FDA 101

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Notice of Conflicts

None

I currently work for FDA.

Disclaimer

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Presentation Overview

- **FDA basics**
- What is a medical device?
- Device classification information and regulation
- Assessing measurement capability
- Considerations

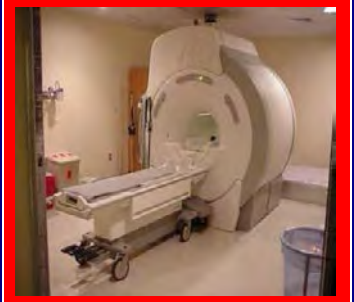
Who does What at FDA?

FDA

Center for
Food
Safety &
Applied
Nutrition

Center for
Drug
Evaluation &
Research

Center for
Biologics
Evaluation &
Research



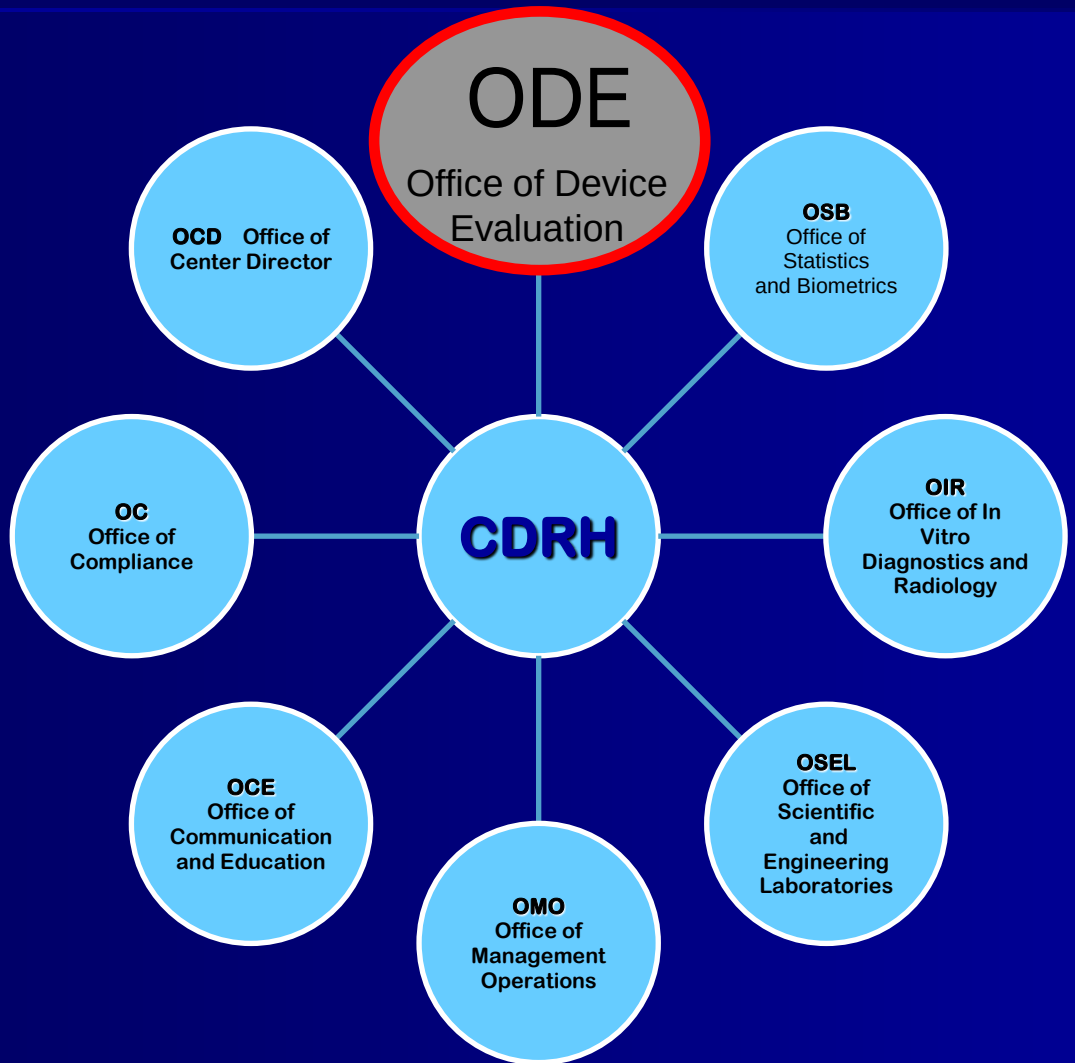
Center for
Devices &
Radiological
Health

