Agenda for Quarterly Meeting on MDUFMA / MDUFA Performance
January 2012

Welcome. *Barbara Zimmerman, CDRH-ODE.*

Guidance Development

- FDA issued 10 medical device guidance documents during the 1st quarter.
  Barbara Zimmerman, CDRH-ODE; *Kate Cook, CBER; Don St. Pierre, CDRH-OIVD*

FDA MDUFMA / MDUFA Performance — Actions through December 31, 2011

- Reports on all decision goals for the FY 2008 - FY 2012 cohorts.
  - CBER: *Kate Cook, 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 – 1st Quarter of FY 2012

- User fee receipts through the 1st quarter of FY 2012.
  David Miller, FDA-OFM.
- Update on budget requests and appropriations. *Noni Buchanan*, CDRH-OMO.

Discussion

- Set date for next meeting, following close of Q2. Target Date: 4/25/2012.

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Medical Device Guidance Documents
Issued through 1st Quarter FY 2012
Through December 31, 2011

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

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First Quarter (September 2011- December 2011)

1. Draft Guidance for Industry and Food and Drug Administration Staff - CDRH Appeals Processes, OCD (12/27/11).
2. Draft Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], ODE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).
3. 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).
4. Draft Guidance for Industry and Food and Drug Administration Staff - Evaluation of Sex Differences in Medical Device Clinical Studies, OCD (12/19/11).
5. Draft Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Applications for Artificial Pancreas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).
6. 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).
7. Draft Guidance for Industry and Food and Drug Administration Staff - Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including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).
8. 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).
9. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: External Pacemaker Pulse Generator, ODE (10/17/11).
10. 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 —

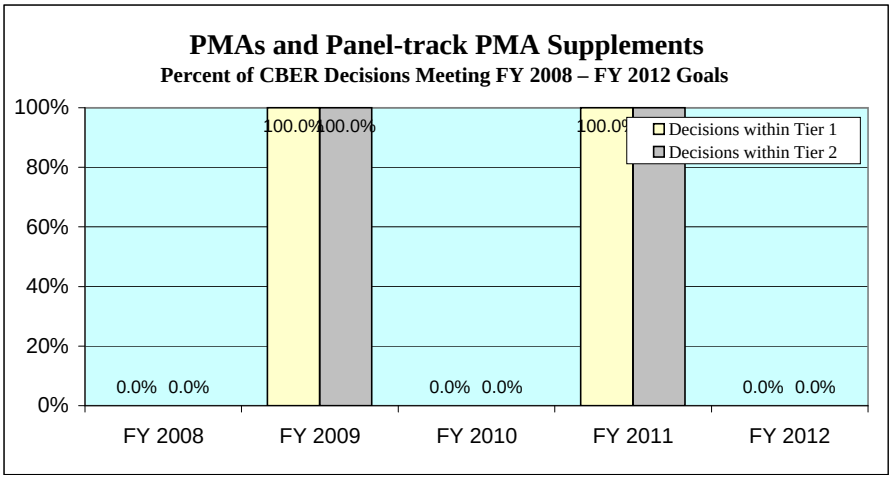
Actions through 31 December 2011

Data on FY 2008 – FY 2012 Cohorts

Actions through 31 December 2011

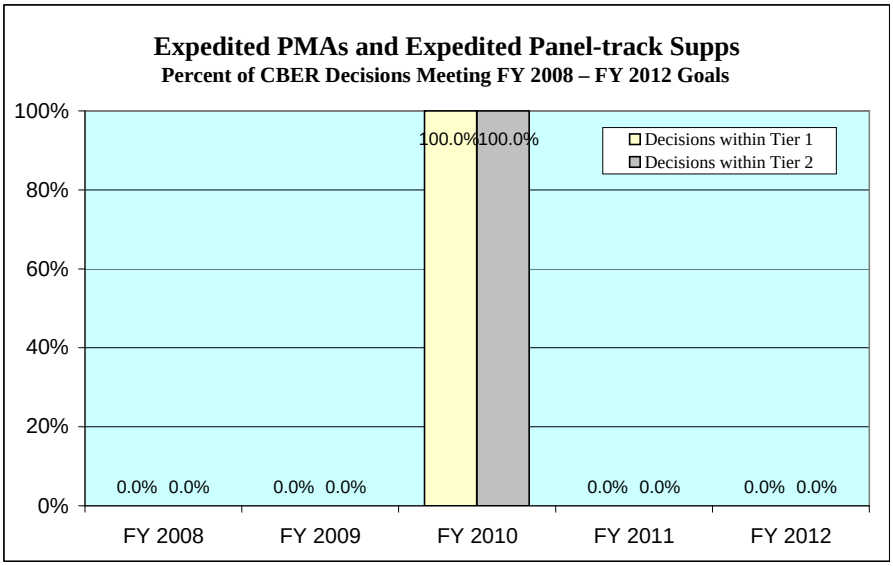
PMAs and Panel-track Supplements

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



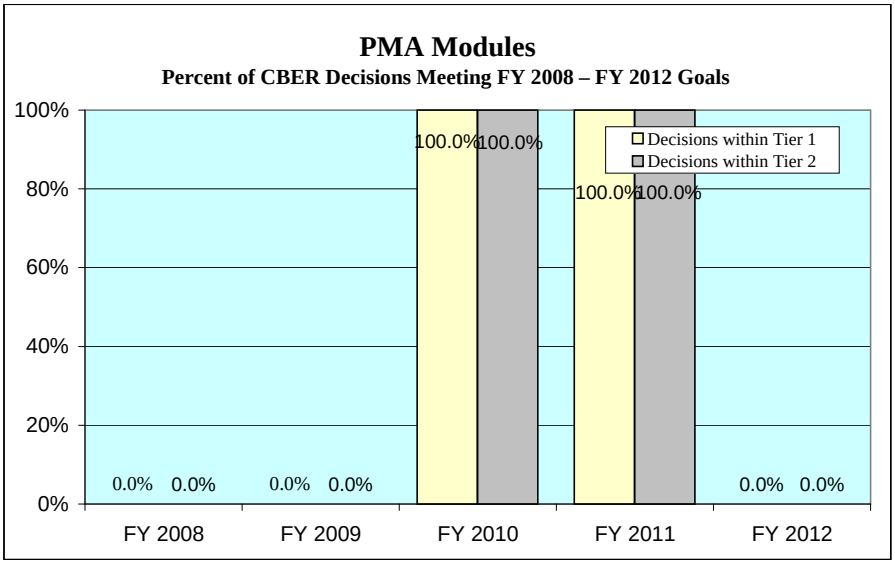
Expedited PMAs and Expedited Panel-track Supplements

	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



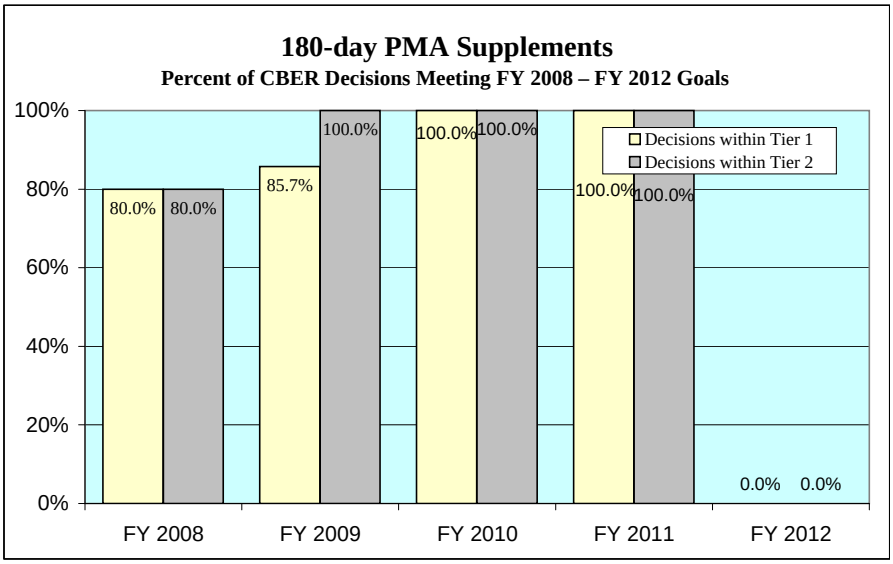
PMA Modules

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



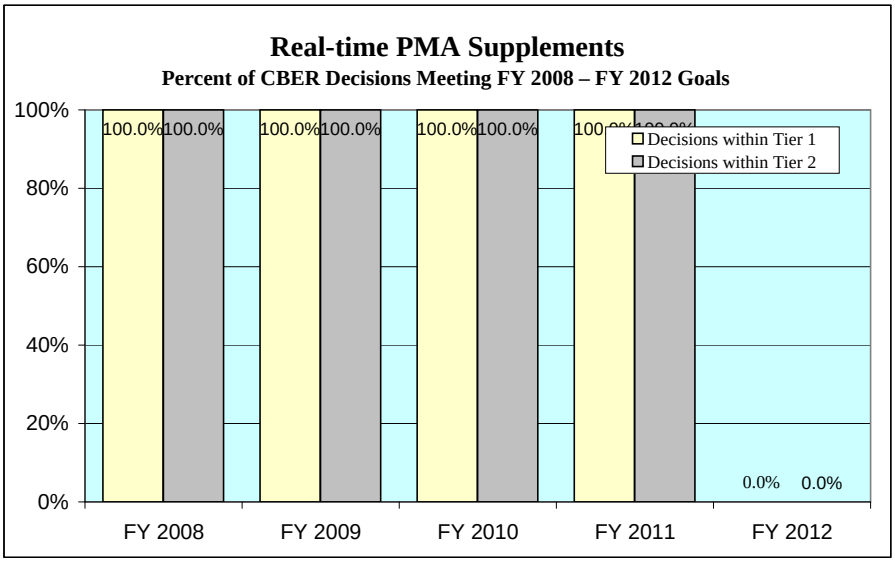
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	9	3
Total FDA Decisions	5	7	7	7	0
Percent within Tier 1 goal (180 days)	80.0%	85.7%	100.0%	100.0%	--
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%	--
Tier 2 goal — *Percent within 210 days*	*95%*	*95%*	*95%*	*95%*	*95%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	Open



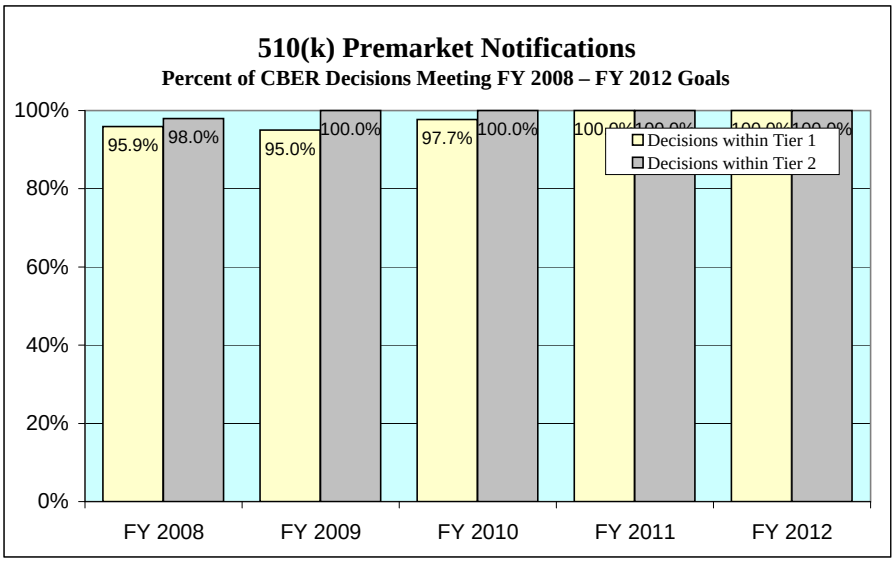
Real-time PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	2	4	2	1	1
Total FDA Decisions	2	4	2	1	0
Percent within Tier 1 goal (60 days)	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%	--
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	12
MDUFMA Cohort	49	40	45	42	12
Total FDA Decisions	49	40	43	23	1
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.7%	100.0%	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



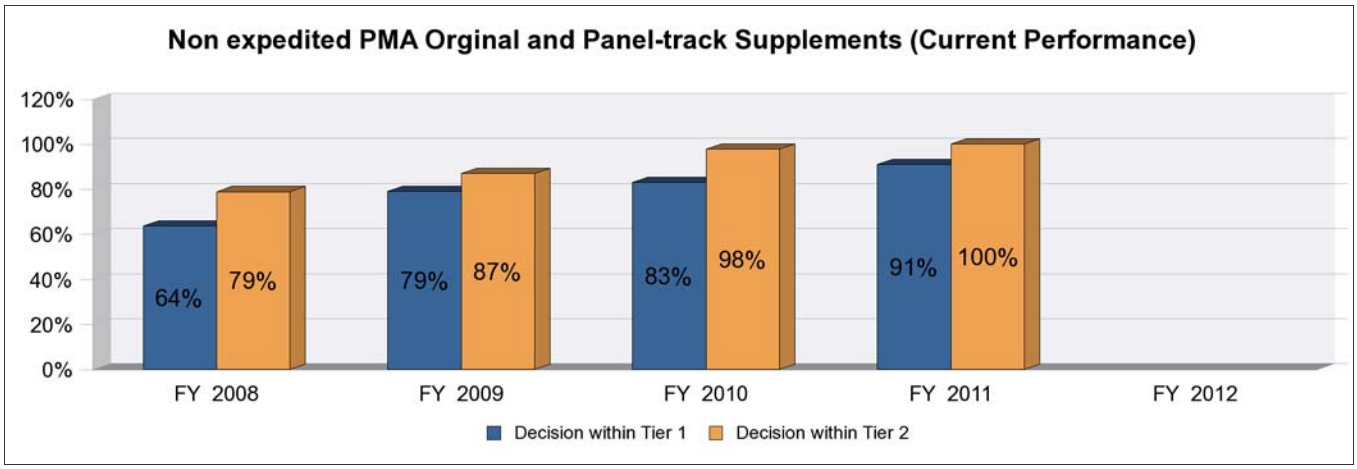
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 31 December 2011

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

For Submissions Filed Between Year 2008 to 2012 as of 12/31/2011 11:59:00 PM

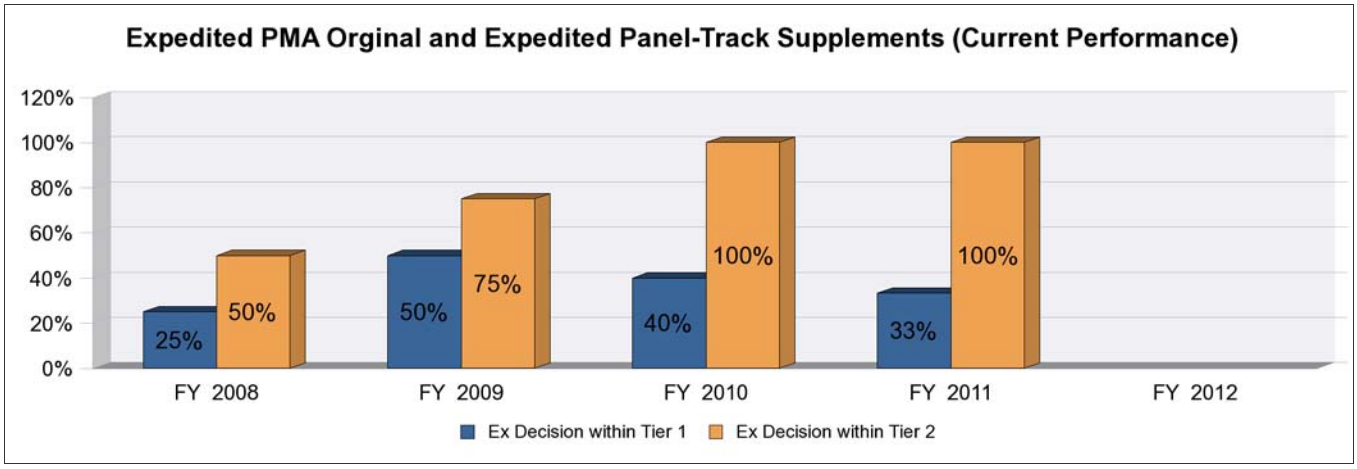
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	33	39	53	43	3
Total FDA Decision	33	38	47	22	0
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown	unknown
Pending Performance-Best Case	64%	77%	79%	84%	100%
Pending Performance-Worst Case	64%	77%	74%	47%	0%
Tier 2 goal -- Percent within 295 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	unknown	unknown	unknown
Pending Performance-Best Case	79%	85%	96%	100%	100%
Pending Performance-Worst Case	79%	85%	87%	51%	0%
Cohort status	Complete	Open	Open	Open	Open



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

For Submissions Filed Between Year 2008 to 2012 as of 12/31/2011 11:59:00 PM

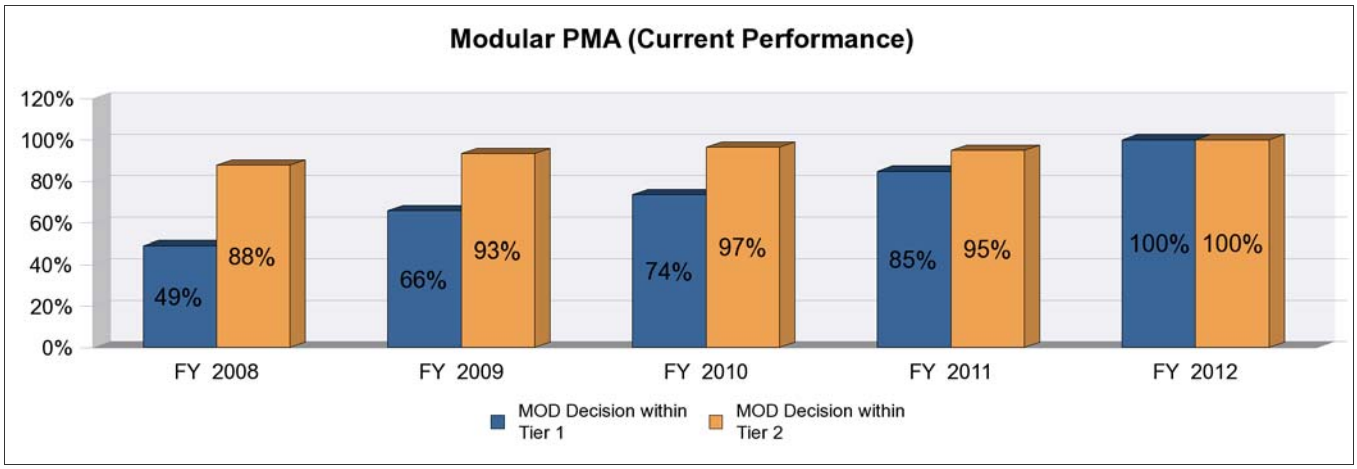
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	4	4	6	7	2
Total FDA Decision	4	4	5	3	0
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	no	unknown	unknown
Pending Performance-Best Case	25%	50%	33%	57%	100%
Pending Performance-Worst Case	25%	50%	33%	14%	0%
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%	43%	0%
Cohort status	Complete	Complete	Open	Open	Open



MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2012 as of 12/31/2011 11:59:00 PM

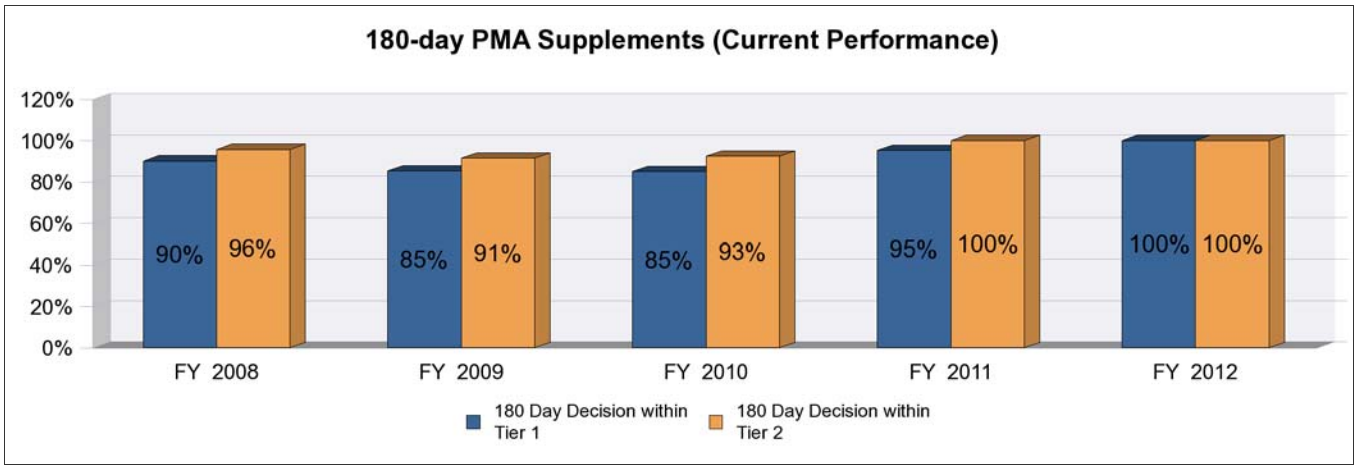
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Cycle Started)	57	90	104	85	12
Total FDA Decision	49	76	87	79	3
Tier 1 goal -- Percent within 90 Days	*75%*	*75%*	*75%*	*75%*	*75%*
Goal met(yes/no/unknown)	no	no	no	yes	unknown
Pending Performance-Best Case	49%	66%	74%	85%	100%
Pending Performance-Worst Case	49%	64%	74%	85%	27%
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%	100%
Pending Performance-Worst Case	88%	91%	97%	95%	27%
Cohort status	Complete	Open	Complete	Complete	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 12/31/2011 11:59:00 PM

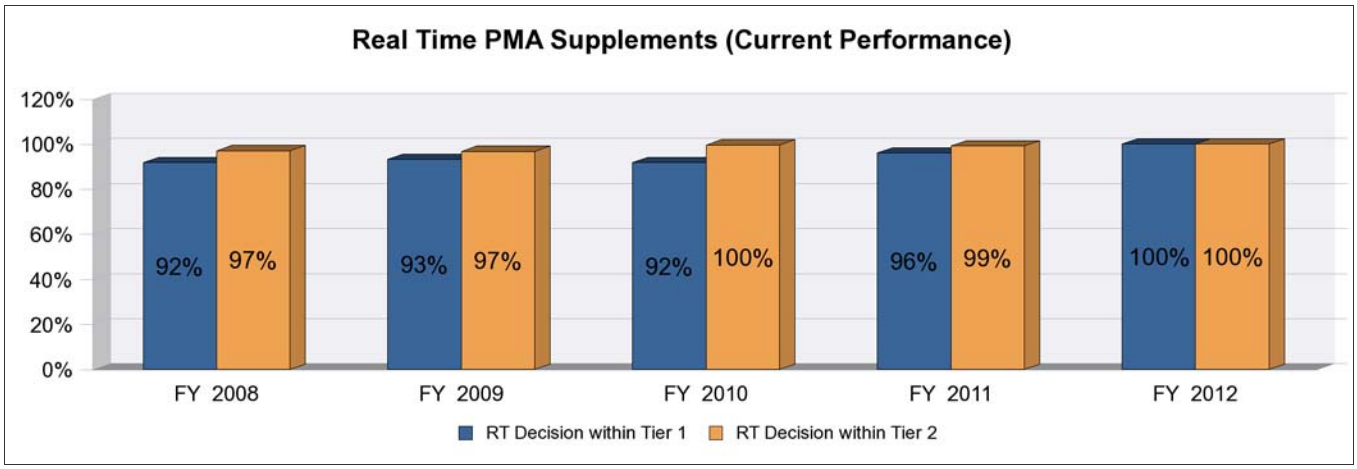
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	170	166	157	145	60
Total FDA Decision	161	163	147	104	1
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	no	unknown	unknown
Pending Performance-Best Case	90%	85%	84%	96%	100%
Pending Performance-Worst Case	90%	85%	83%	69%	2%
Tier 2 goal -- Percent within 210 days	*95%*	*95%*	*95%*	*95%*	*95%*
Goal met(yes/no/unknown)	yes	no	no	unknown	unknown
Pending Performance-Best Case	95%	91%	91%	99%	100%
Pending Performance-Worst Case	95%	91%	91%	72%	2%
Cohort status	Open	Complete	Open	Open	Open



MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 12/31/2011 11:59:00 PM

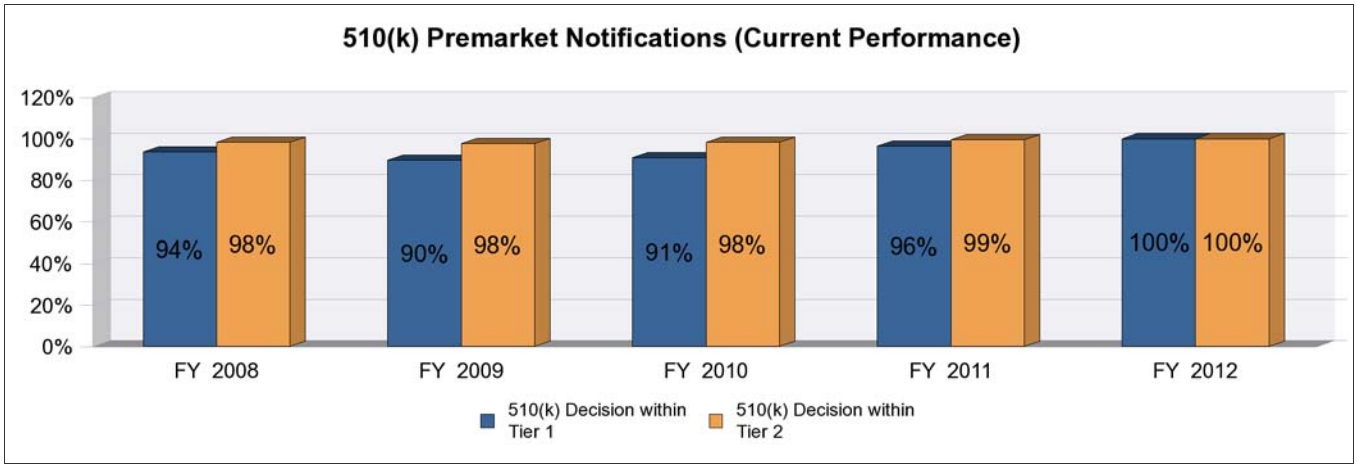
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	249	296	269	245	53
Total FDA Decision	241	280	258	232	33
Tier 1 goal -- Percent within 60 Days	*80%*	*80%*	*80%*	*80%*	*80%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	92%	93%	92%	95%	96%
Pending Performance-Worst Case	92%	93%	92%	95%	62%
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%	100%
Pending Performance-Worst Case	97%	97%	100%	98%	62%
Cohort status	Complete	Complete	Complete	Open	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2012 as of 12/31/2011 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	963
MDUFA Cohort	3,259	3,403	3,152	3,485	959
Total FDA Decision	3,258	3,398	3,129	2,564	151
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown	unknown
Pending Performance-Best Case	94%	90%	91%	97%	100%
Pending Performance-Worst Case	94%	90%	90%	71%	16%
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%	100%	100%
Pending Performance-Worst Case	98%	98%	98%	73%	16%
Cohort status	Open	Open	Open	Open	Open



CLIA Waiver Report for 1st Quarter FY 2012.

Fiscal Year Rece	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	1312	1448
2008 Total		12		
2009	Approved	233		233
		204	64	268
	Denied	740		740
		285		285
		644	7	651
	Telephone Hold	33	1037	1070
		518	260	778
		259	722	981
2009 Total		8		
2010	Approved	77		77
		162	212	374
	Denied	172		172
		266		266
		248		248
	Under Review	636		636
2010 Total		6		
2011	Approved	27		27
		165	87	252
	Request For Additional Information	95	13	108
		95	13	108
	Under Review	120	98	218
2011 Total		5		
2012	Approved	24		24
	Under Review	51		51
2012 Total		2		
Grand Total		33		

Run 1/5/12

January 2012
MDUFA Stakeholder Meeting
Appropriations Update

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:

	FY 2012 Enacted (Dollars in Thousands)	FY 2011 Enacted (Dollars in Thousands)	Net Change (Dollars in Thousands)
Device Program Level	375,989	378,215	(2,226)
Device Program BA	322,672	322,370	302
CDRH BA	241,475	240,486	989

The law:

- Provides $322.672 million in budget authority for the Devices Program.
- Matches the revised MDUFA user fee revenue target published in the Federal Register on August 1, 2011.
- Includes $20.038 million for the Medical Countermeasures Initiative. CDRH is expected to receive approximately $3 million of this funding.

FY 2012 Medical Device User Fee Collections[2]

As of December 31, 2011

Source	FY 2012 Authorized[1]	FY 2012 Fee Revenues				FY 2012 Surplus
		Receipts	Refunds	Net	% of Authorized	*cf.* Authorized
Establishment Registration Fee	$25,869,750	$28,202,852	$2,179	$28,200,673	109.0%	$2,330,923
Application / Reporting Fees	$31,735,250	$9,258,543	$0	$9,258,543	29.2%	-$22,476,707
Total	**$ 57,605,000**	$ 37,461,395	$ 2,179	**$ 37,459,216**	**65.0%**	**-$20,145,784**

[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	$47,584,600	$53,621,585	$63,572,946	$64,344,754

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.