U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

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Regulatory Mandate of Center

1900
EMPLOYEES

22k/year
Premarket Submissions
includes supplements and amendments

18k
Medical Device Manufacturers

570k
Proprietary Brands

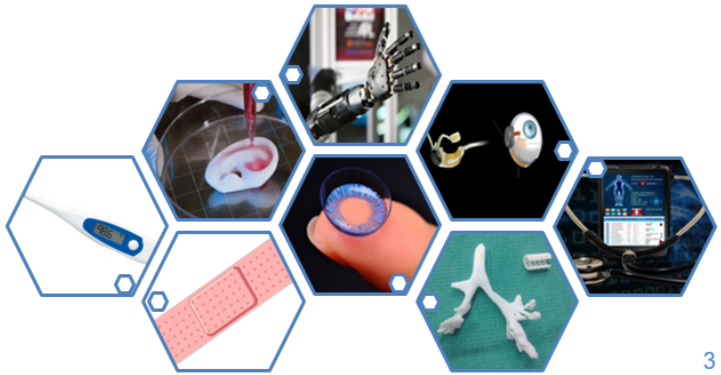
25k
Manufacturing Facilities Worldwide

183,000
Medical Devices
On the U.S. Market

1.4 MILLION/year
Reports on medical device adverse events and malfunctions

Regulatory Mandate of Center

- Medical Devices (including software)
  - Anesthesiology, Respiratory, Infection Control, Dental
  - Cardiovascular
  - Reproductive, Gastro-Renal and Urological
  - Neurological and Physical Medicine
  - Ophthalmic and ENT
  - Orthopaedics
  - Surgical



Regulatory Mandate of Center

- In Vitro Diagnostics
  - Glucose monitors
  - Genetic tests, eg 23 and me
  - Companion diagnostics for drugs

Regulatory Mandate of Center

- Radiological Health

  - MRI, CT scanners
  - Lasers
  - Risk analysis of cellphones (which DO NOT cause cancer)
  - Mammography Quality Standards Act

Research Interests

- Pediatric Devices/ sex specific devices
- Medical Device Development Tools
- Development of computational modeling and simulation as a regulatory tool
- Allowing sponsors to design safety into products
- Other regulatory science priorities at fda.gov

CDRH Reg Science Priorities

- Leverage “Big Data” for regulatory decision-making
- Modernize biocompatibility and biological risk evaluation of device materials
- Leverage real-world evidence and employ evidence synthesis across multiple domains in regulatory decision-making
- Advance tests and methods for predicting and monitoring medical device clinical performance
- Develop methods and tools to improve and streamline clinical trial design
- Develop computational modeling technologies to support regulatory decision-making
- Enhance the performance of Digital Health and strengthen medical device cybersecurity
- Reduce healthcare associated infections by better understanding the effectiveness of antimicrobials, sterilization and reprocessing of medical devices
- Collect and use patient input in regulatory decision-making
- Leverage precision medicine and biomarkers for predicting medical device performance, disease diagnosis and progression

Areas of Current Collaboration

- *In vitro* Respiratory Toxicity of sterilants
  - Some sterilants are class 2 devices
  - O-pthalaldehyde is occasionally used for reprocessing of multiple use instruments
  - The safe levels are not well known or codified in standards or guidance

Potential Future Areas

- We should jointly take a more strategic route
  - Modernize biocompatibility and biological risk evaluation of device materials
  - Reduce healthcare associated infections by better understanding the effectiveness of antimicrobials, sterilization and reprocessing of medical devices

Biocompatibility

- Optimize test methods
  - in situ polymerizing materials
- Advance alternatives to in vivo
- Define chemical equivalence

Reduce Healthcare Infections

- Understanding reprocessing
  - Cleaning, disinfection and sterilization
  - Testing cleanliness of devices
- Methods for the detection, characterization and elimination of biofilms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