SANDLER, TRAVIS & ROSENBERG, P.A.
International Trade, Customs & Export Law

US Imports and Compliance:
FDA Regulation of Medical Devices
FIME
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About Shelly Garg

Shelly Garg is an attorney with Sandler, Travis & Rosenberg's FDA Practice Group.

She represents clients across a broad range of FDA-regulated product categories, including food, beverages and dietary supplements, over-the-counter drugs, medical devices, and cosmetics. She advises in strategic business planning, product development, testing and approval, labeling, advertisement and promotion, liability risk, inspections, responding to regulatory enforcement matters, and related issues.

Her keen insights into the FDA and its inner workings have proven to be of significant value to her clients in successfully resolving matters before the agency.

Agenda

- Import Requirements
- History/Overview of FDA Regulation of Medical Devices
- Device Classification
- Device Registration and Listing
- Device Labeling
- 510(k) Process
- cGMPS
- Adverse event reporting
- Question & Answer

Parties Involved in Import Process

- Importer/Customs Broker Relationship
  - Appoints broker as agent for specified purposes: transact customs business on importer's behalf, file and sign entry documents, export documents, customs bonds, protests, endorse bills of lading, etc.—may add or delete services;
  - May limit liability to $50 per transaction—must read terms and conditions carefully
  - Does not relieve importer of legal responsibility for accuracy of all information on entry documents/electronic filings
- Common carrier: Provides, and assumes responsibility for, transportation of cargo between the U.S. and foreign countries
- Freight forwarder: Organizes movement of goods in order to facilitate shipment by common carrier (e.g., books, arranges cargo space; prepares cargo documents; orders cargo to port, etc.)
- Non-vessel operating common carrier: contracts with shipping lines for space, but does not operate vessels; consolidates and containerizes shipments

Import Issues

- Who Makes Entry?
- Importing Requirements / Entry of Merchandise
- Types of Formal Entries: consumption vs. warehouse entry
- Required Entry Documentation
  - Tariff classification; importer/filer providing necessary entry information to local CBP office. Entry information should identify product code and other information to demonstrate product is in compliance with FDA regulations
- Product admissibility – USPTO, USDA, CPSC, EPA, FDA

FDA Admissibility

- Compliant with General or Special Controls
- Class I, II, or III
- Establishment is Registered and Devices are Listed
- Compliant Labeling
- GMP

FDA Admissibility (continued)

- Notice of Action
  - Issued if product appears to be out of compliance
  - Informal hearing: opportunity to provide written or oral testimony within a period of time (usually 14 days)
  - Reconditioning
- Notice of Release
- Notice of Refusal
  - Must be exported or destroyed within 90 days
  - Failure to comply may result in a Customs Redelivery Notice and an assessment of liquidated damages for up to 3X the value of the lot.

What is a Medical Device?

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices.

Additionally, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology.

Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. EX: diagnostic ultrasound products, x-ray machines and medical lasers.

Definition of Medical Device

- Section 321(h), Federal Food, Drug & Cosmetic Act
- (h) The term “device” (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) 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.

FDA Requirements

- All medical devices regardless of class and manner of market introduction are subject to the general regulatory controls established under the 1938 Act and amplified by the 1976 and later amendments
- General Controls include
  - Basic adulteration and misbranding provisions
  - Applicable good manufacturing practice (GMP) regulations
  - Banned device regulations
  - Notification and repair
  - Replacement
  - Refund requirements

Intended Use as the Driver of FDA Regulation and Device Classification

- Definition of labeling
- Objective and subjective representations
- Testimonials
- Endorsements
- Off-package labeling
- Any other extrinsic evidence

Device Classification

- Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type.
- Most Class I devices are exempt from Premarket Notification 510(k);
- Most Class II devices require Premarket Notification 510(k) (similar intended use, technological characteristics that device is at least as safe and effective as the legally marketed device); and
- Most Class III devices require Premarket Approval.

The Classification Process

- 21 CFR Part 872—Dental Devices

Sec. 872.6390 Dental floss.

(a) *Identification.* Dental floss is a string-like device made of cotton or other fibers intended to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.
(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 872.9.

Sec. 872.3570 OTC denture repair kit.

(a) *Identification.* An OTC denture repair kit is a device consisting of a material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permanently to a denture to mend cracks or breaks. The device may be available for purchase over-the counter.
(b) *Classification.* Class II. The special controls for this device are FDA's:
(1) "Use of International Standard ISO 10993 `Biological Evaluation of Medical Devices--Part I: Evaluation and Testing,'" and
(2) "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits."

