

# Challenges to Regulators Due to Changing Medical Device Technologies

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# The Basic Regulatory Mission

- To promote and protect the public health
- For example, the Mission of the FDA's Center for Devices and Radiological Health follows: **CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products**

# Promoting the Public Health

- Usually suggests making products available to the population as soon as practicable

Pacemaker



# Protecting the Public Health

- Usually suggests preventing problematic devices from reaching the market and removing devices that cause harm from the market



# How to Balance Risk and Benefit

- Regulators must decide when the balance between risk and benefit favors product approval
- “Known” products with incremental improvement
- Challenging for new or changing device technologies

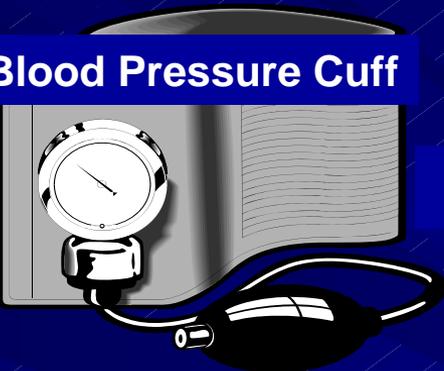


# Diversity of regulated products requires risk based approach:

Patient Examination Table



Blood Pressure Cuff



Contact Lens



Heart Valve



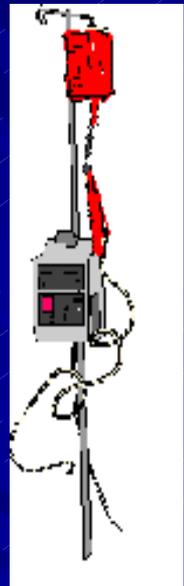
Stethoscope



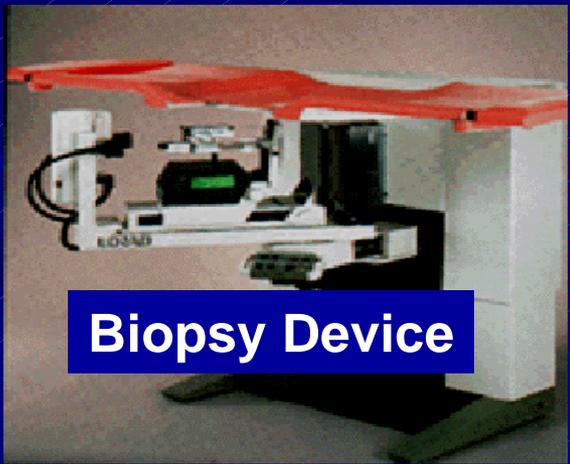
Pacemaker



Infusion pump



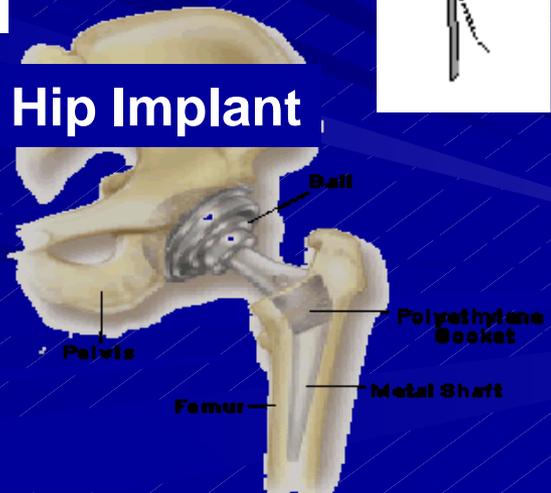
Biopsy Device



Test Strips



Hip Implant



# Major technology trends

- Information science
- Genomics
- Robotics
- Radical miniaturization
- Wirelessness

# Major clinical trends

- Minimal invasiveness
- Improved precision
- Decentralized care
- Personalized medicine
- Late heroic intervention =>  
early Dx and management

