdiction transferred

# CDRH IDEs - Received FY2014 (Decisions 10/1/13 – 12/31/13)



\*Other decisions include product jurisdiction transferred, nonsignificant risk device, RTA , or withdrawn

**Quarterly Update on  
Medical Device Performance Goals  
MDUFA III Performance Data**

**October 1, 2012 – December 31, 2013**

Report prepared by Ellen Pinnow and the MDUFA III Performance Goal Report Team

PMA

Wanda Sawyer-Major  
Nicole Wolanski

510(k)

Margaret McCabe-Janicki  
Eric Rechen  
Marjorie Shulman

Pre-Submission & IDE

Ellen Pinnow

CLIA Waiver/OIR

Jean Cooper  
Elizabeth Hillebrenner

Edaptive Systems

Victor Kuttikattu  
Jerry Logue  
Arkady Soldatov  
Steven Stone

Updated: 1/22/14

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## Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Act
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology Devices
DIHD	Division of Immunology and Hematology Devices
DMD	Division of Microbiology Devices
DRH	Division of Radiological Health
DNPMD	Division of Neurological and Physical Medicine Devices
DOD	Division of Orthopedic Devices
DOED	Division of Ophthalmic and Ear, Nose and Throat Devices
DRGUD	Division of Reproductive, Gastro-Renal, and Urological Devices
DSD	Division of Surgical Devices
IDE	Investigational Device Exemption
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
ODE	Office of Device Evaluation
OIR	Office of In Vitro Diagnostics and Radiological Health
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

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

**Section 1 PMA Originals and Panel Track Supplements**

## PMA Originals and Panel Track Supplements – Center Level

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	34	12			
Closed before RTA action	1	0			
Number with accepted RTA review	26	6			
Number without a RTA Review and > 15 Days since Date Received	1	0			
Number without a RTA Review and <= 15 Days since Date Received	0	3			
Number Not Accepted for Filing Review	6	3			
Rate of submissions not accepted for filing review	18%	33%			

\* RTA was not in place 1st quarter, thus data in Table 1.1 for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	44	12			
Number Accepted <sup>#</sup>	37	6			
Completed RTF	43	7			
Number Not Filed <sup>@</sup>	3	1			
Rate of submissions Not Filed	7%	14%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

**Table 1.3 CDRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	42	6			
SI within 90 FDA days	40*	0			
SI over 90 FDA days	2	0			
SI pending within 90 FDA days	0	6			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	95%*	N/A			

\* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

**Table 1.4 CDRH – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	42	0			
Average number of FDA days to Substantive Interaction	88				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	117				

**Table 1.5 CDRH – PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	33	6			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	12	0			
MDUFA III Decisions within 180 FDA Days	12	0			
PMAs pending MDUFA III Decision	21	6			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6 CDRH – PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	9	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions within 320 FDA Days	1	0			
PMAs pending MDUFA III Decision	8	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	100%	N/A			

**Table 1.7 CDRH – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	12	0			
<b>Average FDA days to MDUFA III decision</b>	159				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	128				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	176				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	179				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	180				
<b>Average Industry days to MDUFA III decision</b>	75				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	7				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	69				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	89				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	115				
Maximum Industry days to MDUFA III decision	194				
<b>Average Total days to MDUFA III decision</b>	234				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	198				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	236				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	277				
Maximum Total days to MDUFA III decision	371				

**Table 1.8 CDRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

**Table 1.9 CDRH – PMA Originals and Panel Track Supplements (without Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	33	6			
Number with MDUFA decision	12	0			
Number of Withdrawals	1	0			
Number of Not Approvable	2	0			
Rate of Withdrawals	8%	N/A			
Rate of Not Approvable	17%	N/A			

**Table 1.10 CDRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	9	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0.0%	N/A			
Rate of Not Approvable	0.0%	N/A			

**Table 1.11 CDRH – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12 CDRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## PMA Originals and Panel Track Supplements – Office Level

**Table 1.1.ODE ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	27	10			
Closed before RTA action	1	0			
Number with accepted RTA review	19	5			
Number without a RTA Review and > 15 Days since Date Received	1	0			
Number without a RTA Review and <= 15 Days since Date Received	0	3			
Number Not Accepted for Filing Review	6	2			
Rate of submissions not accepted for filing review	23%	29%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.ODE for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.ODE ODE – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	34	10			
Number Accepted <sup>#</sup>	27	5			
Completed RTF	33	6			
Number Not Filed <sup>@</sup>	3	1			
Rate of submissions Not Filed	9%	17%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

**Table 1.3.ODE ODE – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	32	5			
SI within 90 FDA days	30	0			
SI over 90 FDA days	2	0			
SI pending within 90 FDA days	0	5			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	94%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	32	0			
Average number of FDA days to Substantive Interaction	88				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	89				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	117				

**Table 1.5.ODE ODE - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	26	5			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	9	0			
MDUFA III Decisions within 180 FDA Days	9	0			
PMAs pending MDUFA III Decision	17	5			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6.ODE ODE – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	6	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	6	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	9	0			
<b>Average FDA days to MDUFA III decision</b>	168				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	178				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	180				
<b>Average Industry days to MDUFA III decision</b>	61				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	36				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	72				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	99				
Maximum Industry days to MDUFA III decision	194				
<b>Average Total days to MDUFA III decision</b>	232				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	187				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	241				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	268				
Maximum Total days to MDUFA III decision	371				

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	26	5			
Number with MDUFA decision	9	0			
Number of Withdrawals	1	0			
Number of Not Approvable	2	0			
Rate of Withdrawals	11%	N/A			
Rate of Not Approvable	22%	N/A			

**Table 1.10.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	6	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.ODE ODE – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.OIR OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	2			
Closed before RTA action	0	0			
Number with accepted RTA review	7	1			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of submissions not accepted for filing review	0%	50%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.OIR for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.OIR OIR – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	2			
Number Accepted <sup>#</sup>	10	1			
Completed RTF	10	1			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.OIR OIR – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	10	1			
SI within 90 FDA days	10*	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	1			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%*	N/A			

\* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	10	0			
Average number of FDA days to Substantive Interaction	89				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	89				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	112				

**Table 1.5.OIR OIR - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	7	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	3	0			
MDUFA III Decisions within 180 FDA Days	3	0			
PMAs pending MDUFA III Decision	4	1			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6.OIR OIR – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	3	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions within 320 FDA Days	1	0			
PMAs pending MDUFA III Decision	2	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	100%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	3	0			
<b>Average FDA days to MDUFA III decision</b>	130				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	106				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	113				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	128				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	151				
Maximum FDA days to MDUFA III decision	174				
<b>Average Industry days to MDUFA III decision</b>	107				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	90				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	109				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	121				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	127				
Maximum Industry days to MDUFA III decision	133				
<b>Average Total days to MDUFA III decision</b>	237				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	199				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	211				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	235				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	271				
Maximum Total days to MDUFA III decision	307				

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	7	1			
Number with MDUFA decision	3	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0.0%	N/A			
Rate of Not Approvable	0.0%	N/A			

**Table 1.11.OIR OIR – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## PMA Originals and Panel Track Supplements – Division Level

**Table 1.1.DAGRID DAGRID – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	0			
Closed before RTA action	0	0			
Number with accepted RTA review	0	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of submissions not accepted for filing review	100%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DAGRID for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DAGRID DAGRID – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Number Accepted <sup>#</sup>	1	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DAGRID      DAGRID – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	0			
SI within 90 FDA days	2	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	85				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	84				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	85				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	85				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	87				

**Table 1.5.DAGRID      DAGRID - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 1.6.DAGRID      DAGRID – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DAGRID DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DAGRID DAGRID – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DAGRID DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DCD DCD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	16	5			
Closed before RTA action	1	0			
Number with accepted RTA review	14	3			
Number without a RTA Review and > 15 Days since Date Received	1	0			
Number without a RTA Review and <= 15 Days since Date Received	0	2			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	0%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DCD DCD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	19	5			
Number Accepted <sup>#</sup>	18	3			
Completed RTF	18	3			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DCD DCD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	18	3			
SI within 90 FDA days	17	0			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	3			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	94%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	18	0			
Average number of FDA days to Substantive Interaction	88				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	117				

**Table 1.5.DCD DCD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	15	3			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	7	0			
MDUFA III Decisions within 180 FDA Days	7	0			
PMAs pending MDUFA III Decision	8	3			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6.DCD DCD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	3	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	3	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	7	0			
<b>Average FDA days to MDUFA III decision</b>	165				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	176				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	178				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	180				
<b>Average Industry days to MDUFA III decision</b>	82				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	42				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	73				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	89				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	103				
Maximum Industry days to MDUFA III decision	194				
<b>Average Total days to MDUFA III decision</b>	248				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	187				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	228				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	255				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	277				
Maximum Total days to MDUFA III decision	371				

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	15	3			
Number with MDUFA decision	7	0			
Number of Withdrawals	1	0			
Number of Not Approvable	2	0			
Rate of Withdrawals	14%	N/A			
Rate of Not Approvable	29%	N/A			

**Table 1.10.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DCD DCD – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DNPMD DNPMD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	2			
Closed before RTA action	0	0			
Number with accepted RTA review	0	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	1			
Number Not Accepted for Filing Review	1	1			
Rate of submissions not accepted for filing review	100%	100%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2. DNPMD DNPMD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	2			
Number Accepted <sup>#</sup>	0	0			
Completed RTF	1	1			
Number Not Filed	0	1			
Rate of submissions Not Filed	0%	100%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3. DNPMD DNPMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	1	0			
SI within 90 FDA days	0	0			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	0%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	1	0			
Average number of FDA days to Substantive Interaction	92				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	92				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	92				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	92				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	92				
Maximum FDA days to Substantive Interaction	92				

**Table 1.5. DNPMD DNPMD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions within 180 FDA Days	1	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6. DNPMD DNPMD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	180				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	180				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	180				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
Maximum Total days to MDUFA III decision	180				

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10. DNPMD DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11. DNPMD DNPMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12. DNPMD DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DOD DOD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	0			
Closed before RTA action	0	0			
Number with accepted RTA review	0	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	N/A	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DOD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DOD DOD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Number Accepted <sup>#</sup>	2	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DOD DOD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	0			
SI within 90 FDA days	2	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	86				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	86				

**Table 1.5.DOD DOD - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	2	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 1.6.DOD DOD – PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DOD DOD – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DOED DOED – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	0			
Closed before RTA action	0	0			
Number with accepted RTA review	4	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of submissions not accepted for filing review	20%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DOED for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DOED DOED – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	0			
Number Accepted <sup>#</sup>	5	0			
Completed RTF	6	0			
Number Not Filed <sup>@</sup>	1	0			
Rate of submissions Not Filed	17%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

**Table 1.3.DOE DOED – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	6	0			
SI within 90 FDA days	6	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 1.4.DOE DOED – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	6	0			
Average number of FDA days to Substantive Interaction	89				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	89				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DOE DOED - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	4	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions within 180 FDA Days	1	0			
PMAs pending MDUFA III Decision	3	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6.DOE DOED – PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	2	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

**Table 1.7.DOE DOED – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	177				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
Maximum FDA days to MDUFA III decision	177				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	177				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
Maximum Total days to MDUFA III decision	177				

**Table 1.8.DOE DOED – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DOE DOED – PMA Originals and Panel Track Supplements (without Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10.DOE DOED – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DOED DOED – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DOED DOED – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DRGUD DRGUD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	0			
Closed before RTA action	0	0			
Number with accepted RTA review	1	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	3	0			
Rate of submissions not accepted for filing review	75%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DRGUD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DRGUD DRGUD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	0			
Number Accepted <sup>#</sup>	1	0			
Completed RTF <sup>@</sup>	4	0			
Number Not Filed	2	0			
Rate of submissions Not Filed	50%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

**Table 1.3.DRGUD DRGUD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	3	0			
SI within 90 FDA days	3	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	3	0			
Average number of FDA days to Substantive Interaction	89				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	89				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DRGUD DRGUD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	3	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	3	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 1.6.DRGUD DRGUD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DRGUD DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DRGUD DRGUD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DRGUD DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DSD DSD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	3			
Closed before RTA action	0	0			
Number with accepted RTA review	0	2			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of submissions not accepted for filing review	N/A	33%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCTD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DSD DSD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	3			
Number Accepted <sup>#</sup>	0	2			
Completed RTF	0	2			
Number Not Filed	0	0			
Rate of submissions Not Filed	N/A	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DSD DSD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	0	2			
SI within 90 FDA days	0	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	2			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	0	0			
Average number of FDA days to Substantive Interaction					
20 <sup>th</sup> Percentile FDA days to Substantive Interaction					
40 <sup>th</sup> Percentile FDA days to Substantive Interaction					
60 <sup>th</sup> Percentile FDA days to Substantive Interaction					
80 <sup>th</sup> Percentile FDA days to Substantive Interaction					
Maximum FDA days to Substantive Interaction					

**Table 1.5.DSD DSD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	0	2			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	2			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 1.6.DSD DSD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

**Table 1.7.DSD**

**DSD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.8.DSD**

**DSD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	2			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DSD DSD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DSD DSD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DSD DSD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DCTD DCTD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Closed before RTA action	0	0			
Number with accepted RTA review	2	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCTD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DCTD DCTD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Number Accepted <sup>#</sup>	2	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DCTD DCTD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	0			
SI within 90 FDA days	2	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	90				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DCTD      DCTD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions within 180 FDA Days	1	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6.DCTD      DCTD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	174				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
Maximum FDA days to MDUFA III decision	174				
<b>Average Industry days to MDUFA III decision</b>	133				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
Maximum Industry days to MDUFA III decision	133				
<b>Average Total days to MDUFA III decision</b>	307				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
Maximum Total days to MDUFA III decision	307				

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	2	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DCTD      DCTD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DCTD      DCTD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DCTD      DCTD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DIHD DIHD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Closed before RTA action	0	0			
Number with accepted RTA review	2	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DIHD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DIHD DIHD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	0			
Number Accepted <sup>#</sup>	4	0			
Completed RTF	4	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DIHD DIHD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	4	0			
SI within 90 FDA days	4*	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%*	N/A			

\* The SI goal for one original PMA was extended beyond 90 days due to the submission of an unsolicited major amendment.

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	4	0			
Average number of FDA days to Substantive Interaction	95				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	99				
Maximum FDA days to Substantive Interaction	112				

**Table 1.5.DIHD DIHD - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	3	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	2	0			
MDUFA III Decisions within 180 FDA Days	2	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 1.6.DIHD DIHD – PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	2	0			
<b>Average FDA days to MDUFA III decision</b>	108				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	102				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	106				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	109				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	113				
Maximum FDA days to MDUFA III decision	116				
<b>Average Industry days to MDUFA III decision</b>	95				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	80				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	90				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	99				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	109				
Maximum Industry days to MDUFA III decision	118				
<b>Average Total days to MDUFA III decision</b>	202				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	193				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	199				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	205				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	211				
Maximum Total days to MDUFA III decision	217				

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	3	0			
Number with MDUFA decision	2	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DIHD DIHD – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DMD DMD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1			
Closed before RTA action	0	0			
Number with accepted RTA review	2	1			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	0%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DMD DMD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1			
Number Accepted <sup>#</sup>	2	1			
Completed RTF	2	1			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DMD DMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	1			
SI within 90 FDA days	2	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	1			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 1.4.DRH DMD – DMD Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	86				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	86				

**Table 1.5.DMD DMD - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	1			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 1.6.DMD DMD – PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	N/A	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11. DMD DMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DRH DRH – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	1			
Closed before RTA action	0	0			
Number with accepted RTA review	1	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of submissions not accepted for filing review	0%	100%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DRH DRH – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1			
Number Accepted <sup>#</sup>	2	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DRH DRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	0			
SI within 90 FDA days	2	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	78				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	70				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	75				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	80				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	85				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DRH DRH - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 1.6.DRH DRH – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions within 320 FDA Days	1	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	100%	N/A			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0.0%	N/A			
Rate of Not Approvable	0.0%	N/A			

**Table 1.11.DRH DRH – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Section 2 PMA 180 Day Supplements**

## PMA 180 Day Supplements – Center Level

**Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	182^	42			
SI within 90 FDA days	167	0			
SI over 90 FDA days	11	0			
SI pending within 90 FDA days	0	42			
SI pending over 90 FDA days	1	0			
Closed without SI	3^	0			
Current SI Performance Percent within 90 FDA days	93%	N/A			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.2 CDRH – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	182^	42			
Non-MDUFA III Decisions	4	0			
MDUFA III Decisions	128	0			
MDUFA III Decisions within 180 FDA Days	127	0			
Supplements pending MDUFA III Decision	50	42			
Supplements pending MDUFA III Decision over 180 FDA days	1	0			
Current Performance Percent within 180 FDA Days	98%	N/A			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.3 CDRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	182 <sup>^</sup>	42			
Number with MDUFA decision	128	0			
Number of Not Approvable	6	0			
Rate of Not Approvable	5%	N/A			

<sup>^</sup> Includes one PMA 180 Day Supplement that was converted.

**Table 2.4 CDRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	182				
Mean Industry days for submissions that missed goal	0				

## PMA 180 Day Supplements – Office Level

**Table 2.1.ODE ODE – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	161^	39			
SI within 90 FDA days	146	0			
SI over 90 FDA days	11	0			
SI pending within 90 FDA days	0	39			
SI pending over 90 FDA days	1	0			
Closed without SI	3	0			
Current SI Performance Percent within 90 FDA days	92%	N/A			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.2.ODE ODE – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	161^	39			
Non-MDUFA III Decisions	4	0			
MDUFA III Decisions	115	0			
MDUFA III Decisions within 180 FDA Days	114	0			
Supplements pending MDUFA III Decision	42	39			
Supplements pending MDUFA III Decision over 180 FDA days	1	0			
Current Performance Percent within 180 FDA Days	98%	N/A			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.3.ODE ODE – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	161 <sup>^</sup>	39			
Number with MDUFA decision	115	0			
Number of Not Approvable	6	0			
Rate of Not Approvable	5%	N/A			

<sup>^</sup> Includes one PMA 180 Day Supplement that was converted.

**Table 2.4.ODE ODE – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	182				
Mean Industry days for submissions that missed goal	0				

**Table 2.1.OIR OIR – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	21	3			
SI within 90 FDA days	21	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	3			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 2.2.OIR OIR – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	21	3			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	13	0			
MDUFA III Decisions within 180 FDA Days	13	0			
Supplements pending MDUFA III Decision	8	3			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.OIR OIR – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	21	3			
Number with MDUFA decision	13	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.OIR OIR – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## PMA 180 Day Supplements – Division Level

**Table 2.1.DAGRID DAGRID – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	9	1			
SI within 90 FDA days	7	0			
SI over 90 FDA days	2	0			
SI pending within 90 FDA days	0	1			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	78%	N/A			

**Table 2.2.DAGRID DAGRID – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	9	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	4	0			
MDUFA III Decisions within 180 FDA Days	4	0			
Supplements pending MDUFA III Decision	5	1			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.DAGRID DAGRID – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	9	1			
Number with MDUFA decision	4	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	25%	N/A			

**Table 2.4.DAGRID DAGRID – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DCD DCD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	115^	28			
SI within 90 FDA days	107	0			
SI over 90 FDA days	5	0			
SI pending within 90 FDA days	0	28			
SI pending over 90 FDA days	0	0			
Closed without SI	3	0			
Current SI Performance Percent within 90 FDA days	96%	N/A			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.2.DCD DCD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	115^	28			
Non-MDUFA III Decisions	3	0			
MDUFA III Decisions	86	0			
MDUFA III Decisions within 180 FDA Days	85	0			
Supplements pending MDUFA III Decision	26	28			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	99%	N/A			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.3.DCD DCD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	115 <sup>^</sup>	28			
Number with MDUFA decision	86	0			
Number of Not Approvable	4	0			
Rate of Not Approvable	5%	N/A			

<sup>^</sup> Includes one PMA 180 Day Supplement that was converted.

**Table 2.4.DCD DCD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	182				
Mean Industry days for submissions that missed goal	0				

**Table 2.1.DNPMD DNPMD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	8	3			
SI within 90 FDA days	7	0			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	3			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	88%	N/A			

**Table 2.2.DNPMD DNPMD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	8	3			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	6	0			
MDUFA III Decisions within 180 FDA Days	6	0			
Supplements pending MDUFA III Decision	1	3			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.DNPMD DNPMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	3			
Number with MDUFA decision	6	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	17%	N/A			

**Table 2.4.DNPMD DNPMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DOD DOD – PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	0			
SI within 90 FDA days	2	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 2.2.DOD DOD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
Supplements pending MDUFA III Decision	2	0			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 2.3.DOD DOD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Number with MDUFA decision	0	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	n/a	N/A			

**Table 2.4.DOD DOD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DOED DOED – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	12	5			
SI within 90 FDA days	11	0			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	5			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	92%	N/A			

**Table 2.2.DOED DOED – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	12	5			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	9	0			
MDUFA III Decisions within 180 FDA Days	9	0			
Supplements pending MDUFA III Decision	3	5			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.DOED DOED – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	12	5			
Number with MDUFA decision	9	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DOED DOED – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DRGUD DRGUD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	10	2			
SI within 90 FDA days	9	0			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	2			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	90%	N/A			

**Table 2.2.DRGUD DRGUD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	10	2			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	8	0			
MDUFA III Decisions within 180 FDA Days	8	0			
Supplements pending MDUFA III Decision	2	2			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.DRGUD DRGUD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	2			
Number with MDUFA decision	8	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DRGUD DRGUD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DSD DSD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	5	0			
SI within 90 FDA days	3	0			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	1	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	60%	N/A			

**Table 2.2.DSD DSD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	5	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	2	0			
MDUFA III Decisions within 180 FDA Days	2	0			
Supplements pending MDUFA III Decision	3	0			
Supplements pending MDUFA III Decision over 180 FDA days	1	0			
Current Performance Percent within 180 FDA Days	67%	N/A			

**Table 2.3.DSD DSD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	0			
Number with MDUFA decision	2	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DSD DSD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DCTD DCTD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	3	0			
SI within 90 FDA days	3	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 2.2.DCTD DCTD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	3	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
Supplements pending MDUFA III Decision	3	0			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	N/A	N/A			

**Table 2.3.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	0			
Number with MDUFA decision	0	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	N/A	N/A			

**Table 2.4.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DIHD DIHD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	6	2			
SI within 90 FDA days	6	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	2			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 2.2.DIHD DIHD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	6	2			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	4	0			
MDUFA III Decisions within 180 FDA Days	4	0			
Supplements pending MDUFA III Decision	2	2			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	2			
Number with MDUFA decision	4	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DMD DMD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	7	0			
SI within 90 FDA days	7	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 2.2.DMD DMD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	7	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	5	0			
MDUFA III Decisions within 180 FDA Days	5	0			
Supplements pending MDUFA III Decision	2	0			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.DMD DMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	0			
Number with MDUFA decision	5	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DMD DMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DRH DRH – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	5	1			
SI within 90 FDA days	5	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	1			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	100%	N/A			

**Table 2.2.DRH DRH – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	5	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	4	0			
MDUFA III Decisions within 180 FDA Days	4	0			
Supplements pending MDUFA III Decision	1	1			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100%	N/A			

**Table 2.3.DRH DRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1			
Number with MDUFA decision	4	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DRH DRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Section 3 PMA Real Time Supplements**

## PMA Real Time Supplements – Center Level

**Table 3.1 CDRH – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	305	57			
Non-MDUFA III Decisions	8	0			
MDUFA III Decisions	295	8			
MDUFA III Decisions within 90 FDA Days	294	8			
Supplements pending MDUFA III Decision	2	49			
Supplements pending MDUFA III Decision over 90 FDA days	1	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 3.2 CDRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	305	57			
Number with MDUFA decision	295	8			
Number of Not Approvable	20	0			
Rate of Not Approvable	7%	0%			

**Table 3.3 CDRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	1	<b>0</b>			
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	0				

## PMA Real Time Supplements – Office Level

**Table 3.1.ODE ODE – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	266	42			
Non-MDUFA III Decisions	7	0			
MDUFA III Decisions	257	7			
MDUFA III Decisions within 90 FDA Days	256	7			
Supplements pending MDUFA III Decision	2	35			
Supplements pending MDUFA III Decision over 90 FDA days	1	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 3.2.ODE ODE – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	266	42			
Number with MDUFA decision	257	7			
Number of Not Approvable	15	0			
Rate of Not Approvable	6%	0%			

**Table 3.3.ODE ODE – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	1	<b>0</b>			
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	0				

**Table 3.1.OIR OIR – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	39	15			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	38	1			
MDUFA III Decisions within 90 FDA Days	38	1			
Supplements pending MDUFA III Decision	0	14			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 3.2.OIR OIR – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	39	15			
Number with MDUFA decision	38	1			
Number of Not Approvable	5	0			
Rate of Not Approvable	13%	0%			

**Table 3.3.OIR OIR – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## PMA Real Time Supplements – Division Level

**Table 3.1.DAGRID DAGRID – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	13	2			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	13	1			
MDUFA III Decisions within 90 FDA Days	13	1			
Supplements pending MDUFA III Decision	0	1			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 3.2.DAGRID DAGRID – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	13	2			
Number with MDUFA decision	13	1			
Number of Not Approvable	1	0			
Rate of Not Approvable	8%	0%			

**Table 3.3.DAGRID      DAGRID – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DCD DCD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	174	27			
Non-MDUFA III Decisions	5	0			
MDUFA III Decisions	168	4			
MDUFA III Decisions within 90 FDA Days	168	4			
Supplements pending MDUFA III Decision	1	23			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 3.2.DCD DCD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	174	27			
Number with MDUFA decision	168	4			
Number of Not Approvable	7	0			
Rate of Not Approvable	4%	0%			

