Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance

July 30, 2013
10:00 A.M.

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 13 medical device guidance documents during the 3rd quarter. *Barbara Zimmerman, CDRH-ODE*; *Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIR, Philip Desjardins, CDRH-OCD.*

FDA MDUFA Performance — Actions through June 30, 2013

- Report on decisions goals for 3rd quarter of FY 2013.
  - CDRH: *Barbara Zimmerman, CDRH.*
  - CBER: *Sheryl Kochman, CBER.*

Qualitative Update on Finances – 3rd Quarter of FY 2013

- User fee receipts through the 3rd quarter of FY 2013. *David Miller*, FDA-OFM.

CDRH Registration and Listing

- Report on registration and listing.

Independent Assessment

- Progress and Update- Don Lipkey and Amber Sligar, FDA-OC.
- Introduction of Contractor - Booze-Allen- Hamilton

CDRH Staff Training Update

- Report on CDRH staff training.

Discussion

- IDE tracking changes- Barb Zimmerman
- eSubmission pilot – Patrick Axtell
- RTA Audit, preliminary results – Geeta Pamidimukkala

Set date for next meeting, following close of Q4. Target Date: Tuesday 11/5/13 at 10:00 am.

Medical Device Related Guidance Documents

(April 1, 2013 thru June 30, 202013)

1. Implanted Blood Access Devices for Hemodialysis - Draft Guidance for Industry and Food and Drug Administration Staff (6/28/2013)
2. Draft Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens (6/19/2013)
3. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff (6/14/2013)
4. Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff - FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations (PDF) (PDF - 564KB) (6/14/2013)
5. Guidance for Industry and Food and Drug Administration Staff - Priority Review of Premarket Submissions for Devices (5/17/2013)
6. Center for Devices and Radiological Health Appeals Processes - Guidance for Industry and Food and Drug Administration Staff (5/17/2013)
7. Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A - Draft Guidance for Industry and Food and Drug Administration Staff (5/17/2013)
8. Assay Migration Studies for In Vitro Diagnostic Devices - Guidance for Industry and FDA Staff (PDF - 1.2MB) (4/25/2013)
9. Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" - Draft Guidance for Industry and Food and Drug Administration Staff (PDF - 522KB) (4/23/2013)
10. Medical Device Classification Product Codes - Guidance for Industry and Food and Drug Administration Staff (4/11/2013)
11. Molecular Diagnostic Instruments with Combined Functions - Draft Guidance for Industry and Food and Drug Administration Staff (4/09/2013)
12. Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications (4/02/2013)
13. Guidance for Industry and Food and Drug Administration Staff - User Fees and Refunds for Premarket Notification Submissions (510(k)s) (4/02/2013)

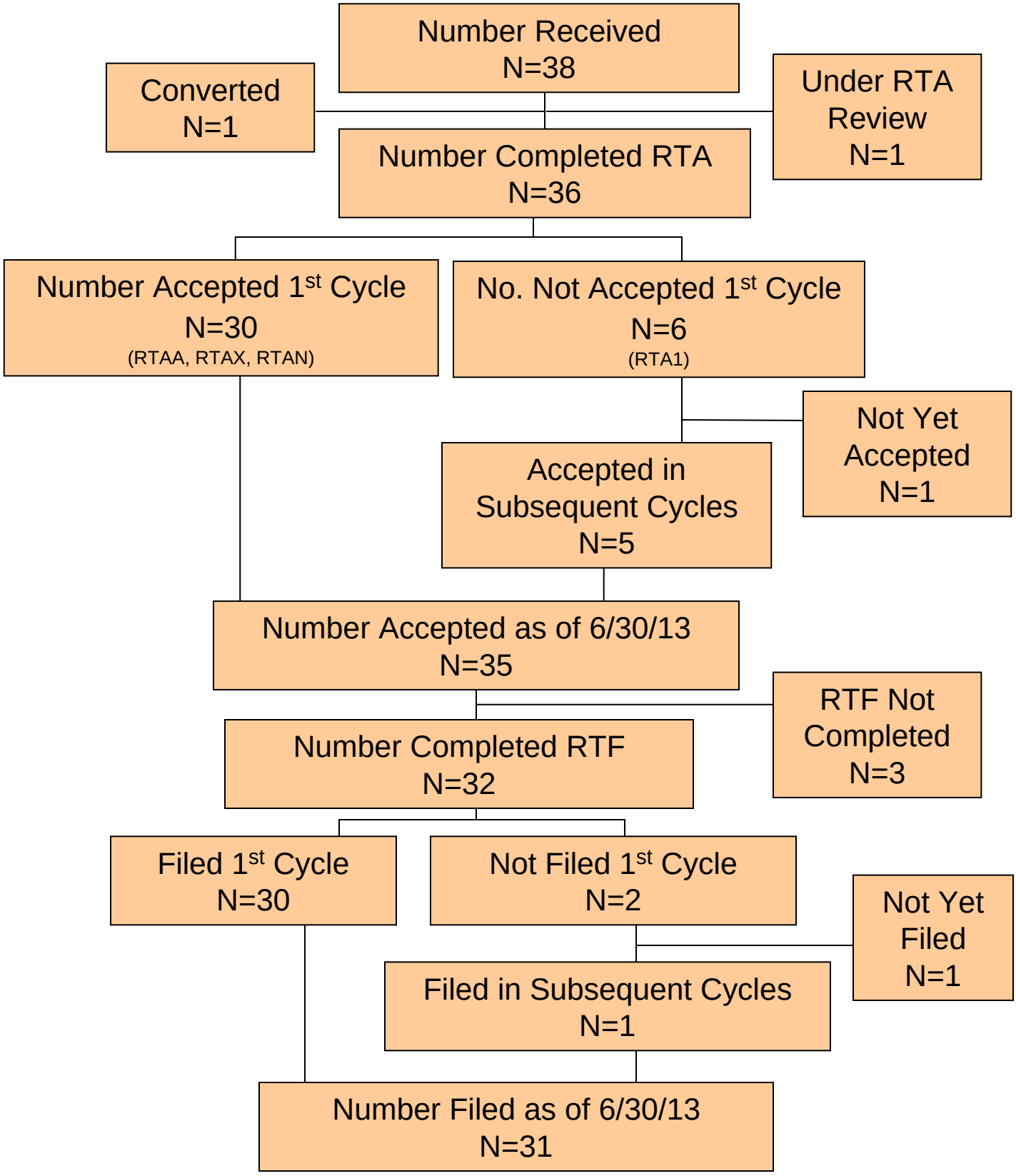
(January 1, 2013 thru March 31, 202013)

1. Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi (3/28/202013)
2. Draft Guidance for Industry and Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex (3/11/202013)
3. Guidance for Industry and FDA Staff - Investigational Device Exemption (IDE) Guidance for Retinal Prostheses (3/6/202013)
4. Types of Communication During the Review of Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff (3/5/202013)
5. Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (3/4/202013)
6. Financial Disclosure by Clinical Investigators- Guidance for Clinical Investigators , Industry, and FDA Staff (PDF - 165KB) (February 202013)
7. Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements - Draft Guidance for Industry and Food and Drug Administration Staff (2/22/202013)
8. Draft Guidance for Industry and Food and Drug Administration Staff - Providing Information about Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act (2/19/202013)
9. Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I - Draft Guidance for Industry, Food and Drug Administration Staff, and Third Party Reviewers (2/15/202013)
10. Clinical Study Designs for Surgical Ablation Devices for Treatment of Atrial Fibrillation - Guidance for Industry and Food and Drug Administration Staff (2/15/202013)
11. Draft Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate (2/7/2013
12. Guidance for Industry and FDA Staff - HUD Designations (PDF - 92KB) (1/24/202013)

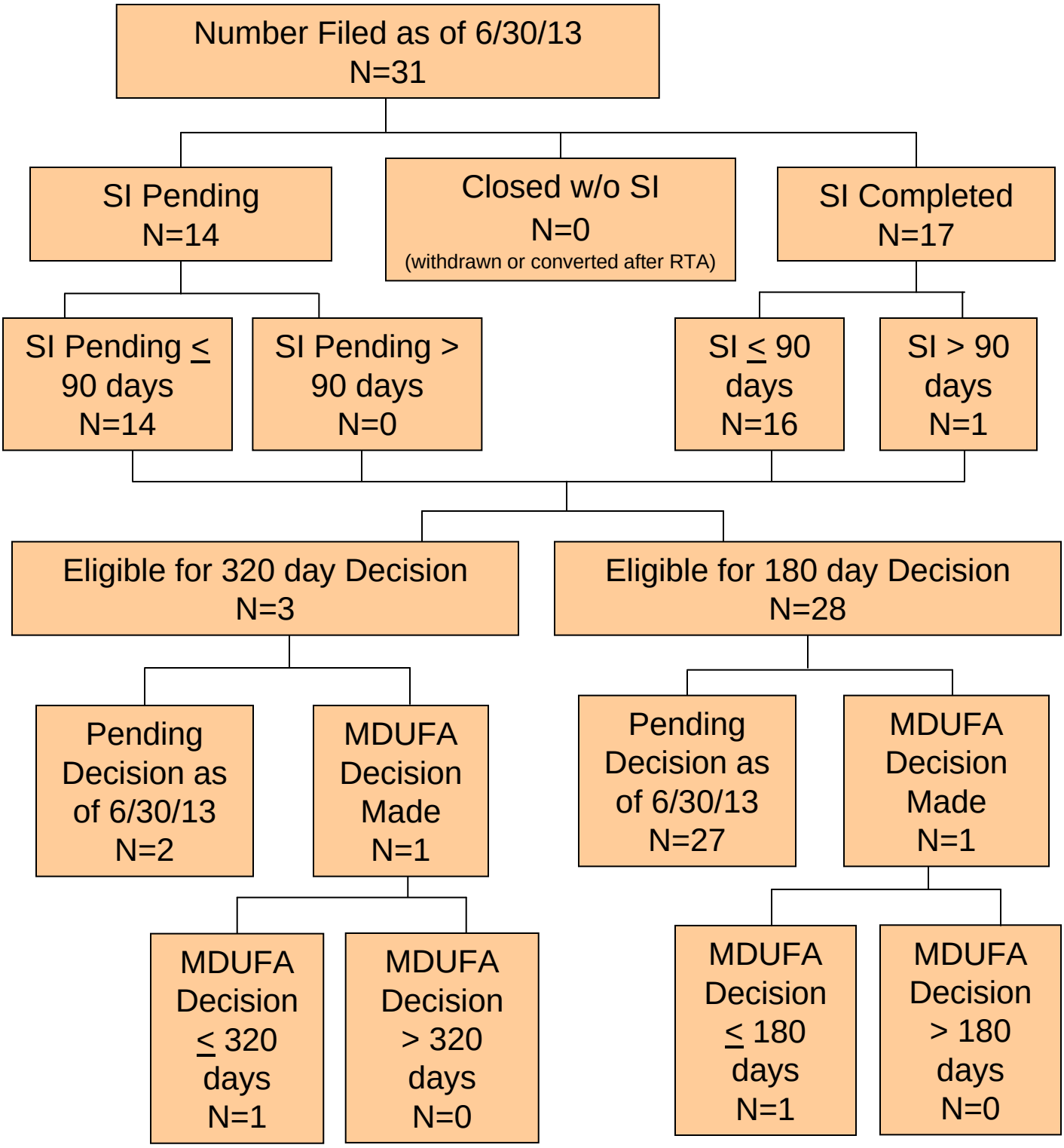
(October 1, 2012 thru December 31, 202013)

1. Guidance for Industry and Food and Drug Administration Staff - Refuse to Accept Policy for 510(k)s (12/31/2012)
2. Guidance for Industry and Food and Drug Administration Staff - Acceptance and Filing Review for Premarket Approval Applications (PMAs) (12/31/2012)
3. Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions (12/31/2012)
4. Draft Guidance for Industry and FDA Staff - Design Considerations for Devices Intended for Home Use (12/12/2012)
5. IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed (11/20/2012)
6. Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems (11/09/2012)
7. Draft Guidance for Industry and Food and Drug Administration Staff - Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices (11/09/2012)
8. Draft Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions (10/17/2012)
9. Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals (10/15/2012)
10. Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals (10/15/2012)

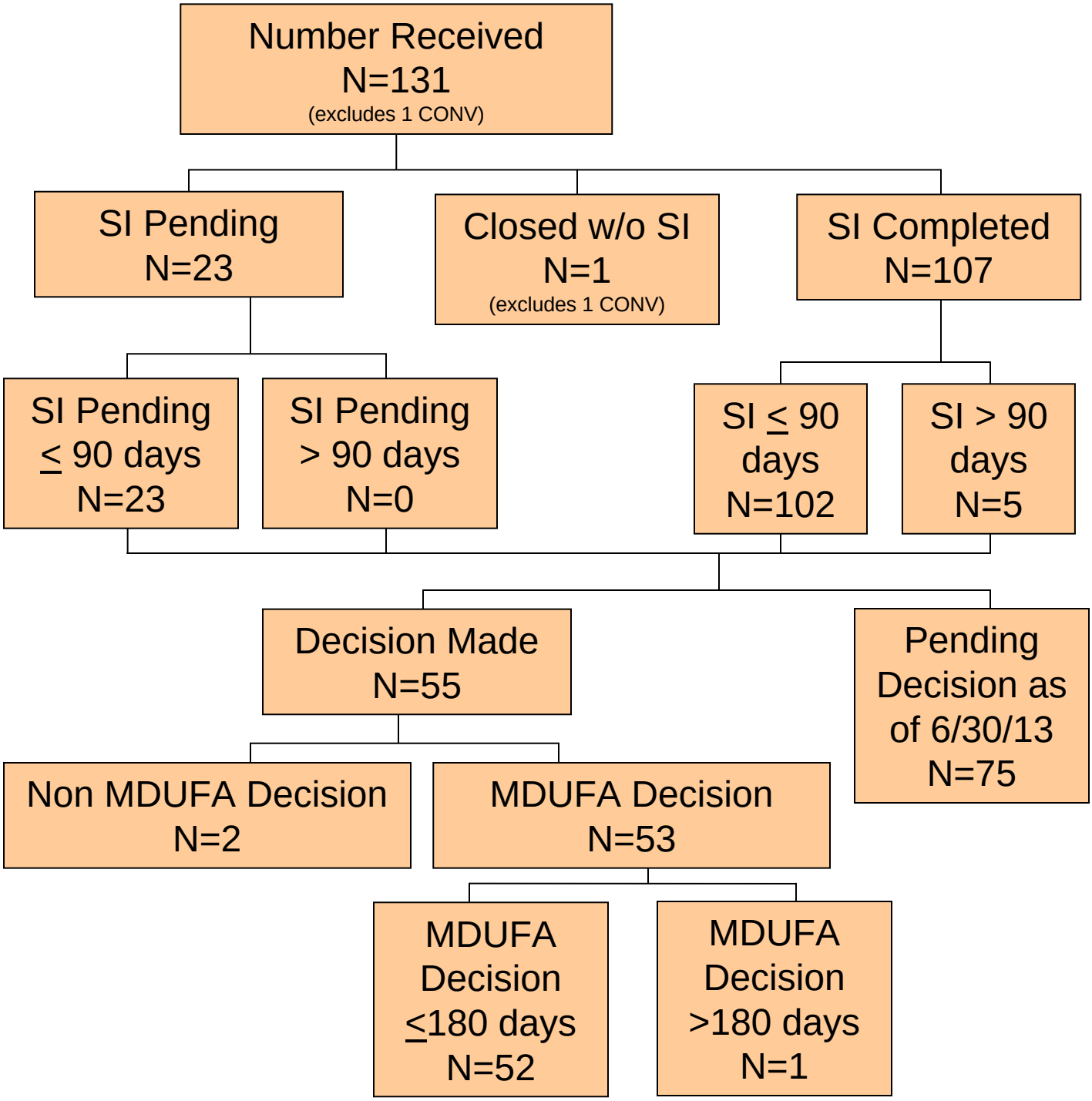
CDRH PMA Original and Panel Track Supplements (10/1/12 – 6/30/13)



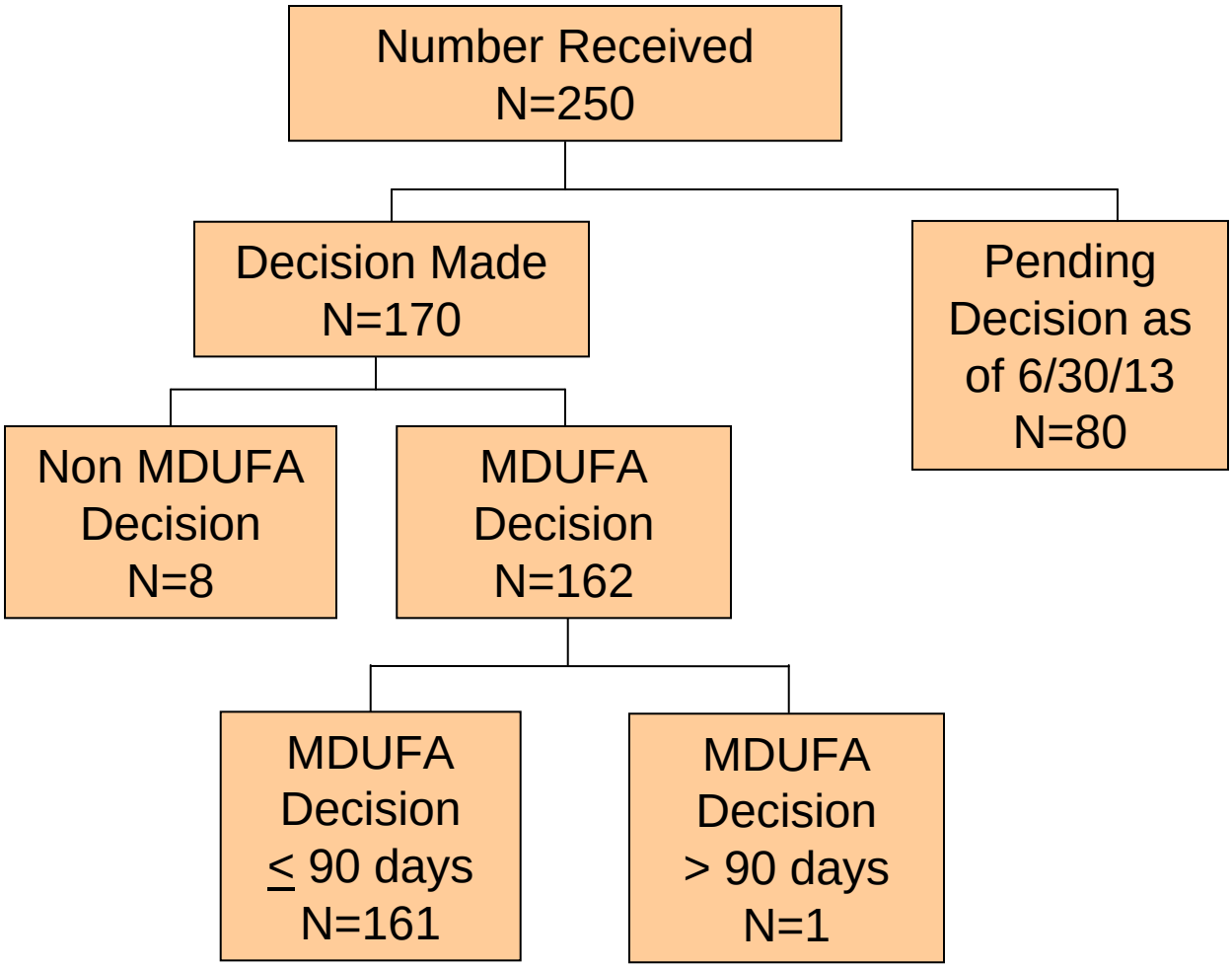
CDRH PMA Original and Panel Track Supplements (10/1/12 – 6/30/13) Con't



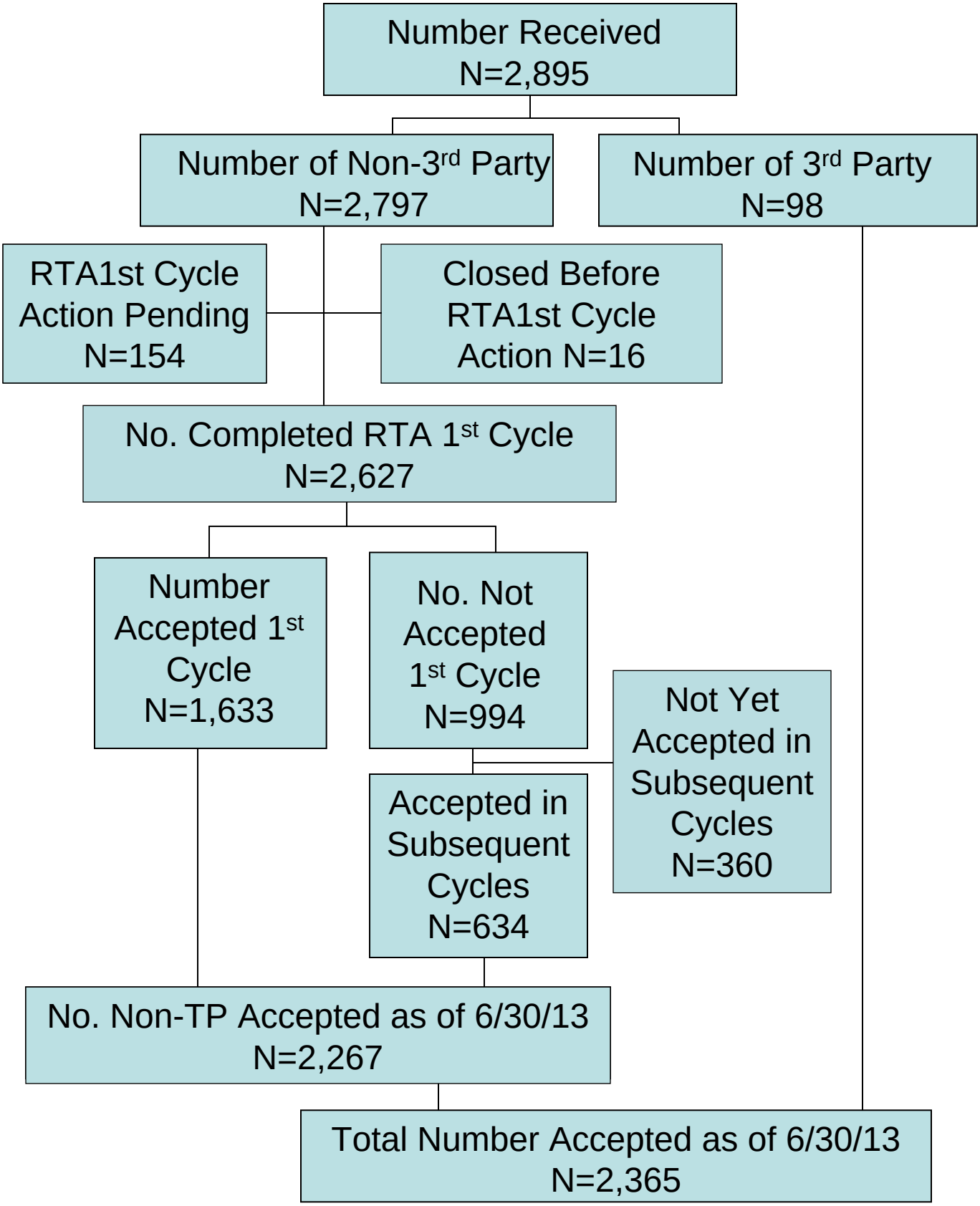
CDRH PMA 180 Day Supplements (10/1/12 – 6/30/13)



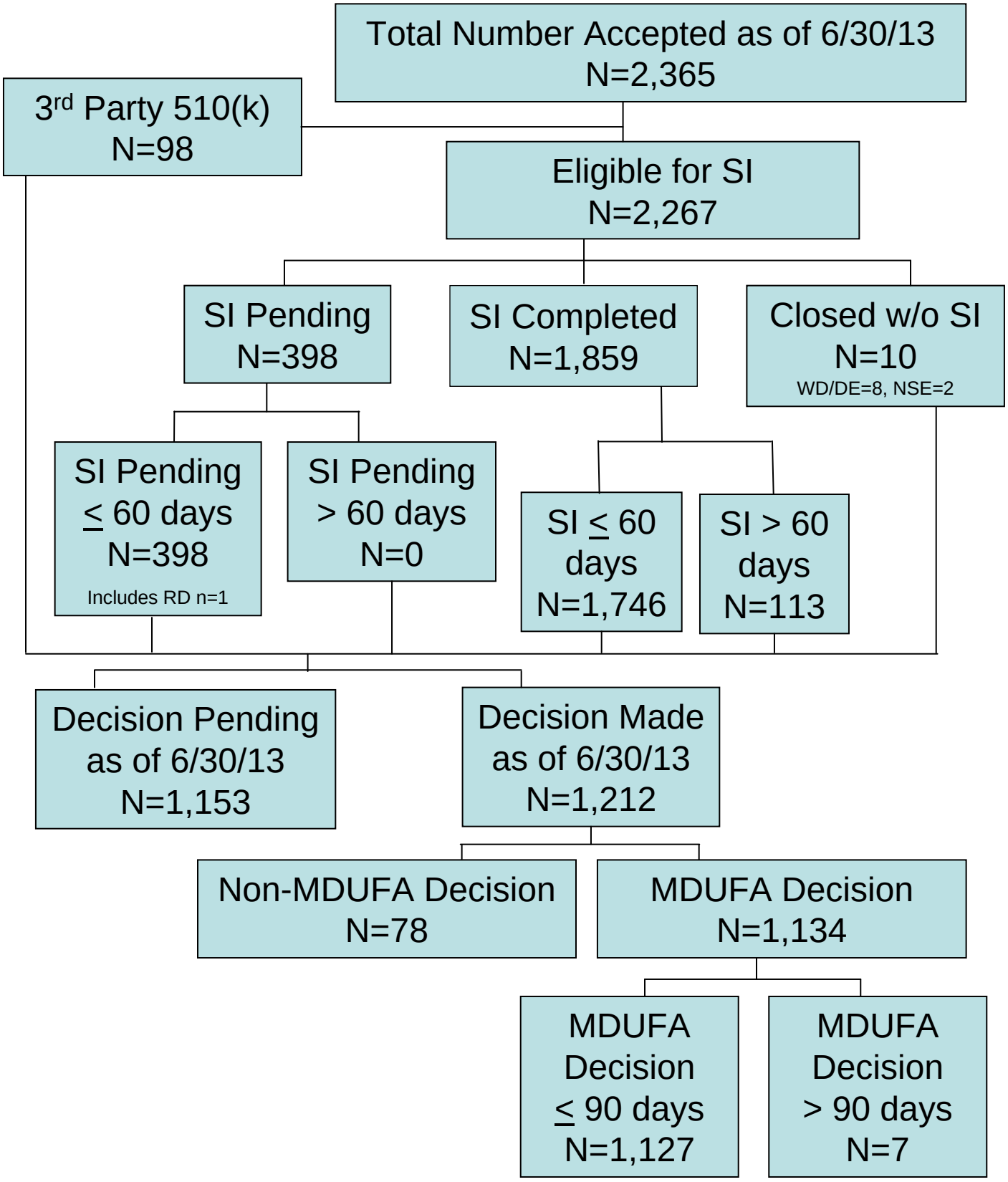
CDRH PMA Real Time Supplements (10/1/12 – 6/30/13)



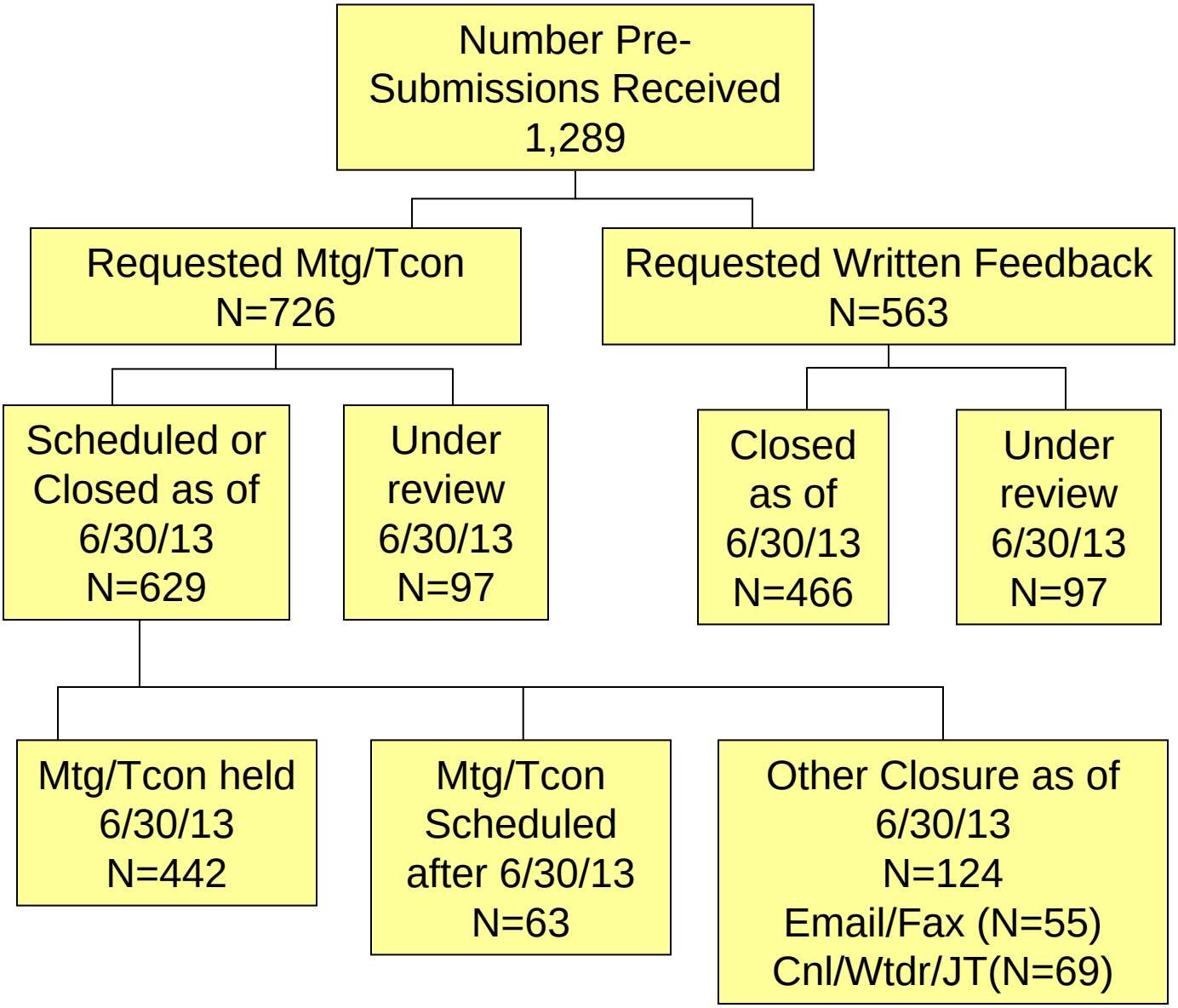
CDRH 510(k)s (10/1/12 – 6/30/13)



