Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance

August 1, 2012
11A.M.

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 5 medical device guidance documents during the 3rd quarter. *Barbara Zimmerman, CDRH-ODE*; *Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIVD*

FDA MDUFMA / MDUFA Performance — Actions through June 30, 2012

- Reports on all decision goals for the FY 2008 - FY 2012 cohorts.
    - CBER: *Sheryl Kochman, CBER.*
    - CDRH: *Barbara Zimmerman, CDRH.*

CLIA Waiver Review Times

- Report on qualitative goals and number of pending waiver requests. *Don St. Pierre,* CDRH-OIVD.

Qualitative Update on Finances and Use of Resources – 3rd Quarter of FY 2012

- User fee receipts through the 3rd quarter of FY 2012. *David Miller*, FDA-OFM.
- Update on budget requests and appropriations. *Noni Buchanan*, CDRH-OMO.

Discussion

- MDUFA III Progression and Updates
    - Training, Guidance Development, Hiring and Registration & Listing.
- FDA questions for industry regarding MDUFA III reporting commitments
- Set date for next meeting, following close of Q4. Target Date: 10/31/2012 at 11:00 am.

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Medical Device Guidance Documents
Issued through 3rd Quarter FY 2012
Through June 30, 2012

A comprehensive list of guidances can be found at the following:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Third Quarter (April 2012 – June 2012)

1. Guidance for Industry and Food and Drug Administration Staff - User Fees for 513(g) Requests for Information, CDRH, CBER (4/6/2012).
2. Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act, CDRH, CBER (4/6/2012).
3. Draft Guidance for Industry and Food and Drug Administration Staff - Pediatric Information for X-ray Imaging Device Premarket Notifications, CDRH. OIVD-DRD, OCER-DMQRP, OSEL-DIAM (5/10/2012).
4. Considerations When Transferring Clinical Investigation Oversight to Another IRB5 (6/12/2012; FDA guidance, including CDRH)
5. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis, CDRH. ODE-DRGRUD (6/20/2012).

Second Quarter (January 2012- March 2012)

6. Guidance for Industry and FDA Staff - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications, CDRH. ODE, OIVD (3/28/12).
7. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System, CDRH. OSEL-DIAM, OIVD-DRD (3/27/12).
8. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens, CDRH-OIVD (3/19/12).
9. Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Norovirus Serological Reagents, CDRH-OIVD (3/9/12).
10. Draft Guidance for Industry and Food and Drug Administration Staff - Medical Device Classification Product Codes, CDRH, CBER (1/3/12).

First Quarter (September 2011- December 2011)

11. Draft Guidance for Industry and Food and Drug Administration Staff - CDRH Appeals Processes, OCD (12/27/11).
12. Draft Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], ODE (12/27/11).

13. Guidance for Industry and Food and Drug Administration Staff - Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices, OIVD (12/20/11).
14. Draft Guidance for Industry and Food and Drug Administration Staff - Evaluation of Sex Differences in Medical Device Clinical Studies, OCD (12/19/11).
15. Draft Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Applications for Artificial Pancreas Device Systems, ODE (12/6/11).
16. Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses, OIVD (11/28/11).
17. Draft Guidance for Industry and Food and Drug Administration Staff - Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies, CDRH (11/10/11).
18. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Yersinia spp. Detection, OIVD (11/7/11).
19. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: External Pacemaker Pulse Generator, ODE (10/17/11).
20. Draft Guidance for Industry and Food and Drug Administration Staff - De Novo Classification Process (Evaluation of Automatic Class III Designation), ODE (10/3/11).