**Table 3.3.DCD DCD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DNPMD DNPMD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	23	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	23	0			
MDUFA III Decisions within 90 FDA Days	23	0			
Supplements pending MDUFA III Decision	0	1			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	N/A			

**Table 3.2.DNPMD DNPMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	23	1			
Number with MDUFA decision	23	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	4%	N/A			

**Table 3.3.DNPMD DNPMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DOD DOD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	8	5			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	8	2			
MDUFA III Decisions within 90 FDA Days	8	2			
Supplements pending MDUFA III Decision	0	3			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 3.2.DOD DOD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	8	5			
Number with MDUFA decision	8	2			
Number of Not Approvable	2	0			
Rate of Not Approvable	25%	0%			

**Table 3.3.DOD DOD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DOED DOED – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	16	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	16	0			
MDUFA III Decisions within 90 FDA Days	16	0			
Supplements pending MDUFA III Decision	0	1			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	N/A			

**Table 3.2.DOED DOED – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	16	1			
Number with MDUFA decision	16	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 3.3.DOED DOED – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DRGUD DRGUD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	19	1			
Non-MDUFA III Decisions	2	0			
MDUFA III Decisions	17	0			
MDUFA III Decisions within 90 FDA Days	17	0			
Supplements pending MDUFA III Decision	0	1			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	N/A			

**Table 3.2.DRGUD DRGUD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	19	1			
Number with MDUFA decision	17	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	6%	N/A			

**Table 3.3.DRGUD DRGUD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DSD DSD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	13	5			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	12	0			
MDUFA III Decisions within 90 FDA Days	11	0			
Supplements pending MDUFA III Decision	1	5			
Supplements pending MDUFA III Decision over 90 FDA days	1	0			
Current Performance Percent within 90 FDA Days	85%	N/A			

**Table 3.2.DSD DSD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	13	5			
Number with MDUFA decision	12	0			
Number of Not Approvable	3	0			
Rate of Not Approvable	25%	N/A			

**Table 3.3.DSD DSD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	0				

**Table 3.1.DCTD DCTD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	6	7			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	6	0			
MDUFA III Decisions within 90 FDA Days	6	0			
Supplements pending MDUFA III Decision	0	7			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	N/A			

**Table 3.2.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	6	7			
Number with MDUFA decision	6	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 3.3.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DIHD DIHD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	20	7			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	19	0			
MDUFA III Decisions within 90 FDA Days	19	0			
Supplements pending MDUFA III Decision	0	7			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	N/A			

**Table 3.2.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	20	7			
Number with MDUFA decision	19	0			
Number of Not Approvable	2	0			
Rate of Not Approvable	11%	N/A			

**Table 3.3.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DMD DMD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	13	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	13	1			
MDUFA III Decisions within 90 FDA Days	13	1			
Supplements pending MDUFA III Decision	0	0			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 3.2.DMD DMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	13	1			
Number with MDUFA decision	13	1			
Number of Not Approvable	3	0			
Rate of Not Approvable	23%	0%			

**Table 3.3.DMD DMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

There were no PMA 180 Day Supplements received by DRH between October 1, 2012 and December 31, 2013.

## **Section 4 Pre-Market Report Submissions**

There were no pre-market reports received by FDA between October 1, 2012 and December 31, 2013.

## **Section 5 PMA Annual Metrics and Goals**

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

## **Section 6 510(k) MDUFA III Performance**

## 510(k) MDUFA III Performance – Center Level

**Table 6.1 CDRH – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,965	885			
Closed before RTA action	12	3			
Number Accepted	1,197	314			
RTA Review not done and > 15 days since Date Received	41	7			
RTA Review not done and <= 15 days since Date Received	0	158			
Number Not Accepted	1,715	403			
Rate of submissions not accepted	58%	56%			

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2 CDRH – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	3,618	488			
Deleted or withdrawn prior to SI	11	0			
SI within 60 FDA days	3,294	192			
SI over 60 FDA days	209	0			
SI pending within 60 FDA days	98	293			
SI pending over 60 FDA days	2	3			
510(k)s NSE without SI	4	0			
Current SI Performance Percent within 60 FDA days	94%	98%			

**Table 6.3 CDRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	3,503	192			
Average number of FDA days to Substantive Interaction	47	38			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	30	26			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	47	29			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	44			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	54			
Maximum FDA days to Substantive Interaction	98	60			

**Table 6.4 CDRH – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	3,746	505			
Non-MDUFA III Decisions	269	2			
MDUFA III Decisions (SE/NSE)	2,587	78			
MDUFA III Decisions within 90 FDA Days	2,556	78			
510(k)s pending MDUFA III Decision	890	425			
510(k) pending MDUFA III Decision over 90 FDA days	10	0			
Current Performance Percent within 90 FDA Days	98%	100%			

**Table 6.5 CDRH – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.64	1.08			
Number with MDUFA decision	2,587	78			
<b>Average FDA days to MDUFA III decision</b>	66	31			
20th Percentile FDA days to MDUFA III decision	38	24			
40th Percentile FDA days to MDUFA III decision	62	27			
60th Percentile FDA days to MDUFA III decision	84	29			
80th Percentile FDA days to MDUFA III decision	88	36			
Maximum FDA days to MDUFA III decision	200	60			
<b>Average Industry days to MDUFA III decision</b>	37	1			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	27	0			
80th Percentile Industry days to MDUFA III decision	66	0			
Maximum Industry days to MDUFA III decision	339	13			
<b>Average Total days to MDUFA III decision</b>	103	32			
20th Percentile Total days to MDUFA III decision	42	24			
40th Percentile Total days to MDUFA III decision	80	27			
60th Percentile Total days to MDUFA III decision	106	29			
80th Percentile Total days to MDUFA III decision	147	37			
Maximum Total days to MDUFA III decision	429	71			

**Table 6.6 CDRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	3,746	505			
Number with MDUFA decision	2,587	78			
Number of SE decisions	2,509	78			
Number of NSE decisions	78	0			
Number of Withdrawals	128	0			
Number deleted	122	0			
Rate of SE decisions	97%	100%			
Rate of NSE decisions	3%	0%			
Rate of Withdrawals	3%	0%			
Rate of Deleted	3%	0%			

**Table 6.7 CDRH – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	31	0			
Mean FDA days for submissions that missed goal	108				
Mean Industry days for submissions that missed goal	98				

## 510(k) MDUFA III Performance – Office Level

**Table 6.1.ODE ODE – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,388	693			
Closed before RTA action	10	3			
Number Accepted	821	209			
RTA Review not done and > 15 days since Date Received	23	6			
RTA Review not done and <= 15 days since Date Received	0	132			
Number Not Accepted	1,534	343			
Rate of submissions not accepted	65%	61%			

\* RTA was not in place 1st quarter, thus Table 6.1.ODE for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.ODE ODE – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	2,869	366			
Deleted or withdrawn prior to SI	10	0			
SI within 60 FDA days	2,596	138			
SI over 60 FDA days	166	0			
SI pending within 60 FDA days	91	226			
SI pending over 60 FDA days	2	2			
510(k)s NSE without SI	4	0			
Current SI Performance Percent within 60 FDA days	94%	99%			

**Table 6.3.ODE ODE – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	2,762	138			
Average number of FDA days to Substantive Interaction	48	38			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	30	26			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	49	29			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	45			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	55			
Maximum FDA days to Substantive Interaction	98	60			

**Table 6.4.ODE ODE – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	2,943	374			
Non-MDUFA III Decisions	226	2			
MDUFA III Decisions (SE/NSE)	1,985	54			
MDUFA III Decisions within 90 FDA Days	1,959	54			
510(k)s pending MDUFA III Decision	732	318			
510(k) pending MDUFA III Decision over 90 FDA days	10	0			
Current Performance Percent within 90 FDA Days	98%	100%			

**Table 6.5.ODE ODE – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.67	1.07			
Number with MDUFA decision	1,985	54			
<b>Average FDA days to MDUFA III decision</b>	68	30			
20th Percentile FDA days to MDUFA III decision	44	24			
40th Percentile FDA days to MDUFA III decision	67	27			
60th Percentile FDA days to MDUFA III decision	85	29			
80th Percentile FDA days to MDUFA III decision	89	35			
Maximum FDA days to MDUFA III decision	200	60			
<b>Average Industry days to MDUFA III decision</b>	37	1			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	6	0			
60th Percentile Industry days to MDUFA III decision	29	0			
80th Percentile Industry days to MDUFA III decision	66	0			
Maximum Industry days to MDUFA III decision	321	13			
<b>Average Total days to MDUFA III decision</b>	105	31			
20th Percentile Total days to MDUFA III decision	49	24			
40th Percentile Total days to MDUFA III decision	85	27			
60th Percentile Total days to MDUFA III decision	110	29			
80th Percentile Total days to MDUFA III decision	149	36			
Maximum Total days to MDUFA III decision	419	71			

**Table 6.6.ODE ODE – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	2,943	374			
Number with MDUFA decision	1,985	54			
Number of SE decisions	1,920	54			
Number of NSE decisions	65	0			
Number of Withdrawals	108	0			
Number deleted	101	0			
Rate of SE decisions	97%	100%			
Rate of NSE decisions	3%	0%			
Rate of Withdrawals	4%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.ODE ODE – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	26	0			
Mean FDA days for submissions that missed goal	108				
Mean Industry days for submissions that missed goal	98				

**Table 6.1.OIR OIR – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	577	192			
Closed before RTA action	2	0			
Number Accepted	376	105			
RTA Review not done and > 15 days since Date Received	18	1			
RTA Review not done and <= 15 days since Date Received	0	26			
Number Not Accepted	181	60			
Rate of submissions not accepted	31%	36%			

\* RTA was not in place 1st quarter, thus Table 6.1.OIR for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.OIR OIR – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	749	122			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	698	54			
SI over 60 FDA days	43	0			
SI pending within 60 FDA days	7	67			
SI pending over 60 FDA days	0	1			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	94%	98%			

**Table 6.3.OIR OIR – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	741	54			
Average number of FDA days to Substantive Interaction	45	38			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	29	26			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	42	29			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	51	43			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	53			
Maximum FDA days to Substantive Interaction	91	60			

**Table 6.4.OIR OIR – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	803	131			
Non-MDUFA III Decisions	43	0			
MDUFA III Decisions (SE/NSE)	602	24			
MDUFA III Decisions within 90 FDA Days	597	24			
510(k)s pending MDUFA III Decision	158	107			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 6.5.OIR OIR – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.53	1.08			
Number with MDUFA decision	602	24			
<b>Average FDA days to MDUFA III decision</b>	60	31			
20th Percentile FDA days to MDUFA III decision	30	26			
40th Percentile FDA days to MDUFA III decision	51	28			
60th Percentile FDA days to MDUFA III decision	76	30			
80th Percentile FDA days to MDUFA III decision	86	35			
Maximum FDA days to MDUFA III decision	121	49			
<b>Average Industry days to MDUFA III decision</b>	35	1			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	18	0			
80th Percentile Industry days to MDUFA III decision	64	0			
Maximum Industry days to MDUFA III decision	339	13			
<b>Average Total days to MDUFA III decision</b>	95	32			
20th Percentile Total days to MDUFA III decision	31	26			
40th Percentile Total days to MDUFA III decision	63	28			
60th Percentile Total days to MDUFA III decision	89	31			
80th Percentile Total days to MDUFA III decision	139	39			
Maximum Total days to MDUFA III decision	429	49			

**Table 6.6.OIR OIR – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	803	131			
Number with MDUFA decision	602	24			
Number of SE decisions	589	24			
Number of NSE decisions	13	0			
Number of Withdrawals	20	0			
Number deleted	21	0			
Rate of SE decisions	98%	100%			
Rate of NSE decisions	2%	0%			
Rate of Withdrawals	2%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.OIR OIR – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	5	0			
Mean FDA days for submissions that missed goal	104				
Mean Industry days for submissions that missed goal	99				

## 510(k) MDUFA III Performance – Division Level

**Table 6.1.DAGRID DAGRID – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	636	153			
Closed before RTA action	6	1			
Number Accepted	189	31			
RTA Review not done and > 15 days since Date Received	5	2			
RTA Review not done and <= 15 days since Date Received	0	24			
Number Not Accepted	436	95			
Rate of submissions not accepted	69%	74%			

\* RTA was not in place 1st quarter, thus Table 6.1.DAGRID for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DAGRID DAGRID – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	739	68			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	681	13			
SI over 60 FDA days	25	0			
SI pending within 60 FDA days	31	55			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	2	0			
Current SI Performance Percent within 60 FDA days	96%	100%			

**Table 6.3.DAGRID DAGRID – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	706	13			
Average number of FDA days to Substantive Interaction	50	38			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	41	25			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	54	28			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	44			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	60	56			
Maximum FDA days to Substantive Interaction	90	60			

