FDA Update

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Summary

- Organizational Update
- CLIA Categorization Administrative Update
- Approvals an Authorizations
- Guidances
- Workshops and Panels

Carol Benson retired

Re-Org info

- OIR – approx 270 people with All Rad Health and Mammography
- DPOM (Division of Program Operations and Management)
  - This is the new policy group
  - One team for program management
  - One team for program operations

Helpful Contacts

- Policy/Process Questions
  - PMA (Kelly Wilkicki, kelly.wilkicki@fda.hhs.gov)
  - 510k (Sara Aguel, sara.aguel@fda.hhs.gov) or (Brendan O'Leary, brendan.oleary@fda.hhs.gov, while Sara is on maternity leave)
  - IDE/Q-Subs (Elizabeth Hillebrenner, elizabeth.hillebrenner@fda.hhs.gov)

Administrative Update

- FDASIA inspired!
- Subject of the following presentation..

PMA Approvals

- Medtronic MiniMed 530G System
  - The MiniMed 530G System is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus in persons, sixteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin.

PMA Approvals

- DEXCOM G4® PLATINUM
  - Approval for the dexcom g4 platinum (pediatric) continuous glucose monitoring system. This device is indicated for: the dexcom g4 platinum (pediatric) continuous glucose monitoring system is a glucose monitoring device indicated for detecting trends and tracking patterns in persons ages 2 to 17 years with diabetes

De Novo Classifications

- CDC's Quantitation of Organophosphate Metabolites in Urine by LC/MS/MS
  - To detect and measure the concentration of specific organophosphate metabolites in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning

De Novo Classifications

- bioMérieux ’s VITEK®MS
  - *VITEK®MS is a mass spectr*ometer system using matrix-assisted laser desorption/ionization - time to flight (MALDI-TOF) for the identification of microorganisms cultured from human specimens. The VITEK®MS is a qualitative in vitro diagnostic device indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial and yeast infections.

De Novo Classifications

- Affymetric's CytoScan DX

  CytoScan® Dx Assay is a qualitative assay intended for the postnatal detection of copy number variations (CNV) in genomic DNA obtained from peripheral whole blood in patients referred for chromosomal testing based on clinical presentation.

De Novo Classifications

- Illumina's MiSeqDX
  - Cystic Fibrosis 139-Variant Assay
  - Cystic Fibrosis Clinical Sequencing Assay
  - MiSeqDx instrument - Class II exempt
  - MiSeqDx Universal Kit – Class I

Emergency Use Authorization

- Quidel's Lyra™ Influenza A Subtype H7N9 Assay.

Guidances

- RUO/IUO guidance
- OTC Glucose Monitors
- POC Glucose Monitors
- Special Controls: John Cunningham Virus Serological Reagents

Workshops and Panel Meetings

- April 1 – High Throughput Sequencing
- March 12 – Cobas HPV - a first-line primary cervical screening test
- March 26 – Epigenomics ProColon
- March 27 – Exact Science Cologuard

Personalize Medicine Report

- Agency's commitment to PM

Warning Letter

- 23andMe
- Atossa
  - FDA safety communication on Nipple Aspirate testing

Thanks