

DEVICE CLASSES

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Class I devices are subject to the least regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. *Class I devices are subject to "General Controls" as are Class II and Class III devices.*

General controls include:

Establishment Registration of companies which are required to register under 21 CFR Part 807.20, such as manufacturers, distributors, repackages and relabelers. Medical Device Listing with FDA of devices to be marketed.

Manufacturing devices in accordance with Good Manufacturing Practices (GMP) in 21 CFR Part 820. Labeling devices in accordance with labeling regulations in 21 CFR Part 801 or 809.

Submission of a premarket notification [510(k)] before marketing a device.

Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

Most Class I devices are exempt from the premarket notification and/or good manufacturing practices regulation. Information on Class I exempt devices is available from the FDA web site located under the heading, "What are Class I/II Exemptions?".

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. A few Class II devices are exempt from the premarket notification. Information on Class II exempt devices is located on the FDA's web site under the heading, "What are Class I/II Exemptions?".

Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance.

Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.

Class III - Premarket Approval

Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls.

Class III devices are usually 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.

Premarket approval is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Not all Class III devices require an approved premarket approval application to be marketed. Class III devices which are equivalent to devices legally marketed before May 28, 1976 may be marketed through the premarket notification [510(k)] process until FDA has published a requirement for manufacturers of that generic type of device to submit premarket approval data.

Class III devices which require an approved premarket approval application to be marketed are those:

1. Regulated as new drugs prior to May 28, 1976, also called transitional devices.
2. Devices found not substantially equivalent to devices marketed prior to May 28, 1976.
3. Class III preamendment devices which, by regulation in 21 CFR, require a premarket approval application.

Examples of Class III devices which require a premarket approval include replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.

Class III devices which can be marketed with a premarket notification 510(k) are those:

1. Postamendment (i.e., introduced to the U.S. market after May 28, 1976) Class III devices which are substantially equivalent to preamendment (i.e., introduced to the U.S. market before May 28, 1976) Class III devices and for which the regulation calling for the premarket approval application has not been published in 21 CFR.

Examples of Class III devices which currently require a premarket notification include implantable pacemaker pulse generators and endosseous implants.