**Table 6.4.DAGRID DAGRID – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	754	70			
Non-MDUFA III Decisions	75	1			
MDUFA III Decisions (SE/NSE)	438	6			
MDUFA III Decisions within 90 FDA Days	431	6			
510(k)s pending MDUFA III Decision	241	63			
510(k) pending MDUFA III Decision over 90 FDA days	4	0			
Current Performance Percent within 90 FDA Days	98%	100%			

**Table 6.5.DAGRID      DAGRID – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.70	1.17			
Number with MDUFA decision	438	6			
<b>Average FDA days to MDUFA III decision</b>	73	25			
20th Percentile FDA days to MDUFA III decision	56	23			
40th Percentile FDA days to MDUFA III decision	80	27			
60th Percentile FDA days to MDUFA III decision	87	27			
80th Percentile FDA days to MDUFA III decision	89	28			
Maximum FDA days to MDUFA III decision	150	28			
<b>Average Industry days to MDUFA III decision</b>	40	2			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	10	0			
60th Percentile Industry days to MDUFA III decision	30	0			
80th Percentile Industry days to MDUFA III decision	70	0			
Maximum Industry days to MDUFA III decision	263	10			
<b>Average Total days to MDUFA III decision</b>	113	26			
20th Percentile Total days to MDUFA III decision	65	23			
40th Percentile Total days to MDUFA III decision	89	27			
60th Percentile Total days to MDUFA III decision	114	28			
80th Percentile Total days to MDUFA III decision	151	28			
Maximum Total days to MDUFA III decision	352	37			

**Table 6.6.DAGRID DAGRID – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	754	70			
Number with MDUFA decision	438	6			
Number of SE decisions	423	6			
Number of NSE decisions	15	0			
Number of Withdrawals	29	0			
Number deleted	42	0			
Rate of SE decisions	97%	100%			
Rate of NSE decisions	3%	0%			
Rate of Withdrawals	4%	0%			
Rate of Deleted	6%	0%			

**Table 6.7.DAGRID DAGRID – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	7	0			
Mean FDA days for submissions that missed goal	105				
Mean Industry days for submissions that missed goal	105				

**Table 6.1.DCD DCD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	336	105			
Closed before RTA action	1	0			
Number Accepted	151	30			
RTA Review not done and > 15 days since Date Received	9	0			
RTA Review not done and <= 15 days since Date Received	0	29			
Number Not Accepted	175	46			
Rate of submissions not accepted	52%	61%			

\* RTA was not in place 1st quarter, thus Table 6.1.DCD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DCD DCD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	424	56			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	375	27			
SI over 60 FDA days	38	0			
SI pending within 60 FDA days	10	29			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	91%	100%			

**Table 6.3.DCD DCD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	413	27			
Average number of FDA days to Substantive Interaction	45	32			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	29	25			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	42	29			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	50	30			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	48			
Maximum FDA days to Substantive Interaction	98	56			

**Table 6.4.DCD DCD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	448	59			
Non-MDUFA III Decisions	10	0			
MDUFA III Decisions (SE/NSE)	360	16			
MDUFA III Decisions within 90 FDA Days	352	16			
510(k)s pending MDUFA III Decision	78	43			
510(k) pending MDUFA III Decision over 90 FDA days	3	0			
Current Performance Percent within 90 FDA Days	97%	100%			

**Table 6.5.DCD DCD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.64	1.06			
Number with MDUFA decision	360	16			
<b>Average FDA days to MDUFA III decision</b>	63	32			
20th Percentile FDA days to MDUFA III decision	30	24			
40th Percentile FDA days to MDUFA III decision	54	27			
60th Percentile FDA days to MDUFA III decision	82	29			
80th Percentile FDA days to MDUFA III decision	89	30			
Maximum FDA days to MDUFA III decision	200	60			
<b>Average Industry days to MDUFA III decision</b>	32	1			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	28	0			
80th Percentile Industry days to MDUFA III decision	56	0			
Maximum Industry days to MDUFA III decision	321	11			
<b>Average Total days to MDUFA III decision</b>	95	32			
20th Percentile Total days to MDUFA III decision	30	24			
40th Percentile Total days to MDUFA III decision	69	27			
60th Percentile Total days to MDUFA III decision	104	29			
80th Percentile Total days to MDUFA III decision	139	30			
Maximum Total days to MDUFA III decision	419	71			

**Table 6.6.DCD DCD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	448	59			
Number with MDUFA decision	360	16			
Number of SE decisions	352	16			
Number of NSE decisions	8	0			
Number of Withdrawals	4	0			
Number deleted	6	0			
Rate of SE decisions	98%	100%			
Rate of NSE decisions	2%	0%			
Rate of Withdrawals	1%	0%			
Rate of Deleted	1%	0%			

**Table 6.7.DCD DCD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	8	0			
Mean FDA days for submissions that missed goal	117				
Mean Industry days for submissions that missed goal	77				

**Table 6.1.DNPMD DNPMD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	189	55			
Closed before RTA action	0	1			
Number Accepted	39	16			
RTA Review not done and > 15 days since Date Received	1	1			
RTA Review not done and <= 15 days since Date Received	0	14			
Number Not Accepted	149	23			
Rate of submissions not accepted	79%	58%			

\* RTA was not in place 1st quarter, thus Table 6.1.DNPMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DNPMD DNPMD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	216	22			
Deleted or withdrawn prior to SI	2	0			
SI within 60 FDA days	174	7			
SI over 60 FDA days	22	0			
SI pending within 60 FDA days	16	15			
SI pending over 60 FDA days	2	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	88%	100%			

**Table 6.3.DNPMD DNPMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	196	7			
Average number of FDA days to Substantive Interaction	51	54			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	42	55			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	52	57			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	59			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	60	60			
Maximum FDA days to Substantive Interaction	80	60			

**Table 6.4.DNPMD DNPMD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	222	22			
Non-MDUFA III Decisions	19	0			
MDUFA III Decisions (SE/NSE)	127	0			
MDUFA III Decisions within 90 FDA Days	125	0			
510(k)s pending MDUFA III Decision	76	22			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	98%	n/a			

**Table 6.5.DNPMD DNPMD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.83	0.00			
Number with MDUFA decision	127	0			
<b>Average FDA days to MDUFA III decision</b>	81				
20th Percentile FDA days to MDUFA III decision	70				
40th Percentile FDA days to MDUFA III decision	88				
60th Percentile FDA days to MDUFA III decision	89				
80th Percentile FDA days to MDUFA III decision	90				
Maximum FDA days to MDUFA III decision	148				
<b>Average Industry days to MDUFA III decision</b>	53				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	22				
60th Percentile Industry days to MDUFA III decision	52				
80th Percentile Industry days to MDUFA III decision	93				
Maximum Industry days to MDUFA III decision	180				
<b>Average Total days to MDUFA III decision</b>	134				
20th Percentile Total days to MDUFA III decision	88				
40th Percentile Total days to MDUFA III decision	108				
60th Percentile Total days to MDUFA III decision	133				
80th Percentile Total days to MDUFA III decision	182				
Maximum Total days to MDUFA III decision	270				

**Table 6.6.DNPMD DNPMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	222	22			
Number with MDUFA decision	127	0			
Number of SE decisions	120	0			
Number of NSE decisions	7	0			
Number of Withdrawals	9	0			
Number deleted	5	0			
Rate of SE decisions	94%	n/a			
Rate of NSE decisions	6%	n/a			
Rate of Withdrawals	4%	n/a			
Rate of Deleted	2%	n/a			

**Table 6.7.DNPMD DNPMD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0			
Mean FDA days for submissions that missed goal	120				
Mean Industry days for submissions that missed goal	86				

**Table 6.1.DOD DOD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	523	163			
Closed before RTA action	0	0			
Number Accepted	181	55			
RTA Review not done and > 15 days since Date Received	0	2			
RTA Review not done and <= 15 days since Date Received	0	21			
Number Not Accepted	342	85			
Rate of submissions not accepted	65%	60%			

\* RTA was not in place 1st quarter, thus Table 6.1.DOD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DOD DOD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	647	103			
Deleted or withdrawn prior to SI	3	0			
SI within 60 FDA days	603	41			
SI over 60 FDA days	28	0			
SI pending within 60 FDA days	13	62			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	96%	100%			

**Table 6.3.DOD DOD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	631	41			
Average number of FDA days to Substantive Interaction	48	36			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	30	26			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	48	29			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	36			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	52			
Maximum FDA days to Substantive Interaction	88	59			

**Table 6.4.DOD DOD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	648	103			
Non-MDUFA III Decisions	42	0			
MDUFA III Decisions (SE/NSE)	492	15			
MDUFA III Decisions within 90 FDA Days	489	15			
510(k)s pending MDUFA III Decision	114	88			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 6.5.DOD DOD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.55	1.00			
Number with MDUFA decision	492	15			
<b>Average FDA days to MDUFA III decision</b>	67	30			
20th Percentile FDA days to MDUFA III decision	44	24			
40th Percentile FDA days to MDUFA III decision	63	27			
60th Percentile FDA days to MDUFA III decision	82	28			
80th Percentile FDA days to MDUFA III decision	88	31			
Maximum FDA days to MDUFA III decision	100	56			
<b>Average Industry days to MDUFA III decision</b>	28	0			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	19	0			
80th Percentile Industry days to MDUFA III decision	48	0			
Maximum Industry days to MDUFA III decision	211	0			
<b>Average Total days to MDUFA III decision</b>	95	30			
20th Percentile Total days to MDUFA III decision	44	24			
40th Percentile Total days to MDUFA III decision	76	27			
60th Percentile Total days to MDUFA III decision	98	28			
80th Percentile Total days to MDUFA III decision	130	31			
Maximum Total days to MDUFA III decision	293	56			

**Table 6.6.DOD DOD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	648	103			
Number with MDUFA decision	492	15			
Number of SE decisions	480	15			
Number of NSE decisions	12	0			
Number of Withdrawals	23	0			
Number deleted	18	0			
Rate of SE decisions	98%	100%			
Rate of NSE decisions	2%	0%			
Rate of Withdrawals	4%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.DOD DOD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3	0			
Mean FDA days for submissions that missed goal	96				
Mean Industry days for submissions that missed goal	103				

**Table 6.1.DOED DOED – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	118	34			
Closed before RTA action	0	0			
Number Accepted	59	17			
RTA Review not done and > 15 days since Date Received	5	0			
RTA Review not done and <= 15 days since Date Received	0	5			
Number Not Accepted	54	12			
Rate of submissions not accepted	46%	41%			

\* RTA was not in place 1st quarter, thus Table 6.1.DOED for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DOED DOED – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	135	21			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	128	11			
SI over 60 FDA days	5	0			
SI pending within 60 FDA days	2	10			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	96%	100%			

**Table 6.3.DOE DOED – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	133	11			
Average number of FDA days to Substantive Interaction	48	47			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	42	30			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	48	45			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	53	56			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	57	57			
Maximum FDA days to Substantive Interaction	88	60			

**Table 6.4.DOE DOED – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	142	21			
Non-MDUFA III Decisions	14	0			
MDUFA III Decisions (SE/NSE)	94	3			
MDUFA III Decisions within 90 FDA Days	91	3			
510(k)s pending MDUFA III Decision	34	18			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	97%	100%			

**Table 6.5.DOE DOED – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.78	1.00			
Number with MDUFA decision	94	3			
<b>Average FDA days to MDUFA III decision</b>	72	38			
20th Percentile FDA days to MDUFA III decision	53	28			
40th Percentile FDA days to MDUFA III decision	73	29			
60th Percentile FDA days to MDUFA III decision	87	35			
80th Percentile FDA days to MDUFA III decision	89	46			
Maximum FDA days to MDUFA III decision	91	56			
<b>Average Industry days to MDUFA III decision</b>	43	0			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	10	0			
60th Percentile Industry days to MDUFA III decision	34	0			
80th Percentile Industry days to MDUFA III decision	72	0			
Maximum Industry days to MDUFA III decision	182	0			
<b>Average Total days to MDUFA III decision</b>	115	38			
20th Percentile Total days to MDUFA III decision	58	28			
40th Percentile Total days to MDUFA III decision	90	29			
60th Percentile Total days to MDUFA III decision	119	35			
80th Percentile Total days to MDUFA III decision	152	46			
Maximum Total days to MDUFA III decision	272	56			

**Table 6.6.DOE DOED – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	142	21			
Number with MDUFA decision	94	3			
Number of SE decisions	92	3			
Number of NSE decisions	2	0			
Number of Withdrawals	6	0			
Number deleted	7	0			
Rate of SE decisions	98%	100%			
Rate of NSE decisions	2%	0%			
Rate of Withdrawals	4%	0%			
Rate of Deleted	5%	0%			

**Table 6.7.DOE DOED – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3	0			
Mean FDA days for submissions that missed goal	91				
Mean Industry days for submissions that missed goal	123				