CDRH 510(k)s (10/1/12 – 6/30/13) Con't



Pre Submissions (10/1/12 – 6/30/13)



Quarterly Update on
Medical Device Performance Goals
MDUFA III Performance Data

October 1, 2012 – June 30, 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
Ellen Pinnow

CLIA Waiver/OIR
Jean Cooper
Elizabeth Hillebrenner

Edaptive Systems
Victor Kuttikattu
Jerry Logue
Arkady Soldatov

Updated: 6/23/2013

Table of Contents

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	28				
Closed before RTA action	1				
Number with accepted RTA review	18				
Number without a RTA Review and > 15 Days since Date Received	1				
Number without a RTA Review and <= 15 Days since Date Received	3				
Number Not Accepted for Filing Review	5				
Rate of submissions not accepted for filing review	21%				

*** 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	38				
Number Accepted[#]	30				
Completed RTF	32				
Number Not Filed[@]	2				
Rate of submissions Not Filed	6%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	31				
SI within 90 FDA days	16				
SI over 90 FDA days	1				
SI pending within 90 FDA days	14				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	94%				

Table 1.4 CDRH – 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	17				
Average number of FDA days to Substantive Interaction	89				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	88				
60th Percentile FDA days to Substantive Interaction	90				
80th 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

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	28				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
PMAs pending MDUFA III Decision	27				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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

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

Table 1.7 CDRH – 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 decision	1				
Average FDA days to MDUFA III decision	116				
20th Percentile FDA days to MDUFA III decision	116				
40th Percentile FDA days to MDUFA III decision	116				
60th Percentile FDA days to MDUFA III decision	116				
80th Percentile FDA days to MDUFA III decision	116				
Maximum FDA days to MDUFA III decision	116				
Average Industry days to MDUFA III decision	71				
20th Percentile Industry days to MDUFA III decision	71				
40th Percentile Industry days to MDUFA III decision	71				
60th Percentile Industry days to MDUFA III decision	71				
80th Percentile Industry days to MDUFA III decision	71				
Maximum Industry days to MDUFA III decision	71				
Average Total days to MDUFA III decision	187				
20th Percentile Total days to MDUFA III decision	187				
40th Percentile Total days to MDUFA III decision	187				
60th Percentile Total days to MDUFA III decision	187				
80th Percentile Total days to MDUFA III decision	187				
Maximum Total days to MDUFA III decision	187				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	206				
20th Percentile FDA days to MDUFA III decision	206				
40th Percentile FDA days to MDUFA III decision	206				
60th Percentile FDA days to MDUFA III decision	206				
80th Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	206				
20th Percentile Total days to MDUFA III decision	206				
40th Percentile Total days to MDUFA III decision	206				
60th Percentile Total days to MDUFA III decision	206				
80th 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	28				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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	3				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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	23				
Closed before RTA action	1				
Number with accepted RTA review	13				
Number without a RTA Review and > 15 Days since Date Received	1				
Number without a RTA Review and <= 15 Days since Date Received	3				
Number Not Accepted for Filing Review	5				
Rate of submissions not accepted for filing review	26%				

*** 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	30				
Number Accepted[#]	22				
Completed RTF	25				
Number Not Filed[@]	2				
Rate of submissions Not Filed	8%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 1 PMA Original or Panel Track Supplement that was 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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	24				
SI within 90 FDA days	11				
SI over 90 FDA days	1				
SI pending within 90 FDA days	12				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	92%				

Table 1.4.ODE ODE – 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	12				
Average number of FDA days to Substantive Interaction	90				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	87				
60th Percentile FDA days to Substantive Interaction	89				
80th 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

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	22				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	22				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

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

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

Table 1.7.ODE ODE – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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	22				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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	2				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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	5				
Closed before RTA action	0				
Number with accepted RTA review	5				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** 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	8				
Number Accepted[#]	8				
Completed RTF	7				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	7				
SI within 90 FDA days	5				
SI over 90 FDA days	0				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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	5				
Average number of FDA days to Substantive Interaction	85				
20th Percentile FDA days to Substantive Interaction	84				
40th Percentile FDA days to Substantive Interaction	90				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

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

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	6				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
PMAs pending MDUFA III Decision	5				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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

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

Table 1.7.OIR OIR – 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 decision	1				
Average FDA days to MDUFA III decision	116				
20th Percentile FDA days to MDUFA III decision	116				
40th Percentile FDA days to MDUFA III decision	116				
60th Percentile FDA days to MDUFA III decision	116				
80th Percentile FDA days to MDUFA III decision	116				
Maximum FDA days to MDUFA III decision	116				
Average Industry days to MDUFA III decision	71				
20th Percentile Industry days to MDUFA III decision	71				
40th Percentile Industry days to MDUFA III decision	71				
60th Percentile Industry days to MDUFA III decision	71				
80th Percentile Industry days to MDUFA III decision	71				
Maximum Industry days to MDUFA III decision	71				
Average Total days to MDUFA III decision	187				
20th Percentile Total days to MDUFA III decision	187				
40th Percentile Total days to MDUFA III decision	187				
60th Percentile Total days to MDUFA III decision	187				
80th Percentile Total days to MDUFA III decision	187				
Maximum Total days to MDUFA III decision	187				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	206				
20th Percentile FDA days to MDUFA III decision	206				
40th Percentile FDA days to MDUFA III decision	206				
60th Percentile FDA days to MDUFA III decision	206				
80th Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	206				
20th Percentile Total days to MDUFA III decision	206				
40th Percentile Total days to MDUFA III decision	206				
60th Percentile Total days to MDUFA III decision	206				
80th 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	6				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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	1				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of submissions not accepted for filing review	100%				

*** 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				
Number Accepted[#]	1				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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

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

Table 1.4.DAGRID DAGRID – 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				
Average number of FDA days to Substantive Interaction	87				
20th Percentile FDA days to Substantive Interaction	87				
40th Percentile FDA days to Substantive Interaction	87				
60th Percentile FDA days to Substantive Interaction	87				
80th Percentile FDA days to Substantive Interaction	87				
Maximum FDA days to Substantive Interaction	87				

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

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

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

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

Table 1.7.DAGRID DAGRID – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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	2				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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	14				
Closed before RTA action	1				
Number with accepted RTA review	11				
Number without a RTA Review and > 15 Days since Date Received	1				
Number without a RTA Review and <= 15 Days since Date Received	1				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	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	17				
Number Accepted[#]	16				
Completed RTF	15				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	15				
SI within 90 FDA days	5				
SI over 90 FDA days	1				
SI pending within 90 FDA days	9				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	83%				

Table 1.4.DCD DCD – 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	6				
Average number of FDA days to Substantive Interaction	93				
20th Percentile FDA days to Substantive Interaction	87				
40th Percentile FDA days to Substantive Interaction	89				
60th Percentile FDA days to Substantive Interaction	90				
80th 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

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	13				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	13				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

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

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

Table 1.7.DCD DCD – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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	13				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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	2				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of submissions not accepted for filing review	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				
Number Accepted[#]	0				
Completed RTF	0				
Number Not Filed	0				
Rate of submissions Not Filed	n/a				

[#] 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

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

Table 1.4. DNPMD DNPMD – 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	0				
Average number of FDA days to Substantive Interaction					
20th Percentile FDA days to Substantive Interaction					
40th Percentile FDA days to Substantive Interaction					
60th Percentile FDA days to Substantive Interaction					
80th Percentile FDA days to Substantive Interaction					
Maximum FDA days to Substantive Interaction					

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

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

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

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

Table 1.7. DNPMD DNPMD – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	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				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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

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

Table 1.4.DOD DOD – 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				
Average number of FDA days to Substantive Interaction	86				
20th Percentile FDA days to Substantive Interaction	86				
40th Percentile FDA days to Substantive Interaction	86				
60th Percentile FDA days to Substantive Interaction	86				
80th 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

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

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

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

Table 1.7.DOD DOD – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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	3				
Closed before RTA action	0				
Number with accepted RTA review	2				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	1				
Rate of submissions not accepted for filing review	33%				

*** 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	4				
Number Accepted[#]	3				
Completed RTF	4				
Number Not Filed[@]	1				
Rate of submissions Not Filed	25%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

[@] Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	4				
SI within 90 FDA days	2				
SI over 90 FDA days	0				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

Table 1.4.DOED DOED – 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				
Average number of FDA days to Substantive Interaction	88				
20th Percentile FDA days to Substantive Interaction	87				
40th Percentile FDA days to Substantive Interaction	87				
60th Percentile FDA days to Substantive Interaction	88				
80th Percentile FDA days to Substantive Interaction	89				
Maximum FDA days to Substantive Interaction	89				

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

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	4				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	n/a				

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

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

Table 1.7.DOED DOED – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

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

Table 1.9.DOED 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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.10.DOED 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	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	2				
Number Not Accepted for Filing Review	2				
Rate of submissions not accepted for filing review	100%				

*** 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				
Number Accepted[#]	0				
Completed RTF	2				
Number Not Filed	1				
Rate of submissions Not Filed	50%				

[#] Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

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

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

Table 1.4.DRGUD DRGUD – 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				
Average number of FDA days to Substantive Interaction	90				
20th Percentile FDA days to Substantive Interaction	90				
40th Percentile FDA days to Substantive Interaction	90				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

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

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

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

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

Table 1.7.DRGUD DRGUD – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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	1				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

There were no PMA Original or Panel Track Supplements received by DSD between October 1, 2012 and June 30, 2013.

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				
Closed before RTA action	0				
Number with accepted RTA review	2				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0%				

*** 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				
Number Accepted[#]	2				
Completed RTF	2				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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

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

Table 1.4.DCTD DCTD – 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				
Average number of FDA days to Substantive Interaction	90				
20th Percentile FDA days to Substantive Interaction	90				
40th Percentile FDA days to Substantive Interaction	90				
60th Percentile FDA days to Substantive Interaction	90				
80th 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

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

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

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

Table 1.7.DCTD DCTD – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

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

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

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

Table 1.10.DCTD DCTD – 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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.11.DCTD DCTD – 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				
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

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

*** 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				
Number Accepted[#]	4				
Completed RTF	3				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	3				
SI within 90 FDA days	3				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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	3				
Average number of FDA days to Substantive Interaction	90				
20th Percentile FDA days to Substantive Interaction	89				
40th Percentile FDA days to Substantive Interaction	90				
60th Percentile FDA days to Substantive Interaction	90				
80th Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

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

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

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

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

Table 1.7.DIHD DIHD – 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 decision	1				
Average FDA days to MDUFA III decision	116				
20th Percentile FDA days to MDUFA III decision	116				
40th Percentile FDA days to MDUFA III decision	116				
60th Percentile FDA days to MDUFA III decision	116				
80th Percentile FDA days to MDUFA III decision	116				
Maximum FDA days to MDUFA III decision	116				
Average Industry days to MDUFA III decision	71				
20th Percentile Industry days to MDUFA III decision	71				
40th Percentile Industry days to MDUFA III decision	71				
60th Percentile Industry days to MDUFA III decision	71				
80th Percentile Industry days to MDUFA III decision	71				
Maximum Industry days to MDUFA III decision	71				
Average Total days to MDUFA III decision	187				
20th Percentile Total days to MDUFA III decision	187				
40th Percentile Total days to MDUFA III decision	187				
60th Percentile Total days to MDUFA III decision	187				
80th Percentile Total days to MDUFA III decision	187				
Maximum Total days to MDUFA III decision	187				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	n/a				

Table 1.10.DIHDDIHD – 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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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	1				
Closed before RTA action	0				
Number with accepted RTA review	1				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	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	1				
Number Accepted[#]	1				
Completed RTF	1				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	1				
SI within 90 FDA days	0				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	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	0				
Average number of FDA days to Substantive Interaction					
20th Percentile FDA days to Substantive Interaction					
40th Percentile FDA days to Substantive Interaction					
60th Percentile FDA days to Substantive Interaction					
80th Percentile FDA days to Substantive Interaction					
Maximum FDA days to Substantive Interaction					

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

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

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

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

Table 1.7.DMD DMD – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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	0				
Closed before RTA action	0				
Number with accepted RTA review	0				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	n/a				

*** 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	1				
Number Accepted[#]	1				
Completed RTF	1				
Number Not Filed	0				
Rate of submissions Not Filed	0%				

[#] 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 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	1				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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	1				
Average number of FDA days to Substantive Interaction	65				
20th Percentile FDA days to Substantive Interaction	65				
40th Percentile FDA days to Substantive Interaction	65				
60th Percentile FDA days to Substantive Interaction	65				
80th Percentile FDA days to Substantive Interaction	65				
Maximum FDA days to Substantive Interaction	65				

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

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

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

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

Table 1.7.DRH DRH – 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 decision	0				
Average FDA days to MDUFA III decision					
20th Percentile FDA days to MDUFA III decision					
40th Percentile FDA days to MDUFA III decision					
60th Percentile FDA days to MDUFA III decision					
80th Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
Average Industry days to MDUFA III decision					
20th Percentile Industry days to MDUFA III decision					
40th Percentile Industry days to MDUFA III decision					
60th Percentile Industry days to MDUFA III decision					
80th Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
Average Total days to MDUFA III decision					
20th Percentile Total days to MDUFA III decision					
40th Percentile Total days to MDUFA III decision					
60th Percentile Total days to MDUFA III decision					
80th 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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number with MDUFA decision	1				
Average FDA days to MDUFA III decision	206				
20th Percentile FDA days to MDUFA III decision	206				
40th Percentile FDA days to MDUFA III decision	206				
60th Percentile FDA days to MDUFA III decision	206				
80th Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
Average Industry days to MDUFA III decision	0				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	O				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	206				
20th Percentile Total days to MDUFA III decision	206				
40th Percentile Total days to MDUFA III decision	206				
60th Percentile Total days to MDUFA III decision	206				
80th 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	0				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
Number with MDUFA decision	1				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	n/a				
Rate of Not Approvable	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				
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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	132^				
SI within 90 FDA days	102				
SI over 90 FDA days	5				
SI pending within 90 FDA days	23				
SI pending over 90 FDA days	0				
Closed without SI	2^				
Current SI Performance Percent within 90 FDA days	95%				

^ Includes one PMA 180 Day Supplement that was converted.

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	132^				
Non-MDUFA III Decisions	2				
MDUFA III Decisions	53				
MDUFA III Decisions within 180 FDA Days	52				
Supplements pending MDUFA III Decision	77^*				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	98%				

^ Includes one PMA 180 Day Supplement that was converted.

* Includes one PMA 180 Day Supplement that was closed without SI.

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	132^				
Number with MDUFA decision	53				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

^ 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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	118^				
SI within 90 FDA days	89				
SI over 90 FDA days	5				
SI pending within 90 FDA days	22				
SI pending over 90 FDA days	0				
Closed without SI	2^				
Current SI Performance Percent within 90 FDA days	95%				

^ Includes one PMA 180 Day Supplement that was converted.

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	118^				
Non-MDUFA III Decisions	2				
MDUFA III Decisions	46				
MDUFA III Decisions within 180 FDA Days	45				
Supplements pending MDUFA III Decision	70^*				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	98%				

^ Includes one PMA 180 Day Supplement that was converted.

* Includes one PMA 180 Day Supplement that was closed without SI.

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	118^				
Number with MDUFA decision	46				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

^ 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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	14				
SI within 90 FDA days	13				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	14				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	7				
MDUFA III Decisions within 180 FDA Days	7				
Supplements pending MDUFA III Decision	7				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	14				
Number with MDUFA decision	7				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	8				
SI within 90 FDA days	4				
SI over 90 FDA days	2				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	67%				

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	8				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	8				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	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	8				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	83^				
SI within 90 FDA days	66				
SI over 90 FDA days	2				
SI pending within 90 FDA days	13				
SI pending over 90 FDA days	0				
Closed without SI	2^				
Current SI Performance Percent within 90 FDA days	97%				

^ Includes one PMA 180 Day Supplement that was converted.

