Implantable Medical Devices: Accelerating Standards Development to Streamline Regulation

Joshua Price | August 2, 2018

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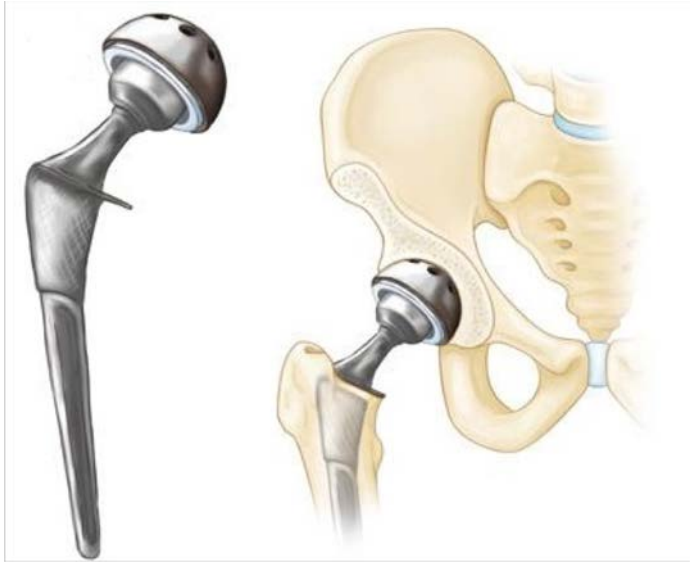
Are You Affected by Implantable Medical Devices?

Pacemakers

188,700

new pacemakers in the US every year

Artificial Hips and Knees



1.05 million

new artificial hips and knees in the US every year

Defining Implantable Medical Device

Medical Device

- Instrument or machine
- Intended to diagnose, cure, treat, or prevent disease
- Non-chemical action

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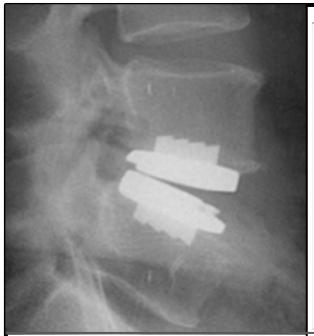
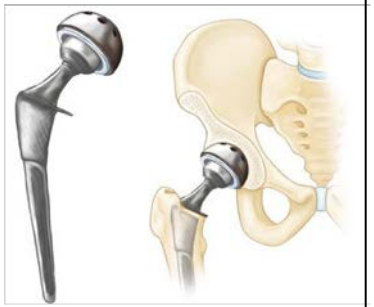
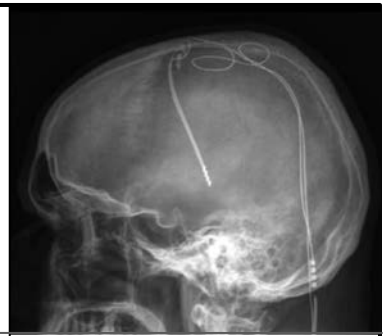
***Implantable* Medical Device**