**Table 6.1.DRGUD DRGUD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	211	75			
Closed before RTA action	0	1			
Number Accepted	66	28			
RTA Review not done and > 15 days since Date Received	0	1			
RTA Review not done and <= 15 days since Date Received	0	17			
Number Not Accepted	145	28			
Rate of submissions not accepted	69%	49%			

\* RTA was not in place 1st quarter, thus Table 6.1.DRGUD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DRGUD DRGUD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	251	40			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	232	15			
SI over 60 FDA days	8	0			
SI pending within 60 FDA days	8	24			
SI pending over 60 FDA days	0	1			
510(k)s NSE without SI	2	0			
Current SI Performance Percent within 60 FDA days	96%	94%			

**Table 6.3.DRGUD DRGUD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	240	15			
Average number of FDA days to Substantive Interaction	47	39			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	33	24			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	49	30			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	55	53			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	57			
Maximum FDA days to Substantive Interaction	73	60			

**Table 6.4.DRGUD DRGUD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	264	42			
Non-MDUFA III Decisions	20	1			
MDUFA III Decisions (SE/NSE)	170	3			
MDUFA III Decisions within 90 FDA Days	170	3			
510(k)s pending MDUFA III Decision	74	38			
510(k) pending MDUFA III Decision over 90 FDA days	1	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 6.5.DRGUD DRGUD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.79	1.33			
Number with MDUFA decision	170	3			
<b>Average FDA days to MDUFA III decision</b>	66	25			
20th Percentile FDA days to MDUFA III decision	39	15			
40th Percentile FDA days to MDUFA III decision	64	21			
60th Percentile FDA days to MDUFA III decision	83	28			
80th Percentile FDA days to MDUFA III decision	87	35			
Maximum FDA days to MDUFA III decision	90	43			
<b>Average Industry days to MDUFA III decision</b>	48	4			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	15	0			
60th Percentile Industry days to MDUFA III decision	38	3			
80th Percentile Industry days to MDUFA III decision	92	8			
Maximum Industry days to MDUFA III decision	274	13			
<b>Average Total days to MDUFA III decision</b>	114	30			
20th Percentile Total days to MDUFA III decision	55	15			
40th Percentile Total days to MDUFA III decision	87	21			
60th Percentile Total days to MDUFA III decision	119	30			
80th Percentile Total days to MDUFA III decision	170	43			
Maximum Total days to MDUFA III decision	362	56			

**Table 6.6.DRGUD DRGUD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	264	42			
Number with MDUFA decision	170	3			
Number of SE decisions	159	3			
Number of NSE decisions	11	0			
Number of Withdrawals	11	0			
Number deleted	8	0			
Rate of SE decisions	94%	100%			
Rate of NSE decisions	6%	0%			
Rate of Withdrawals	4%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.DRGUD DRGUD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 6.1.DSD DSD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	375	108			
Closed before RTA action	3	0			
Number Accepted	136	32			
RTA Review not done and > 15 days since Date Received	3	0			
RTA Review not done and <= 15 days since Date Received	0	22			
Number Not Accepted	233	54			
Rate of submissions not accepted	63%	63%			

\* RTA was not in place 1st quarter, thus Table 6.1.DSD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DSD DSD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	457	56			
Deleted or withdrawn prior to SI	3	0			
SI within 60 FDA days	403	24			
SI over 60 FDA days	40	0			
SI pending within 60 FDA days	11	31			
SI pending over 60 FDA days	0	1			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	91%	96%			

**Table 6.3.DSD DSD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	443	24			
Average number of FDA days to Substantive Interaction	45	38			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	27	27			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	43	30			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	55	46			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	50			
Maximum FDA days to Substantive Interaction	90	57			

**Table 6.4.DSD DSD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	465	57			
Non-MDUFA III Decisions	46	0			
MDUFA III Decisions (SE/NSE)	304	11			
MDUFA III Decisions within 90 FDA Days	301	11			
510(k)s pending MDUFA III Decision	115	46			
510(k) pending MDUFA III Decision over 90 FDA days	2	0			
Current Performance Percent within 90 FDA Days	98%	100%			

**Table 6.5.DSD DSD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.68	1.09			
Number with MDUFA decision	304	11			
<b>Average FDA days to MDUFA III decision</b>	62	32			
20th Percentile FDA days to MDUFA III decision	30	21			
40th Percentile FDA days to MDUFA III decision	58	26			
60th Percentile FDA days to MDUFA III decision	79	29			
80th Percentile FDA days to MDUFA III decision	87	45			
Maximum FDA days to MDUFA III decision	150	51			
<b>Average Industry days to MDUFA III decision</b>	40	1			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	8	0			
60th Percentile Industry days to MDUFA III decision	28	0			
80th Percentile Industry days to MDUFA III decision	74	0			
Maximum Industry days to MDUFA III decision	298	13			
<b>Average Total days to MDUFA III decision</b>	102	33			
20th Percentile Total days to MDUFA III decision	37	21			
40th Percentile Total days to MDUFA III decision	74	26			
60th Percentile Total days to MDUFA III decision	109	29			
80th Percentile Total days to MDUFA III decision	150	50			
Maximum Total days to MDUFA III decision	396	58			

**Table 6.6.DSD DSD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	465	57			
Number with MDUFA decision	304	11			
Number of SE decisions	294	11			
Number of NSE decisions	10	0			
Number of Withdrawals	26	0			
Number deleted	15	0			
Rate of SE decisions	97%	100%			
Rate of NSE decisions	3%	0%			
Rate of Withdrawals	6%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.DSD DSD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3	0			
Mean FDA days for submissions that missed goal	114				
Mean Industry days for submissions that missed goal	112				

**Table 6.1.DCTD DCTD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	188	51			
Closed before RTA action	1	0			
Number Accepted	118	30			
RTA Review not done and > 15 days since Date Received	0	1			
RTA Review not done and <= 15 days since Date Received	0	6			
Number Not Accepted	69	14			
Rate of submissions not accepted	37%	31%			

\* RTA was not in place 1st quarter, thus Table 6.1.DCTD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DCTD DCTD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	243	35			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	242	16			
SI over 60 FDA days	0	0			
SI pending within 60 FDA days	1	19			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	100%	100%			

**Table 6.3.DCTD DCTD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	242	16			
Average number of FDA days to Substantive Interaction	41	35			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	28	25			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	38	28			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	45	39			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	52	50			
Maximum FDA days to Substantive Interaction	60	54			

**Table 6.4.DCTD DCTD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	243	35			
Non-MDUFA III Decisions	13	0			
MDUFA III Decisions (SE/NSE)	165	3			
MDUFA III Decisions within 90 FDA Days	164	3			
510(k)s pending MDUFA III Decision	65	32			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 6.5.DCTD DCTD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.63	1.00			
Number with MDUFA decision	165	3			
<b>Average FDA days to MDUFA III decision</b>	59	27			
20th Percentile FDA days to MDUFA III decision	30	26			
40th Percentile FDA days to MDUFA III decision	49	27			
60th Percentile FDA days to MDUFA III decision	77	28			
80th Percentile FDA days to MDUFA III decision	86	28			
Maximum FDA days to MDUFA III decision	99	28			
<b>Average Industry days to MDUFA III decision</b>	46	0			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	32	0			
80th Percentile Industry days to MDUFA III decision	87	0			
Maximum Industry days to MDUFA III decision	307	0			
<b>Average Total days to MDUFA III decision</b>	105	27			
20th Percentile Total days to MDUFA III decision	30	26			
40th Percentile Total days to MDUFA III decision	54	27			
60th Percentile Total days to MDUFA III decision	105	28			
80th Percentile Total days to MDUFA III decision	168	28			
Maximum Total days to MDUFA III decision	395	28			

**Table 6.6.DCTD DCTD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	243	35			
Number with MDUFA decision	165	3			
Number of SE decisions	162	3			
Number of NSE decisions	3	0			
Number of Withdrawals	9	0			
Number deleted	4	0			
Rate of SE decisions	98%	100%			
Rate of NSE decisions	2%	0%			
Rate of Withdrawals	4%	0%			
Rate of Deleted	2%	0%			

**Table 6.7.DCTD DCTD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	99				
Mean Industry days for submissions that missed goal	193				

**Table 6.1.DIHD DIHD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	73	18			
Closed before RTA action	1	0			
Number Accepted	52	8			
RTA Review not done and > 15 days since Date Received	3	0			
RTA Review not done and <= 15 days since Date Received	0	3			
Number Not Accepted	17	7			
Rate of submissions not accepted	24%	47%			

\* RTA was not in place 1st quarter, thus Table 6.1.DIHD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DIHD DIHD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	86	8			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	83	3			
SI over 60 FDA days	1	0			
SI pending within 60 FDA days	2	5			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	99%	100%			

**Table 6.3.DIHD DIHD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	84	3			
Average number of FDA days to Substantive Interaction	48	42			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	41	31			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	50	41			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	55	48			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	53			
Maximum FDA days to Substantive Interaction	63	58			

**Table 6.4.DIHD DIHD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	86	8			
Non-MDUFA III Decisions	17	0			
MDUFA III Decisions (SE/NSE)	40	0			
MDUFA III Decisions within 90 FDA Days	40	0			
510(k)s pending MDUFA III Decision	29	8			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	n/a			

**Table 6.5.DIHD DIHD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.88	0.00			
Number with MDUFA decision	40	0			
<b>Average FDA days to MDUFA III decision</b>	69				
20th Percentile FDA days to MDUFA III decision	49				
40th Percentile FDA days to MDUFA III decision	74				
60th Percentile FDA days to MDUFA III decision	83				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	90				
<b>Average Industry days to MDUFA III decision</b>	94				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	55				
60th Percentile Industry days to MDUFA III decision	129				
80th Percentile Industry days to MDUFA III decision	169				
Maximum Industry days to MDUFA III decision	253				
<b>Average Total days to MDUFA III decision</b>	164				
20th Percentile Total days to MDUFA III decision	77				
40th Percentile Total days to MDUFA III decision	118				
60th Percentile Total days to MDUFA III decision	215				
80th Percentile Total days to MDUFA III decision	255				
Maximum Total days to MDUFA III decision	328				

**Table 6.6.DIHD DIHD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	86	8			
Number with MDUFA decision	40	0			
Number of SE decisions	36	0			
Number of NSE decisions	4	0			
Number of Withdrawals	2	0			
Number deleted	13	0			
Rate of SE decisions	90%	n/a			
Rate of NSE decisions	10%	n/a			
Rate of Withdrawals	2%	n/a			
Rate of Deleted	15%	n/a			

**Table 6.7.DIHD DIHD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 6.1.DMD DMD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	21			
Closed before RTA action	0	0			
Number Accepted	55	17			
RTA Review not done and > 15 days since Date Received	0	0			
RTA Review not done and <= 15 days since Date Received	0	4			
Number Not Accepted	4	0			
Rate of submissions not accepted	7%	0%			

\* RTA was not in place 1st quarter, thus Table 6.1.DMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DMD DMD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	80	17			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	79	10			
SI over 60 FDA days	1	0			
SI pending within 60 FDA days	0	7			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	99%	100%			

**Table 6.3.DMD DMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	80	10			
Average number of FDA days to Substantive Interaction	43	31			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	28	25			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	39	28			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	53	28			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	57	31			
Maximum FDA days to Substantive Interaction	61	59			

**Table 6.4.DMD DMD – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	80	17			
Non-MDUFA III Decisions	4	0			
MDUFA III Decisions (SE/NSE)	66	7			
MDUFA III Decisions within 90 FDA Days	66	7			
510(k)s pending MDUFA III Decision	10	10			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 6.5.DMD DMD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.26	1.00			
Number with MDUFA decision	66	7			
<b>Average FDA days to MDUFA III decision</b>	57	28			
20th Percentile FDA days to MDUFA III decision	29	25			
40th Percentile FDA days to MDUFA III decision	42	27			
60th Percentile FDA days to MDUFA III decision	76	29			
80th Percentile FDA days to MDUFA III decision	81	29			
Maximum FDA days to MDUFA III decision	89	36			
<b>Average Industry days to MDUFA III decision</b>	26	0			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	0	0			
80th Percentile Industry days to MDUFA III decision	48	0			
Maximum Industry days to MDUFA III decision	175	0			
<b>Average Total days to MDUFA III decision</b>	83	28			
20th Percentile Total days to MDUFA III decision	29	25			
40th Percentile Total days to MDUFA III decision	47	27			
60th Percentile Total days to MDUFA III decision	80	28			
80th Percentile Total days to MDUFA III decision	122	29			
Maximum Total days to MDUFA III decision	256	36			