# Emerging Device Trends

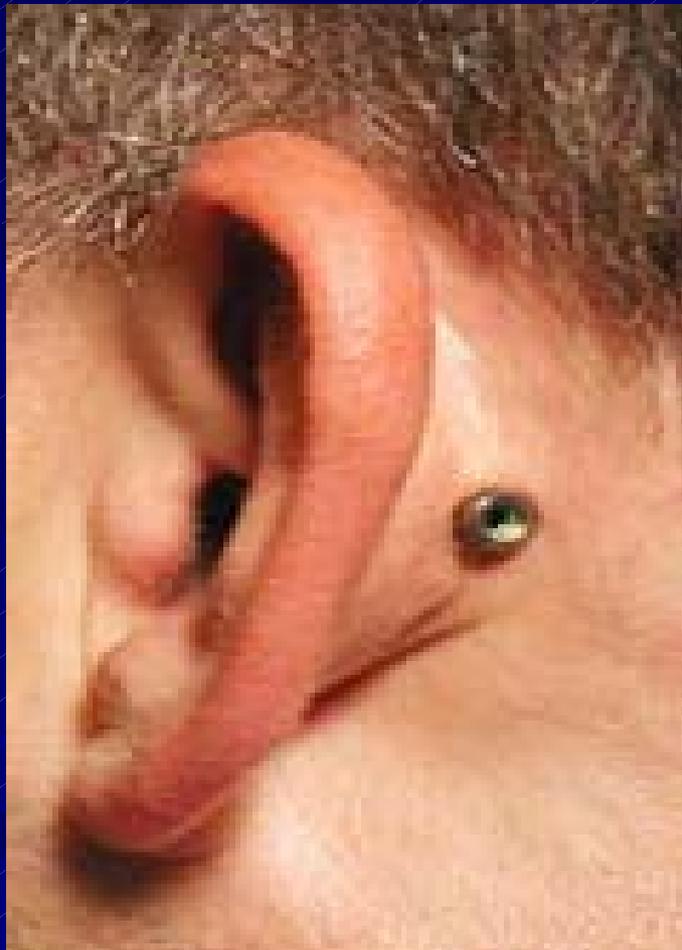
## THE STANDARD FUTURE

- Computer-related Technology
- Molecular Medicine
- Wireless Systems
- Portable, Mobile Systems
- Robotics
- MEMS, Nanotechnology
- Decentralized healthcare
- Minimally Invasive Technologies
- Device/Drug Products
- Organ Replacements and Assists

# Emerging Technology Trends

- **Computer-related Technology**
  - > CADx: Computer Aided Diagnosis
  - > Modularity, interoperability
  - > Ubiquitous distributed intelligence
    - Software everywhere; bugs everywhere
    - Single-state/mega-state devices
    - Personalized devices
    - The basic unit: systems of devices

# A Computer That Helps You Hear





# Emerging Technology Trends

- **Molecular Medicine**
  - > Genomics
  - > Proteomics
  - > Gene therapy
  - > Bioinformatics
  - > Personalized medicine