- Inserted surgically or otherwise
- Remains for at least 30 days

				
Artificial disc	Pacemaker	Hip prosthesis	Intrauterine Device	Neurostimulator

Medical Device Regulation

The Players

FDA U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health
CDRH

The Goals

Safety

Performance

Clinical Efficacy

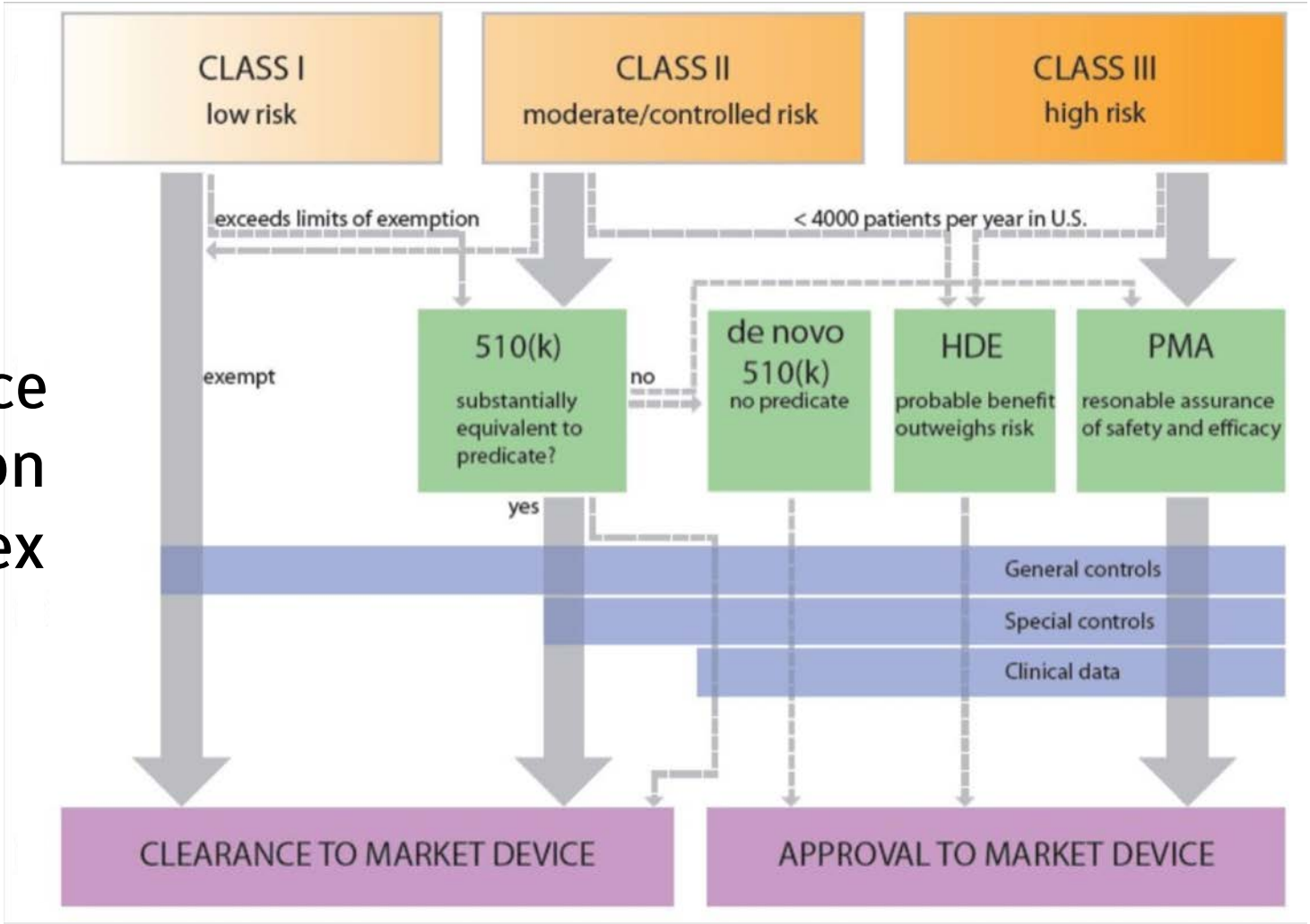
Balancing Device Safety and Innovation

FDA reviews
2600 device proposals
per year

In 2011, US patients waited
3.5 years longer
than patients in the EU for new medical devices

For the past 20 years, companies have been
moving R&D abroad
due to regulatory imbalances

FDA Device Regulation is Complex



New Implant Regulation: The PMA Process

Investigational Device Exemption (IDE)	Clinical Trials	Pre-Market Approval (PMA)	Post-Approval Studies (PAS)
Approval from FDA to run clinical trials Parallel to Investigational Review Board (IRB) review	Gold standard is double-blind, randomized, controlled Trial but most aren't 3 yrs long on average	Information on: 1. Clinical Trials 2. Production facilities 98% of PMAs approved	FDA can order PAS to confirm long-term safety and effectiveness FDA often does not enforce PAS
2 mo. to 2 yrs	3 mo. to 7 yrs	180 days	No limit