**Table 6.6.DMD DMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	80	17			
Number with MDUFA decision	66	7			
Number of SE decisions	66	7			
Number of NSE decisions	0	0			
Number of Withdrawals	2	0			
Number deleted	2	0			
Rate of SE decisions	100%	100%			
Rate of NSE decisions	0%	0%			
Rate of Withdrawals	3%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.DMD DMD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 6.1.DRH DRH – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	257	102			
Closed before RTA action	0	0			
Number Accepted	151	50			
RTA Review not done and > 15 days since Date Received	15	0			
RTA Review not done and <= 15 days since Date Received	0	13			
Number Not Accepted	91	39			
Rate of submissions not accepted	35%	44%			

\* RTA was not in place 1st quarter, thus Table 6.1.DRH for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DRH DRH – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	340	62			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	294	25			
SI over 60 FDA days	41	0			
SI pending within 60 FDA days	4	36			
SI pending over 60 FDA days	0	1			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	88%	96%			

**Table 6.3.DRH DRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	335	25			
Average number of FDA days to Substantive Interaction	47	42			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	31	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	44	38			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	46			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	56			
Maximum FDA days to Substantive Interaction	91	60			

**Table 6.4.DRH DRH – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	394	71			
Non-MDUFA III Decisions	9	0			
MDUFA III Decisions (SE/NSE)	331	14			
MDUFA III Decisions within 90 FDA Days	327	14			
510(k)s pending MDUFA III Decision	54	57			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 6.5.DRH DRH – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.50	1.14			
Number with MDUFA decision	331	14			
<b>Average FDA days to MDUFA III decision</b>	59	34			
20th Percentile FDA days to MDUFA III decision	31	29			
40th Percentile FDA days to MDUFA III decision	52	30			
60th Percentile FDA days to MDUFA III decision	73	33			
80th Percentile FDA days to MDUFA III decision	87	45			
Maximum FDA days to MDUFA III decision	121	49			
<b>Average Industry days to MDUFA III decision</b>	24	1			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	12	0			
80th Percentile Industry days to MDUFA III decision	40	0			
Maximum Industry days to MDUFA III decision	339	13			
<b>Average Total days to MDUFA III decision</b>	84	35			
20th Percentile Total days to MDUFA III decision	34	29			
40th Percentile Total days to MDUFA III decision	63	31			
60th Percentile Total days to MDUFA III decision	85	34			
80th Percentile Total days to MDUFA III decision	114	45			
Maximum Total days to MDUFA III decision	429	49			

**Table 6.6.DRH DRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	394	71			
Number with MDUFA decision	331	14			
Number of SE decisions	325	14			
Number of NSE decisions	6	0			
Number of Withdrawals	7	0			
Number deleted	2	0			
Rate of SE decisions	98%	100%			
Rate of NSE decisions	2%	0%			
Rate of Withdrawals	2%	0%			
Rate of Deleted	1%	0%			

**Table 6.7.DRH DRH – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	0			
Mean FDA days for submissions that missed goal	105				
Mean Industry days for submissions that missed goal	75				

## **Section 7 510(k) Annual General Metrics**

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

**Section 8 Annual Metrics for De Novo Requests**

## Annual Metrics for De Novo Requests – Center Level

**Table 8.1 CDRH – Annual General Metric Report for *De Novo* Requests**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of <i>De Novo</i> Requests Received	46				
Number of <i>De Novo</i> Requests with Decision	20				
Number of <i>De Novo</i> Requests with Decision Pending	26				
Average Number of Days to Decision	103				

**Section 9 Pre-Submissions**

## Pre-Submissions – Center Level

**Table 9.1 CDRH – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	1781	451			
Number requesting a meeting or teleconference	973	260			
Number with meetings or teleconferences held	960	52			
Average days to meeting	59	46			
20 <sup>th</sup> Percentile days to meeting	38	30			
40 <sup>th</sup> Percentile days to meeting	55	45			
60 <sup>th</sup> Percentile days to meeting	66	53			
80 <sup>th</sup> Percentile days to meeting	77	60			
Maximum days to meeting	183	76			

## Pre-Submissions – Office Level

**Table 9.1.ODE ODE – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	983	292			
Number requesting a meeting or teleconference	613	192			
Number with meetings or teleconferences held	451	32			
Average days to meeting	62	47			
20 <sup>th</sup> Percentile days to meeting	40	36			
40 <sup>th</sup> Percentile days to meeting	57	49			
60 <sup>th</sup> Percentile days to meeting	68	54			
80 <sup>th</sup> Percentile days to meeting	79	60			
Maximum days to meeting	183	72			

**Table 9.1.OIR OIR – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	798	159			
Number requesting a meeting or teleconference	360	68			
Number with meetings or teleconferences held	299	20			
Average days to meeting	55	43			
20 <sup>th</sup> Percentile days to meeting	37	26			
40 <sup>th</sup> Percentile days to meeting	53	41			
60 <sup>th</sup> Percentile days to meeting	63	51			
80 <sup>th</sup> Percentile days to meeting	71	63			
Maximum days to meeting	138	76			

## Pre-Submissions – Division Level

**Table 9.1.DAGRID      DAGRID – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	156	51			
Number requesting a meeting or teleconference	82	27			
Number with meetings or teleconferences held	59	6			
Average days to meeting	69	38			
20 <sup>th</sup> Percentile days to meeting	52	29			
40 <sup>th</sup> Percentile days to meeting	66	37			
60 <sup>th</sup> Percentile days to meeting	75	45			
80 <sup>th</sup> Percentile days to meeting	85	53			
Maximum days to meeting	121	55			

**Table 9.1.DCD DCD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	308	92			
Number requesting a meeting or teleconference	215	66			
Number with meetings or teleconferences held	173	17			
Average days to meeting	56	47			
20 <sup>th</sup> Percentile days to meeting	35	37			
40 <sup>th</sup> Percentile days to meeting	49	45			
60 <sup>th</sup> Percentile days to meeting	61	52			
80 <sup>th</sup> Percentile days to meeting	74	58			
Maximum days to meeting	134	68			

**Table 9.1.DNPMD DNPMD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	79	25			
Number requesting a meeting or teleconference	51	17			
Number with meetings or teleconferences held	31	1			
Average days to meeting	71	59			
20 <sup>th</sup> Percentile days to meeting	47	59			
40 <sup>th</sup> Percentile days to meeting	64	59			
60 <sup>th</sup> Percentile days to meeting	77	59			
80 <sup>th</sup> Percentile days to meeting	91	59			
Maximum days to meeting	163	59			

**Table 9.1.DOD DOD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	98	33			
Number requesting a meeting or teleconference	61	25			
Number with meetings or teleconferences held	37	3			
Average days to meeting	61	59			
20 <sup>th</sup> Percentile days to meeting	45	52			
40 <sup>th</sup> Percentile days to meeting	58	57			
60 <sup>th</sup> Percentile days to meeting	69	62			
80 <sup>th</sup> Percentile days to meeting	80	67			
Maximum days to meeting	129	72			

**Table 9.1.DOED DOED – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	87	21			
Number requesting a meeting or teleconference	49	17			
Number with meetings or teleconferences held	35	3			
Average days to meeting	66	45			
20 <sup>th</sup> Percentile days to meeting	53	30			
40 <sup>th</sup> Percentile days to meeting	64	45			
60 <sup>th</sup> Percentile days to meeting	70	55			
80 <sup>th</sup> Percentile days to meeting	83	60			
Maximum days to meeting	118	66			

**Table 9.1.DRGUD DRGUD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	131	34			
Number requesting a meeting or teleconference	76	19			
Number with meetings or teleconferences held	60	2			
Average days to meeting	60	56			
20 <sup>th</sup> Percentile days to meeting	48	53			
40 <sup>th</sup> Percentile days to meeting	61	55			
60 <sup>th</sup> Percentile days to meeting	68	57			
80 <sup>th</sup> Percentile days to meeting	72	59			
Maximum days to meeting	133	61			

**Table 9.1.DSD DSD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	124	36			
Number requesting a meeting or teleconference	79	21			
Number with meetings or teleconferences held	56	0			
Average days to meeting	61	n/a			
20 <sup>th</sup> Percentile days to meeting	37	n/a			
40 <sup>th</sup> Percentile days to meeting	63	n/a			
60 <sup>th</sup> Percentile days to meeting	71	n/a			
80 <sup>th</sup> Percentile days to meeting	83	n/a			
Maximum days to meeting	183	n/a			

**Table 9.1.DCTD DCTD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	219	30			
Number requesting a meeting or teleconference	107	11			
Number with meetings or teleconferences held	91	5			
Average days to meeting	51	39			
20 <sup>th</sup> Percentile days to meeting	36	30			
40 <sup>th</sup> Percentile days to meeting	49	35			
60 <sup>th</sup> Percentile days to meeting	59	41			
80 <sup>th</sup> Percentile days to meeting	68	46			
Maximum days to meeting	90	51			

**Table 9.1.DIHD DIHD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	275	67			
Number requesting a meeting or teleconference	149	36			
Number with meetings or teleconferences held	124	11			
Average days to meeting	62	47			
20 <sup>th</sup> Percentile days to meeting	43	20			
40 <sup>th</sup> Percentile days to meeting	58	52			
60 <sup>th</sup> Percentile days to meeting	69	63			
80 <sup>th</sup> Percentile days to meeting	83	70			
Maximum days to meeting	138	76			

**Table 9.1.DMD DMD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	234	53			
Number requesting a meeting or teleconference	59	14			
Number with meetings or teleconferences held	49	1			
Average days to meeting	53	56			
20 <sup>th</sup> Percentile days to meeting	42	56			
40 <sup>th</sup> Percentile days to meeting	51	56			
60 <sup>th</sup> Percentile days to meeting	61	56			
80 <sup>th</sup> Percentile days to meeting	67	56			
Maximum days to meeting	81	56			

**Table 9.1.DRH DRH – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	70	9			
Number requesting a meeting or teleconference	46	7			
Number with meetings or teleconferences held	35	3			
Average days to meeting	45	33			
20 <sup>th</sup> Percentile days to meeting	31	22			
40 <sup>th</sup> Percentile days to meeting	42	35			
60 <sup>th</sup> Percentile days to meeting	56	43			
80 <sup>th</sup> Percentile days to meeting	63	46			
Maximum days to meeting	71	48			

## **Section 10      CLIA Waiver Annual Metrics**

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

## **Section 11      Investigational Device Exemptions (IDEs)**

## IDEs – Center Level

Table 11.1 CDRH - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	66			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

## IDEs – Office Level

Table 11.1.ODE ODE - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	47			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

Table 11.1.OIR OIR - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	19			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

## IDEs – Division Level

Table 11.1.DAGRID DAGRID - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	1			
Average number of cycles to approval to or conditional approval of the IDE	n/a	n/a			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	n/a			

Table 11.1.DCD DCD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	12			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

Table 11.1.DNPMD DNPMD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	11			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

**Table 11.1.DOD DOD - IDE Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of IDEs received	n/a	3			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

**Table 11.1.DOED DOED - IDE Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of IDEs received	n/a	8			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

**Table 11.1.DRGUD DRGUD - IDE Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of IDEs received	n/a	8			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

**Table 11.1.DSD DSD - IDE Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
<b>Number of IDEs received</b>	<b>n/a</b>	<b>4</b>			
<b>Average number of cycles to approval to or conditional approval of the IDE</b>	<b>n/a</b>	<b>1</b>			
<b>Average number of amendments prior to approval or conditional approval of the IDE</b>	<b>n/a</b>	<b>0</b>			

Table 11.1.DCTD DCTD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	8			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

Table 11.1.DIHD DIHD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	7			
Average number of cycles to approval to or conditional approval of the IDE	n/a	1			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	0			

Table 11.1.DMD DMD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	0			
Average number of cycles to approval to or conditional approval of the IDE	n/a	n/a			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	n/a			

Table 11.1.DRH DRH - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	n/a	4			
Average number of cycles to approval to or conditional approval of the IDE	n/a	n/a			
Average number of amendments prior to approval or conditional approval of the IDE	n/a	n/a			

## 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 (see definition for the Received cohort above).
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 (see definition for the Received cohort above).
2	Number Accepted <sup>#</sup>	Number Received (line 1) that got "RTA Accepted" (RTAA), RTAX, 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).

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013

**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 within 90 FDA days	Number of submissions with SI action within 90 FDA days.
3	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days.
4	SI pending within 90 FDA days	Number of submissions that are under review for not more than 90 FDA days and with no SI.
5	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no SI.
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 within 90 FDA days	Number of submissions with SI within 90 FDA days (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 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> 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 III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 180 FDA Days	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision over 180 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III 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 III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 320 FDA Days	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision over 320 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 320 FDA Days	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III 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 III 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 III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> 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 III 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 III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> 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 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	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

**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	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	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 III 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 III 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).