Quarterly Update on
Medical Device Performance Goals
— CBER Performance Data —

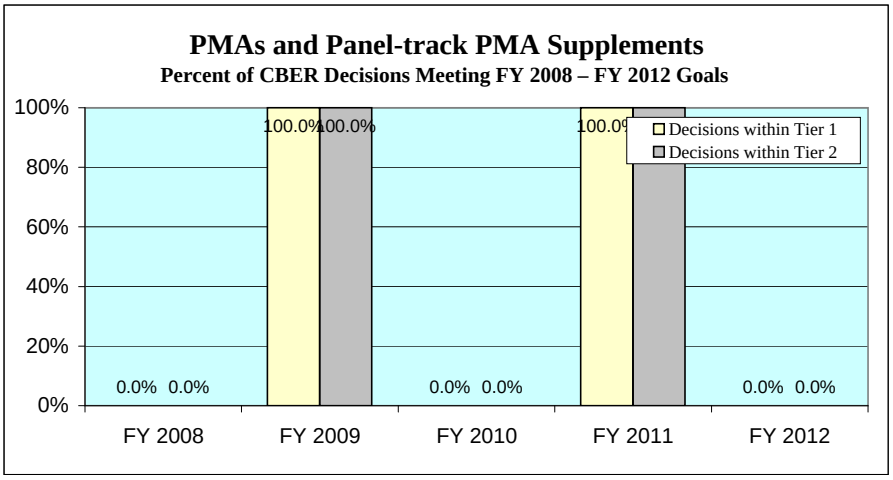
Actions through 30 June 2012

Data on FY 2008 – FY 2012 Cohorts

Actions through 30 June 2012

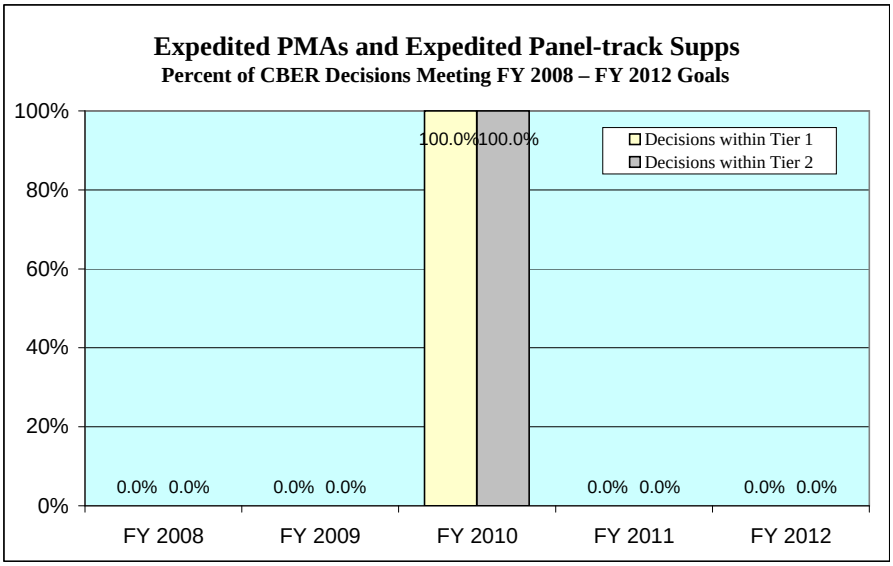
PMAs and Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	2	0	1	2
Total FDA Decisions	0	2	0	1	0
Percent within Tier 1 goal (180 days)	--	100.0%	--	100.0%	0.0%
Tier 1 goal — *Percent within 180 days*	*60%*	*60%*	*60%*	*60%*	*60%*
Percent within Tier 2 goal (295 days)	--	100.0%	--	100.0%	0.0%
Tier 2 goal — *Percent within 295 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



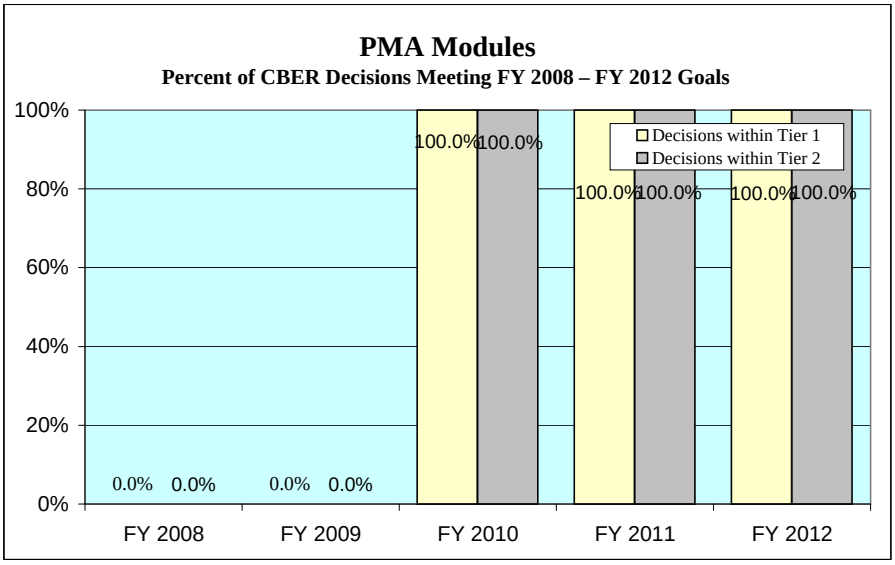
Expedited PMAs and Expedited Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	0	0
Total FDA Decisions	0	0	1	0	0
Percent within Tier 1 goal (180 days)	--	--	100.0%	--	--
Tier 1 goal — *Percent within 180 days*	*50%*	*50%*	*50%*	*50%*	*50%*
Percent within Tier 2 goal (280 days)	--	--	100.0%	--	--
Tier 2 goal — *Percent within 280 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



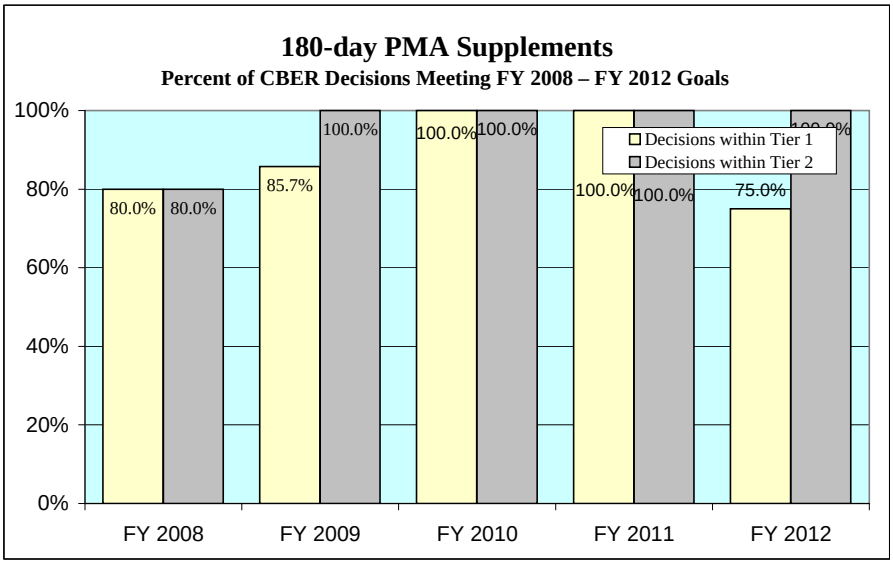
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	5	3
MDUFMA Cohort	0	0	1	5	3
Total FDA Decisions	0	0	1	5	3
Percent within Tier 1 goal (90 days)	--	--	100.0%	100.0%	100.0%
Tier 1 goal — *Percent within 90 days*	*75%*	*75%*	*75%*	*75%*	*75%*
Percent within Tier 2 goal (120 days)	--	--	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 120 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



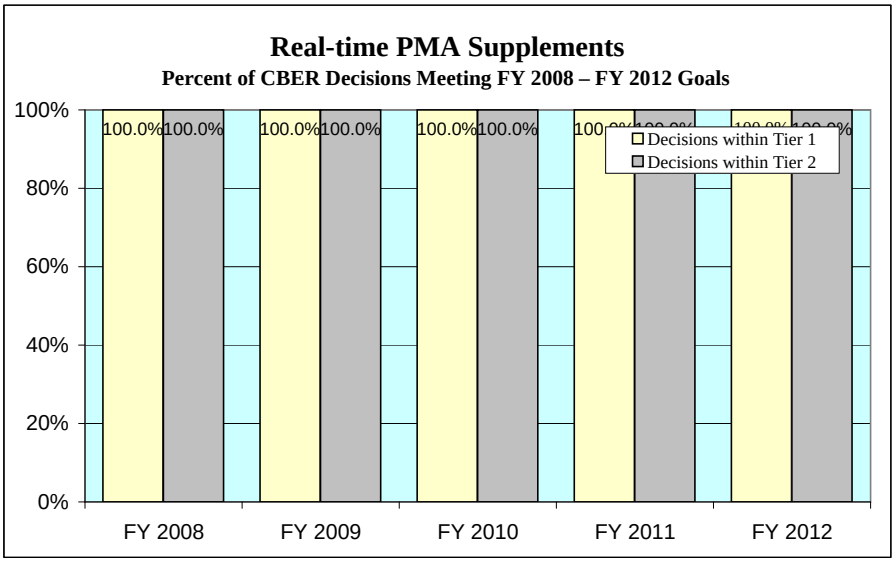
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	9	6
Total FDA Decisions	5	7	7	9	4
Percent within Tier 1 goal (180 days)	80.0%	85.7%	100.0%	100.0%	75.0%
Tier 1 goal — *Percent within 180 days*	*85%*	*85%*	*85%*	*85%*	*85%*
Percent within Tier 2 goal (210 days)	80.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 210 days*	*95%*	*95%*	*95%*	*95%*	*95%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



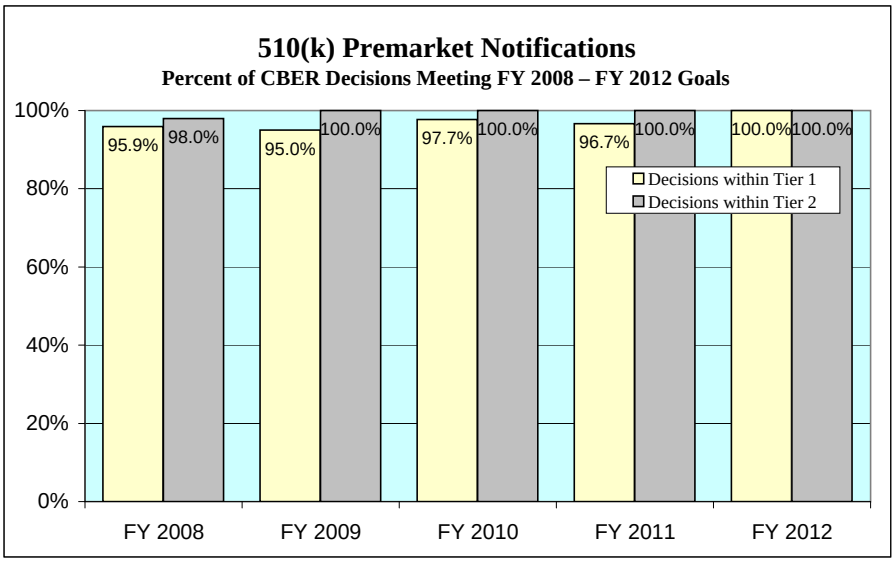
Real-time PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	2	4	2	1	3
Total FDA Decisions	2	4	2	1	1
Percent within Tier 1 goal (60 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 1 goal — *Percent within 60 days*	*80%*	*80%*	*80%*	*80%*	*80%*
Percent within Tier 2 goal (90 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	53	50	55	44	38
MDUFMA Cohort	49	40	45	35	37
Total FDA Decisions	49	40	43	30	15
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.7%	96.7%	100.0%
Tier 1 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Percent within Tier 2 goal (150 days)	98.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	*Complete*	*Complete*	Open	Open	Open



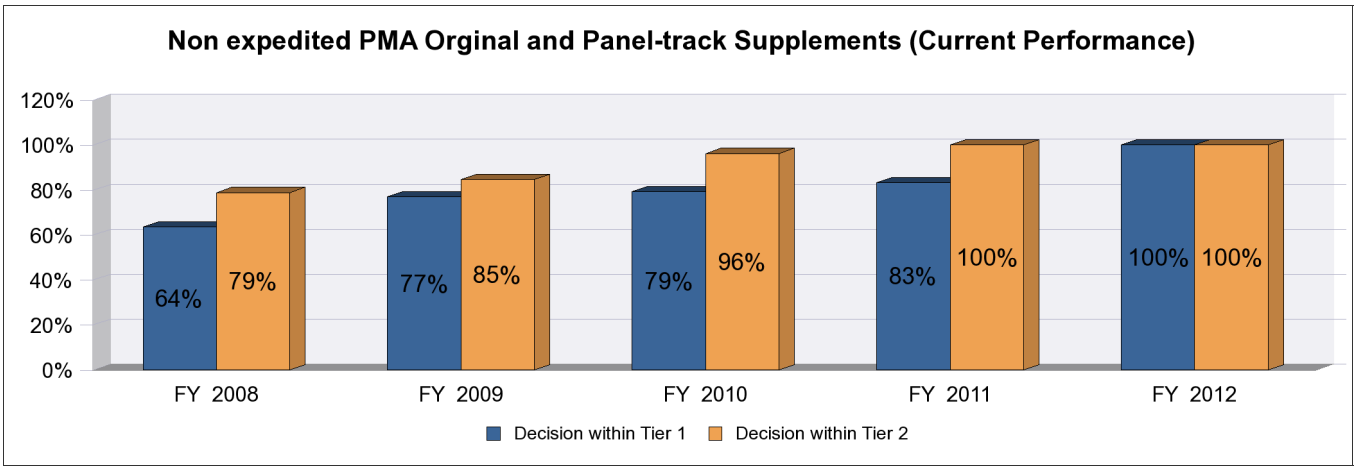
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 30 June 2012

MDUFA II Quarterly (Non expedited PMA Orginal and Panel-track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 6/30/2012 11:59:00 PM

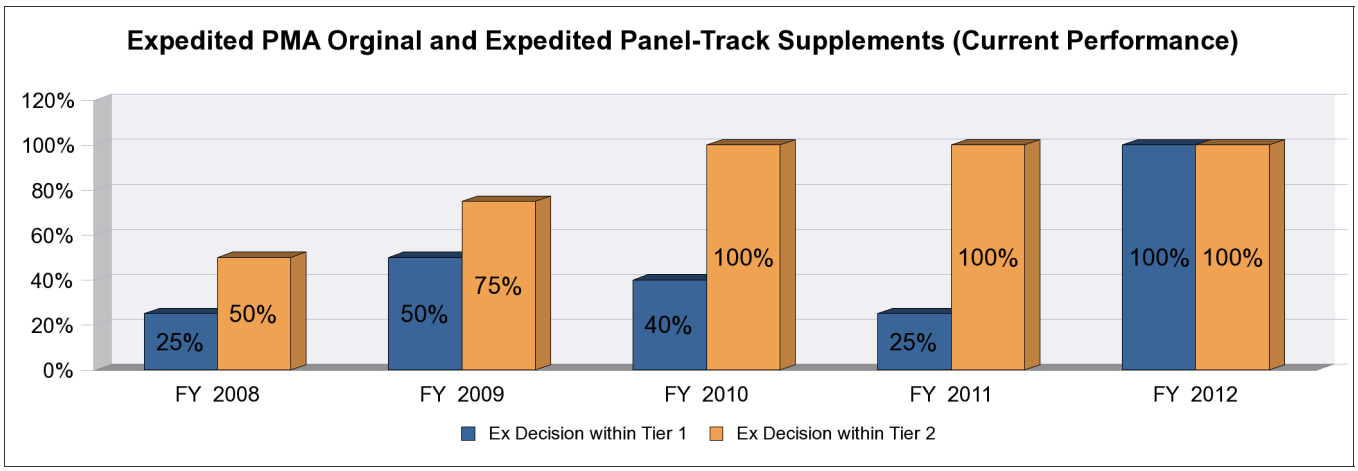
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	33	39	53	44	24
Total FDA Decision	33	39	53	36	2
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	64%	77%	79%	82%	100%
Pending Performance-Worst Case	64%	77%	79%	68%	8%
Tier 2 goal -- Percent within 295 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	yes	unknown	unknown
Pending Performance-Best Case	79%	85%	96%	98%	100%
Pending Performance-Worst Case	79%	85%	96%	82%	8%
Cohort status	Complete	Complete	Complete	Open	Open



MDUFA II Quarterly (Expedited PMA Orginal and Expedited Panel-Track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 6/30/2012 11:59:00 PM

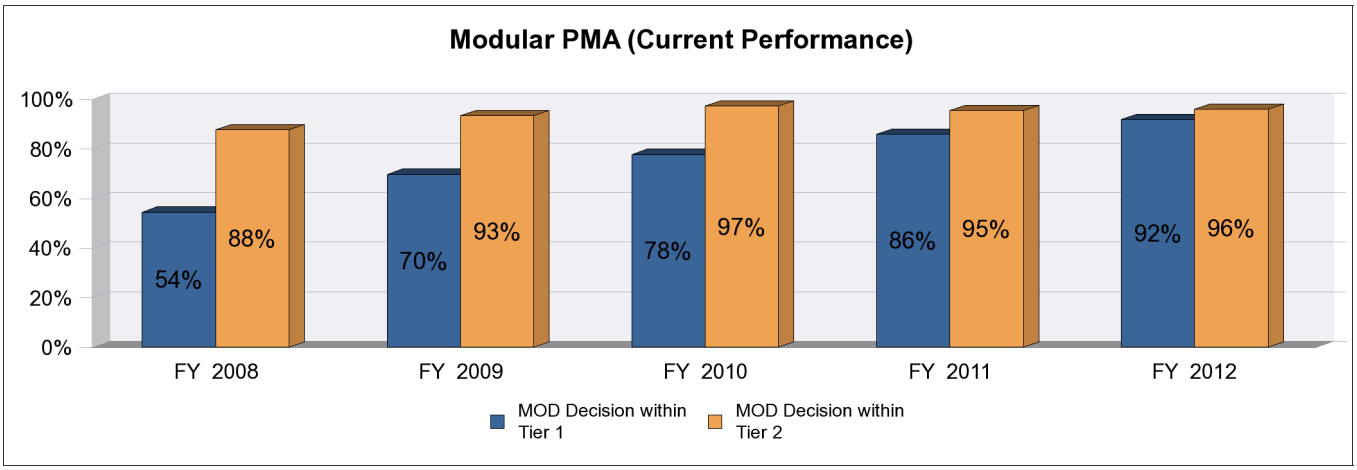
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	4	4	6	7	3
Total FDA Decision	4	4	5	4	1
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	no	no	unknown
Pending Performance-Best Case	25%	50%	33%	14%	100%
Pending Performance-Worst Case	25%	50%	33%	14%	33%
Tier 2 goal -- Percent within 280 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	no	unknown	unknown
Pending Performance-Best Case	50%	75%	83%	100%	100%
Pending Performance-Worst Case	50%	75%	83%	57%	33%
Cohort status	Complete	Complete	Open	Open	Open



MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2012 as of 6/30/2012 11:59:00 PM

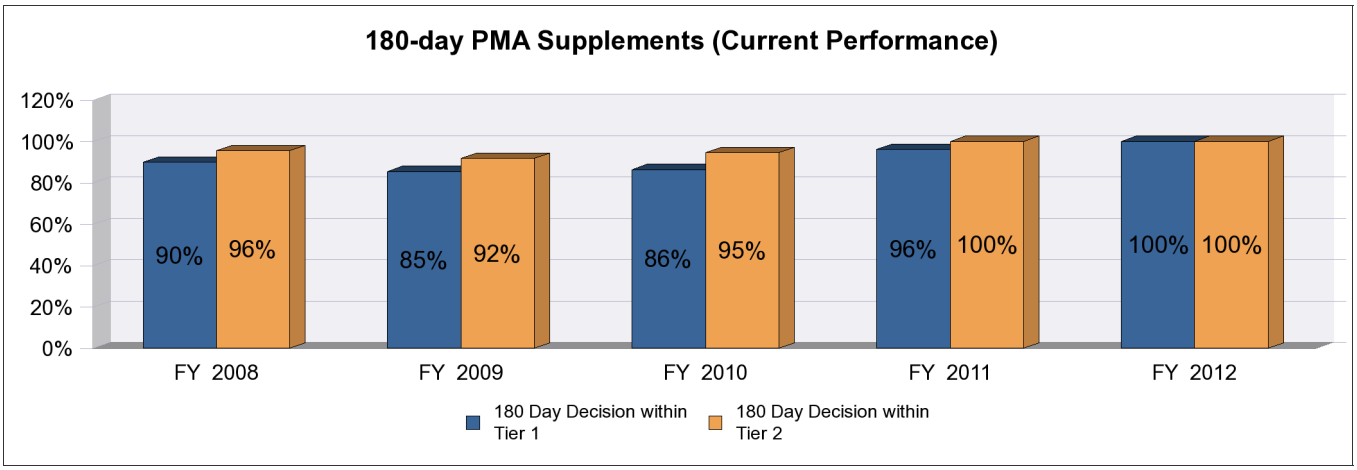
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Cycle Started)	57	90	104	85	43
Total FDA Decision	57	89	103	85	24
Tier 1 goal -- Percent within 90 Days	*75%*	*75%*	*75%*	*75%*	*75%*
Goal met(yes/no/unknown)	no	no	yes	yes	unknown
Pending Performance-Best Case	54%	70%	78%	86%	95%
Pending Performance-Worst Case	54%	69%	78%	86%	51%
Tier 2 goal -- Percent within 120 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	yes	yes	yes	unknown
Pending Performance-Best Case	88%	93%	97%	95%	97%
Pending Performance-Worst Case	88%	92%	97%	95%	53%
Cohort status	Complete	Open	Complete	Complete	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 6/30/2012 11:59:00 PM

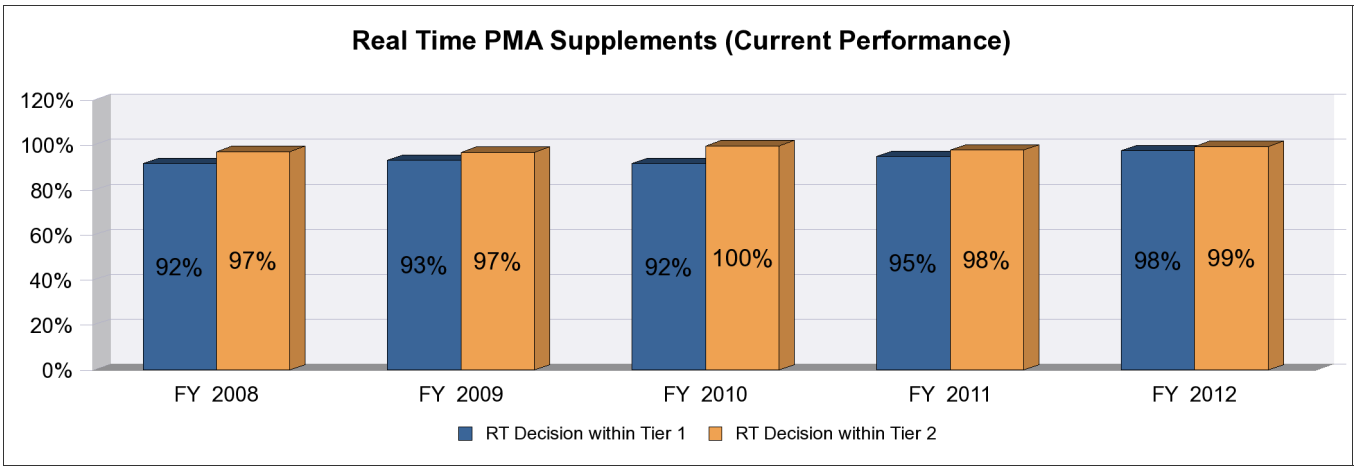
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	170	165	157	145	132
Total FDA Decision	160	158	132	128	38
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	90%	85%	86%	96%	99%
Pending Performance-Worst Case	90%	85%	86%	93%	29%
Tier 2 goal -- Percent within 210 days	*95%*	*95%*	*95%*	*95%*	*95%*
Goal met(yes/no/unknown)	yes	no	no	yes	unknown
Pending Performance-Best Case	96%	92%	94%	100%	99%
Pending Performance-Worst Case	96%	92%	94%	97%	29%
Cohort status	Complete	Complete	Open	Open	Open



MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 6/30/2012 11:59:00 PM

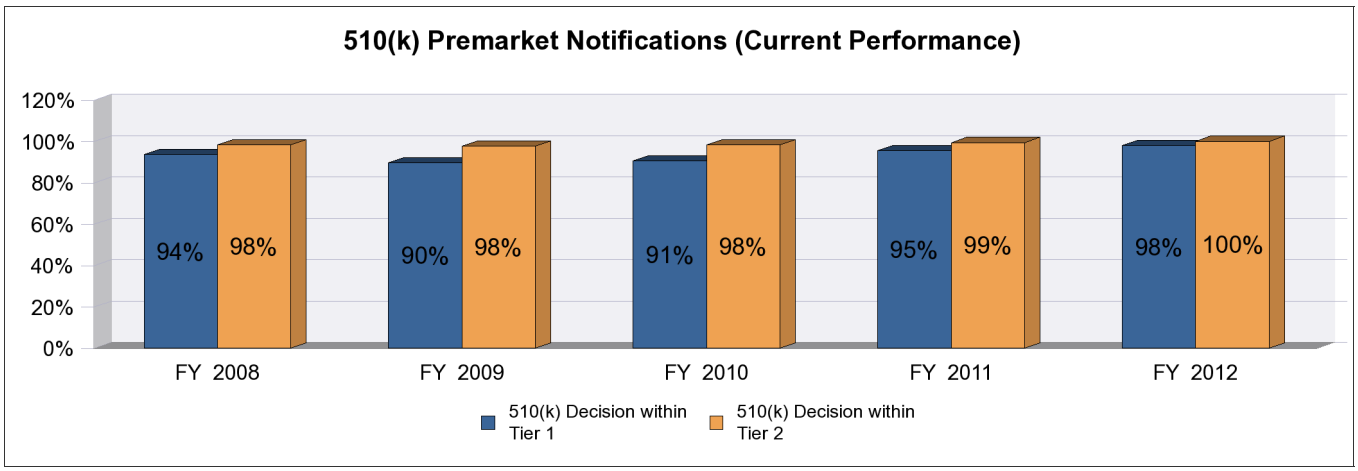
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	249	296	269	245	201
Total FDA Decision	241	280	257	235	161
Tier 1 goal -- Percent within 60 Days	*80%*	*80%*	*80%*	*80%*	*80%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	92%	93%	92%	95%	96%
Pending Performance-Worst Case	92%	93%	92%	95%	81%
Tier 2 goal -- Percent within 90 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	97%	97%	100%	98%	97%
Pending Performance-Worst Case	97%	97%	100%	98%	83%
Cohort status	Complete	Complete	Complete	Complete	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2012 as of 6/30/2012 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	3,848	4,103	3,880	3,833	2,878
MDUFA Cohort	3,260	3,403	3,146	3,250	2,780
Total FDA Decision	3,259	3,398	3,139	3,071	1,289
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	94%	90%	91%	96%	99%
Pending Performance-Worst Case	94%	90%	90%	90%	45%
Tier 2 goal -- Percent within 150 Days	*98%*	*98%*	*98%*	*98%*	*98%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown	unknown
Pending Performance-Best Case	98%	98%	98%	99%	100%
Pending Performance-Worst Case	98%	98%	98%	94%	46%
Cohort status	Open	Open	Open	Open	Open