Standards and Device Regulation

Technical Standard

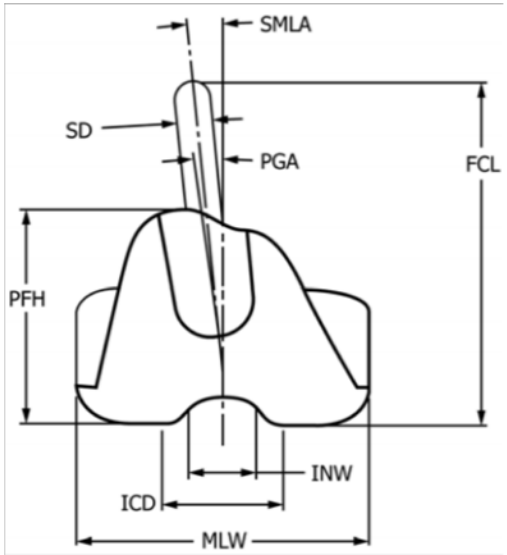
A “set of technical definitions and guidelines… for designers, manufacturers, and users… that promote safety, reliability, productivity, and efficiency” (ASME)

National Institute of Standards and Technology
U.S. Department of Commerce

OMB Circular A-119 (1995)

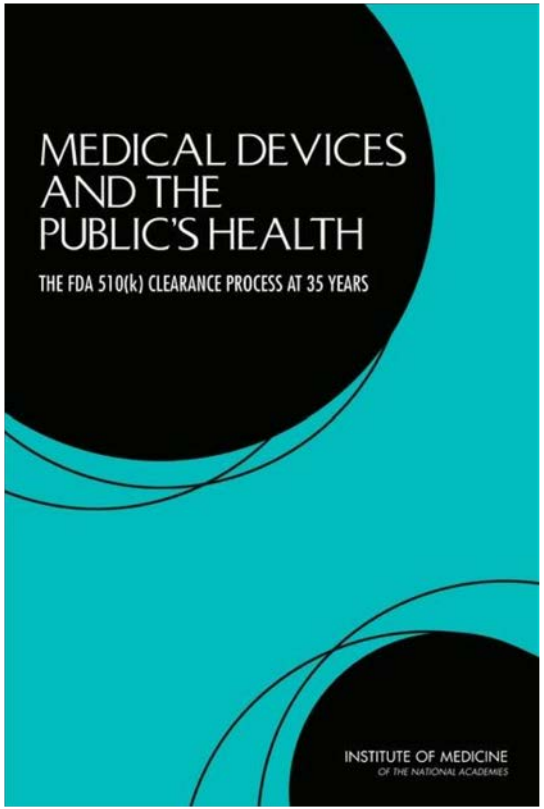
Example: ASTM F2083-12

Standard Specification for Knee Replacement Prosthesis



Recommendations

1. National Academies to Review Standards Role



The Health and Medicine Division Should:

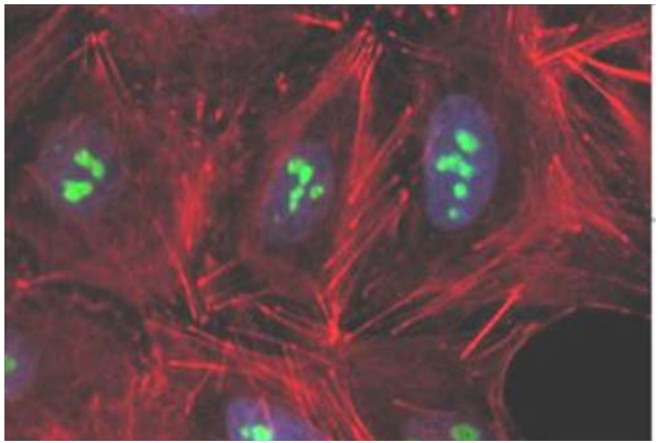
Publish a review report about the impact of technical standards on:

1. Time to approve new devices
2. IDE and PMA approval rates
3. Clinical trial success rates
4. Number of new device applications

Authorize and appropriate $1 million

2. NIST Medical Implant Standards Program

Example of NIST Program:
Standards for Immuno-histochemical imaging



NIST Should:

- Establish a program to identify and promote the development of new medical device standards
- Emphasis on modeling, simulation, validation, and measurements

Authorize and appropriate $500,000 annually

3. NIST-CDRH Medical Implant Center of Excellence

Example of Center of Excellence:

CHiMaD

Center for Hierarchical Materials and Design

Collaboration between NIST and selected research institutions to advance a specific research area.

NIST and CDRH Should:

Establish a Center of Excellence (CoE) to perform R&D necessary for medical implant standards in emerging areas utilizing CDRH data and domain expertise.

Authorize and appropriate $5 million annually

In Conclusion

Safety

Performance

Clinical Efficacy

Innovation

Thank You

Questions?

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