## 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. See definition of the received cohort above.
2	SI within 90 FDA days	Number of submissions with an SI action taken within 90 FDA days.
3	SI over 90 FDA days	Number of submissions with an SI action taken in more than 90 FDA days.
4	SI pending within 90 FDA days	Submissions that are under review for not more than 90 FDA days and that do not have an SI.
5	SI pending over 90 FDA days	Submissions that are under review for more than 90 FDA days and that do not have an SI.
6	Closed without SI	Number of submissions that are closed with a MDUFA or NON-MDUFA decision but without an SI.
7	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within 90 FDA days (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 III Decisions	Supplements received (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA III Decisions	Supplements received (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 180 FDA Days	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	Supplements pending MDUFA III Decision	Number of supplements received (line 1) that do not have a MDUFA III decision or a final decision.
6	Supplements pending MDUFA III Decision over 180 FDA days	Number of supplements pending MDUFA III Decision (line 5) for more than allowed number of FDA Days. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent within 180 FDA Days	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III 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 (line 2).

**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 III 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. See the Received cohort definition above.
2	Non-MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions within 90 FDA Days	Submissions with MDUFA III decisions (line 3) made in less than or equal to 90 FDA days.
5	Supplements pending MDUFA III Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA III decision and are not closed with a final decision.
6	Supplements pending MDUFA III Decision over 90 FDA days	Number of supplements pending MDUFA III Decision (line 5) for more than 90 FDA Days. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent within 90 FDA Days	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III 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 PMA (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) – Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non-Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority 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 III decision and 5% of submissions with the highest number of Total Days to MDUFA III 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 FY20111 and FY2012 Total Time to MDUFA II (two) decision will be used.

## Section 6 510(k) MDUFA III Performance

**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. See definition for received cohort above. Third party reviews shall be excluded from this table.
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 got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	RTA Review not done and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN or RTAS) 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	RTA Review not done 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 "Refuse to accept" decision in the first RTA review cycle.
7	Rate of submissions not accepted	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 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions with RTA review accepted in this fiscal year (RTAA, RTAX, RTAN, or RTAS.). Third party 510(k) submissions are excluded from SI performance report.
2	510(k) withdrawn or deleted prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made before or on the cutoff date and before any SI action: WD, DD, DE, HD, K4, NR, RC, RD .
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 under review for not more than 60 FDA days and that do not have an SI.
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 (or with an AN, DN, or ON decision where Date Received does not equal Date Final 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) 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 6.3 and Tables 6.3.x****510(k) Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of 510(k) submissions accepted in this fiscal year that had an SI. Third party 510(k) submissions shall be excluded from this report.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all 510(k) submissions with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 6.4 and Tables 6.4.x****510(k) MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions accepted in this fiscal year. Third party 510(k) shall also be included into this report.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not SE or NSE).
3	MDUFA III Decisions (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA III decision (SE or NSE).
4	MDUFA III Decisions within 90 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA III Decision over 90 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 90 FDA Days	Number of submissions with MDUFA III Decisions within 90 FDA Days (line 4) divided by the total number of submissions with MDUFA III 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 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 III Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

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

#	Measure	Description
1	Number Accepted	Number of 510(k) submissions accepted in this fiscal year. See definition for Accepted cohort above.
2	Number with MDUFA decision	Number submissions accepted (line 1) that also had a MDUFA decision.
3	Number of SE decisions	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE decisions	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) and closed with Withdrawal (WD) final decision.
6	Number deleted	Number of submissions accepted (line 1) and closed with Delete (DE) final decision.
7	Rate of SE decisions	Number of SE decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of NSE decisions	Number of NSE decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number Received (line 1).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number Received (line 1).

**Table 6.7 and Tables 6.7.x****510(k) Performance Metrics – Submissions Missing Performance Goals - 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. Third Party 510(k) submissions shall also be included into this report.
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).

## Section 7 510(k) Annual General Metrics

**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. Third party 510(k) submissions shall also be included into this count.
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. Third-party 510(k) submissions shall also be included into this report.
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 decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA III Decision	Total number of 510(k) submissions accepted (line 1) that had a MDUFA III decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) divided by the total of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA III decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA III Decision (line 4) excluding 2% of submissions with the lowest number of Total Days to MDUFA III decision and 2% of submissions with the highest number of Total Days to MDUFA III decision.
7	Average Total Time to MDUFA III decision	Average Total Time (FDA and Industry) to MDUFA decision. If the cohort is not closed (less than 99% of 510(k) submissions have a decision) "N/A" shall be displayed instead.

## Section 8 Annual Metrics for De Novo Requests

**Table 8.1 CDRH – Annual General Metric Report for *De Novo* Requests - Definitions**

#	Measure	Description
1	Number of <i>De Novo</i> Requests Received	Total number of <i>de novo</i> requests received in this fiscal year as of the report cutoff date.
2	Number of <i>De Novo</i> Requests with Decision	Number of <i>de novo</i> requests received (line 1) which also have a final decision (AN, DN, or ON) as of the report cutoff date.
3	Number of <i>De Novo</i> Requests with Decision Pending	Number <i>de novo</i> requests received (line 1) which do not have a final decision (AN, DN, or ON) as of the report cutoff date.
4	Average Number of Days to Decision	Average total number of days to decision (days between <i>De Novo</i> Date Received and <i>De Novo</i> Decision Date) for <i>de novo</i> requests with Decision (line 2).

## Section 9 Pre-Submissions

Table 9.1 and Tables 9.1.x Pre-Submissions Performance Metrics - Definitions

#	Measure	Description
1	Number of all qualified Pre-Submissions received	Number of all qualified Pre-Submissions received. This include those with a type="pre-sub" either with a meeting request or written feedback requested in the fiscal year.
2	Number requesting a meeting or teleconference	Number of qualified Pre-submission received (line 1) with the Sub-Type of "Pre-Sub Meeting Request".
3	Number with meetings or teleconferences held	Number requesting a meeting or teleconference (line 2) with Actual Meeting Date populated with a value prior to the cutoff date.
4	Days to meeting	Table shall show average days from Date FDA Initial Clock Start to Actual Meeting Date as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for days to meeting days, Industry days, and Total days. The calculation includes meetings where the Actual Meeting Date is greater than the Date FDA Initial Clock Start and the Actual Meeting Date is prior to as of the cutoff date.

## Section 10 CLIA Waiver Annual Metrics

**Table 10.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Deleted or withdrawn prior to SI	Number of submissions with MDUFA Decision WTDR 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	Number of submissions that are under review for not more than 90 FDA days and with no SI
6	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no 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 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1)

**Table 10.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications 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 CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 10.3 CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals) – Definitions**

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 180 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 180 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 180 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA III Decisions within 180 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 10.4 CLIA Waiver (with Panel Review) MDUFA Decision Performance Goals) – Definitions**

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 330 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 330 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 10.5 CLIA Waiver (without Panel Review) Time to MDUFA Decision – Definitions**

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

**Table 10.6 CLIA Waiver (with Panel Review) Time to MDUFA Decision - Definitions**

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

## Section 11 IDE Performance Metrics

Table 11.1 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.

**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA III CBER Performance Data ----  
Action through 31 December 2013**

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

**Table 1.1 CBER – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	1			
Closed before RTA action	0	0			
Number Accepted	1	1			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0.0%	0.0%			
Completed RTF	0	0			
Number Not Filed	0	1			
Rate of submissions Not Filed	0.0%	100.0%			

**Table 1.2 CBER – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	1	1			
SI within 90 FDA days	0	0			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	1			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	0.0%	0.0%			

**Table 1.3 CBER – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1	0			
Average number of FDA days to Substantive Interaction	101	0			
20th Percentile FDA days to Substantive Interaction	101	0			

40th Percentile FDA days to Substantive Interaction	101	0			
60th Percentile FDA days to Substantive Interaction	101	0			
80th Percentile FDA days to Substantive Interaction	101	0			
Maximum FDA days to Substantive Interaction	101	0			

**Table 1.4 CBER – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	1			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	0.0%	0.0%			

**Table 1.5 CBER – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	0.0%	0.0%			

**Table 1.6 CBER – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA III decision	0	0			

<b>Average FDA days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile FDA days to MDUFA III decision	0	0			
40th Percentile FDA days to MDUFA III decision	0	0			
60th Percentile FDA days to MDUFA III decision	0	0			
80th Percentile FDA days to MDUFA III decision	0	0			
Maximum FDA days to MDUFA III decision	0	0			
<b>Average Industry days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	0	0			
80th Percentile Industry days to MDUFA III decision	0	0			
Maximum Industry days to MDUFA III decision	0	0			
<b>Average Total days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Total days to MDUFA III decision	0	0			
40th Percentile Total days to MDUFA III decision	0	0			
60th Percentile Total days to MDUFA III decision	0	0			
80th Percentile Total days to MDUFA III decision	0	0			
Maximum Total days to MDUFA III decision	0	0			

**Table 1.7 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	0			
<b>Average FDA days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile FDA days to MDUFA III decision	0	0			
40th Percentile FDA days to MDUFA III decision	0	0			
60th Percentile FDA days to MDUFA III decision	0	0			
80th Percentile FDA days to MDUFA III decision	0	0			
Maximum FDA days to MDUFA III decision	0	0			

<b>Average Industry days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	0	0			
80th Percentile Industry days to MDUFA III decision	0	0			
Maximum Industry days to MDUFA III decision	0	0			
<b>Average Total days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Total days to MDUFA III decision	0	0			
40th Percentile Total days to MDUFA III decision	0	0			
60th Percentile Total days to MDUFA III decision	0	0			
80th Percentile Total days to MDUFA III decision	0	0			
Maximum Total days to MDUFA III decision	0	0			

**Table 1.8 CBER – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0.0%	0.0%			
Rate of Not Approvable	0.0%	0.0%			

**Table 1.9 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0.0%	0.0%			
Rate of Not Approvable	0.0%	0.0%			

**Table 1.10 CBER – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean industry days for submissions that missed goal	0	0			

**Table 1.11 CBER – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean industry days for submissions that missed goal	0	0			

## Section 2 PMA 180 Day Supplements - Center Level

**Table 2.1 CBER – PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	1	0			
SI within 90 FDA days	1	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	0			
SI pending over 90 FDA days	0	0			
Closed without SI	1	0			
Current SI Performance Percent within 90 FDA days	100.0%	0.0%			

**Table 2.2 CBER – PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	3	0			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions within 180 FDA Days	1	0			
Supplements pending MDUFA III Decision	1	0			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100.0%	0.0%			

**Table 2.3 CBER – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	0			
Number with MDUFA decision	1	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.0%	0.0%			

**Table 2.4 CBER – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean Industry days for submissions that missed goal	0	0			

### Section 3 PMA Real Time Supplements - Center Level Metrics

**Table 3.1 CBER – Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	3	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	3	0			
MDUFA III Decisions within 90 FDA Days	3	0			
Supplements pending MDUFA III Decision	0	1			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100.0%	0.0%			

**Table 3.2 CBER – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	1			
Number with MDUFA decision	3	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.0%	0.0%			

**Table 3.3 CBER – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean Industry days for submissions that missed goal	0	0			

## 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 2013	FY 2014	FY 2015	FY 2016	FY 2017
Premarket Report Submissions	0	0			
Original PMAs (Panel) – Priority	0	0			
Original PMAs (No Panel) – Priority	0	0			
Original PMAs (Panel) – Non-Priority	1	0			
Original PMAs (No Panel) – Non-Priority	0	1			
Panel-Tracked Supplements (Panel) – Priority	0	0			
Panel-Tracked Supplements (No Panel) – Priority	0	0			
Panel-Tracked Supplements (Panel) – Non-Priority	0	0			
Panel-Tracked Supplements (No Panel) – Non-Priority	0	0			
PMA Modules	7	1			
180-Day Supplements	3	0			
Real-Time Supplements	3	1			

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with a decision (MDUFA or Non-MDUFA)	1	0			
% of FY closed	0.0%	0.0%			

## Section 6 510(k) Center Level Metrics

**Table 6.1 CBER – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	14			
Closed before RTA action	3	1			
Number Accepted	46	6			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	4			
Number Not Accepted	10	3			
Rate of submissions not accepted for review	21.7%	21.4%			

**Table 6.2 CBER – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	46	6			
SI within 60 FDA days	40	3			
SI over 60 FDA days	6	0			
SI pending within 60 FDA days	0	2			
SI pending over 60 FDA days	0	1			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	87.0%	50.0%			

**Table 6.3 CBER – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	46	3			
Average number of FDA days to Substantive Interaction	49	33			
20th Percentile FDA days to Substantive Interaction	29	0			
40th Percentile FDA days to Substantive Interaction	46	21			
60th Percentile FDA days to Substantive Interaction	58	21			
80th Percentile FDA days to Substantive Interaction	60	28			
Maximum FDA days to Substantive Interaction	90	50			

**Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals**

**Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	46	6			
Non-MDUFA III Decisions	41	0			
MDUFA III Decisions (SE/NSE)	26	2			
MDUFA III Decisions within 90 FDA Days	26	2			
510(k)s pending MDUFA III Decision	15	4			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100.0%	100.0%			

