Medical Device Regulatory Decision Points

Medical Device Classification
Benefit Risk
Regulatory Path
Predicate Devices
Valid Scientific Evidence
Least Burdensome Approach

Medical Devices Classified by Risk

- **CLASS I**
  - Low risk
  - Most exempt from premarket submission
  - Subject to general controls (sterilization, misbranding, etc.)

EXAMPLES

- Visual acuity charts
- Reflex hammers
- Tuning forks

- **CLASS II**
  - Moderate risk
  - Premarket Notification [510(k)]
  - Substantial Equivalence (SE)
  - Subject to both general controls and device specific special controls

- EEG, EMG, Nerve conduction
- ECGs, cardiac output monitors
- Biofeedback devices

- **CLASS III**
  - Highest risk
  - Safety and effectiveness data required
  - Subject to both general controls and Premarket Approval (PMA)

- Deep Brain Stimulators
- Intracranial stents
- Fetal heart monitor with waveform analysis of the fetal ECG

Types of Device Premarket Submissions

- **Premarket Notification [510(k)]:**
  - Required for most Class II devices (low-moderate risk)
  - Sponsor must demonstrate device to be marketed is at least as safe and effective (i.e., "substantially equivalent") as a legally marketed device
  - FDA "clears" 510(k)s
- **Premarket approval (PMA):**
  - Most stringent type of device marketing application for all Class III devices (highest risk)
  - Approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).
  - PMA devices are "approved" by FDA

Recently Cleared "Wearable" Technologies

- **Personal Kinetigraph (PKG) System (K140086):** Intended to quantify kinematics of movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is indicated for use in individuals 46 to 83 years of age.
- **MotionWatch and PRO-Diary (K132764):** The MotionWatch and PRO-Diary are compact, lightweight, body-worn activity monitoring devices that may be used to document physical movement associated with applications in physiological monitoring. The devices are intended to monitor limb or body movements during daily living and sleep. The MotionWatch and PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired.

Additional Regulatory Pathways

- **De Novo Petition**
  - For new device type with low/moderate risk:
    - No identifiable predicate device;
    - New intended use; or
    - Different technology that raises new types of questions of safety or effectiveness
- **Humanitarian Device Exemption (HDE)**
  - Treating or diagnosing a condition with annual US incidence less than 4000 individuals
  - Approval standards:
    - Safety: information showing no unreasonable/significant risks
    - Effectiveness: Probable benefit
  - May only be used at facilities with IRB oversight

Medical Devices Development Tool (MDDT)

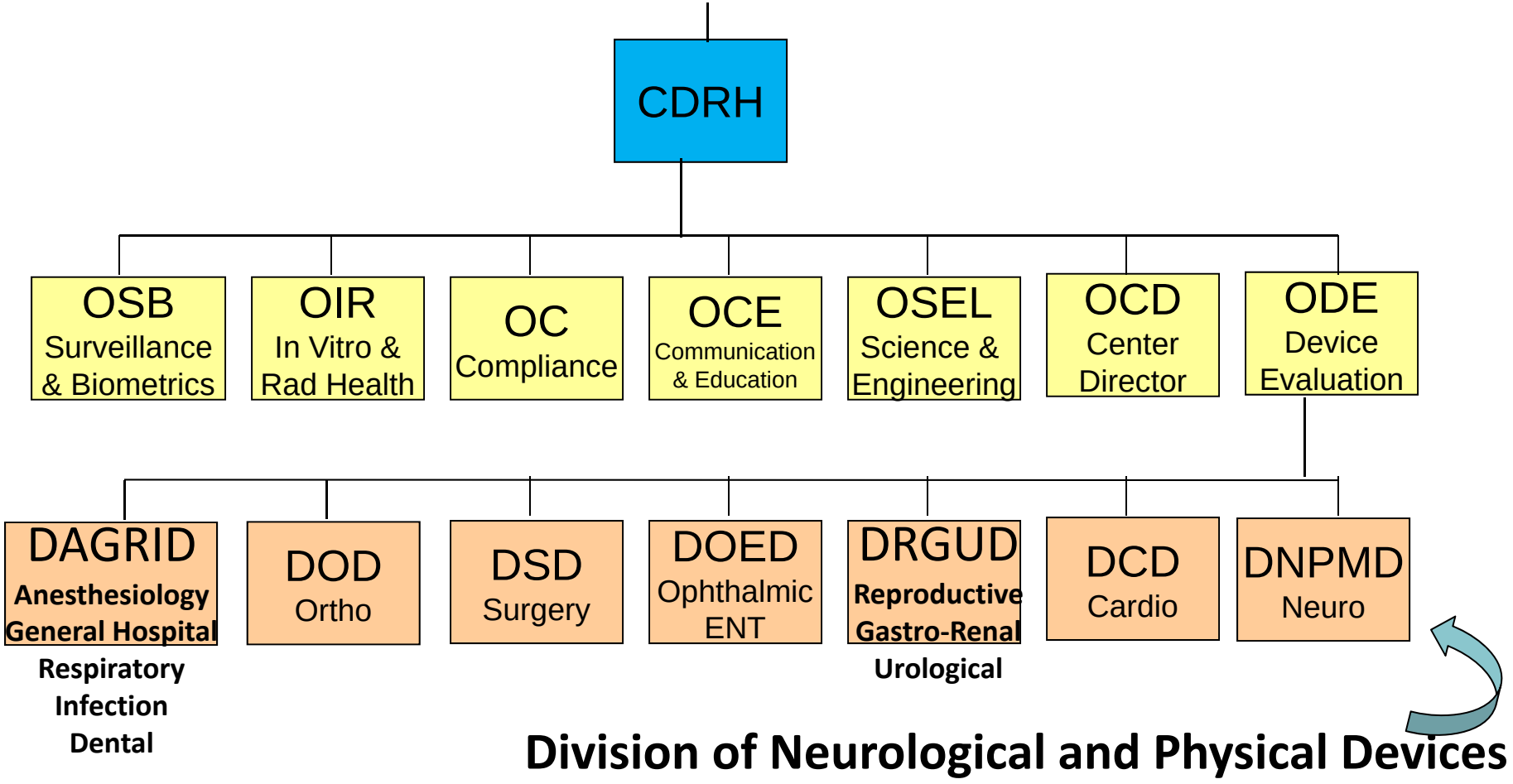
- Draft Guidance issued November, 2013
- A qualified MDDT is a scientifically validated tool that aids device development and regulatory evaluation
- Three defined categories of MDDT:
  - Clinical Outcome Assessment (e.g. rating scales)
  - Biomarker Test (e.g., assay for a chemical analyte, imaging method)
    - Biomarker Test (BT) is a test or instrument or other objective measurement method used to detect or measure a biomarker
    - A biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or responses to a therapeutic intervention
  - Nonclinical Assessment Model (e.g. in vitro, animal or computational model)

Medical Devices Development Tool (MDDT)

- Context of Use key aspect of qualification
  - Describes way the MDDT should be used and purpose of the use
- Different categories of context of use for a MDDT:
  - Aid in Diagnosis
    - As a definition of an adverse event (AE) within a clinical study
    - As a clinical reference standard to assist in diagnosis
  - Patient Selection
    - For selection of clinical trial subjects (i.e., enrichment)
    - To stratify patient population
  - Clinical Endpoints
    - As an intermediate endpoint
    - As a surrogate endpoint
- Non-clinical device assessment
- MDDT link: http://www.fda.gov/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentToolsMDDT/

Center for Devices and Radiological Health (CDRH) Organization

Pathway for Neurological and Physical Medicine Regulatory Submissions



Division of Neurological and Physical Devices