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	83^				
Non-MDUFA III Decisions	2				
MDUFA III Decisions	40				
MDUFA III Decisions within 180 FDA Days	40^*				
Supplements pending MDUFA III Decision	39				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	98%				

^ Includes one PMA 180 Day Supplement that was converted.

* Includes one PMA 180 Day Supplement that was closed without SI.

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	83^				
Number with MDUFA decision	41				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

^ 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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	6				
SI within 90 FDA days	3				
SI over 90 FDA days	0				
SI pending within 90 FDA days	3				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	6				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	5				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	6				
Number with MDUFA decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
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 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	1				
SI within 90 FDA days	1				
SI over 90 FDA days	0				
SI pending within 90 FDA days	0				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	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	1				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	9				
SI within 90 FDA days	8				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	9				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	8				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	9				
Number with MDUFA decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	7				
SI within 90 FDA days	5				
SI over 90 FDA days	0				
SI pending within 90 FDA days	2				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

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

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	7				
Number with MDUFA decision	2				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	4				
SI within 90 FDA days	2				
SI over 90 FDA days	1				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	67%				

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	1				
MDUFA III Decisions within 180 FDA Days	1				
Supplements pending MDUFA III Decision	3				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	4				
Number with MDUFA decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
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

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

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	1				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	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	1				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	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				
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

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

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 180 FDA Days	3				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	4				
Number with MDUFA decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA Days	FY 2015 85% SI within 90 FDA Days	FY 2016 95% SI within 90 FDA Days	FY 2017 95% SI within 90 FDA Days
Eligible for SI	5				
SI within 90 FDA days	4				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	100%				

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

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

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	5				
Number with MDUFA decision	1				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

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				
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

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

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

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	4				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 180 FDA Days	3				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	100%				

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	4				
Number with MDUFA decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	100%				

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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	250				
Non-MDUFA III Decisions	8				
MDUFA III Decisions	162				
MDUFA III Decisions within 90 FDA Days	161				
Supplements pending MDUFA III Decision	80				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	250				
Number with MDUFA decision	162				
Number of Not Approvable	7				
Rate of Not Approvable	4%				

Table 3.3 CDRH – 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	1				
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	73				

PMA Real Time Supplements – Office Level

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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	212				
Non-MDUFA III Decisions	7				
MDUFA III Decisions	137				
MDUFA III Decisions within 90 FDA Days	136				
Supplements pending MDUFA III Decision	68				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	212				
Number with MDUFA decision	137				
Number of Not Approvable	7				
Rate of Not Approvable	5%				

Table 3.3.ODE ODE – 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	1				
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	73				

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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	38				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	25				
MDUFA III Decisions within 90 FDA Days	25				
Supplements pending MDUFA III Decision	12				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	38				
Number with MDUFA decision	25				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 3.3.OIR OIR – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	11				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	9				
MDUFA III Decisions within 90 FDA Days	9				
Supplements pending MDUFA III Decision	2				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	11				
Number with MDUFA decision	9				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 3.3.DAGRID DAGRID – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	139				
Non-MDUFA III Decisions	5				
MDUFA III Decisions	85				
MDUFA III Decisions within 90 FDA Days	85				
Supplements pending MDUFA III Decision	49				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	139				
Number with MDUFA decision	85				
Number of Not Approvable	2				
Rate of Not Approvable	2%				

Table 3.3.DCD DCD – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	22				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	16				
MDUFA III Decisions within 90 FDA Days	16				
Supplements pending MDUFA III Decision	6				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	22				
Number with MDUFA decision	16				
Number of Not Approvable	1				
Rate of Not Approvable	6%				

Table 3.3.DNPMD DNPMD – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	3				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 90 FDA Days	0				
Supplements pending MDUFA III Decision	3				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	n/a				

Table 3.2.DOD DOD – 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				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 3.3.DOD DOD – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	11				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	7				
MDUFA III Decisions within 90 FDA Days	7				
Supplements pending MDUFA III Decision	4				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	11				
Number with MDUFA decision	7				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 3.3.DOED DOED – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	17				
Non-MDUFA III Decisions	2				
MDUFA III Decisions	12				
MDUFA III Decisions within 90 FDA Days	12				
Supplements pending MDUFA III Decision	3				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	17				
Number with MDUFA decision	12				
Number of Not Approvable	1				
Rate of Not Approvable	8%				

Table 3.3.DRGUD DRGUD – 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%				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	9				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	8				
MDUFA III Decisions within 90 FDA Days	7				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	88%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	9				
Number with MDUFA decision	8				
Number of Not Approvable	3				
Rate of Not Approvable	38%				

Table 3.3.DSD DSD – 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	1				
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	73				

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

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

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

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

Table 3.3.DCTD DCTD – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	20				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	12				
MDUFA III Decisions within 90 FDA Days	12				
Supplements pending MDUFA III Decision	7				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	20				
Number with MDUFA decision	12				
Number of Not Approvable	0				
Rate of Not Approvable	0%				

Table 3.3.DIHD DIHD – 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				
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

Performance Goals:	FY 2013 90% within 90 FDA days	FY 2014 90% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
Supplements received	12				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	9				
MDUFA III Decisions within 90 FDA Days	9				
Supplements pending MDUFA III Decision	3				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

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

Table 3.3.DMD DMD – 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				
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 June 30, 2013.

Section 4 Pre-Market Report Submissions

There were no pre-market reports received by FDA between October 1, 2012 and June 30, 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	1870				
Closed before RTA action	11				
Number Accepted	685				
RTA Review not done and > 15 days since Date Received	29				
RTA Review not done and <= 15 days since Date Received	154				
Number Not Accepted	991				
Rate of submissions not accepted	58%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	2267				
Deleted or withdrawn prior to SI	8				
SI within 60 FDA days	1746				
SI over 60 FDA days	113				
SI pending within 60 FDA days	398				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	2				
Current SI Performance Percent within 60 FDA days	94%				

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	1859				
Average number of FDA days to Substantive Interaction	45				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	44				
60th Percentile FDA days to Substantive Interaction	53				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	98				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	2365				
Non-MDUFA III Decisions	78				
MDUFA III Decisions (SE/NSE)	1134				
MDUFA III Decisions within 90 FDA Days	1127				
510(k)s pending MDUFA III Decision	1153				
510(k) pending MDUFA III Decision over 90 FDA days	3				
Current Performance Percent within 90 FDA Days	99%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.55				
Number with MDUFA decision	1134				
Average FDA days to MDUFA III decision	60				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	53				
60th Percentile FDA days to MDUFA III decision	76				
80th Percentile FDA days to MDUFA III decision	87				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	24				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	15				
80th Percentile Industry days to MDUFA III decision	46				
Maximum Industry days to MDUFA III decision	187				
Average Total days to MDUFA III decision	84				
20th Percentile Total days to MDUFA III decision	30				
40th Percentile Total days to MDUFA III decision	62				
60th Percentile Total days to MDUFA III decision	90				
80th Percentile Total days to MDUFA III decision	126				
Maximum Total days to MDUFA III decision	262				

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	2365				
Number with MDUFA decision	1134				
Number of SE decisions	1108				
Number of NSE decisions	26				
Number of Withdrawals	48				
Number deleted	20				
Rate of SE decisions	98%				
Rate of NSE decisions	2%				
Rate of Withdrawals	2%				
Rate of Deleted	1%				

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	7				
Mean FDA days for submissions that missed goal	99				
Mean Industry days for submissions that missed goal	56				

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	1514				
Closed before RTA action	9				
Number Accepted	459				
RTA Review not done and > 15 days since Date Received	14				
RTA Review not done and <= 15 days since Date Received	126				
Number Not Accepted	906				
Rate of submissions not accepted	66%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	1773				
Deleted or withdrawn prior to SI	7				
SI within 60 FDA days	1354				
SI over 60 FDA days	84				
SI pending within 60 FDA days	326				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	2				
Current SI Performance Percent within 60 FDA days	94%				

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	1438				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	45				
60th Percentile FDA days to Substantive Interaction	54				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	98				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	1832				
Non-MDUFA III Decisions	63				
MDUFA III Decisions (SE/NSE)	848				
MDUFA III Decisions within 90 FDA Days	843				
510(k)s pending MDUFA III Decision	921				
510(k) pending MDUFA III Decision over 90 FDA days	3				
Current Performance Percent within 90 FDA Days	99%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.59				
Number with MDUFA decision	848				
Average FDA days to MDUFA III decision	62				
20th Percentile FDA days to MDUFA III decision	30				
40th Percentile FDA days to MDUFA III decision	57				
60th Percentile FDA days to MDUFA III decision	80				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	25				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	20				
80th Percentile Industry days to MDUFA III decision	46				
Maximum Industry days to MDUFA III decision	187				
Average Total days to MDUFA III decision	87				
20th Percentile Total days to MDUFA III decision	30				
40th Percentile Total days to MDUFA III decision	69				
60th Percentile Total days to MDUFA III decision	92				
80th Percentile Total days to MDUFA III decision	127				
Maximum Total days to MDUFA III decision	262				

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	1832				
Number with MDUFA decision	848				
Number of SE decisions	824				
Number of NSE decisions	24				
Number of Withdrawals	36				
Number deleted	19				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	2%				
Rate of Deleted	1%				

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	5				
Mean FDA days for submissions that missed goal	98				
Mean Industry days for submissions that missed goal	72				

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	356				
Closed before RTA action	2				
Number Accepted	226				
RTA Review not done and > 15 days since Date Received	15				
RTA Review not done and <= 15 days since Date Received	28				
Number Not Accepted	85				
Rate of submissions not accepted	26%				

*** 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.**

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

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	494				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	392				
SI over 60 FDA days	29				
SI pending within 60 FDA days	72				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	93%				

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	421				
Average number of FDA days to Substantive Interaction	45				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	42				
60th Percentile FDA days to Substantive Interaction	51				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	91				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	533				
Non-MDUFA III Decisions	15				
MDUFA III Decisions (SE/NSE)	286				
MDUFA III Decisions within 90 FDA Days	284				
510(k)s pending MDUFA III Decision	232				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.42				
Number with MDUFA decision	286				
Average FDA days to MDUFA III decision	54				
20th Percentile FDA days to MDUFA III decision	28				
40th Percentile FDA days to MDUFA III decision	41				
60th Percentile FDA days to MDUFA III decision	65				
80th Percentile FDA days to MDUFA III decision	83				
Maximum FDA days to MDUFA III decision	109				
Average Industry days to MDUFA III decision	22				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	41				
Maximum Industry days to MDUFA III decision	183				
Average Total days to MDUFA III decision	76				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	45				
60th Percentile Total days to MDUFA III decision	79				
80th Percentile Total days to MDUFA III decision	114				
Maximum Total days to MDUFA III decision	252				

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	533				
Number with MDUFA decision	286				
Number of SE decisions	284				
Number of NSE decisions	2				
Number of Withdrawals	12				
Number deleted	1				
Rate of SE decisions	99%				
Rate of NSE decisions	0.7%				
Rate of Withdrawals	2%				
Rate of Deleted	0.2%				

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	2				
Mean FDA days for submissions that missed goal	100				
Mean Industry days for submissions that missed goal	15				

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	407				
Closed before RTA action	6				
Number Accepted	110				
RTA Review not done and > 15 days since Date Received	4				
RTA Review not done and <= 15 days since Date Received	26				
Number Not Accepted	261				
Rate of submissions not accepted	70%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	436				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	331				
SI over 60 FDA days	16				
SI pending within 60 FDA days	88				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	1				
Current SI Performance Percent within 60 FDA days	95%				

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	347				
Average number of FDA days to Substantive Interaction	48				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	49				
60th Percentile FDA days to Substantive Interaction	57				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	90				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	447				
Non-MDUFA III Decisions	15				
MDUFA III Decisions (SE/NSE)	173				
MDUFA III Decisions within 90 FDA Days	173				
510(k)s pending MDUFA III Decision	259				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.61				
Number with MDUFA decision	173				
Average FDA days to MDUFA III decision	66				
20th Percentile FDA days to MDUFA III decision	44				
40th Percentile FDA days to MDUFA III decision	60				
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				
Average Industry days to MDUFA III decision	26				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	22				
80th Percentile Industry days to MDUFA III decision	52				
Maximum Industry days to MDUFA III decision	173				
Average Total days to MDUFA III decision	92				
20th Percentile Total days to MDUFA III decision	49				
40th Percentile Total days to MDUFA III decision	77				
60th Percentile Total days to MDUFA III decision	98				
80th Percentile Total days to MDUFA III decision	133				
Maximum Total days to MDUFA III decision	261				

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	447				
Number with MDUFA decision	173				
Number of SE decisions	168				
Number of NSE decisions	5				
Number of Withdrawals	7				
Number deleted	5				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	2%				
Rate of Deleted	1%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	218				
Closed before RTA action	0				
Number Accepted	91				
RTA Review not done and > 15 days since Date Received	5				
RTA Review not done and <= 15 days since Date Received	22				
Number Not Accepted	100				
Rate of submissions not accepted	51%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	273				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	210				
SI over 60 FDA days	21				
SI pending within 60 FDA days	42				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	91%				

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	231				
Average number of FDA days to Substantive Interaction	44				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	36				
60th Percentile FDA days to Substantive Interaction	49				
80th Percentile FDA days to Substantive Interaction	58				
Maximum FDA days to Substantive Interaction	98				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	293				
Non-MDUFA III Decisions	1				
MDUFA III Decisions (SE/NSE)	168				
MDUFA III Decisions within 90 FDA Days	166				
510(k)s pending MDUFA III Decision	124				
510(k) pending MDUFA III Decision over 90 FDA days	2				
Current Performance Percent within 90 FDA Days	98%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.52				
Number with MDUFA decision	168				
Average FDA days to MDUFA III decision	58				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	47				
60th Percentile FDA days to MDUFA III decision	70				
80th Percentile FDA days to MDUFA III decision	88				
Maximum FDA days to MDUFA III decision	113				
Average Industry days to MDUFA III decision	21				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	18				
80th Percentile Industry days to MDUFA III decision	40				
Maximum Industry days to MDUFA III decision	187				
Average Total days to MDUFA III decision	79				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	53				
60th Percentile Total days to MDUFA III decision	90				
80th Percentile Total days to MDUFA III decision	121				
Maximum Total days to MDUFA III decision	262				

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	293				
Number with MDUFA decision	168				
Number of SE decisions	166				
Number of NSE decisions	2				
Number of Withdrawals	0				
Number deleted	1				
Rate of SE decisions	99%				
Rate of NSE decisions	1%				
Rate of Withdrawals	0%				
Rate of Deleted	0.3%				

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	2				
Mean FDA days for submissions that missed goal	105				
Mean Industry days for submissions that missed goal	31				

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	130				
Closed before RTA action	0				
Number Accepted	24				
RTA Review not done and > 15 days since Date Received	1				
RTA Review not done and <= 15 days since Date Received	15				
Number Not Accepted	90				
Rate of submissions not accepted	78%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	132				
Deleted or withdrawn prior to SI	2				
SI within 60 FDA days	93				
SI over 60 FDA days	5				
SI pending within 60 FDA days	32				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	95%				

