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

Class	Description	Examples
I	Minimum Risk	Surgical instruments, Cast material, Crutches
II	Safety & Efficacy Information Exists	Bone screws & plates, IM rods, Cemented THA
III	New Device	Ligament replacements, Bone substitutes

FDA Evaluation Pathways

Pre-Market Notification 510[k]	Substantial equivalency to pre-Amendment or predicate device. Clinical and/or non-clinical testing. e.g.: design parameter changes
Pre-Market Approval PMA	New device or new intended use. Safety & efficacy data required, usually including clinical trials ($ $ $).
Investigational Device Exemption IDE	Clinical trials of new devices. Limited numbers, controlled settings, IRB & FDA approval. Not for commercial distribution

FDA Data Requirements

Data Required	510 [k]	PMA	IDE
General (e.g.name, description, materials, design, labeling, intended use)	Yes	Yes	Yes
Non-clinical data (e.g. bench tests, animal tests)	Usually	Yes	Yes
Clinical data	Occasionally	Yes	When available

FDA Marketing Release Requirements

Requirement	Class I	Class II	Class III
510 [k]	Yes	Yes	No
PMA	No	No	Yes
IDE *	No	Sometimes	Yes

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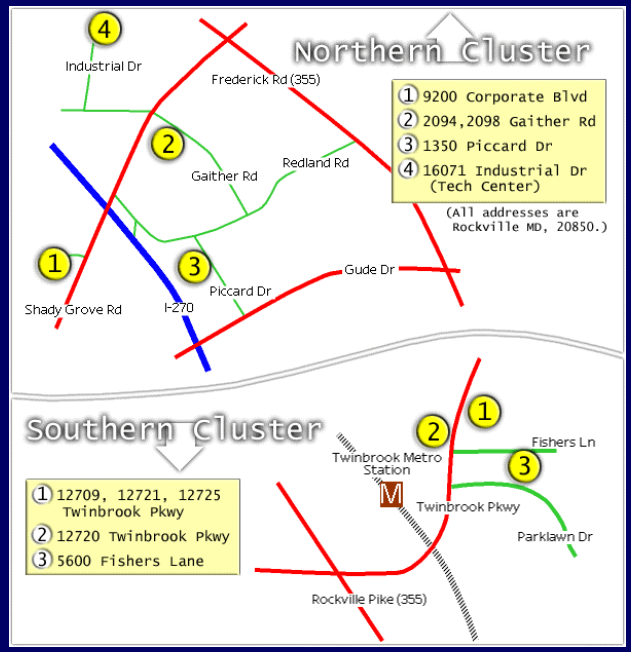
* Limited to participating trial center(s)

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

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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

11 Staff Engineers

Restorative Devices Branch
Theodore Stevens

Orthopaedic and Rehabilitation Devices Panel

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  Office of Device Evaluation/DGRND

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  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:

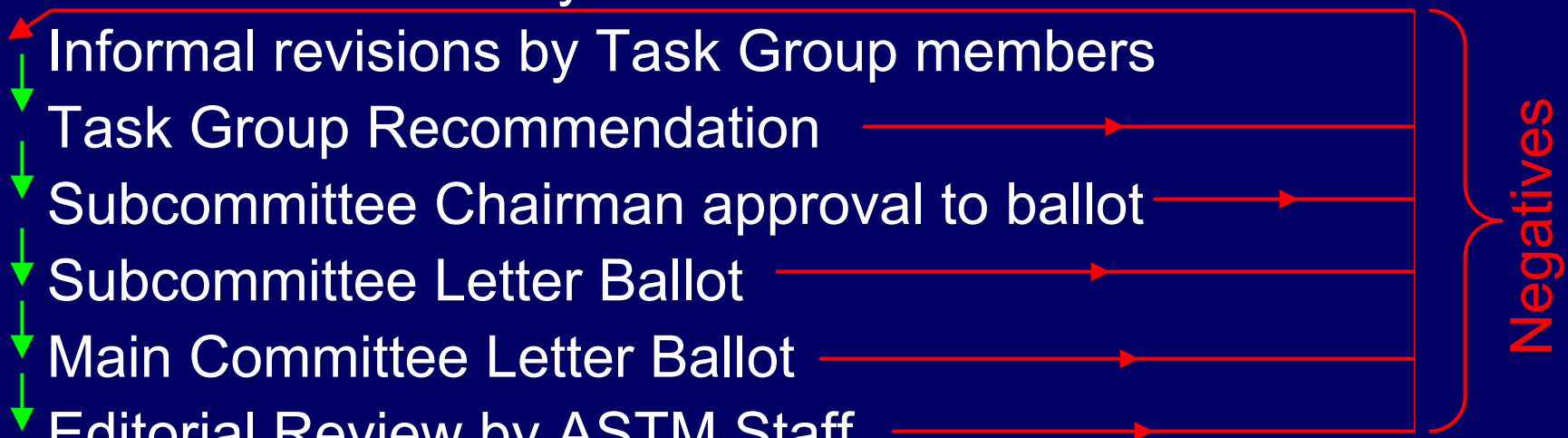
F04 Medical & Surgical Materials & Devices

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