**Table 6.5 CBER – 510(k) Time to MDUFA Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.46	1.00			
Number with MDUFA III decision	26	2			
<b>Average FDA days to MDUFA III decision</b>	65	25			
20th Percentile FDA days to MDUFA III decision	28	0			
40th Percentile FDA days to MDUFA III decision	49	0			
60th Percentile FDA days to MDUFA III decision	85	21			
80th Percentile FDA days to MDUFA III decision	88	21			
Maximum FDA days to MDUFA III decision	90	28			
<b>Average Industry days to MDUFA III decision</b>	43	0			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	0	0			
80th Percentile Industry days to MDUFA III decision	83	0			
Maximum Industry days to MDUFA III decision	222	0			
<b>Average Total days to MDUFA III decision</b>	108	25			
20th Percentile Total days to MDUFA III decision	28	0			
40th Percentile Total days to MDUFA III decision	49	0			
60th Percentile Total days to MDUFA III decision	90	21			

80th Percentile Total days to MDUFA III decision	142	21			
Maximum Total days to MDUFA III decision	307	28			

**Table 6.6 CBER – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	46	6			
Number with MDUFA decision	26	2			
Number of SE decisions	24	2			
Number of NSE decisions	2	0			
Number of Withdrawals	5	1			
Number deleted	0	0			
Rate of SE decisions	52.2%	33.3%			
Rate of NSE decisions	4.3%	0.0%			
Rate of Withdrawals	10.9%	16.7%			
Rate of Deleted	0.0%	0.0%			

**Table 6.7 CBER – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean industry days for submissions that missed goal	0	0			

## Section 7 510(k) Annual General Metrics

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	46	6			
Number of Traditional submissions	33	4			
Number of Special submissions	9	2			

Number of Abbreviated submissions	4	0			
Average number of days to Accept / Refuse to Accept	13	12			
Number of Third Party submissions	0	0			

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

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Accepted	46	6			
Currently Under Review	15	4			
Number with Non-MDUFA Decision	41	0			
Number with MDUFA III Decision	26	2			
Percent of cohort closed	67.4%	33.3%			
Number with MDUFA III decision after trimming the upper and lower 2%	16	0			
Average Total Time to MDUFA III decision	108	25			

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## Section 8 De Novo Petitions

**Table 8.1 CBER – Annual General Metric Report for De Novo Classification Petitions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of De Novo Petitions Received	2	0			
Number of De Novo Petitions with Decision	0	0			
Number of De Novo Petitions with Decision Pending	2	0			
Average Number of Days to Decision	0	0			

## Section 9 Pre-Submissions

### Section 9 Pre-Submission Center Level Metrics

**Table 9.1 CBER – Pre-Submission Center Level Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	45	9			
Number requesting a meeting or teleconference	35	5			
Number with meetings or teleconferences granted	32	5			
Number with meeting granted and industry cancelled	12	0			
Number with meeting granted and FDA cancelled	0	0			
Number with meeting granted and pending within timeframe	0	2			
Number with meeting granted and pending outside timeframe	3	1			
Number with meetings or teleconferences held	15	2			
Average days to meeting	68	92			
20th Percentile days to meeting	55	0			
40th Percentile days to meeting	58	0			
60th Percentile days to meeting	61	91			
80th Percentile days to meeting	70	91			
Maximum days to meeting	122	92			

## BLAs

### CBER – Annual General Metric Report for BLAs

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard BLAs Filed	9	0			
Number of Standard BLA First Actions less than or equal to 10 months	4	0			
Number of Standard BLA First Actions greater than 10 months	0	0			
Number of Standard BLAs Pending	5	0			
Number of Priority BLA Filed	0	0			
Number of Priority BLA First Actions less than or equal to 10 months	0	0			
Number of Priority BLA First Actions greater than 10 months	0	0			
Number of Priority BLAs Pending	0	0			

## BLA Efficacy Supplements

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard Efficacy Supplements Filed	0	0			
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0	0			
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0			
Number of Standard Efficacy Supplements Pending	0	0			
Number of Priority Efficacy Supplements Filed	0	0			
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0			

Number of Priority Efficacy Supplements First Actions greater than 10 months	0	0			
Number of Priority Efficacy Supplements Pending	0	0			

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard PAS Supplements Filed	20	1			
Number of Standard PAS Supplements First Actions less than or equal to 4months	20	0			
Number of Standard PAS Supplements First Actions greater than 4 months	0	0			
Number of Standard PAS Supplements Pending	0	1			

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Class 1 Resubmissions Received	10	0			
Number of Class 1 Resubmission Actions less than or equal to 2 months	10	0			
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0	0			
Number of Class 1 Resbumssions Pending	0	0			
Number of Class 2 Resubmissions Received	0	1			
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	0			
Number of Class 2 Resubmission Actions greater than 6 months	0	0			

Number of Class 2 Resubmissions Pending	0	1			
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<b>FY 2014 Medical Device User Fee Collections</b>					
<b>as of December 31, 2013</b> <sup>/1, 2</sup>					
Excludes Unearned Fees					
	<b>Receipts</b>	<b>Refunds</b>	<b>Net</b>	<b>Authorized</b>	<b>% of Authorized</b>
Registration Fees	\$64,690,400	\$0	\$64,690,400		
Application Fees	\$11,702,571	\$0	\$11,702,571		
<b>Total</b>	<b>\$76,392,971</b>	<b>\$0</b>	<b>\$76,392,971</b>	<b>\$115,055,000</b>	<b>66%</b>

<b>Medical Device User Fee Collection History</b> <sup>/3</sup>					
Excludes Unearned Fees, Includes Refunds					
	<b>FY 2003</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
MD I	\$21,620,549	\$26,280,073	\$31,814,416	\$35,047,878	\$28,723,939
	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
MD II	\$47,521,207	\$55,790,145	\$62,786,714	\$69,586,954	\$64,910,688
	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
MD III	\$98,208,765				

*Notes:*

<sup>/1</sup> Figures are based on Q1 data; subject to revision.

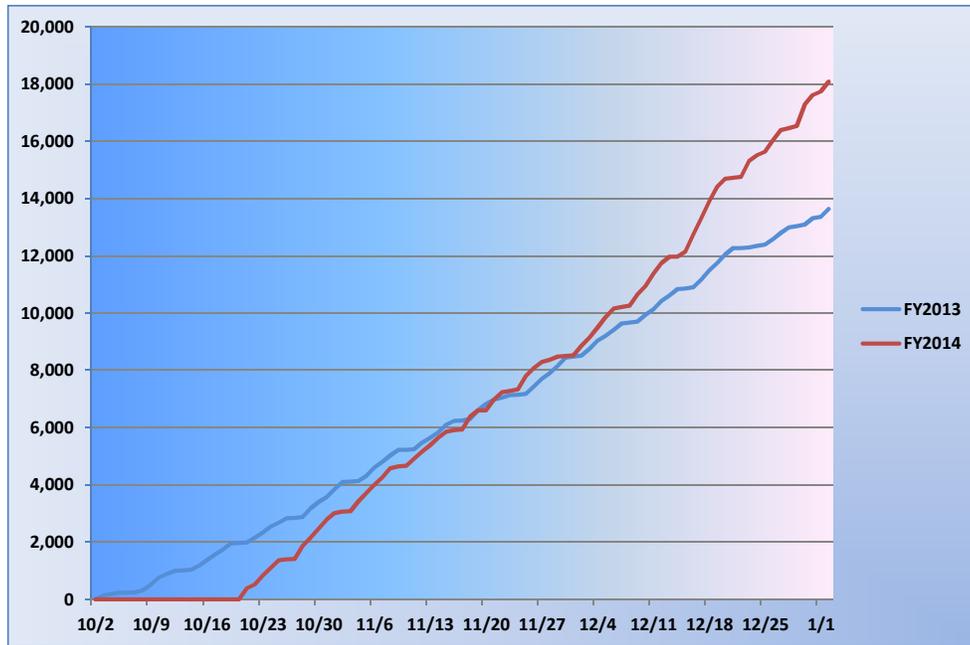
<sup>/2</sup> Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 2014.

<sup>/3</sup> Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

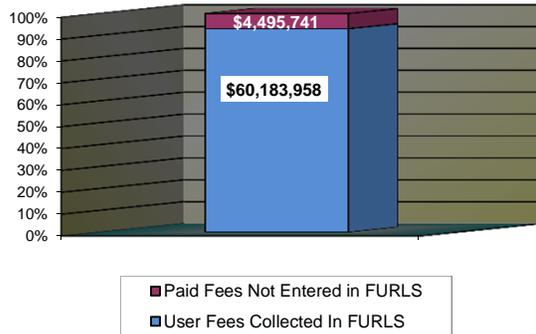
# MDUFA III, Registrations, First Quarter Summary FY2014

Registrations by Type Est Type	FY14 to Date (Currently Active)			FY2013 Year End Active Totals			Difference Thru 12/31/13
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	4,539	6,764	11,303	5,517	8,376	13,893	-2,590
Contract Manufacturer	635	838	1,473	786	1,014	1,800	-327
Contract Sterilizer	67	88	155	73	107	180	-25
Specification Developer	1,232	297	1,529	1,661	363	2,024	-495
Reprocessor of Single Use Devices	15	1	16	21	2	23	-7
U.S. Manufacturer of Export Only Devices	105		105	127		127	-22
Repackager/Relabeler	763	120	883	1,164	169	1,333	-450
Remanufacturer	16	13	29	28	19	47	-18
Foreign Exporter/Private Label Distributor	0	458	458	0	630	630	-172
Initial Importer	2,185	0	2,185	3,272		3,272	-1,087
Unknown	6	7	13	15	8	23	-10
<b>Total:</b>	<b>9,563</b>	<b>8,586</b>	<b>18,149</b>	<b>12,664</b>	<b>10,688</b>	<b>23,352</b>	<b>-5,203</b>

**Registration Progress - FY2013 Versus FY2014**

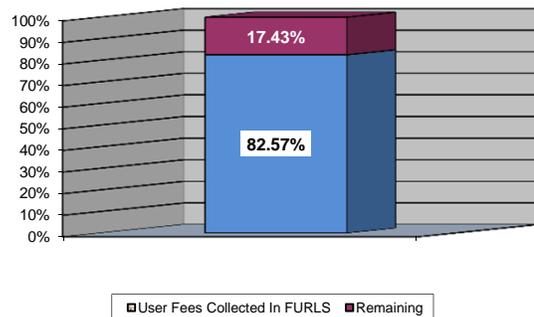


**User Fees Collected Versus User Fees Paid**



**User Fee Progress**

**Goals - \$72,886,000 fees; 22,000 Registrations**



# MDUFA III Quarterly Performance Update

## Independent Assessment of Medical Device Review Process

1st Quarter FY 2014 Status – January 29, 2014

### Objectives

Pursuant to the Performance Goals and Procedures adopted under the 2012 Medical Device User Fee Amendments (MDUFA III), FDA agreed to participate with the device industry in a comprehensive assessment of the process for the review of device applications.

This requirement is to conduct a comprehensive assessment of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket applications. Primary objectives include:

#### Phase 1:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- In-depth analyses of the elements of the review process in order to identify best practices and opportunities for improvement, including root cause analyses of selected significant factors
- Assessment of resource allocation to premarket device reviews across FDA
- Development of implementation plans for selected recommendations
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results

#### Phase 2:

- Evaluation of the implementation of selected recommendations

### Timeline

Milestone	Planned	Status
<b>FY 2013</b>		
Publish Federal Register notice	December 2012	Completed
Award contract	May 2013	Completed June 2013
Contract kickoff meeting between FDA and contractor	June 2013	Completed July 2013
Final workplan for Phase 1	July 2013	Completed August 2013
Report on preliminary findings and high-priority recommendations	December 2013	Completed December 2013
<b>FY 2014</b>		
Implementation plan for high-priority recommendations	June 2014	
Final report on complete findings and recommendations	June 2014	
Implementation plan for final recommendations	December 2014	

Milestone	Planned	Status
<b>FY 2015</b>		
Phase 2 kickoff meeting between FDA and contractor	April 2015	
Final workplan for Phase 2	May 2015	
<b>FY 2016</b>		
Final evaluation report	February 1, 2016	

**Progress to-date:**

- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1<sup>st</sup> Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 2012
- Spoke with industry representatives regarding SOW feedback – January 29, 2013
- Received comments from Federal Register notice – February 4, 2013
- Finalized SOW based on feedback from Federal Register notice – March 25, 2013
- Issued request for proposal – April 19, 2013
- Awarded task order to Booz Allen Hamilton (BAH) – June 11, 2013
- Held kick-off meeting – July 1, 2013
- Received draft workplan – July 19, 2013
- Final workplan – August 2, 2013
- Focus group with Medical Device Industry representatives – August 17, 2013
- Report on preliminary findings and high-priority recommendations – December 11, 2013
- BAH meeting with Medical Device Industry representatives – January 17, 2014

**Planned Progress prior to 2nd Quarter Meeting FY 2014:**

- Contractual progress reports and updates from BAH assessment team – Ongoing