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	98				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	48				
60th Percentile FDA days to Substantive Interaction	56				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	77				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	138				
Non-MDUFA III Decisions	6				
MDUFA III Decisions (SE/NSE)	45				
MDUFA III Decisions within 90 FDA Days	44				
510(k)s pending MDUFA III Decision	87				
510(k) pending MDUFA III Decision over 90 FDA days	1				
Current Performance Percent within 90 FDA Days	96%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.71				
Number with MDUFA decision	45				
Average FDA days to MDUFA III decision	78				
20th Percentile FDA days to MDUFA III decision	64				
40th Percentile FDA days to MDUFA III decision	87				
60th Percentile FDA days to MDUFA III decision	88				
80th Percentile FDA days to MDUFA III decision	90				
Maximum FDA days to MDUFA III decision	92				
Average Industry days to MDUFA III decision	36				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	9				
60th Percentile Industry days to MDUFA III decision	35				
80th Percentile Industry days to MDUFA III decision	73				
Maximum Industry days to MDUFA III decision	151				
Average Total days to MDUFA III decision	113				
20th Percentile Total days to MDUFA III decision	67				
40th Percentile Total days to MDUFA III decision	90				
60th Percentile Total days to MDUFA III decision	120				
80th Percentile Total days to MDUFA III decision	162				
Maximum Total days to MDUFA III decision	240				

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	138				
Number with MDUFA decision	45				
Number of SE decisions	43				
Number of NSE decisions	2				
Number of Withdrawals	5				
Number deleted	0				
Rate of SE decisions	96%				
Rate of NSE decisions	4%				
Rate of Withdrawals	4%				
Rate of Deleted	0%				

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	1				
Mean FDA days for submissions that missed goal	92				
Mean Industry days for submissions that missed goal	82				

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	332				
Closed before RTA action	0				
Number Accepted	102				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	14				
Number Not Accepted	216				
Rate of submissions not accepted	68%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	423				
Deleted or withdrawn prior to SI	3				
SI within 60 FDA days	324				
SI over 60 FDA days	13				
SI pending within 60 FDA days	83				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	96%				

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	337				
Average number of FDA days to Substantive Interaction	45				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	44				
60th Percentile FDA days to Substantive Interaction	53				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	88				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	424				
Non-MDUFA III Decisions	14				
MDUFA III Decisions (SE/NSE)	215				
MDUFA III Decisions within 90 FDA Days	214				
510(k)s pending MDUFA III Decision	195				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.51				
Number with MDUFA decision	215				
Average FDA days to MDUFA III decision	62				
20th Percentile FDA days to MDUFA III decision	30				
40th Percentile FDA days to MDUFA III decision	57				
60th Percentile FDA days to MDUFA III decision	75				
80th Percentile FDA days to MDUFA III decision	87				
Maximum FDA days to MDUFA III decision	100				
Average Industry days to MDUFA III decision	19				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	10				
80th Percentile Industry days to MDUFA III decision	40				
Maximum Industry days to MDUFA III decision	140				
Average Total days to MDUFA III decision	82				
20th Percentile Total days to MDUFA III decision	34				
40th Percentile Total days to MDUFA III decision	67				
60th Percentile Total days to MDUFA III decision	90				
80th Percentile Total days to MDUFA III decision	118				
Maximum Total days to MDUFA III decision	212				

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	424				
Number with MDUFA decision	215				
Number of SE decisions	210				
Number of NSE decisions	5				
Number of Withdrawals	8				
Number deleted	5				
Rate of SE decisions	98%				
Rate of NSE decisions	2%				
Rate of Withdrawals	2%				
Rate of Deleted	1%				

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	1				
Mean FDA days for submissions that missed goal	100				
Mean Industry days for submissions that missed goal	65				

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	66				
Closed before RTA action	0				
Number Accepted	28				
RTA Review not done and > 15 days since Date Received	2				
RTA Review not done and <= 15 days since Date Received	5				
Number Not Accepted	31				
Rate of submissions not accepted	51%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	73				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	60				
SI over 60 FDA days	3				
SI pending within 60 FDA days	10				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	95%				

Table 6.3.DOED 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	63				
Average number of FDA days to Substantive Interaction	49				
20th Percentile FDA days to Substantive Interaction	43				
40th Percentile FDA days to Substantive Interaction	49				
60th Percentile FDA days to Substantive Interaction	50				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	88				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	79				
Non-MDUFA III Decisions	2				
MDUFA III Decisions (SE/NSE)	37				
MDUFA III Decisions within 90 FDA Days	36				
510(k)s pending MDUFA III Decision	40				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	97%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.86				
Number with MDUFA decision	37				
Average FDA days to MDUFA III decision	70				
20th Percentile FDA days to MDUFA III decision	48				
40th Percentile FDA days to MDUFA III decision	61				
60th Percentile FDA days to MDUFA III decision	88				
80th Percentile FDA days to MDUFA III decision	90				
Maximum FDA days to MDUFA III decision	91				
Average Industry days to MDUFA III decision	33				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	7				
60th Percentile Industry days to MDUFA III decision	21				
80th Percentile Industry days to MDUFA III decision	68				
Maximum Industry days to MDUFA III decision	175				
Average Total days to MDUFA III decision	103				
20th Percentile Total days to MDUFA III decision	57				
40th Percentile Total days to MDUFA III decision	90				
60th Percentile Total days to MDUFA III decision	107				
80th Percentile Total days to MDUFA III decision	128				
Maximum Total days to MDUFA III decision	244				

Table 6.6.DOED 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	79				
Number with MDUFA decision	37				
Number of SE decisions	36				
Number of NSE decisions	1				
Number of Withdrawals	1				
Number deleted	0				
Rate of SE decisions	97%				
Rate of NSE decisions	3%				
Rate of Withdrawals	1%				
Rate of Deleted	0%				

Table 6.7.DOED 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	1				
Mean FDA days for submissions that missed goal	91				
Mean Industry days for submissions that missed goal	153				

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	133				
Closed before RTA action	0				
Number Accepted	32				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	15				
Number Not Accepted	86				
Rate of submissions not accepted	73%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	161				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	123				
SI over 60 FDA days	4				
SI pending within 60 FDA days	32				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	1				
Current SI Performance Percent within 60 FDA days	96%				

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	127				
Average number of FDA days to Substantive Interaction	46				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	47				
60th Percentile FDA days to Substantive Interaction	52				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	66				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	170				
Non-MDUFA III Decisions	8				
MDUFA III Decisions (SE/NSE)	74				
MDUFA III Decisions within 90 FDA Days	74				
510(k)s pending MDUFA III Decision	88				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.78				
Number with MDUFA decision	74				
Average FDA days to MDUFA III decision	63				
20th Percentile FDA days to MDUFA III decision	32				
40th Percentile FDA days to MDUFA III decision	57				
60th Percentile FDA days to MDUFA III decision	82				
80th Percentile FDA days to MDUFA III decision	86				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	39				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	11				
60th Percentile Industry days to MDUFA III decision	37				
80th Percentile Industry days to MDUFA III decision	74				
Maximum Industry days to MDUFA III decision	164				
Average Total days to MDUFA III decision	101				
20th Percentile Total days to MDUFA III decision	44				
40th Percentile Total days to MDUFA III decision	78				
60th Percentile Total days to MDUFA III decision	108				
80th Percentile Total days to MDUFA III decision	148				
Maximum Total days to MDUFA III decision	252				

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	170				
Number with MDUFA decision	74				
Number of SE decisions	67				
Number of NSE decisions	7				
Number of Withdrawals	5				
Number deleted	3				
Rate of SE decisions	91%				
Rate of NSE decisions	9%				
Rate of Withdrawals	3%				
Rate of Deleted	2%				

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				
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	228				
Closed before RTA action	3				
Number Accepted	72				
RTA Review not done and > 15 days since Date Received	2				
RTA Review not done and <= 15 days since Date Received	29				
Number Not Accepted	122				
Rate of submissions not accepted	62%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	275				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	213				
SI over 60 FDA days	22				
SI pending within 60 FDA days	39				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	91%				

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	235				
Average number of FDA days to Substantive Interaction	41				
20th Percentile FDA days to Substantive Interaction	23				
40th Percentile FDA days to Substantive Interaction	31				
60th Percentile FDA days to Substantive Interaction	51				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	90				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	281				
Non-MDUFA III Decisions	17				
MDUFA III Decisions (SE/NSE)	136				
MDUFA III Decisions within 90 FDA Days	136				
510(k)s pending MDUFA III Decision	128				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.57				
Number with MDUFA decision	136				
Average FDA days to MDUFA III decision	54				
20th Percentile FDA days to MDUFA III decision	23				
40th Percentile FDA days to MDUFA III decision	42				
60th Percentile FDA days to MDUFA III decision	69				
80th Percentile FDA days to MDUFA III decision	86				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	22				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	20				
80th Percentile Industry days to MDUFA III decision	39				
Maximum Industry days to MDUFA III decision	143				
Average Total days to MDUFA III decision	77				
20th Percentile Total days to MDUFA III decision	24				
40th Percentile Total days to MDUFA III decision	54				
60th Percentile Total days to MDUFA III decision	89				
80th Percentile Total days to MDUFA III decision	119				
Maximum Total days to MDUFA III decision	216				

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	281				
Number with MDUFA decision	136				
Number of SE decisions	134				
Number of NSE decisions	2				
Number of Withdrawals	10				
Number deleted	5				
Rate of SE decisions	99%				
Rate of NSE decisions	1%				
Rate of Withdrawals	4%				
Rate of Deleted	2%				

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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	123				
Closed before RTA action	1				
Number Accepted	82				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	8				
Number Not Accepted	32				
Rate of submissions not accepted	28%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	162				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	143				
SI over 60 FDA days	0				
SI pending within 60 FDA days	19				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	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	143				
Average number of FDA days to Substantive Interaction	41				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	38				
60th Percentile FDA days to Substantive Interaction	45				
80th Percentile FDA days to Substantive Interaction	53				
Maximum FDA days to Substantive Interaction	60				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	162				
Non-MDUFA III Decisions	6				
MDUFA III Decisions (SE/NSE)	75				
MDUFA III Decisions within 90 FDA Days	75				
510(k)s pending MDUFA III Decision	81				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.44				
Number with MDUFA decision	75				
Average FDA days to MDUFA III decision	52				
20th Percentile FDA days to MDUFA III decision	29				
40th Percentile FDA days to MDUFA III decision	37				
60th Percentile FDA days to MDUFA III decision	58				
80th Percentile FDA days to MDUFA III decision	84				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	28				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	8				
80th Percentile Industry days to MDUFA III decision	63				
Maximum Industry days to MDUFA III decision	183				
Average Total days to MDUFA III decision	80				
20th Percentile Total days to MDUFA III decision	29				
40th Percentile Total days to MDUFA III decision	38				
60th Percentile Total days to MDUFA III decision	71				
80th Percentile Total days to MDUFA III decision	141				
Maximum Total days to MDUFA III decision	244				

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	162				
Number with MDUFA decision	75				
Number of SE decisions	75				
Number of NSE decisions	0				
Number of Withdrawals	6				
Number deleted	0				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	4%				
Rate of Deleted	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	0				
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

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

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	51				
Closed before RTA action	1				
Number Accepted	34				
RTA Review not done and > 15 days since Date Received	3				
RTA Review not done and <= 15 days since Date Received	3				
Number Not Accepted	10				
Rate of submissions not accepted	21%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	62				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	48				
SI over 60 FDA days	1				
SI pending within 60 FDA days	13				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	98%				

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	49				
Average number of FDA days to Substantive Interaction	48				
20th Percentile FDA days to Substantive Interaction	42				
40th Percentile FDA days to Substantive Interaction	49				
60th Percentile FDA days to Substantive Interaction	54				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	63				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	62				
Non-MDUFA III Decisions	2				
MDUFA III Decisions (SE/NSE)	10				
MDUFA III Decisions within 90 FDA Days	10				
510(k)s pending MDUFA III Decision	50				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.8				
Number with MDUFA decision	10				
Average FDA days to MDUFA III decision	63				
20th Percentile FDA days to MDUFA III decision	44				
40th Percentile FDA days to MDUFA III decision	62				
60th Percentile FDA days to MDUFA III decision	77				
80th Percentile FDA days to MDUFA III decision	83				
Maximum FDA days to MDUFA III decision	89				
Average Industry days to MDUFA III decision	70				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	36				
60th Percentile Industry days to MDUFA III decision	76				
80th Percentile Industry days to MDUFA III decision	144				
Maximum Industry days to MDUFA III decision	177				
Average Total days to MDUFA III decision	133				
20th Percentile Total days to MDUFA III decision	67				
40th Percentile Total days to MDUFA III decision	102				
60th Percentile Total days to MDUFA III decision	148				
80th Percentile Total days to MDUFA III decision	224				
Maximum Total days to MDUFA III decision	252				

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	62				
Number with MDUFA decision	10				
Number of SE decisions	9				
Number of NSE decisions	1				
Number of Withdrawals	0				
Number deleted	0				
Rate of SE decisions	90%				
Rate of NSE decisions	10%				
Rate of Withdrawals	0%				
Rate of Deleted	0%				

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				
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	28				
Closed before RTA action	0				
Number Accepted	24				
RTA Review not done and > 15 days since Date Received	0				
RTA Review not done and <= 15 days since Date Received	2				
Number Not Accepted	2				
Rate of submissions not accepted	8%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	46				
Deleted or withdrawn prior to SI	0				
SI within 60 FDA days	33				
SI over 60 FDA days	0				
SI pending within 60 FDA days	13				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	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	33				
Average number of FDA days to Substantive Interaction	44				
20th Percentile FDA days to Substantive Interaction	29				
40th Percentile FDA days to Substantive Interaction	42				
60th Percentile FDA days to Substantive Interaction	53				
80th Percentile FDA days to Substantive Interaction	57				
Maximum FDA days to Substantive Interaction	60				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	46				
Non-MDUFA III Decisions	3				
MDUFA III Decisions (SE/NSE)	23				
MDUFA III Decisions within 90 FDA Days	23				
510(k)s pending MDUFA III Decision	20				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.22				
Number with MDUFA decision	23				
Average FDA days to MDUFA III decision	61				
20th Percentile FDA days to MDUFA III decision	32				
40th Percentile FDA days to MDUFA III decision	60				
60th Percentile FDA days to MDUFA III decision	76				
80th Percentile FDA days to MDUFA III decision	80				
Maximum FDA days to MDUFA III decision	89				
Average Industry days to MDUFA III decision	30				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	47				
Maximum Industry days to MDUFA III decision	173				
Average Total days to MDUFA III decision	91				
20th Percentile Total days to MDUFA III decision	32				
40th Percentile Total days to MDUFA III decision	72				
60th Percentile Total days to MDUFA III decision	80				
80th Percentile Total days to MDUFA III decision	123				
Maximum Total days to MDUFA III decision	250				

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	46				
Number with MDUFA decision	23				
Number of SE decisions	23				
Number of NSE decisions	0				
Number of Withdrawals	2				
Number deleted	1				
Rate of SE decisions	100%				
Rate of NSE decisions	0%				
Rate of Withdrawals	4%				
Rate of Deleted	2%				

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				
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	154				
Closed before RTA action	0				
Number Accepted	86				
RTA Review not done and > 15 days since Date Received	12				
RTA Review not done and <= 15 days since Date Received	15				
Number Not Accepted	41				
Rate of submissions not accepted	29%				

*** 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 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	224				
Deleted or withdrawn prior to SI	1				
SI within 60 FDA days	168				
SI over 60 FDA days	28				
SI pending within 60 FDA days	27				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	86%				

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	196				
Average number of FDA days to Substantive Interaction	47				
20th Percentile FDA days to Substantive Interaction	30				
40th Percentile FDA days to Substantive Interaction	42				
60th Percentile FDA days to Substantive Interaction	55				
80th Percentile FDA days to Substantive Interaction	60				
Maximum FDA days to Substantive Interaction	91				

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

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	263				
Non-MDUFA III Decisions	4				
MDUFA III Decisions (SE/NSE)	178				
MDUFA III Decisions within 90 FDA Days	176				
510(k)s pending MDUFA III Decision	81				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	99%				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Average review cycles	1.41				
Number with MDUFA decision	178				
Average FDA days to MDUFA III decision	53				
20th Percentile FDA days to MDUFA III decision	27				
40th Percentile FDA days to MDUFA III decision	42				
60th Percentile FDA days to MDUFA III decision	65				
80th Percentile FDA days to MDUFA III decision	84				
Maximum FDA days to MDUFA III decision	109				
Average Industry days to MDUFA III decision	17				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	29				
Maximum Industry days to MDUFA III decision	167				
Average Total days to MDUFA III decision	70				
20th Percentile Total days to MDUFA III decision	28				
40th Percentile Total days to MDUFA III decision	45				
60th Percentile Total days to MDUFA III decision	77				
80th Percentile Total days to MDUFA III decision	107				
Maximum Total days to MDUFA III decision	247				

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	263				
Number with MDUFA decision	178				
Number of SE decisions	177				
Number of NSE decisions	1				
Number of Withdrawals	4				
Number deleted	0				
Rate of SE decisions	99%				
Rate of NSE decisions	1%				
Rate of Withdrawals	2%				
Rate of Deleted	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	2				
Mean FDA days for submissions that missed goal	100				
Mean Industry days for submissions that missed goal	15				

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 Petitions

De Novo Petition Metrics will be reported in the Annual Report.

