Pharm 411 Medical Devices Overview of Device Regulations

Tom Hazlet
Pharmaceutical Outcomes Research & Policy Program
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- Regulatory Stuff: definitions, history
- “To market, to market ...” and device classification
- Where to look for information
- Unique identifiers for medical products & associated billing issues
- “We don’t stock this” story
- Unsubstantiated medical device claims -- complaints
- Questions – whenever

fix
- unique identifiers for medical products & associated billing issues
- we don’t stock this
- unsubstantiated medical device claims -- complaints

FDA
- Center for Medical Devices and Radiological Health (CDRH)
- firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States.
- radiation emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

www.fda.gov/cdrh

With thanks to Dave Pettenski, USFDA, from whose material much of this talk was poached.
The term “device” ... means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

1969 HEW survey: 10 years 10,000 injuries & 751 fatalities

FDA survey: 858 deaths

Independent survey 36,000 complications in one year

Dalkon Shield, an IUD, marketed w/o proper testing:
- removal rate of 26.4%
- an infection rate of 5%
- 25 miscarriages, 16 deaths

Cardiac pacemakers defects necessitated 30 recalls involving 23,000 units

May 28, 1976

Key features of the 1976 Amendments
- Classification for regulatory purposes
- Pre-market approval: implanted & life supporting devices
- Interstate commerce is presumed in all cases
- Authority to issue GMP's, Access to industry records
- Registration and list, Authority to ban devices
FDA History

- **Safe Medical Devices Act of 1990**
  - Post-Market Surveillance
  - Enforcement Provisions
  - Establishes Office of International Relations for harmonization
  - GMP now includes Pre-production Design control requirements (QSR)

MDUFMA: The Medical Device User Fee and Modernization Act of 2002

- User fees for device reviews.
- Establishment inspections may be conducted by accredited persons (third-parties),
- New regulatory requirements for reprocessed single-use devices.

Basic Device Regulatory Requirements

- Premarket Notification 510(k), unless exempt, or Premarket Approval (PMA),
- Establishment registration
- Medical Device Listing
- Quality System (QS) regulation,
- Labeling requirements, and
- Medical Device Reporting (MDR)

FDA “powers”

- If FD&C Act/regulations are not followed the result is a Prohibited Act
  - adulteration
  - misbranding
- Sanctions
  - Non-regulatory (meeting, untitled letter, warning letter, civil penalties)
  - Judicial Actions (seizure, injunction, prosecution; successful enforcement actions)
  - Criminal prosecution
Medical Device Classification & Regulatory Requirements

- **Class I - General Controls** (with & w/o exemptions)
- **Class II – General Controls and Special Controls** (with & w/o exemptions)
- **Class III – General Controls and Premarket Approval**

Class I - General Controls

- Known information provides reasonable assurance of safety & effectiveness using General Controls OR
- Known information does not assure S & E, BUT the device
  - Does not support or sustain human life, OR
  - Is not used to prevent impairment of human health AND
  - No unreasonable risk of illness or injury

Examples of Class I Devices

- Examination Gloves [21CFR880.6250](#)
- Dental Hand Instrument [21CFR872.4565](#)
- Elastic Bandages [21CFR880.5075](#)
- Pacemaker Charger [21CFR870.3670](#)
- Ultrasonic Cleaner for Medical Instruments [21CFR880.6150](#)
- Hand-held (Manual) Surgical Instruments [21CFR878.4800](#)
Class II - Special Controls

- General Controls alone are insufficient to provide assurance of Safety & Effectiveness
  - BUT
- Information exists to establish Special Controls

Special Controls

- General Controls +
- Special Labeling Requirements
- Performance Standards
- Postmarket Surveillance
- Patient Registries
- Guidelines
- Recommendations
- Any other appropriate actions

Examples of Class II Devices

- Cardiac Monitor 21CFR870.2300
- Elbow Joint Metal/Polymer Constrained Cemented Prosthesis 21CFR888.3150
- Pediatric hospital bed 21CFR880.5140
- Infusion Pump 21CFR880.5725
- Powered Wheelchair 21CFR890.3860
- Surgical Drapes 21CFR878.4370
- TENS device 21CFR882.5890

Class III - Premarket Approval

- Not enough information to classify as either Class I or II
- Device usually supports/sustains life,
  - is of substantial importance in preventing impairment of human health or
  - presents a potential, unreasonable risk of illness or injury
Premarket Approval

- Extensive submission including data showing Safety & Effectiveness
- Conditions of Approval
- Annual Reports

Examples of Class III Devices

- Implantable 21CFR870.3610
- Replacement heart valve 21CFR870.3925
- Cranial electrotherapy 21CFR882.5800
- Implanted electrical urinary continence device 21CFR876.5270
- Silicone gel-filled breast implant 21CFR878.3540
- Implanted cerebella stimulator 21CFR882.5820

