FDA Regulation of Medical Devices

FDA Background
The U.S. Food and Drug Administration is one of the most high-profile government agencies. In addition to regulating medical devices, the FDA also regulates food, drugs, dietary supplements, cosmetics, and radiation-emitting products – and as of 2009, tobacco. It also regulates food, drugs, and medical devices for veterinary use.

The genesis of the FDA began in 1867 when the U.S. Department of Agriculture began investigating the adulteration of food products. It has gone through many changes since then, with formal jurisdiction over medical devices given in 1938. Significant changes to the law were made in 1976, which established the basic scheme governing medical devices that we have today.

Risk-Based Regulation of Medical Devices
Medical devices are placed into one of three classes, based on risk. The lowest risk devices are in Class 1, and most can be marketed without prior FDA permission. However, Class 1 devices are still subject to other FDA regulations, such as labeling, listing, and quality control requirements.

Most devices are in Class 2 and may be marketed via the filing of a “510(k)” application demonstrating the device is “substantially equivalent” in terms of safety and effectiveness to a “predicate device” already legally marketed in the U.S. A device is substantially equivalent if it has the same intended use as the predicate device and either (a) the same technological characteristics or (b) different technological characteristics that do not raise new questions of safety and effectiveness and the device is as safe and effective as the predicate device. The mere filing of a 510(k) application claiming substantial equivalence is not an admission of patent infringement, though of course other statements made in a 510(k) application may implicate infringement.

Identifying a suitable predicate device can often be a challenge when preparing a 510(k) application. In addition, as there is no 510(k) “form” to fill out, determining what factors are relevant to establish substantial equivalence for a particular device can be daunting. The FDA does have guidance documents for some devices, and compliance with recognized standards can also help to streamline the process.

Human clinical trial data is usually not required, though if it is information regarding the trial, it must be filed with the National Institutes of Health.

A small percentage of devices are in Class 3, which are high risk or novel devices for which no “predicate device” exists. If a new device is believed to not warrant Class 3 status, it is possible to petition the FDA for reclassification. Class 3 devices require the filing of a “premarket approval application,” which must demonstrate that the device is safe and effective, usually based on human clinical trials. A PMA is a very expensive and rigorous undertaking.

Investigational Device Exemptions
If a human clinical trial is necessary to obtain FDA marketing authorization for a medical device, it must be conducted in compliance with the FDA’s “investigational device exemption” regulations. It is highly recommended to hold a “pre-IDE” meeting with the FDA to come to agreement on the protocol of the trial so that the FDA will accept the results as scientifically sound. Common features of a clinical trial include proper design, informed consent of subjects, monitoring, recordkeeping, and reporting to the FDA of any unanticipated adverse events.
Labeling
The FDA has regulations governing the proper labeling of medical devices, including for OTC and prescription devices. A few devices have specific labeling requirements.

Registration and Listing
All domestic and foreign “establishments” (i.e. physical locations) that are engaged in FDA-regulated activity pertaining to medical devices must “register” with the FDA, including but not limited to manufacturers, contract manufacturers, specification developers, initial importers, and repackers. Once registered, the establishment is subject to FDA inspection, though the FDA prioritizes its resources and manufacturers of low risk Class 1 devices are less likely to be inspected than manufacturers of high risk Class 3 devices.

In addition, most establishments must “list” with the FDA the devices for which they are engaged in regulated activity. Listing is not the same as marketing authorization, and the requirement to list applies to all devices, even if they are exempt from the 510(k) program.

Quality System Regulation
The QSR sets forth general requirements for design controls, production, storage, labeling, distribution, complaints, etc. It does not specify precise actions every manufacturer must take, but rather sets up a general framework of issues for each manufacturer to consider when adopting procedures for its particular circumstances. Some Class 1 devices are exempt from the QSR.

Medical Device Reporting
Each manufacturer must maintain complaint files, and promptly report to the FDA if a medical device might have caused or contributed to death or serious injury, or malfunctioned in a way that could lead to death or serious injury. Corrective actions (refund, repair, replacement, or recall) may be necessary for problem devices.

Export Regulations
In general, devices that have been authorized by the FDA for marketing in the United States (or Class 1 devices that do not require prior FDA authorization) may be freely exported. Export of devices that a manufacturer believes in good faith to be “substantially equivalent” and that could be marketed via a 510(k) application requires only recordkeeping. However, export of devices that could be marketed only under a PMA or other high risk devices that have been approved by a developed “Tier 1” country requires both recordkeeping and notification to the FDA. Finally, devices that could be marketed only under a PMA or other high risk devices that have not been approved by a “Tier 1” country require prior authorization from the FDA before being exported.

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Fish & Richardson’s Regulatory Group specializes in all aspects of medical device regulation. We have helped bring to market innovative and lifesaving technologies including CPR-assist devices, 3D diagnostic x-ray equipment, and cellphone-based software, as well as advised clients on reporting adverse incidents, conducting corrective actions, and preparing for FDA inspections.

For more information about the regulation of medical devices, please visit our website, www.fr.com/Regulatory-Services.