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	1289				
Number requesting a meeting or teleconference	726				
Number with meetings or teleconferences held	442				
Average days to meeting	56				
20th Percentile days to meeting	35				
40th Percentile days to meeting	50				
60th Percentile days to meeting	63				
80th Percentile days to meeting	75				
Maximum days to meeting	183				

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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	691				
Number requesting a meeting or teleconference	459				
Number with meetings or teleconferences held	263				
Average days to meeting	58				
20th Percentile days to meeting	35				
40th Percentile days to meeting	52				
60th Percentile days to meeting	65				
80th Percentile days to meeting	77				
Maximum days to meeting	183				

Table 9.1.OIR OIR – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	598				
Number requesting a meeting or teleconference	267				
Number with meetings or teleconferences held	179				
Average days to meeting	53				
20th Percentile days to meeting	34				
40th Percentile days to meeting	49				
60th Percentile days to meeting	61				
80th Percentile days to meeting	72				
Maximum days to meeting	138				

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	107				
Number requesting a meeting or teleconference	61				
Number with meetings or teleconferences held	37				
Average days to meeting	67				
20th Percentile days to meeting	41				
40th Percentile days to meeting	65				
60th Percentile days to meeting	75				
80th Percentile days to meeting	87				
Maximum days to meeting	121				

Table 9.1.DCD DCD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	216				
Number requesting a meeting or teleconference	160				
Number with meetings or teleconferences held	104				
Average days to meeting	51				
20th Percentile days to meeting	29				
40th Percentile days to meeting	46				
60th Percentile days to meeting	55				
80th Percentile days to meeting	71				
Maximum days to meeting	104				

Table 9.1.DNPMD DNPMD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	56				
Number requesting a meeting or teleconference	39				
Number with meetings or teleconferences held	20				
Average days to meeting	68				
20th Percentile days to meeting	44				
40th Percentile days to meeting	61				
60th Percentile days to meeting	76				
80th Percentile days to meeting	90				
Maximum days to meeting	148				

Table 9.1.DOD DOD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	68				
Number requesting a meeting or teleconference	47				
Number with meetings or teleconferences held	20				
Average days to meeting	53				
20th Percentile days to meeting	33				
40th Percentile days to meeting	47				
60th Percentile days to meeting	61				
80th Percentile days to meeting	77				
Maximum days to meeting	98				

Table 9.1.DOED DOED – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	66				
Number requesting a meeting or teleconference	40				
Number with meetings or teleconferences held	23				
Average days to meeting	63				
20th Percentile days to meeting	50				
40th Percentile days to meeting	60				
60th Percentile days to meeting	67				
80th Percentile days to meeting	73				
Maximum days to meeting	118				

Table 9.1.DRGUD DRGUD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	94				
Number requesting a meeting or teleconference	56				
Number with meetings or teleconferences held	35				
Average days to meeting	56				
20th Percentile days to meeting	39				
40th Percentile days to meeting	58				
60th Percentile days to meeting	62				
80th Percentile days to meeting	70				
Maximum days to meeting	115				

Table 9.1.DSD DSD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	84				
Number requesting a meeting or teleconference	56				
Number with meetings or teleconferences held	24				
Average days to meeting	66				
20th Percentile days to meeting	37				
40th Percentile days to meeting	59				
60th Percentile days to meeting	73				
80th Percentile days to meeting	84				
Maximum days to meeting	183				

Table 9.1.DCTD DCTD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	170				
Number requesting a meeting or teleconference	82				
Number with meetings or teleconferences held	56				
Average days to meeting	47				
20th Percentile days to meeting	30				
40th Percentile days to meeting	43				
60th Percentile days to meeting	53				
80th Percentile days to meeting	67				
Maximum days to meeting	89				

Table 9.1.DIHD DIHD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	207				
Number requesting a meeting or teleconference	114				
Number with meetings or teleconferences held	77				
Average days to meeting	61				
20th Percentile days to meeting	39				
40th Percentile days to meeting	59				
60th Percentile days to meeting	70				
80th Percentile days to meeting	83				
Maximum days to meeting	138				

Table 9.1.DMD DMD – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	176				
Number requesting a meeting or teleconference	43				
Number with meetings or teleconferences held	29				
Average days to meeting	50				
20th Percentile days to meeting	37				
40th Percentile days to meeting	49				
60th Percentile days to meeting	60				
80th Percentile days to meeting	67				
Maximum days to meeting	74				

Table 9.1.DRH DRH – Pre-Submissions Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	45				
Number requesting a meeting or teleconference	28				
Number with meetings or teleconferences held	17				
Average days to meeting	39				
20th Percentile days to meeting	9				
40th Percentile days to meeting	35				
60th Percentile days to meeting	50				
80th Percentile days to meeting	62				
Maximum days to meeting	71				

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)

Investigational Device Exemption data will be reported for FY2014 –FY2017.

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[#]	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).

[#] 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	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th 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^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

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

#	Measure	Description
1	Number with MDUFA 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^{th}, 40^{th}, 60^{th}, 80^{th} percentiles) and the Maximum Days (100^{th} percentile) for FDA days, Industry days, and Total days.

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

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number with MDUFA 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 (line2).

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

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA 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 (line2).

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 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) decision in the first RTA review cycle automatically recorded by CTS at the end of day 14 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 (see the definition for Accepted cohort above), excluding submissions with the following NON-MDUFA decisions made before or on the cutoff date: WD, DD, DE, HD, K4, NR, RC, RD. 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 accepted, but were withdrawn or deleted prior to 60 days.
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 AN, DN, ON decisions 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	20th Percentile FDA days to Substantive Interaction	20th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40th Percentile FDA days to Substantive Interaction	40th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60th Percentile FDA days to Substantive Interaction	60th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80th Percentile FDA days to Substantive Interaction	80th percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100th 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).
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 (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th 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 have more than 90 FDA days to MDUFA III decision. 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 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 Received 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 Submission Received Date and the Actual Meeting Date is prior to as of the cutoff date.

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				
Closed before RTA action	0				
Number Accepted	1				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	0				
Number Not Accepted for Filing Review	0				
Rate of submissions not accepted for filing review	0.0%				
Completed RTF	0				
Number Not Filed	0				
Rate of submissions Not Filed	0.0%				

Table 1.2 CBER – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	1				
SI within 90 FDA days	0				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	0				
Current SI Performance Percent within 90 FDA days	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	0				
Average number of FDA days to Substantive Interaction	0				
20th Percentile FDA days to Substantive Interaction	0				

40th Percentile FDA days to Substantive Interaction	0				
60th Percentile FDA days to Substantive Interaction	0				
80th Percentile FDA days to Substantive Interaction	0				
Maximum FDA days to Substantive Interaction	0				

Table 1.4 CBER – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals

Performance Goals:	FY 2013 70% within 180 FDA days	FY 2014 80% within 180 FDA days	FY 2015 80% within 180 FDA days	FY 2016 90% within 180 FDA days	FY 2017 90% within 180 FDA days
Number of PMAs filed	0				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
PMAs pending MDUFA III Decision	0				
PMAs pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	0.0%				

Table 1.5 CBER – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA Decision Performance Goals

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

Average FDA days to MDUFA III decision	**0**				
20th Percentile FDA days to MDUFA III decision	0				
40th Percentile FDA days to MDUFA III decision	0				
60th Percentile FDA days to MDUFA III decision	0				
80th Percentile FDA days to MDUFA III decision	0				
Maximum FDA days to MDUFA III decision	0				
Average Industry days to MDUFA III decision	**0**				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	**0**				
20th Percentile Total days to MDUFA III decision	0				
40th Percentile Total days to MDUFA III decision	0				
60th Percentile Total days to MDUFA III decision	0				
80th Percentile Total days to MDUFA III decision	0				
Maximum Total days to MDUFA III decision	0				

Table 1.7 CBER – PMA Original and Panel Track Supplements (with 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				
Average FDA days to MDUFA III decision	**0**				
20th Percentile FDA days to MDUFA III decision	0				
40th Percentile FDA days to MDUFA III decision	0				
60th Percentile FDA days to MDUFA III decision	0				
80th Percentile FDA days to MDUFA III decision	0				
Maximum FDA days to MDUFA III decision	0				

Average Industry days to MDUFA III decision	**0**				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
Average Total days to MDUFA III decision	**0**				
20th Percentile Total days to MDUFA III decision	0				
40th Percentile Total days to MDUFA III decision	0				
60th Percentile Total days to MDUFA III decision	0				
80th Percentile Total days to MDUFA III decision	0				
Maximum Total days to MDUFA III decision	0				

Table 1.8 CBER – 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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0.0%				
Rate of Not Approvable	0.0%				

Table 1.9 CBER – 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				
Number with MDUFA decision	0				
Number of Withdrawals	0				
Number of Not Approvable	0				
Rate of Withdrawals	0.0%				
Rate of Not Approvable	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				
Mean FDA days for submissions that missed goal	0				
Mean industry days for submissions that missed goal	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				
Mean FDA days for submissions that missed goal	0				
Mean industry days for submissions that missed goal	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 65% SI within 90 FDA days	FY 2014 75% SI within 90 FDA days	FY 2015 85% SI within 90 FDA days	FY 2016 95% SI within 90 FDA days	FY 2017 95% SI within 90 FDA days
Eligible for SI	2				
SI within 90 FDA days	0				
SI over 90 FDA days	0				
SI pending within 90 FDA days	1				
SI pending over 90 FDA days	0				
Closed without SI	1				
Current SI Performance Percent within 90 FDA days	0.0%				

Table 2.2 CBER – PMA 180 Day Supplements MDUFA Decision Performance Goals

Performance Goals:	FY 2013 85% within 180 FDA days	FY 2014 90% within 180 FDA days	FY 2015 90% within 180 FDA days	FY 2016 95% within 180 FDA days	FY 2017 95% within 180 FDA days
Supplements received	2				
Non-MDUFA III Decisions	1				
MDUFA III Decisions	0				
MDUFA III Decisions within 180 FDA Days	0				
Supplements pending MDUFA III Decision	1				
Supplements pending MDUFA III Decision over 180 FDA days	0				
Current Performance Percent within 180 FDA Days	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	2				
Number with MDUFA decision	0				
Number of Not Approvable	0				
Rate of Not Approvable	0.0%				

Table 2.4 CBER – 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				
Mean FDA days for submissions that missed goal	0				
Mean Industry days for submissions that missed goal	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				
Non-MDUFA III Decisions	0				
MDUFA III Decisions	3				
MDUFA III Decisions within 90 FDA Days	3				
Supplements pending MDUFA III Decision	0				
Supplements pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	100.0%				

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				
Number with MDUFA decision	3				
Number of Not Approvable	0				
Rate of Not Approvable	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				
Mean FDA days for submissions that missed goal	0				
Mean Industry days for submissions that missed goal	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				
Original PMAs (Panel) – Priority	0				
Original PMAs (No Panel) – Priority	0				
Original PMAs (Panel) – Non-Priority	1				
Original PMAs (No Panel) – Non-Priority	0				
Panel-Tracked Supplements (Panel) – Priority	0				
Panel-Tracked Supplements (No Panel) – Priority	0				
Panel-Tracked Supplements (Panel) – Non-Priority	0				
Panel-Tracked Supplements (No Panel) – Non-Priority	0				
PMA Modules	3				
180-Day Supplements	2				
Real-Time Supplements	3				

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	0				
Number with a decision (MDUFA or Non-MDUFA)	0				
% of FY closed	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	40				
Closed before RTA action	1				
Number Accepted	27				
Number without a RTA Review and > 15 Days since Date Received	0				
Number without a RTA Review and <= 15 Days since Date Received	4				
Number Not Accepted	8				
Rate of submissions not accepted for filing review	22.9%				

Table 6.2 CBER – 510(k) Substantive Interaction Performance Goals

Substantive Interaction (SI) Performance Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA days	FY 2015 85% SI within 60 FDA days	FY 2016 95% SI within 60 FDA days	FY 2017 95% SI within 60 FDA days
Eligible for SI	27				
SI within 60 FDA days	21				
SI over 60 FDA days	5				
SI pending within 60 FDA days	1				
SI pending over 60 FDA days	0				
510(k)s NSE without SI	0				
Current SI Performance Percent within 60 FDA days	77.8%				

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	26				
Average number of FDA days to Substantive Interaction	50				
20th Percentile FDA days to Substantive Interaction	28				
40th Percentile FDA days to Substantive Interaction	43				
60th Percentile FDA days to Substantive Interaction	55				
80th Percentile FDA days to Substantive Interaction	59				
Maximum FDA days to Substantive Interaction	90				

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	27				
Non-MDUFA III Decisions	22				
MDUFA III Decisions (SE/NSE)	14				
MDUFA III Decisions within 90 FDA Days	14				
510(k)s pending MDUFA III Decision	10				
510(k) pending MDUFA III Decision over 90 FDA days	0				
Current Performance Percent within 90 FDA Days	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	1.36				
Number with MDUFA III decision	14				
Average FDA days to MDUFA III decision	63				
20th Percentile FDA days to MDUFA III decision	26				
40th Percentile FDA days to MDUFA III decision	29				
60th Percentile FDA days to MDUFA III decision	86				
80th Percentile FDA days to MDUFA III decision	89				
Maximum FDA days to MDUFA III decision	90				
Average Industry days to MDUFA III decision	26				
20th Percentile Industry days to MDUFA III decision	0				
40th Percentile Industry days to MDUFA III decision	0				
60th Percentile Industry days to MDUFA III decision	0				
80th Percentile Industry days to MDUFA III decision	49				
Maximum Industry days to MDUFA III decision	120				
Average Total days to MDUFA III decision	89				
20th Percentile Total days to MDUFA III decision	26				
40th Percentile Total days to MDUFA III decision	29				
60th Percentile Total days to MDUFA III decision	89				

80th Percentile Total days to MDUFA III decision	127				
Maximum Total days to MDUFA III decision	207				

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	27				
Number with MDUFA decision	14				
Number of SE decisions	13				
Number of NSE decisions	1				
Number of Withdrawals	4				
Number deleted	0				
Rate of SE decisions	72.2%				
Rate of NSE decisions	5.6%				
Rate of Withdrawals	22.2%				
Rate of Deleted	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				
Mean FDA days for submissions that missed goal	0				
Mean industry days for submissions that missed goal	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	27				
Number of Traditional submissions	21				
Number of Special submissions	5				

