FDA Fact Sheets:
Classification

FDA is responsible for assuring the safety and effectiveness of medical devices in the United States and regulates these products using a three-tiered, risk-based classification system:

- Class I: General Controls;
- Class II: General and Special Controls; and
- Class III: General Controls, Special Controls and Premarket Approval.

Each classification level is associated with distinct regulatory requirements, including General Controls and/or Special Controls. Class designation is determined by the product's intended use, indications for use, and technological characteristics, as well as the risk posed to the patient and/or the user of the device in relation to the knowledge that exists to mitigate risks. In general, Class I devices are those with the lowest risk while Class III are the higher risk. Over 1,700 generic device types are classified by regulation (21 CFR 862-892), which also specify controls and exemptions applicable to these generic device types.

All devices are subject to General Controls, which include establishment registration under 21 CFR 807.20; medical device listing; compliance with Quality Systems requirements (QS) (21 CFR 820); labeling requirements (21 CFR 801 and 809); and submission of a premarket notification (510(k)) prior to marketing the device, unless it is a 510(k)-exempt device. Most Class I devices are exempt from 510(k) requirements and a few are exempt from QS requirements.

Class II devices may be subject to Special Controls in addition to General Controls. Special labeling requirements, mandatory performance standards and postmarket surveillance are some examples of the types of Special Controls that may be required of Class II medical devices. Some Class II devices are 510(k) exempt as well.

Premarket Approval is required for Class III devices, because FDA has determined General or Special Controls are insufficient to assure safety and effectiveness of these devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury