Orthopaedic Sensing, Measuring, and Advanced Reporting Technology (SMART) Devices

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Workshop Objectives

- The purpose of the workshop is to discuss the development of Orthopaedic SMART Devices while drawing on lessons learned in the application of SMART devices in other device specialty areas. The workshop is intended to enhance engagement with stakeholders to facilitate device development and to discuss scientific and regulatory challenges associated with Orthopaedic SMART Devices. Public input and feedback gained through this workshop may aid in the efficient development of innovative, safe and effective, Orthopaedic SMART Devices, for better patient care.

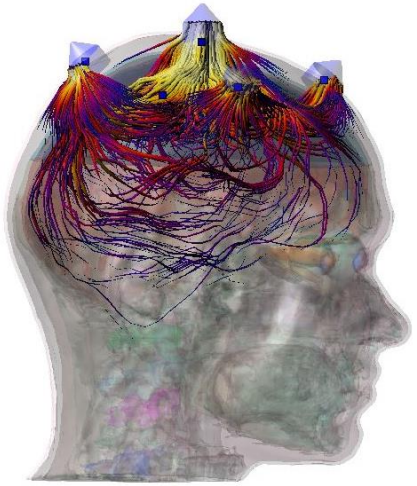
Please note that discussion or presentation of any specific device or example does not imply FDA endorsement.

CDRH

White Oak Campus showing CDRH buildings

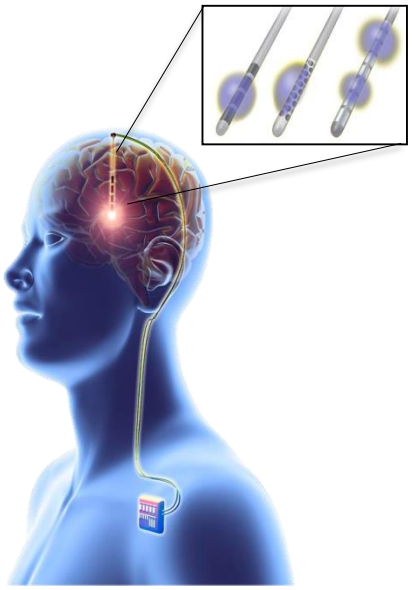
CDRH in Perspective

- CDRH oversees:
  - 190,000 medical devices on US market
  - 570,000 proprietary brands on the US market
  - 18,000 medical device manufacturers
  - 25,000 medical device facilities worldwide



- Each year we receive
  - 22,000 premarket submissions (including supplements and amendments)
  - 1.4 million reports on medical device adverse events and malfunctions

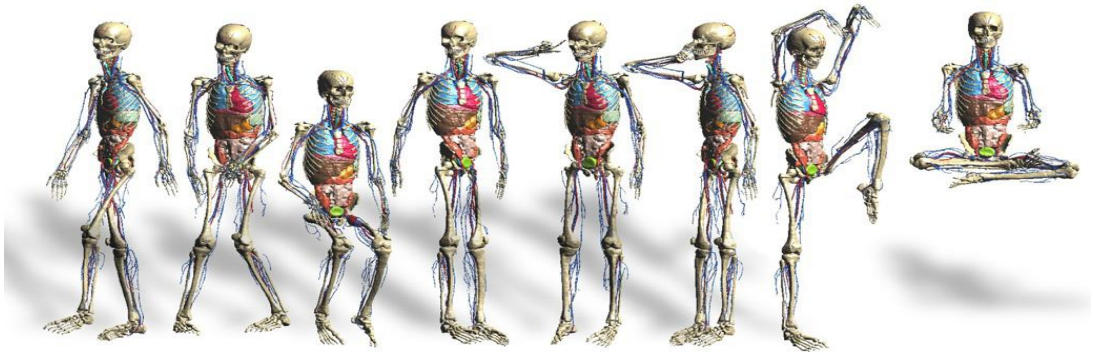
- CDRH employees c. 1,800 staff



CDRH in Perspective

…We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee.

We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

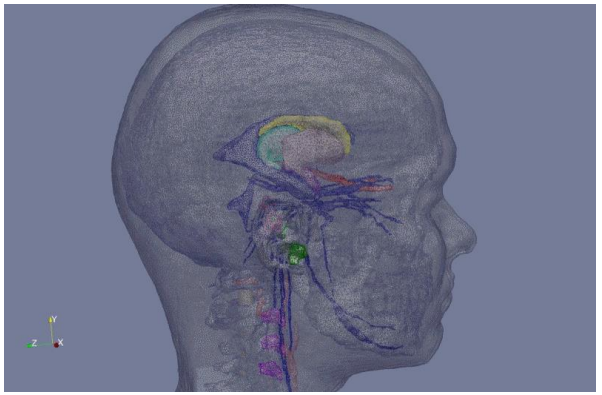


Office of Science and Engineering Labs

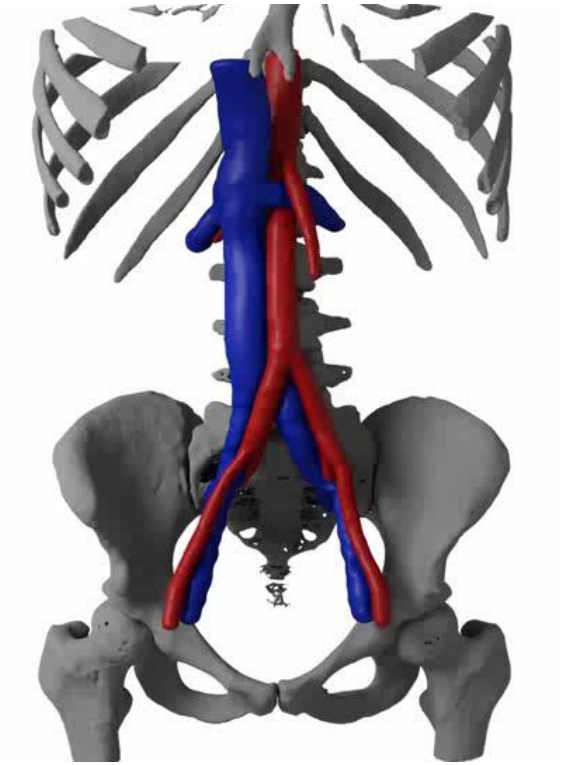
Our job is to ensure that CDRH never has to say "I don't know"

- Ensure readiness for emerging and innovative medical technologies
- Develop appropriate evaluation strategies and testing standards
- Create accessible and understandable public health information
- Deliver timely and accurate decisions for products across their life cycle

Office of Science and Engineering Labs



- Crazy breadth of technologies
  - Rapid detection of cleanliness for endoscopes
  - Early biomarkers for traumatic brain injury
  - Additive Manufacturing
  - Prediction of hemolysis and thrombogenicity in blood contacting devices
  - In silico clinical trials
  - Digital pathology
  - Outcome measures for upper limb prostheses
  - Failure mechanisms for early onset scoliosis devices
  - High intensity therapeutic ultrasound applications
  - Particle transport through PPE
  - Test methods for rapid testing of VADs
  - Simulation of performance and failure of IVC filters



SMART Implants

- Today is all about discussion:
  - Smart implants have been on the agenda for many years for other device specialty areas: the time seems to be here for orthopaedics
  - Smart implants encompass bewildering breadth of examples
  - FDA does not have (all) the answers
  - First stage is to identify the right questions
  - FR Notice comment period ends on May 29th, 2018: https://www.gpo.gov/fdsys/pkg/FR-2018-02-13/html/2018-02923.htm

+ Devices