Device Classification – risk-based

- Roughly 1700 different device types
- 16 Medical Specialties

<table>
<thead>
<tr>
<th>Class</th>
<th>Approval Prior to Marketing</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Generally exempt</td>
<td>Wheelchair</td>
</tr>
<tr>
<td>II</td>
<td>510(k) substantially equivalent</td>
<td>Oxygen generator, portable</td>
</tr>
<tr>
<td>III</td>
<td>Premarketting Agreement (PMA)</td>
<td>Electroconvulsive therapy device</td>
</tr>
</tbody>
</table>

Where to find information

- FDA web site → CDRH → “Device Advice” → “Classify your device”
- find “PRODUCT CODE CLASSIFICATION DATABASE”
- select “Go to simple search”
- enter product name – “pregnancy test kit”
- select hot link
- select CFR citation
“performance standards” – vestige of ’76 Act that has never been completed for many products, see specific information in CFR, or Guidance Documents.

CDRH → “search guidance database” → do “simple search”

Class I – Wheelchair

Product Classification Database

<table>
<thead>
<tr>
<th>Device</th>
<th>Chair, With Casters</th>
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</thead>
<tbody>
<tr>
<td>Device Description</td>
<td>Mechanical chair.</td>
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<tr>
<td>Medical Specialty</td>
<td>Physical Medicine</td>
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<tr>
<td>Product Code</td>
<td>INM</td>
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<tr>
<td>Regulation Number</td>
<td>890.3100</td>
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<tr>
<td>Device Class</td>
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<tr>
<td>GMP Exempt?</td>
<td>No</td>
</tr>
<tr>
<td>510(k) Exempt?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

... but compare: Sec. 890.3880 Special grade wheelchair

Class II – Oxygen Generator

Product Classification Database

<table>
<thead>
<tr>
<th>Device</th>
<th>Generator, Oxygen, Portable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Description</td>
<td>Portable oxygen generator.</td>
</tr>
<tr>
<td>Medical Specialty</td>
<td>Anesthesiology</td>
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<tr>
<td>Product Code</td>
<td>CAW</td>
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<tr>
<td>Regulation Number</td>
<td>868.5440</td>
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<tr>
<td>Device Class</td>
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<tr>
<td>GMP Exempt?</td>
<td>No</td>
</tr>
<tr>
<td>510(k) Exempt?</td>
<td>No</td>
</tr>
</tbody>
</table>

Class III – Electroconvulsive therapy device

PART 802 -- NEUROLOGICAL DEVICES

Subpart F — Neurological Therapeutic Devices
Sec. 802.5940 Electroconvulsive therapy device.

[a] Identification. An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient’s head.

[b] Classification. Class III (premarket approval).

[c] Data PMA or notice of completion of a 510(k) is required. No effective date has been established for the requirement for premarket approval. See § 801.3.

Social Security Act Section 1861(n) – DHHS | CMS

(n) The term “durable medical equipment” includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual’s medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient’s home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual’s use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations); except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

http://www.cms.hhs.gov/suppliers/dmepos/

Home Test Kits

- Regulated as “in vitro diagnostics”
  - FDA CDRH Office of In Vitro Diagnostics (OIVD)
- 500+
- Most – diabetes – associated
- Pregnancy, ovulation
- Fecal occult blood, colon cancer
- “drug” testing

Ostomy Supplies

<table>
<thead>
<tr>
<th>New Search</th>
<th>Product Code</th>
<th>Device Class</th>
<th>Regulation Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appliance, Colostomy, Disposable</td>
<td>EZS</td>
<td>1</td>
<td>876.5900</td>
</tr>
<tr>
<td>Bag, Drainage, With Adhesive, Ostomy</td>
<td>FON</td>
<td>1</td>
<td>876.5900</td>
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<tr>
<td>Bag, Stomal</td>
<td>GDS</td>
<td>1</td>
<td>876.5900</td>
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<tr>
<td>Bag, Urinary, Ileostomy</td>
<td>EXH</td>
<td>1</td>
<td>876.5900</td>
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<tr>
<td>Bag, Urine Collecting, Ureterostomy</td>
<td>EXG</td>
<td>1</td>
<td>876.5900</td>
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<td>Cement, Stomatal Appliance, Ostomy</td>
<td>EZR</td>
<td>1</td>
<td>876.5900</td>
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<tr>
<td>Collector, Ostomy</td>
<td>EXB</td>
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<td>876.5900</td>
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<tr>
<td>Irrigator, Ostomy</td>
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<tr>
<td>Pouch, Colostomy</td>
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<td>876.5900</td>
</tr>
<tr>
<td>Protector, Ostomy</td>
<td>EXE</td>
<td>1</td>
<td>876.5900</td>
</tr>
</tbody>
</table>

Miscellaneous Stuff

- Unique identifiers for medical products & associated billing issues
- “We don’t stock this” story
- Unsubstantiated medical device claims - complaints
Questions