**U.S. Food and Drug Administration**
Protecting and Promoting *Your* Health

# Regulatory Controls



## Introduction

Federal law (Federal Food, Drug, and Cosmetic Act, section 513), established the risk-based device classification system for medical devices. Each device is assigned to one of three regulatory classes: Class I, Class II or Class III, based on the level of control necessary to provide reasonable assurance of its safety and effectiveness. For information related to device classification, please refer to "**Classify Your Medical Device (/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm2005371.htm)**."

As device class increases from Class I, to Class II to Class III, the regulatory controls also increase, with Class I devices subject to the least regulatory control, and Class III devices subject to the most stringent regulatory control.
The regulatory controls for each device class include:

- Class I (low to moderate risk): general controls
- Class II (moderate to high risk): general controls and Special Controls
- Class III (high risk): general controls and Premarket Approval (PMA)

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## General Controls

General controls are regulatory requirements authorized by the FD&C Act, under sections 501, 502, 510, 516, 518, 519, and 520. General controls apply to all medical devices, unless exempted by regulations. If a device is exempted from one of the general controls, such exemption is stated in the classification regulation for that device.

For example, the classification regulation for manual tooth brush, 21 CFR 872.6855, states the general controls from which tooth brushes are exempted and certain limitations on the exemptions.

General controls are described in the following sections of the FD&C Act:

- 501: Adulterated devices
- 502: Misbranded devices
- 510: Registration of producers of devices
  - Establishment registration and device listing
  - Premarket Notification (510k)
  - Reprocessed single-use devices
- 516: Banned devices
- 518: Notifications and other remedies
  - Notification
  - Repair
  - Replacement
  - Refund
  - Reimbursement
  - Mandatory recall
- 519: Records and reports on devices
  - Adverse event report
  - Device tracking
  - Unique device identification system
  - Reports of removals and corrections
- 520: General provisions respecting control of devices intended for human use
  - Custom device
  - Restricted device

- Good manufacturing practice requirements
- Exemptions for devices for investigational use
- Transitional provisions for devices considered as new drugs
- Humanitarian device exemption

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## Special Controls

Special controls are regulatory requirements for class II devices. FDA classifies into class II devices for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.
Special controls are usually device-specific and include:

- Performance standards
- Postmarket surveillance
- Patient registries
- Special labeling requirements
- Premarket data requirements
- Guidelines

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## Premarket Approval (PMA)

Under federal law, class III devices are subject to approval of a **Premarket Approval Application (PMA). (/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm2000000.htm)**

Devices that are not within a type marketed before the date of the Medical Device Amendments of 1976 – referred to preamendments devices – are classified into class III automatically under federal law.. In addition, the FDA classifies into class III devices intended to be used in supporting or sustaining human life or preventing impairment of human health, or that may present a potential

unreasonable risk of illness or injury for which general controls and special controls are insufficient to provide reasonable assurance of the safety and effectiveness of a device, or for which there is insufficient information to make such a determination.

For more information on PMA, please read the following sections:

- **FD&C Act section 513 and section 515 (/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/ucm2005640.htm)**
- **21CFR Part 814 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=814)**
- **Device Advice on PMA (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm2007514.htm)**

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More in Regulatory Controls (Medical Devices) (/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm)

General Controls for Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm)