

FDA Update

Office of In Vitro Diagnostics and
Radiological Health (OIR)

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IVD Roundtable November 18, 2014



Outline

- ❑ OIR – Organizational Update
- ❑ CDRH Priorities
- ❑ MDUFA III
- ❑ PMA / De novo Approvals
- ❑ Meetings
- ❑ Guidance
- ❑ Other



Organizational Update

285 staff

{ ~2/3 IVD (1/3 Rad Health); ~40% \leq 3yrs }

DCTD – Chemistry Toxicology - 45

DMD – Microbiology - 52

DIHD – Immunology Hematology - 32

DMGP – Molecular Genetics and Pathology - 32



CDRH 2014-2015 Priorities

- ***Strengthen the Clinical Trial Enterprise***
 - Reduce cycles/Increase early feasibility & FIH
 - Expand interactions/Better PreSub utilization
- ***Strike the Right Balance Between Premarket & Postmarket Data Collection***
 - EAP/Pre-Post Balance/LB considerations
- ***Provide Excellent Customer Service***
 - Customer survey/[Staff Training](#)



OIR's IVD Additional 2014-2015 Priorities

- ❑ **LDTs**
- ❑ **Personalize Medicine**
- ❑ **Emergency Use Authorizations**
- ❑ **Regulatory Strategies to Support Innovation**
- ❑ **Artificial Pancreas**
- ❑ **Antimicrobial Resistance**
- ❑ **Moving Freight.....**



OIR Staff Training

- ❑ Mentors
- ❑ Product Specialists
- ❑ Supervisory QC
- ❑ Internal training
- ❑ Working Group/Branch/Division/Office mtgs
- ❑ Go-To Group
- ❑ DPOM
- ❑ Staff College
- ❑ Travel / Conferences



MDUFA III status

- ❑ Quarterly reports
 - google – mdufma performance reports
 - Everything you wanted to know, but were afraid to ask
- ❑ So far looking pretty good
- ❑ Independent Assessment



CY 2014 PMA Approvals IVDs

- ❑ Roche cobas HPV Test – P100020/S008
- ❑ Roche Elecsys HBeAg Immunoassay – P130015
- ❑ Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System – P120005/S002
- ❑ Qiagen *therascreen* KRAS RGQ PCR Kit– P110027
- ❑ Siemens Advia Centaur HBsAgII – P110041



CY 2014 PMA Approvals IVDs

- ❑ Qiagen CMV DNA Assay– P130027
- ❑ Exact Science Cologuard – P130017
- ❑ Dexcom G4 Platinum Continuous Glucose Monitoring System - P120005/S018



CY2014 Denovos

Affymetrix CytoScan® Dx Assay	K130313
Euroimmun Anti-PLA2R IFA	K132379
Quidel Lyra™ Direct HSV 1 + 2/VZV Assay	K133448
Focus Simplexa™ HSV 1 & 2 Direct	K133621
Quidel Lyra Direct Strep Assay	K133883



Notable CY2014 OIR Meetings

Advisory Panels: March 12 – HPV
 March 26 – Epigenomics
 March 27 – Exact Sciences

Public Workshop (April 1) – Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification and Detection of Antimicrobial Resistance Markers



CY2014 OIR Guidances

□ **Final Guidances:**

- Administrative Procedures (CLIA);
Companion Dx; Multiplex

□ **Class II Special Controls Guidelines:**

- John Cunningham Virus; Dengue; TB;
Tryptase



CY2014 OIR Guidances

□ Drafts:

- LDT Guidances
- Blood Glucose Monitoring Systems for Prescription Point-of-Care Use; Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use
- EGR1 Gene FISH Test System
- Surveying, Leveling, or Alignment Laser Products; Policy Clarification for Certain Fluoroscopic Equipment



CY2014 CDRH Guidances

- ☐ GUDID
- ☐ UDI
- ☐ MDDS
- ☐ 510(k) Benefit/Risk (draft)
- ☐ Evaluation of SE in 510(k)s
- ☐ Appeals
- ☐ Premarket Assessment of Pediatric Devices
- ☐ HDE Q&A (draft)
- ☐ PreSub Guidance
- ☐ Q&A on eMDR



CY2014 CDRH Guidances

- ☐ Annual Reports for PMAs
- ☐ EAP (draft)
- ☐ Premarket/ Postmarket Balance (draft)
- ☐ Types of Communications
- ☐ Voluntary Consensus Standards (draft)
- ☐ Home Use
- ☐ Denovo (draft)
- ☐ FDA Decisions for IDEs
- ☐ Custom Devices



EUAs / CLIA Waiver

- 2014 Ebola Virus Emergency Use Authorization

- CLIA (CY2014)
 - 7 Approval Decisions
 - 3 Dual Pre-Subs
 - 1 Dual 510(k)/CLIA Waiver Submission



Thanks