Standards and Regulatory Considerations for Orthopaedic Implants
Constituencies

- Patients
- Payers (Insurance)
- Physicians
- Manufacturers
- Research Community
- Government
- Legal Community
Professional Organizations

- **Implant Companies**
  - Large (e.g. Zimmer, DePuy)
  - Medium (e.g., Implex, Synthes)
  - Small (e.g. Kinetikos)
  - OSMA

- **Physician Societies**
  - AAOS
    - Committee on BME
  - Specialty
    - OTA
    - AAHKS
    - Hip Society
    - AOFAS

- **Research**
  - ORS
  - SFB
  - ASME
  - ASB/ISB

- **Standards**
  - ASTM
  - ISO

- **Government**
  - FDA
  - NIH/CDC/VA

**Device Forum**
Food and Drug Administration

Charge: Ensure that all medical device products that are brought to market are safe and effective.
Statutory Authority

- Federal Food & Drugs Act of 1905
  - Upton Sinclair (*The Jungle*) et al.
  - Theodor Roosevelt → James Wilson

- Federal Food, Drug, & Cosmetic Act of 1938

- *Medical Device Amendment Act of 1976*
  - May 28, 1976: Pre-Amendment Devices
# FDA Device Classifications

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Minimum Risk</td>
<td>Surgical instruments, Cast material, Crutches</td>
</tr>
<tr>
<td>II</td>
<td>Safety &amp; Efficacy Information Exists</td>
<td>Bone screws &amp; plates, IM rods, Cemented THA</td>
</tr>
<tr>
<td>III</td>
<td>New Device</td>
<td>Ligament replacements, Bone substitutes</td>
</tr>
<tr>
<td>FDA Evaluation Pathways</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>Pre-Market Notification</td>
<td>Substantial equivalency to pre-Amendment or predicate device. Clinical and/or non-clinical testing. e.g.: design parameter changes</td>
<td></td>
</tr>
<tr>
<td>510[k]</td>
<td></td>
<td></td>
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<tr>
<td>Pre-Market Approval</td>
<td>New device or new intended use. Safety &amp; efficacy data required, usually including clinical trials ($ $ $).</td>
<td></td>
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<tr>
<td>PMA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigational Device Exemption</td>
<td>Clinical trials of new devices. Limited numbers, controlled settings, IRB &amp; FDA approval. Not for commercial distribution</td>
<td></td>
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<tr>
<td>IDE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# FDA Data Requirements

<table>
<thead>
<tr>
<th>Data Required</th>
<th>510 [k]</th>
<th>PMA</th>
<th>IDE</th>
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</thead>
<tbody>
<tr>
<td>General</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>(e.g. name, description, materials, design, labeling, intended use)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-clinical data</td>
<td>Usually</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>(e.g. bench tests, animal tests)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical data</td>
<td>Occasionally</td>
<td>Yes</td>
<td>When available</td>
</tr>
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</table>
## FDA Marketing Release Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td>510 [k]</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>PMA</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>IDE *</td>
<td>No</td>
<td>Sometimes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* Limited to participating trial center(s)
Guidance Documents

- Public Domain
- **Suggested** information that FDA needs
- Developed “by FDA Staff”
  - Outside Experts
    - Vetting
    - Drafting
  - Invited commentary from industry
  - Heavy reliance on consensus standards (esp. ASTM)
Center for Devices and Radiological Health (CDRH)

Rockville, MD

- 3,507 new products received marketing clearance in 2001
  - 1,098 ongoing device trials
  - 216 new clinical studies
Division of General, Restorative and Neurological Devices, CDRH

Director
Celia M. Witten, Ph.D., M.D.

