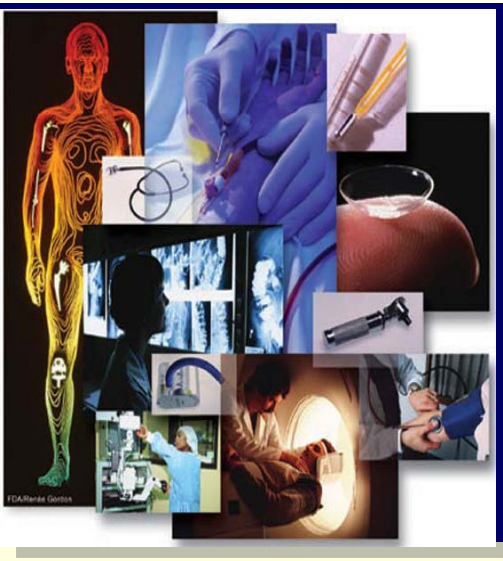


# FDA Regulation of Hearing Aids

**Eric A. Mann, MD, PhD**

**Clinical Deputy Director**

**Division of Ophthalmic and ENT Devices**

**ODE/CDRH/FDA**

# Presentation Outline

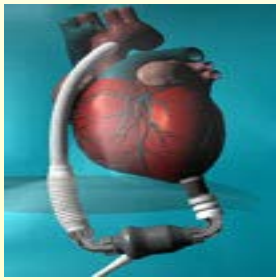
- Overview of device regulations and risk-based regulatory approach
- Hearing aid regulations
  - Labeling
  - Conditions for sale

FDA

**Office of Medical Products and Tobacco**

**C**enter for **D**rug **E**valuation & **R**esearch (CDER)

**C**enter for **B**iologics **E**valuation & **R**esearch (CBER)

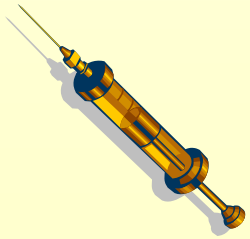


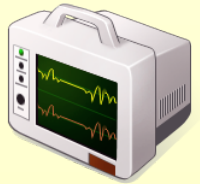
**Center for Devices & Radiological Health (CDRH)**

**C**enter for **T**obacco **P**roducts (CTP)

# Definition of a Medical Device

- Intended to diagnose, cure, mitigate, treat or prevent a disease/condition, or
- Intended to affect the structure or function of the body, and
- Does not achieve intended use through chemical action or metabolism

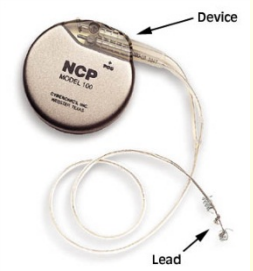


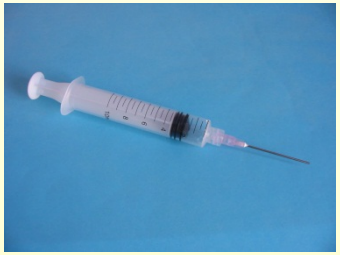


*Sec. 201, Food, Drug and Cosmetic Act*

# The Diversity of Medical Devices





# Regulatory Process for Devices

**Medical Device Amendments of 1976:**

Created a tiered, ***risk-based*** classification with regulatory requirements gauged to risks:

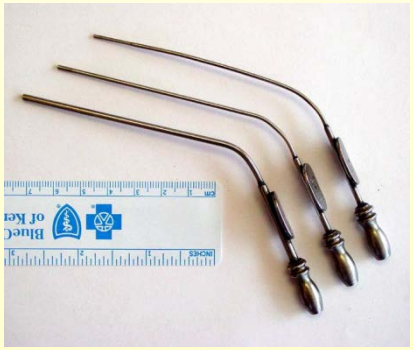
| Class | Risk | Regulatory Requirements |
|---|---|---|
| Class I | Low | General Controls |
| Class II | Moderate | General Controls and Special Controls |
| Class III | High | General Controls and Premarket Approval (PMA) |

# Regulatory Classification for Hearing-Related Devices

| Class | Risk | Examples |
|---|---|---|
| Class I | Low | Air-conduction hearing aid |
| Class II | Moderate | Wireless air-conduction hearing aid (Class II exempt)<br>Transcutaneous air-conduction hearing aid<br>Bone-conduction hearing aid<br>Bone-anchored hearing aid<br>Tinnitus masker |
| Class III | High | Cochlear implant<br>Implantable middle ear hearing device<br>Auditory brainstem implant |

# Class I (Low Risk) : General Controls

- prohibition of adulterated or misbranded devices
- GMPs
- Registration of manufacturing facilities and listing of device types
- Record keeping
- Repair, replacement, refund
- Premarket notification [510(k)]: most Class I devices now exempted



# Additional Hearing Aid Regulations

- Most air conduction hearing aids are **not prescription** devices,

**BUT**

- Hearing aids are restricted by regulation with respect to **device labeling** (21 CFR 801.420) and **conditions for sale** (21 CFR 801.421).

# Hearing Aid Regulations: Patient/Professional Labeling (21 CFR 420)

- User Instructional Brochure
  - Instructions for use, expectations
  - “Warning to Hearing Aid Dispensers”—red flag signs and symptoms
  - “Important Notice for Prospective Hearing Aid Users”
  - Technical performance data (ANSI S3.22-2003)

# Hearing Aid Regulations (cont'd): Conditions for Sale (21 CFR 421)

- Medical evaluation by a licensed physician within the preceding 6 months prior to dispensing
- Waiver of medical evaluation possible for users ≥ 18 years
  - Sign statement acknowledging that medical evaluation is in his/her best health interest
  - Dispenser may not actively encourage waiver
  - Opportunity to review User Instructional Brochure
- Record keeping (3 years)

# 21 CFR 801.421 (Conditions for Sale)

**Preamble (1977):**

- "The Commissioner emphasizes…that the medical evaluation requirement is based upon the recognition that an unnecessary or partially effective hearing aid may be substituted for primary medical or surgical treatment, thus depriving the patient of …appropriate medical diagnosis and care resulting in a detriment to health."

# CDRH Internet Resources

- **FDA Laws/Code of Federal Regulations**

  http://www.fda.gov/RegulatoryInformation/

- **CDRH Home Page**

  http://www.fda.gov/medicaldevices

- **CDRH Databases (including prior device clearances and approvals)**

  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/

- **Device Advice**

  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/

- **Medical Device Reporting (MDR) for adverse events:**

  http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/

# Questions?

- **Contact Information:**

**Eric A. Mann, M.D., Ph.D.**
**Clinical Deputy Director**
**DOED/ODE/CDRH**

eric.mann@fda.hhs.gov

(301) 796-6460