Center for
Veterinary
Medicine

Center for
Tobacco
Products

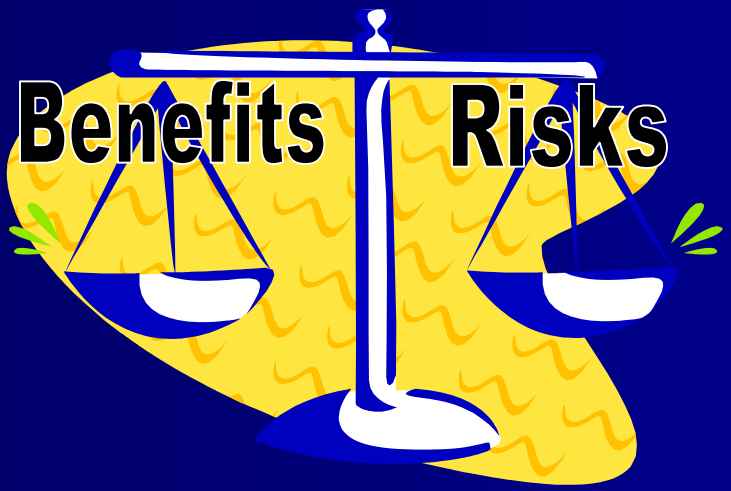
National
Center for
Toxicological
Research

Center for Devices and Radiological Health - CDRH



CDRH's Mission is: Protect & Promote the public health

Getting safe and effective devices to market as quickly as possible…



… while ensuring that devices and radiological products currently on the market remain safe and effective.

Helping the public get science-based accurate information about medical devices and radiological products needed to improve health

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A Medical Device is Defined as…

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent…or accessory, which is
- Intended for use in the diagnosis of disease, or in the cure, mitigation, treatment or prevention of a disease or condition…
- Affects the structure or any function, which does not achieve its intended purposes through chemical action…

Food, Drug and Cosmetic Act, Section 201(h)

CDRH Regulates All Medical Devices

- Firms who manufacture, repackage, re-label, and/or import medical devices sold in the US
- Radiation-emitting electronic products (medical and *non-medical*)
  - TVs, X-ray, ultrasound, microwave ovens

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FDA Resources: Device Classifications

- CLASS I
  - Simple design, low risk
  - Most are exempt from premarket submission
- CLASS II
  - More complex, higher risk
  - Substantial Equivalence via Premarket Notification [510(k)]
  - Compared to legally marketed device of same intended use and technology
- CLASS III
  - Most complex, highest risk
  - Marketing approval via Premarket Approval [PMA] application
  - Demonstrate reasonable assurance of safety and effectiveness

Device Classification

Class I – Low Risk, General Controls

- General Controls:
  - Most Class I devices are exempt from 510(k) requirement, but still must meet other requirements
    - May need to demonstrate substantial equivalence to a legally marketed predicate device
  - Must not be adulterated or misbranded
  - Manufacturers/Distributors must “register and list” with FDA
  - 21 CFR 820 – Quality Systems Regulation
    - Maintain adequate records and reports of manufacturing process, quality control, medical device reports (also 21 CFR 803)

