

In the United States, the Food and Drug Administration (FDA) requires manufacturers of clinical devices that may have a negative consequence on the patients' health with improper use to prove both the device is safe and it is effective prior to sale. However, some policymakers and device manufacturers have labeled U.S. device regulation as slow, risk-averse, and expensive. FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repack, relabel, and/or import medical devices sold in the United States.

In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions. Manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA. All 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. In addition to registration, foreign manufacturers must also designate a U.S. Agent.

Most class I devices, such as blood pressure monitors are low level-risk and subject only to "general controls." Class II devices meet general controls as well as "special controls," such as additional labeling requirements. These moderate-risk devices generally pass through the 510(k) review pathway, which refers to the section of the Food, Drug, and Cosmetic Act dealing with premarket notification. In this process, the FDA and the manufacturer rely on similarities between the device at issue and a previously cleared device.

Products requiring PMAs are Class III devices are high risk devices that pose a significant risk of illness or injury, or devices found not substantially equivalent to Class I and II predicate through the 510(k) process. The PMA process is more involved and includes the submission of clinical data to support claims made for the device. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification 510(k) submission to FDA. Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of nonsignificant risk must be approved by the IRB only before the study can begin.

The following table provides information on recent FDA device approvals. Stents, IOLs and molecular testing were among the larger categories of newly approved devices.

# Kalorama Information Report Rfid In Pharmaceutical Manufacturing

**Michael Seilmaier**



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