Deputy Director I
Mark N. Melkerson

Deputy Director II
Miriam Provost

Plastic & Reconstructive Surgery Devices Branch
Stephen Rhodes

General Surgery Devices Branch
Neil R. Ogden

Orthopedic Devices Branch
Barbara Zimmerman

Restorative Devices Branch
Theodore Stevens

11 Staff Engineers
Orthopaedic and Rehabilitation Devices Panel

• EXEC SEC
  Hany Demian, M.S.
  Center for Devices and Radiological Health
  Office of Device Evaluation/DGRND

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  University of Minnesota

• Sally Maher, ESQ.
  INDUSTRY REPRESENTATIVE - Nonvoting
  Director, Regulatory Affairs & Clinical Research
  Smith & Nephew Richards

• Karen R. Rue
  CONSUMER REPRESENTATIVE - Nonvoting
  Director Quality Improvement
  Acadian Health Care Alliance
DIVISION OF GENERAL, RESTORATIVE, AND NEUROLOGICAL DEVICES

Serves as the primary source for scientific and medical expertise on general surgery, plastic and reconstructive surgery, orthopedic and restorative devices with regard to safety and effectiveness.

Performs, coordinates, directs and monitors all actions including scientific and medical review and evaluation for documents related to classification, petitions, premarket notification submissions (510(k)s), premarket approval applications (PMAs), product development protocols (PDPs), and investigational device exemptions (IDEs), and supplements or amendments to these submissions.

Makes equivalence and nonequivalence determinations; approves or disapproves actions related to classification, petitions, 510(k)s, PMAs, PDPs, and IDEs, and all supplements and amendments to these submissions, as authorized.

Provides executive secretarial support and other technical and nontechnical support to device advisory panels and panel members and consultants, and takes action on panel recommendations.

Provides liaison, coordinates and takes action, as appropriate, on classification actions, petitions, 510(k)s, PMAs, PDPs, and IDEs with Center and agency components; Federal, State, and international agencies; and industry, consumer, and professional organizations.
American Society for Testing and Materials

(ASTM)
ASTM

- Organized in 1898
- Voluntary Standards Participants:
  - Producers
  - Users
  - Consumers
  - General Interest (Government, Academia)
- Coverage:
  - Materials
  - Products
  - Systems
  - Services
Uses for Standards

- Product R&D
- Manufacturing Quality Control
- Contracts & Purchase Agreements
- Scientific Protocols
- Regulatory Agencies
- Litigation
ASTM

- 33,000 members
- 134 standards-writing committees
  - Test methods, specifications, practices, guides, classifications, terminology
  - Metals, paints, plastics, textiles, petroleum, construction, energy, environment, consumer products, electronics, medical devices, etc.
- 8,500 standards published per year
- Annual Book of ASTM Standards (68 vols)
134 Technical Committees, incl:

**F04 Medical & Surgical Materials & Devices**

26 Subcommittees, incl:

- **F04.21 Osteosynthesis**
  - 6 Task Groups:
    - F04.21.01 Bone Screws
    - F04.21.03 Intermedullary Rods
    - F04.21.04 External Fixation Devices
    - F04.21.05 Bone Staples
    - F04.21.06 Wires & Cables
    - F04.21.11 Bone Plates

- **F04.22 Arthroplasty**
  - 26 Task Groups, incl:
    - F04.22.04 Total Shoulder
    - F04.22.06 Total Wrist
    - F04.22.09 Femoral Stems
    - F04.22.10 Hip Wear
    - F04.22.11 Knee Wear
    - F04.22.12 Tibial Trays
    - F04.22.15 Femoral Head Finish
Standards Development Process

- Written request → ASTM Staff Review
- Assignment to Committee → Subcommittee → Task Group
- F4 committee meets twice/year
- Document drafted by Technical Contact
- Informal revisions by Task Group members
- Task Group Recommendation
- Subcommittee Chairman approval to ballot
- Subcommittee Letter Ballot
- Main Committee Letter Ballot
- Editorial Review by ASTM Staff
- Publication (~ 2-3 years)
ASTM Medical Devices Standards

• 391 Currently on the Books (Vol. 13)
  – Classification
  – Terminology
  – Practice
  – Guide
  – Test Method
  – Specification

• 5 Year Duration, Renewable