General Information:
Classification:
Devices are classified according to their perceived risk using a 3-tiered system (class I, II, or III).

Class I devices (lowest risk) are subject to general controls, which are published standards pertaining to labeling, manufacturing, post-market surveillance, and reporting. Devices are placed into class I when there is reasonable assurance that general controls alone are adequate to assure safety and effectiveness. The general controls that typically apply to class I devices include prohibitions against adulteration and misbranding, requirements for establishing registration and device listing, adverse event reporting, and good manufacturing practices. Furthermore, remedies including seizure, injunction, criminal prosecution, civil penalties, and recall authority are provided to FDA. Formal FDA review is not required for most class I devices before their market introduction.

Class II devices are those higher-risk devices for which general controls alone have been found to be insufficient to provide reasonable assurance of safety and effectiveness, but for which there is adequate information available to establish special controls. Special controls may include performance standards, design controls, and post-market surveillance programs. In addition, most class II devices require FDA clearance of a premarket notification application (PMA or 510[k]) before the device may be marketed. In the 510(k) application, the medical device manufacturer must provide data to demonstrate that the new device is “substantially equivalent” to a legally marketed device. Although substantial equivalence can usually be demonstrated on the basis of bench and animal testing alone, approximately 10% of 510(k) applications include clinical data.

Class III devices, such as heart valves, pacemakers/implantable cardioverter-defibrillators, and coronary stents, are judged to pose the highest potential risk. These devices are either life-sustaining/supporting, of substantial importance in preventing impairment of human health, or present a high risk of illness or injury. Consequently, general and special controls alone are inadequate to provide reasonable assurance of safety and effectiveness. Most class III devices require FDA approval of a PMA before they can be legally marketed. Approval of the PMA generally requires clinical data demonstrating reasonable assurance that the device is safe and effective in the target population.

The Human Device Exemption (HDE) is a new pathway to allow for commercialization of class III devices designed to address small markets, ie, diseases or conditions that affect fewer than 4000 patients in the United States each year. Approval of an HDE requires demonstration that the device is safe and the probable benefits outweigh the probable risks. Although the process may require smaller clinical trials, an HDE device must continue to operate under local IRB approval at each participating institution and must continue to collect case report forms akin to an ongoing clinical trial. The PMA process typically involves a series of studies starting with first clinical use and culminating in a multicenter, prospective randomized control trial (pivotal trial). The complexity and extent of the clinical testing program is dictated by the nature of the device and its proposed use. The clinical study program is developed by the company in conjunction with clinician investigators, all in close collaboration with FDA/CDRH.

The European Union system relies on notified bodies (NBs), which are independent commercial organizations to implement regulatory control over medical devices. NBs have the ability to issue the CE mark, the official marking required for certain medical devices. NBs are designated, monitored, and audited by the relevant member states via the national competent authorities. Many functions performed by the FDA/CDRH within the United States are performed by NBs, including medical device certification, device type designation, assessment and verification of quality systems, and review of design dossiers for high-risk devices. Currently, there are more than 50 active NBs within Europe. A company is free to choose any notified body designated to cover the particular class of device under review. After approval, post-market surveillance functions are the responsibility of the member state via the competent authority.