Number of Abbreviated submissions	1				
Average number of days to Accept / Refuse to Accept	11				
Number of Third Party submissions	0				

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

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	27				
Currently Under Review	10				
Number with Non-MDUFA Decision	22				
Number with MDUFA III Decision	14				
Percent of cohort closed	63.0%				
Number with MDUFA III decision after trimming the upper and lower 2%	10				
Average Total Time to MDUFA III decision	89				

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				
Number of De Novo Petitions with Decision	0				
Number of De Novo Petitions with Decision Pending	2				
Average Number of Days to Decision	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	33				
Number requesting a meeting or teleconference	26				
Number with meetings or teleconferences granted	22				
Number with meeting granted and industry cancelled	9				
Number with meeting granted and FDA cancelled	0				
Number with meeting granted and pending within timeframe	3				
Number with meeting granted and pending outside timeframe	0				
Number with meetings or teleconferences held	9				
Average days to meeting	61				
20th Percentile days to meeting	42				
40th Percentile days to meeting	57				
60th Percentile days to meeting	58				
80th Percentile days to meeting	60				
Maximum days to meeting	91				

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	14				
Number of Standard BLA First Actions less than or equal to 10 months	7				
Number of Standard BLA Frist Actions greater than 10 months	0				
Number of Standard BLAs Pending	7				
Number of Priority BLA Filed	0				
Number of Priority BLA First Actions less than or equal to 10 months	0				
Number of Priority BLA Frist Actions greater than 10 months	0				
Number of Priority BLAs Pending	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				
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0				
Number of Standard Efficacy Supplements Frist Actions greater than 10 months	0				
Number of Standard Efficacy Supplements Pending	0				
Number of Priority Efficacy Supplements Filed	0				
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0				

Number of Priority Efficacy Supplements Frist Actions greater than 10 months	0				
Number of Priority Efficacy Supplements Pending	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	10				
Number of Standard PAS Supplements First Actions less than or equal to 4months	9				
Number of Standard PAS Supplements First Actions greater than 4 months	0				
Number of Standard PAS Supplements Pending	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				
Number of Class 1 Resubmission Actions less than or equal to 2 months	0				
Number of Standard Class 1 Resubmission Frist Actions greater than 2 months	0				
Number of Class 1 Resbumssions Pending	10				
Number of Class 2 Resubmissions Received	0				
Number of Class 2 Resubmission Actions less than or equal to 6 months	0				
Number of Class 2 Resubmission Actions greater than 6 months	0				

Number of Class 2 Resubmissions Pending	0				

FY 2013 Medical Device User Fee Collections as of June 30, 2013 [/1] Excludes Unearned Fees					
	Receipts	**Refunds**	**Net**	**Authorized**	**% of Authorized**
Registration Fees	$59,403,614	$318,070	$59,085,544		
Application Fees	$27,218,985	$513,064	$26,705,921		
Total	**$86,622,599**	**$831,134**	**$85,791,465**	**$97,722,301**	**89%**

Medical Device User Fee Collection History [/2] Excludes Unearned Fees, Includes Refunds					
	FY 2003	**FY 2004**	**FY 2005**	**FY 2006**	**FY 2007**
MD I	$21,620,549	$26,280,073	$31,680,296	$34,470,161	$27,808,956
	FY 2008	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012**
MD II	$47,520,942	$55,777,392	$62,806,751	$69,683,803	$65,388,115

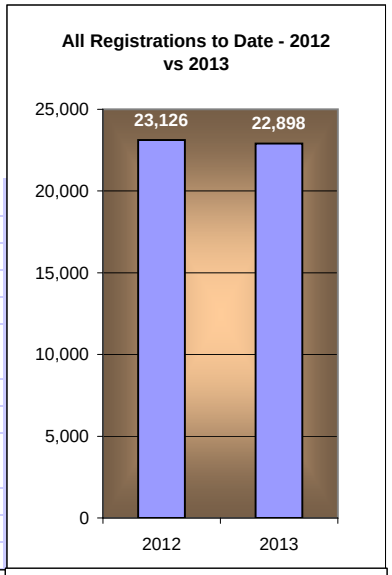
Notes:

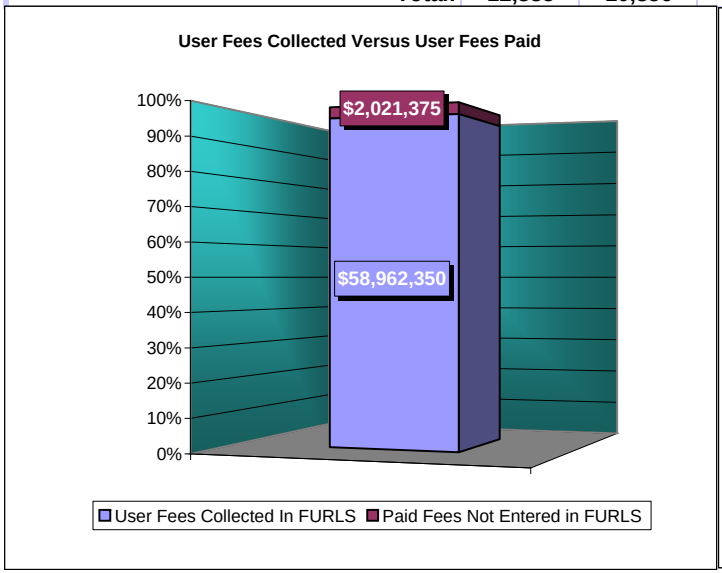
[/1] Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 2013.

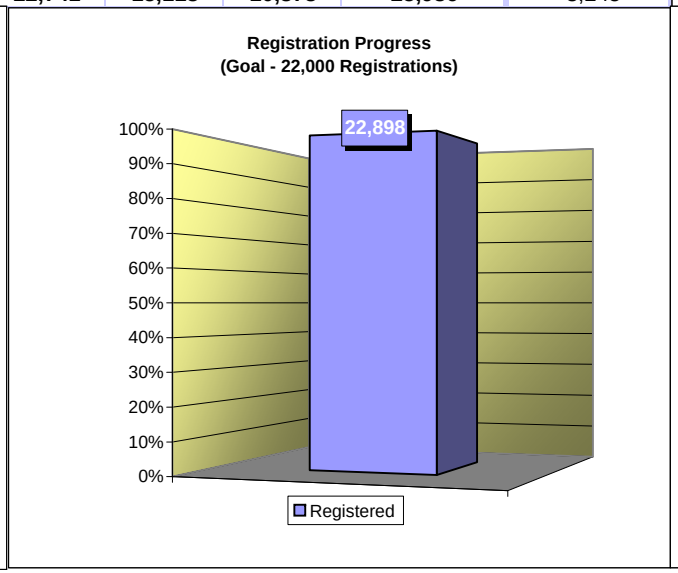
[/2] Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

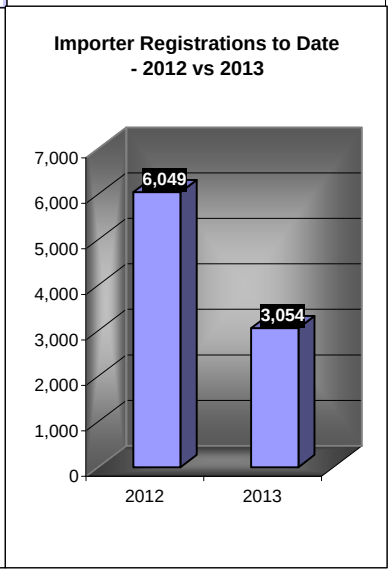
MDUFA III, Third Quarter Summary FY2013

Registrations by Type	FY13 to Date (Currently Active)			FY2012 Year End Totals			Difference Thru 6/30/13
Est Type	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,521	8,120	13,641	5,291	7,785	13,076	565
Contract Manufacturer	754	977	1,731	305	726	1,031	700
Contract Sterilizer	73	104	177	21	43	64	113
Specification Developer	1,623	363	1,986	1,599	342	1,941	45
Reprocessor of Single Use Devices	21	2	23	16	1	17	6
U.S. Manufacturer of Export Only Devices	143		143	133		133	10
Repackager/Relabeler	1,194	164	1,358	2,030	483	2,513	-1,155
Remanufacturer	30	19	49	71	105	176	-127
Foreign Exporter/Private Label Distributor	0	607	607	0	1,388	1,388	-781
Initial Importer	3,026		3,026	5,639		5,639	-2,613
Unknown			0	8		8	-8
Total:	**12,385**	**10,356**	**22,741**	**15,113**	**10,873**	**25,986**	-3,245









MDUFA III Quarterly Performance Update
Independent Assessment of Medical Device Review Process

3nd Quarter FY 2013 Status – July 30, 2013

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
FY 2013		
Publish Federal Register notice	December 2012	Completed December 2012.
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	On target.
Report on preliminary findings and high-priority recommendations	November 2013	
FY 2014		
Implementation plan for high-priority recommendations	May 2014	
Final report on complete findings and recommendations	May 2014	
Implementation plan for final recommendations	November 2014	

Milestone	Planned	Status
FY 2015		
Phase 2 kickoff meeting between FDA and contractor	April 2015	
Final workplan for Phase 2	May 2015	
FY 2016		
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) – 1st 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 – June 11, 2013
- Held kick-off meeting – July 1, 2013
- Received draft workplan – July 19, 2013
- Final workplan – XXXX, 2013

Planned Progress prior to 3rd Quarter Meeting FY 2013:

- Progress reports and updates from assessment team - Ongoing

Evaluations and Studies of New Drug Review Programs Under PDUFA IV
Contract No. HHSF223201010017B, Order No. 22313004

Independent Assessment of Premarket Device Review Process under MDUFA

Industry Organization Discussion

White Oak, MD
July 30, 2013

Today's Objectives

- Introduce Booz Allen
- Outline the project objectives, tasks and key milestones
- Discuss our proposed approach to industry engagement
- Solicit input from industry representatives

Booz | Allen | Hamilton

Founded 1914 Public Company $5B in Annual Sales

Who We Are

- One of the oldest, largest and most experienced strategy and technology consulting firms
- Our business model is driven by global industry practices emphasizing industry expertise to better serve clients
- We bring a global perspective – serving clients from over 100 offices in over 30 countries
- We are not aligned with any other integration firms or software vendors – we bring an objective and independent viewpoint to all of our clients

Booz Allen combines strategy with technology, and insight with action, working with clients to deliver results today that endure tomorrow

26,000+ Employees

What We Do

- Booz Allen Hamilton delivers tailored solutions based on client objectives
- We leverage our federal experience supporting a variety of US government agencies which impact virtually every major industry sector
- We bring industry-specific talent for the most complex consulting engagements
- We utilize our global expertise from our offices around the world
- We work closely with senior management in guiding the strategic transformation of their businesses

Examples of Booz Allen Experience with FDA Program Evaluation

- PDUFA III Evaluation
- PDUFA IV GRMPs Assessment
- PDUFA IV Electronic Submission Environment Assessment
- 21st Century Review Assessment
- Post-Marketing Commitments Study
- Risk Evaluation and Mitigation Strategies (REMS) Implementation Assessment

Examples of Booz Allen Experience with CDRH and Medical Devices

- CDRH Center Electronic Submissions (CeSub)
  - eRadHealth
  - eMDR
  - eCopies
  - ISO1375; OIVD
- CDRH FDA Adverse Events Reporting System
- Unique Device Identification Database (UDID)
- Project Priority Nomination
- CDRH HL7 RPS Data Model

The primary objective of the project is to evaluate and recommend improvements to the medical device submission review process

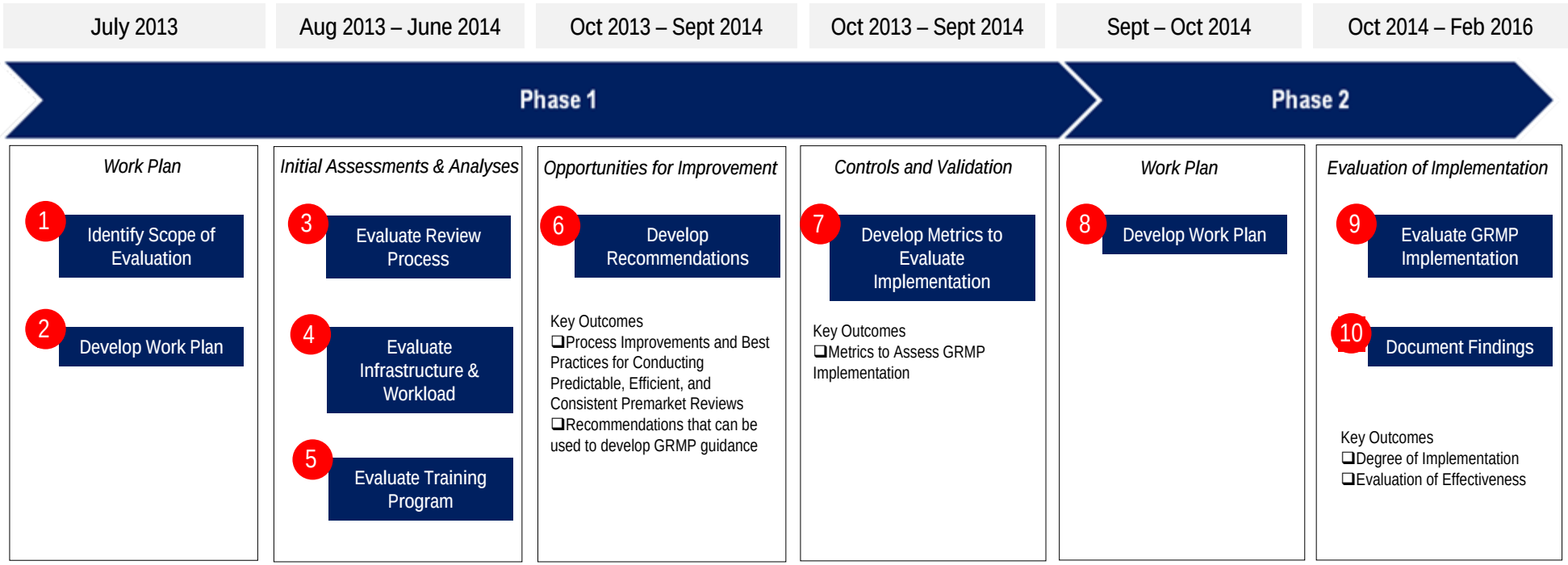
Primary Objectives

- Identification of best practices and prioritization of process improvements for FDA to conduct predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- Analysis of elements of the review process to identify opportunities for improvement
- Assessment of resource allocation to premarket medical device reviews across FDA
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results
- Evaluation of implementation of selected recommendations ***(Phase 2)***