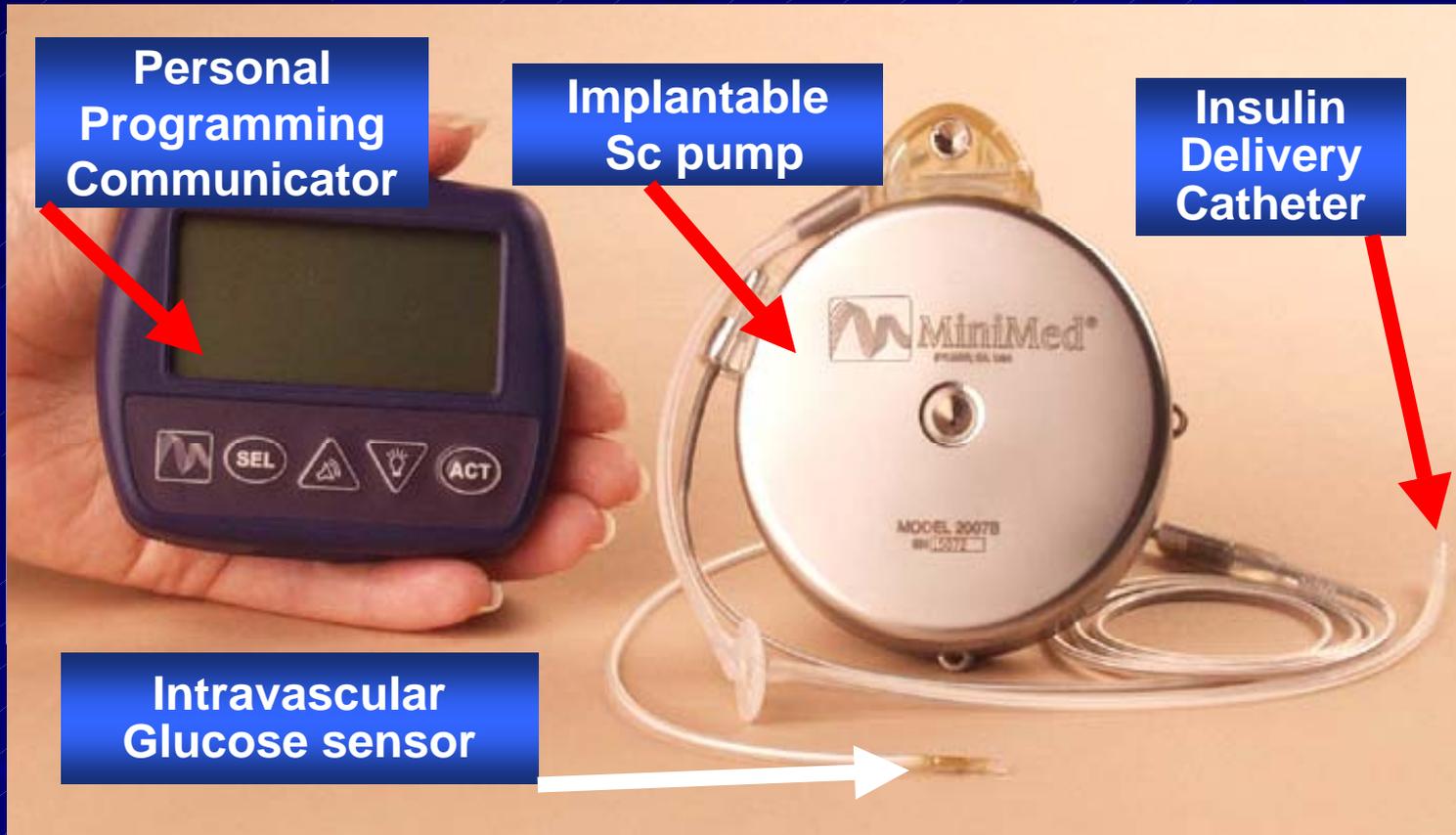
# Emerging Technology Trends

- **Portable, Mobile Systems**
  - > Point-of-care devices
  - > Wearable computer products
  - > Wireless connectivity

## Device/drug products

- > More coatings/elutions
- > Drug-impregnated smart materials

# “Smart” Drug Delivery Devices



**Information-Rich Therapeutics**

# Some challenging issues

- What's a device?
- Human factors, esp. in adverse events
- Labeling
  - Communication to providers/patients
  - Unique Device Identification
- Interacting systems of devices
  - Interoperability
- Architectural considerations: smart buildings
- Software reliability

## Some more challenging issues

- EMC (electromagnetic compatibility) as the wireless environment evolves
- Reliability of extremely miniaturized devices
- Closed loop systems
- Nanotechnology toxicology
- Increased skill requirements
  - Preparing future scientists/engineers?

# The Times They Are A-Changin'

- Consistency is important in a regulatory environment; however, ...
- As technology advances, our expectations for performance change
- Our tolerance for adverse events also changes, usually decreasing
- Use of international standards can help keep the playing field level and make sense of regulatory decision-making

# Sailing to the Future

- Educate, communicate, systems approaches
  - Educate regulators about the technology in new products
  - Educate the public to adjust their expectations to reality: virtually no device is risk-free
  - Communicate from regulator to regulator – especially international vigilance
  - Feedback loops, e.g., from post-market to premarket, from lab science to premarket

