



FDA Update

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Office of In Vitro Diagnostic Device Evaluation and Safety

CLIAC Meeting

August 31, 2011

Atlanta, Georgia

Organizational Change – OIVD

- Working reducing manager/reviewer ratio currently 1/27 - ideal 1/10
- New Hires
 - DCTD 0
 - DMD 6
 - DIHD 1
 - Radiology 3

Organizational Change

- Tamara Feldblyum
 - Associate Director Virology
- Yun-Fu Hu
 - Associate Director Immunology
- Ruth Chesler
 - Associate Director Chemistry

Center Initiatives

- Internal program review – 510(k)
 - Implementation of recommendations
 - Meeting most of the ambitious goals
- IOM review
 - Report published end of July
 - Center will hold public meeting to elicit comments

Center Initiatives – Public Meetings

- Public Workshop - Center for Devices and Radiological Health's Innovation Initiative, March 15, 2011
- Public Workshop - Study Methodologies for Diagnostics in the Postmarket Setting, May 12, 2011
- Ultra High Throughput Sequencing for Clinical Diagnostic Applications - Approaches to Assess Analytical Validity, June 23, 2011

Center Initiatives – Public Meetings

- Unique Device Identification (UDI) for Postmarket Surveillance and Compliance Public Workshop, September 12-13, 2011
- Mobile Apps and Clinical Decision Support Software Sept 12th and 13th
- IOM report Sept 16th
- Advancing Regulatory Science for Highly Multiplexed Microbiology/MCM Devices, October 13, 2011

Guidances

- Chlamydia trachomatis and/or Neisseria gonorrhoea
- Class II Special Controls Guidance
Document: In Vitro Diagnostic Devices for Bacillus spp. Detection
- Detection of methicillin-resistant Staphylococcus aureus (MRSA) for Culture Based Devices

Guidances

- Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices
- In Vitro Companion Diagnostic Devices
- Detection or Detection and Differentiation of Influenza Viruses
- Mobile Medical Applications

Guidances

- 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device
- Herpes Simplex Virus Types 1 and 2 Serological Assays
- Factors to Consider when Making Benefit-Risk Determinations in Medical Device Premarket Review

Guidances

- Design Considerations for Pivotal Clinical Investigations for Medical Devices
- Postmarket Surveillance Under Section 522 of the Federal Food, Drug and Cosmetic Act

Notable Clearances

- Luminex Molecular Diagnostics, Inc xTAG® Respiratory Viral Panel FAST
- Department of the Army SMART Leish
- Idaho Technology, Inc Q Fever Detection
- VIDAS® Toxo IgG Avidity Assay
- KeyPath™ MRSA/MSSA Blood Culture Test

Notable Clearances

- Xpert® C. difficile/Epi
- RIDASCREEN® Norovirus 3rd Generation EIA
- Bio-Rad Laboratories Platelia™ Aspergillus EIA
- CYFRA 21-1 EIA kit monitoring disease progression of lung cancer
- Affymetrix Gene Profiling Reagents

Notable Clearances

- Invader® Factor V test
- Invader® MTHFR 1298 test
- Invader□ Factor II test
- ImmunoCAP Specific IgE
- Vysis CLL FISH Probe Kit

Notable PMAs

- cobas® 4800 BRAF V600 Mutation Test - August 17, 2011
- VITROS® Immunodiagnostic Products Anti-HBe - July 20, 2011
- Elecsys® Anti-HBc Immunoassay on the Elecsys® 2010 - June 27, 2011
- Elecsys® Anti-HBc Immunoassay on the E170- June 22, 2011
- INFORM HER2 Dual ISH DNA Probe Cocktail - June 14, 2011

Notable PMAs

- Abbott RealTime HCV - May 17, 2011
- VITROS® Immunodiagnostic Products HBeAg - May 11, 2011
- cobas HPV Test - April 19, 2011
- OraQuick HCV Rapid Antibody Test - February 18, 2011

Notable Panel Meetings

- TB down classification

Significant Recalls

- GEM Premier 4000 PAK Cartridges for Use on the GEM Premier 4000 System (potassium)
- Global Focus Marketing & Distribution, Ltd., Silencer® S2200 Centrifuge
- Roche Diagnostics Operations, ACCU-CHEK Performa Strip (France)
- Beckman Coulter, Inc., Synchron LX Clinical Systems Ion Selective Electrolyte (ISE) Flow Cell

Significant Recalls

- bioMérieux, Inc., VITEK® 2 Gram Negative Susceptibility Cards Containing Piperacillin/Tazobactam (TZP2) – Expanded Recall
- Gen-Probe Inc., AccuProbe Group B Streptococcus Culture Identification Test, AccuProbe Mycobacterium Tuberculosis Complex Culture Identification Test, and AccuProbe Mycobacterium Avium Complex Culture Identification Test

Warning Letters

- Beckman Coulter, Inc.
- Church & Dwight Inc



Thanks