Device Classification Risk-Based Paradigm

Class I: simple, low risk devices

- General controls
- Most exempt from premarket submission requirements

Class 1 Medical Devices

Device Classification

Class II – Moderate Risk, Special Controls

- May include special controls:
  - Includes all General Controls
  - 510(k) Premarket Notification usually required
  - Specific Performance Tests may be required for comparability to a predicate device and may be needed as per special controls
  - Performance tests may include clinical trials
    - Non-Significant Risk Study – abbreviated IDE requirements (21 CFR 812.2(b)); Institutional Review Board (IRB) approval
    - Significant Risk Study - Investigational Device Exemption (IDE) Study (21 CFR 812)

Device Classification Risk-Based Paradigm

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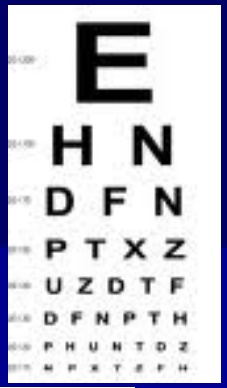


Class 1 Medical Devices

Class II: more complex, higher risk

- Subject to specific regulations or special controls
- Premarket Notification [510(k)]
- Substantial equivalence
- 10-15% require clinical data

Class 2 Medical Devices

Device Classification

Class III – High Risk, Premarket Application

- Premarket Application (PMA), must include:
  - Data must stand alone to support approval
  - Description of Manufacturing and Quality Control Procedures as part of review process
  - Reasonable assurance of Safety and Effectiveness for intended use and indications for use, including:
    - Preclinical performance and validation tests
    - Description and results of clinical trial (IDE study, Outside-US study, or valid clinical data from published literature)
  - Complete labeling review such that no changes can be made without FDA notification or approval

Device Classification Risk-Based Paradigm

Class I: simple, low risk devices

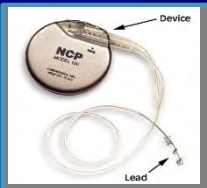
- General controls
- Most exempt from premarket submission requirements

Class 1 Medical Devices

Class II: more complex, higher risk

- Likely requires premarket notification
- May be subject to special controls

Class 2 Medical Devices



Life-supporting or sustaining or critical in preventing impairment of human health.

Class 3 Medical Devices

Informational needs for FDA

- Valid scientific evidence
- Performance specifications
- Tissue effects
- MoA - like to have
- Clinical effects
- Device Labeling

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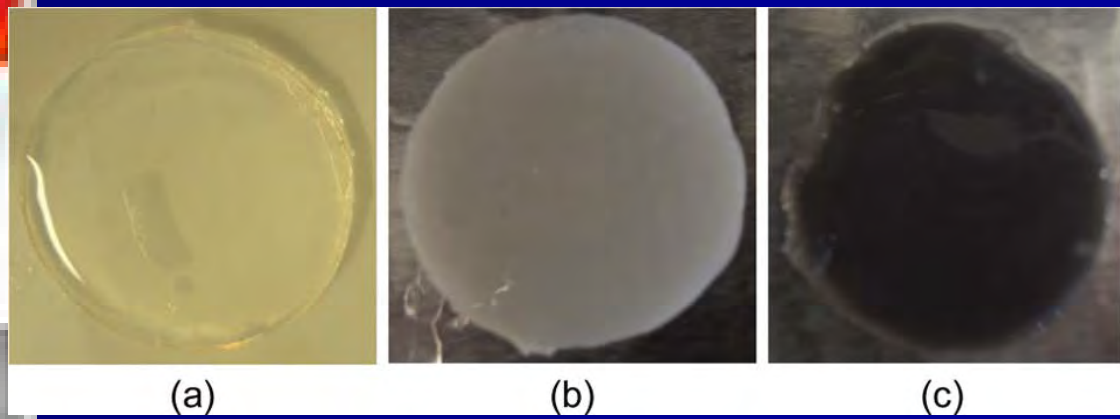
Considerations

Draft for your comment

Medical Device Development Tools - Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff

http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm374427.htm

Considerations




THANK YOU
For your Attention!