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Medical Devices

Device Approvals and Clearances

Welcome to FDA's information about medical device approvals. The following information is available:

- [New Device Approvals](#)¹ that include some of the newest medical technology available.
- Monthly listings of [Premarket Notification \[510\(k\)\]](#)² and [Premarket Approval \(PMA\) decisions](#)³
- Information on [Humanitarian Device Exemption \(HDE\)](#)⁴ approvals
- [Searchable databases](#) of devices previously approved for marketing or declared substantially equivalent to a legally marketed device.

Databases

CDRH maintains searchable databases on its website containing 510(k) and PMA information

A 510(k) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE) to a legally marketed device that is not subject to premarket approval (PMA). 510(k) (premarket notification) to FDA is required at least 90 days before marketing unless the device is exempt from 510(k) requirements.

- [Search the 510\(k\) Database](#)⁵
- [Monthly listing of 510\(k\)s](#)⁶

Premarket Approval (PMA) is the most stringent type of device marketing application required by FDA. A PMA is an application submitted to FDA to request approval to market. Unlike premarket notification, PMA approval is to be based on a determination by FDA that the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective for its intended use or uses.

- [Search the PMA Database](#)⁷
- [Monthly listing of PMAs](#)⁸

Regulation also provides for the submission of a humanitarian device exemption (HDE) application. A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. The (HDE) application is similar in both form and content to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of a PMA.

CDRH also [has available a number of other databases](#)⁹ relating to medical devices and radiation-emitting products. Information not contained in the CDRH databases must be requested via a [Freedom of Information request](#)¹⁰.

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