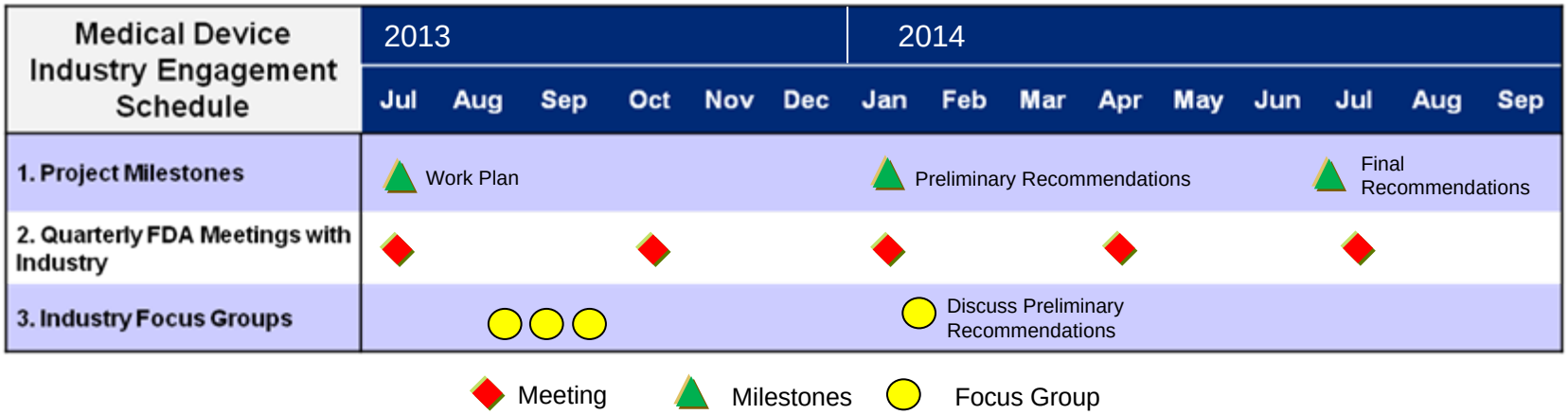
Key Tasks

- Develop a project work plan
  - Draft technical approach
  - Obtain feedback from FDA and industry stakeholders
  - Finalize work plan
- Conduct a series of assessments and analyses of various aspects of the medical device premarket review process
- Identify opportunities for improvements, best practices, and areas that require additional assessment
- Develop findings and recommendations for the improvements of the medical device review process
  - High-priority recommendations
  - Full report on findings and recommendations
- Present an evaluation plan including metrics to assess the implementation and impact of the recommendations adopted

Phase 1 will focus on assessing the review process and developing recommendations, which will be evaluated in Phase 2



We propose a set of initial focus groups to capture industry concerns, followed by updates during quarterly meetings



Example Industry Focus Group Options (Choose one or specify an alternative)

Specific Topic Focus

- Three 2-hour focus group sessions with all industry stakeholder groups present
- Each session will covered specific topic areas (e.g., electronic submission process, review process interactions)

Industry Group Focus

- One 2-hour focus group session with each industry stakeholder group
- Each session will address multiple topic areas

General Topic Focus

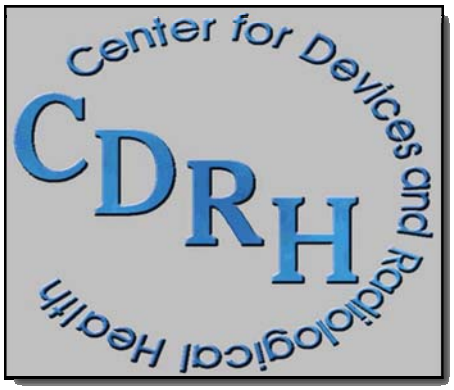
- Two 3-hour focus group sessions with all industry stakeholder groups present.
- Each session will focus on generalized topic areas (e.g., submission process, review process)

Discussion items

- Industry perspective, concerns, and priorities
- Recent surveys conducted by industry organizations
- Industry preference for early engagement

Staff College Internal Training Summary Report

From 10/1/2012 to 6/30/2013



As of: **7/3/2013**

Q1 + Q2 + Q3 FY13 *(October 1, 2012 – June 30, 2013)* MDUFA-Related Training

FDA continues to invest in internal and external training opportunities supporting the medical device review process. CDRH's Staff College is a workforce development organization that designs and delivers internal training opportunities to meet the professional needs of FDA staff. As medical device reviews grow increasingly complex, training must keep pace with these advancements. Staff College is committed to leveraging internal and external resources to enhance the training provided to Center staff.

Table X provides a summary of internal training conducted between October 1, 2012 and June 30, 2013. Staff College offered 445 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and activities. Overall, 86% (1283) of the approximately 1500 Center staff participated in training and on average attended 14 (6383÷445) learning events.

Table X: MDUFA Q1 + Q2 + Q3 FY13 CDRH Staff College Internal Training

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended Between 10/1/12– 6/30/13
Regulatory and Law (LAW)	278	2279	9244	• Reviewer Certification Program – Introduction to Medical Device Law – Basic Food and Drug Law – How to Write Deficiencies in Four-Part Harmony • Master Technical Writing: A Plain Writing Workshop • Compiling the Administrative File for Premarket Submission Decisions – Online
➢ ***MDUFA III Training****	*6*	*461*	*1146*	• *Introduction to MDUFA III* • *510(k)s* • *PMAs* • *Pre-Submissions* • *CLIA Waivers* • *Electronic Workload Management*
➢ ***ELP***	*14*	*110*	*1648*	
Leadership Education and Development (LED)	41	608	4301	• Adaptive Leadership • CDRH Employee and Labor Relations for Managers • Leading in a Telework Environment • Masterful e-Meetings • 10 Steps to Leadership Excellence • Managing Risk and Seeing Opportunity
➢ ***LEAD****	*27*	*63*	*1181*	• *Adaptive Leadership* • *Giving and Receiving Feedback* • *CDRH Employee/Labor Relations for Managers*
Professional Development (PRO)	40	603	4197	• Building High Performing Teams • Effective Communication skills for Scientific and Technical Professionals • Effective Briefing and Presentation Skills • Negotiation with Confidence • The 7 Habits of Highly Effective People • Decision Making and Critical Thinking Techniques for Results
➢ ***New Employee Orientation (NEO)*****	*3*	*63*	*441*	• *New Employee Orientation: Discover the Mission, Embrace the Vision*
Science (SCI)	86	2893	8354	• CDRH Science Sharing Seminars – Topics include: – Medical Devices Incorporating Immobilized Nanomaterials: A Biological Response • Basics of Human Factors Engineering and Device Design • Current 510(k) Sterility Review Practices – Part 1: Sterility in Devices – Part 2: Labeling Recommendations • UDI: A Foundation of Health Informatics Initiatives - Online • Safety Case Assurance for Reviewers
Total:	**445**	**6383**	**26096**	

*** The MDUFA III data has been incorporated under the Law category within the subsequent data charts.**
****No ELP site visits occurred between October 2012 and June 2013. The 2013 ELP Program site visits will begin in Q4.**
*****The LEAD data has been incorporated under the Leadership category within the subsequent data charts.**
******The NEO data has been incorporated under the Professional Development category within the subsequent data charts.**

Leadership Readiness Program (LRP) Graduates ROI Update 2013

LRP Program Year	# of Enrolled Participants	# of Participant Completions
2006-2007*	OIVD=3 ODE =13 Total = 16	OIVD = 3 ODE = 12 Total = 15
2008-2009	OIVD=3 ODE = 10 Total = 30	OIVD = 3 ODE = 10 Total = 29
2010-2011	OIVD = 3 ODE = 9 Total = 20	OIVD = 3 ODE = 8 Total = 19
2012-2013	OIVD = 3 ODE = 6 Total = 20	OIVD = 3 ODE = 6 Total = 20
Sub total	**OIVD=12** **ODE =38** **Total = 86**	**OIVD = 12** **ODE = 36** **Total = 83**

*The 2006-2007 LRP consisted of participants from ODE and OIVD only.

Q1 + Q2 + Q3 FY13 Percentage of Center Participation by Category

October 1, 2012 – June 30, 2013

Category	Center Participation (Unique)	% of Center Participation (Unique)
LAW	753	54%
LED	221	16%
PRO	383	27%
SCI	810	58%

Q1 + Q2 + Q3 FY13 Participant Attendance by Office

October 1, 2012 – June 30, 2013

Office	Total # of Participants	% of Office Participation*
OC	152	82%
OCD	66	63%
OCER	103	64%
ODE	397	100%
OIR	165	87%
OMO	42	56%
OSB	163	96%
OSEL	174	98%

***These percentages are based on the Office staffing levels as of October 2012. This data will be used as our baseline throughout FY13.**

MDUFA III Training Data

September 2012 – June 2013

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
MDUFA III	16	5363	13422	– Introduction to MDUFA III – 510(k)s – PMAs – Pre-Submissions – CLIA Waivers – Electronic Workload Management

MDUFA Total Training Attendance

Number of participants who took at least one MDUFA class

Office	# of Completions	Completion Percentage
ODE	388 out of 391 who were required	99%
OIR	181 out of 182 who were required	99%

Office	Student Completions	# of Completions
ODE	Completed All	341
	Completed Some	47
	Completed None	3
	Total:	**391**
OIR	Completed All	178
	Completed Some	3
	Completed None	1
	Total:	**182**

ODE and OIR Reviewer Certification Program (RCP) Training Data

September 2011 – June 2013

RCP Training Data by Office

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
RCP	40	141	12,995	– Introduction to Medical Devices – How to Write Deficiencies in Four-Part Harmony – How to Write Effective Pre-market Consulting Reviews – Effective Communication Skills for Scientific and Technical Professionals – Basic Food and Drug Law – Freedom of Information (FOI) Training – The 7 Habits of Highly Effective People – 510(k) Essentials Online – MDUFA III Training – Introduction to IDE Webcast

	Cohort	# of Attendees	Total Training Hours
ODE	**Fall 2011**	11	885
	Spring 2012	19	1711
	Summer 2012	15	1360
	Fall 2012	22	2082
	Spring 2013	18	1485
Totals:	**5 Cohorts**	**85 Participants**	**7, 523 Hours**

	Cohort	# of Attendees	Total Training Hours
OIR	**Fall 2011**	5	416
	Spring 2012	18	1790
	Summer 2012	8	863
	Fall 2012	12	1207
	Spring 2013	13	1196
Totals:	**5 Cohorts**	**56 Participants**	**5,472 Hours**

*** The Summer 2013 RCP cohort was not conducted due to a low number of new review staff hires. The Fall 2013 cohort will begin in Q4.**

FY12 Experiential Learning Program (ELP)

May 2012 – September 2012

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
ELP	14	110	1648	Topic areas addressed during the ELP site visits include: – Orthopedic and Dental Device Coatings – Implantable Pacemakers/Defibrillators – Patient-matched Technologies – Clinical Trials – Microbiology Manufacturing – Molecular Devices – Diabetes Care Devices

FY 2012 Experiential Learning Program (ELP) by Office				
Office	**# of Site Visits**	**# of Training Days**	**# of Attendees**	**Training Conducted**
ODE	9	16	63	– Coatings on Orthopedic and Dental Devices – Manufacturing of Implantable Pacemakers/Defibrillators – Patient-matched Technologies – Clinical Trial Conduct - Meeting with Institutional Review Boards (IRBs)
OIR	5	10	47	– Microbiology Manufacturing – Molecular – Diabetes Care

***Responses to the FY13 ELP Federal Registry Notice and the program budget were received in Q3. The FY13 site visits will begin in Q4.**

Q1 + Q2 + Q3 FY13 ODE and OIR Leadership Development Training

October 1, 2012 – June 30, 2013

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended
LEAD	27	63	1181	• Adaptive Leadership • Giving and Receiving Feedback • CDRH Employee/Labor Relations for Managers • Leading at the Speed of Trust • Leading in a Telework Environment • The Foundation of Leadership – The New Supervisor • Introduction to Situational Leadership

Office	Total # of Managers/Supervisors*	Number of Participants	Number of Hours Completed	Participation Percentage
ODE	46	41	795	89%
OIR	22	22	386	100%

***The total number of managers and supervisors is based on current data as of October 2012. This data will be used as our baseline throughout FY13.**

eSubmission

What is it?

It is TurboTax-like software for constructing and submitting medical device submissions to the FDA. It is also intended to be used as a resource by industry, as an all inclusive guide describing information that is required when submitting.

What is the scope of submissions/centers?

The pilot will cover only Traditional, Abbreviated and Special 510(k)s for ODE. The software is intended to later include additional submission types as well as OIR submission types.

What platform/software will be used?

The pilot will use the eSubmitter software to evaluate the steps that walk the sponsor through the process, and as a proving ground for the infrastructure. The production solution will be based on feedback from the pilot and could include other options and approaches.

When will testing begin?

The pilot is intended to be ready for accepting applications by December 31, 2013. The template for the interface is already substantially complete, and we hope to make available for review by interested parties in the fall.

eSubmission Software

- eSubmitter is an application available on http://www.FDA.gov
- eSubmitter is used for submitting OIR's Turbo 510(k), eCopy and many other items.
- Sponsors use the software to construct the submission package, which is saved locally on the users computer
- It will collect data in structured fields (text fields, dropdowns, checkboxes), and unstructured fields (large text fields, document attachments) where appropriate.
- The software supports help text, links, business rules (e.g., if the device does not use software, the Software node will not display). It will only request what is needed.
- We are working to make the submission process completely electronic, with no CD or paper submission needed.

eSubmission Design

- The design is based on guidances, standards, regulations, etc specific to the FDA (elements of the RTA guidance are built in).
- Included questions and fields are pulled from these FDA guidances, regulations, etc.
- Content of GUDID and eSubmission will be made consistent where possible.
- As guidances, regulations, etc are modified, eSubmission will be modified accordingly.

eSubmission Industry Benefits

- Easier/Faster submission process:
  - One stop shop for submission guidance will help smaller companies know what is needed, without requiring navigation of several resources/websites
  - Reduce misunderstandings of requirements, and subsequent deficiencies
  - We are working to eliminate paper copies
- Reduce time to final decision:
  - Review of the submission may commence the same day it is sent
  - Automated data collection reduces time of manual entry by DCC and reviewers
  - Reduce (or eliminate) RTA reviews
  - A standardized submission is far easier to review and to find information in, potentially resulting in notably reduced review times
  - Future use of structured data will reduce time needed manually scanning previously cleared/approved device documents for data
- The structure of the interface (i.e., questions and fields) will complement what the reviewers use to review; it will be a more explicit definition of what we look for when reviewing.

eSubmission & RPS

RPS is a separate project with the same intention of collecting granular submission data electronically.

- Scope of RPS encompasses several agencies from around the world, as well as FDA CBER.
- RPS will include PMA submission types, as well as Traditional 510(k)s.
- Both will use an XML backbone that defines the structure. The raw data and XML may be submitted for both RPS or eSubmission.
- The primary process to construct a submission is via the use of an Implementation Guide for RPS, or the software interface for eSubmission.

510(k) RTA Audit

February- April 2013

Geeta Pamidimukkala, MS
510(k) Staff
July 30, 2013

Audit Background

- Original 510(k) submissions received February 1- April 30, 2013
  - ODE & OIR
- Traditional, Abbreviated, Converted Special Files
  - 785 files with completed RTA review
    - 235 Feb, 257 March, 293 April
  - 498 files with first round RTA1 decision
    - 63% rejection rate
  - 76 files audited

Sampling Method

- Weighting by division workload
- Same number of files per division/month
  - No weighting by month
- Random selection of audited files
- Files randomly assigned to auditors

Audit Method

- 2 auditors
  - former reviewers
- Most frequently missed by industry
- Occurrences of substantive review during RTA review
- Discrepancy for criteria marked “no”
- General Info
  - Avg. # FDA days to RTA1 decision
  - Avg. # of RTA1 decisions/file

Preliminary Results

- Top 15 Criteria most frequently missed by industry
- Shelf life (purple) and biocompatibility (peach) are problematic sections
- Outcome: increase training to industry to address all criteria, even if not applicable

Criteria #	Rate
28	54%
9	47%
36	33%
4a	32%
17a	32%
26	32%
30	30%
16	29%
29	29%
8	28%
18	22%
12	21%
31	21%
13c	20%
15a	20%

General Info

- Avg. FDA days to RTA1 decision: 10
- Number of audited files that were converted special to traditional: 10
- Files that included a sponsor completed checklist: 9
- Files that were ultimately accepted: 52
  - Majority of files accepted in 2nd RTA review
    - 8 files accepted after 2 prior rejections
- Files that have been rejected more than once (never accepted): 9