CLIA Waiver by Application Workload July 2012

Fiscal Year	Recommendation	Total FDA Days	Total Mfr Days	Total days
2008	Approved	398		398
		61		61
		248	38	286
		248	38	286
		398		398
	Denied	287		287
		199		199
		189		189
		320	424	744
		129		129
		102		102
	Telephone Hold	136	1501	1637
2008 Count	12			
2009	Approved	233		233
		204	64	268
	Denied	740		740
		285		285
		644	7	651
	Telephone Hold	33	1226	1259
	Under Review	262	908	1170
2009 Count	7			
2010	Approved	77		77
		105	106	211
	Denied	172		172
		266		266
		248		248
2010 Count	5			
2011	Approved	27		27
		229	97	326
		165	87	252
	Request For Additional Information	95	202	297
		95	202	297
2011 Count	5			
2012	Approved	79		79
		24		24
	Denied	153		153
		150		150
	Under Review	73		73
2012 Count	5			
Grand Total	34			

FY 2012 Medical Device User Fee Collections[2]
As of June 30, 2012

Source	FY 2012 Authorized[1]	FY 2012 Fee Revenues				FY 2012 Surplus
		Receipts	Refunds	Net	% of Authorized	*cf.* Authorized
Establishment Registration Fe	$25,869,750	$33,197,817	$34,914	$33,162,903	128.2%	$7,293,153
Application / Reporting Fees	$31,735,250	$25,185,474	$24,410	$25,161,064	79.3%	-$6,574,186
Total	**$ 57,605,000**	$58,383,291	$ 59,324	**$58,323,967**	**101.2%**	**$718,967**

[3]Comparison:
Medical Device User Fee Collection in Prior Years
Excludes Unearned Fees, Includes Refunds

FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
$21,620,549	$25,309,853	$31,801,091	$35,059,601	$28,726,239	$47,571,809	$53,568,425	$63,477,683	$65,300,830

Notes:

1. The Authorized revenues shown for Establishment Registration fees assume 12,750 establishments will register and pay the fee of $2,029. The Authorized revenues shown for Application / Reporting Fees represents the difference between the Total authorized fee revenues and the amount shown for authorized Establishment Registration revenues. The calculation for the total FY 2012 authorized fee revenues is specified in the FY 2012 FR Notice for publishing fees.
2. Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 12.
3. Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

FY 2012 Appropriations Update

Public Law 112-55, the Fiscal Year 2012 Agriculture, Commerce/Justice/Science (CJS), and Transportation/Housing and Urban Development (THUD) Appropriations bill, also known as the "Mini-bus," included the following funding for the Devices Program:

- Provided $322.672 million in budget authority for the Devices Program of which CDRH received $241.475 million.
- Includes $20.038 million for the Medical Countermeasures Initiative. CDRH received approximately $3 million of this funding.

FY 2013 Appropriations Update

The FY 2013 budget request for the Devices Program is $319,127,000. The request includes an additional $723,000 for CDRH in support of the Medical Countermeasures Initiative.