The Classification Process (Continued)

- 21 CFR Part 872—Dental Devices (Continued)

Sec. 872.3940 Total temporomandibular joint prosthesis.

(a) *Identification.* A total temporomandibular joint prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and augment the glenoid fossa to functionally reconstruct the temporomandibular joint.
(b) *Classification.* Class III.
(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a total temporomandibular joint prosthesis that was in commercial distribution before May 28, 1976. Any other total temporomandibular joint prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

FDA Final Guidance RE "General Wellness: Policy for Low Risk Devices"

- FDA established approach to not regulate "general wellness products" if such devices meet the definitions and conditions established by the guidance – i.e. mobile apps, smart watches, other products intended to help monitor and improve consumers' physical fitness, nutrition, or other similar goals.
- Definition of "general wellness products" – products that:
  - Are intended for only general wellness use and
  - Present a low risk to the safety of users and other persons
- Intended uses fall into 2 categories:
  - Products that make claims about "sustaining or offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions"
  - Products that make claims about "sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions." Includes products that are intended to promote, track and/or encourage choices which, part of a healthy lifestyle, either (1) may help reduce the risk of certain chronic diseases or (2) may help living well with certain chronic diseases

Is the Product a Medical Device?

- Sunglasses: Class I, requires compliance with general controls, including impact resistance and drop ball certificate testing
- Dental Guard: Class II, requires premarket notification, i.e. 510(k)
- Contact lenses: Class II or Class II, 510(k) or PMA
- Decorative contact lenses – non-corrective used to change normal appearance of the eye in decorative fashion (celebrities, Halloween costumes) – how are these regulated?

General Hospital Devices

- Adjustable Hospital Bed, Class 2, 510(k) Exempt, 21 CFR 880.5100
- Medical Chair and Table, Class I, 510(k) Exempt, 21 CFR 880.6140

Establishment Registration 21 CFR Part 807

- Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA.
- Establishment registrations must be submitted electronically unless a waiver has been granted by FDA.
- All registration information must be verified annually between October 1st and December 31st of each year.
- Foreign manufacturers must also designate a U.S. Agent.
- User Fees
- FDA Solutions Group can register your establishment and serve as US Agent

Device Labeling

- Intended Use
- Name and Place of Business
- Adequate Directions for Use
- Prominence and Conspicuousness

Good Manufacturing Practice 21 CFR Part 820

- Regulations govern activities such as:
  - Production and process controls
  - Packaging and labeling controls
  - Distribution
  - Recordkeeping
- Covers manufacture, pre-production design validation, packing, storage, and installation of a device

Adverse Event Reporting

- Require manufacturers and importers to make a medical device report (MDR) whenever they receive information from any source that "reasonably suggests" that one of their devices "may have caused or contributed to a death or serious injury" or "has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." (21 CFR 803.40(a) and (b) (importers); 803.50(a) manufacturers
- Manufacturers and importers must submit an MDR within 30 days of acquiring such information
- Manufacturers must report within 5 days if the reportable event "necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health." (21 CFR 803.40, 50 & 53)

Adulteration and Misbranding

- Section 501(a): a device (or drug) is adulterated "if it consists in whole or in part of any filthy, putrid or decomposed substance, or if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."
- Section 502(a): a device (or drug) is misbranded "if its labeling is false or misleading in any particular" (Section 502(f) states that it is misbranded "unless its labeling bears adequate directions for use.")

Exporting Devices

- Any medical devices legally in the U.S. may be exported without prior FDA notification or approval
- Devices that have not been approved or cleared in the U.S. must follow the requirements under the FDCA
- Foreign establishments that manufacture medical devices and/or products that emit radiation that are imported into the U.S. must comply with applicable requirements – includes performance standards, labeling, and submission of radiation safety product reports.

Enforcement Activity

- FDA's Import Alert #89-08, "Detention without Physical Examination of Devices without Approved PMA's or IDE's and Other Devices not Equivalent or no 510(k)"
- Warning Letters issued:
  - Lack of premarket approval or clearance
  - Failure to comply with GMPs
  - Misbranding charges
- Medical Device Recalls/CDRH Inspection Database

Compliance Strategies

- Evaluate supply chain parties to ensure all parties are properly registered/devices listed
- Ensure proper tariff classification, device names, and product codes are entered to ease admissibility
- Class I, compliant with general controls
- Class II or III, 510(k) or PMA
- GMP/QSR compliant
- MDR reporting

Questions?
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