Introduction

Although most medical devices enter the United States market by obtaining either 510(k) clearance or Premarket Approval (PMA), there are other paths available, which are less frequently invoked. Below are high-level descriptions of pathways available to device companies.

Credit: http://www.medicaldesignandoutsourcing.com/needed-break-u-s-market/

1. 510(k) Notification

Devices that present relatively low risk (i.e., such as class I or class II) require the manufacturer to seek 510(k) clearance from the FDA, unless exempted from this requirement by regulation. Such clearance is generally granted when a new device is “substantially equivalent” in intended use and technological characteristics to a “predicate device,” which is generally a legally marketed class I or class II device. Products that are exempt from 510(k) clearance may enter the market so long as they are within the parameters defined by its predicate devices within the classification..

2. Premarket approval (PMA)

A medical device that does not qualify for 510(k) clearance is placed, by default, in class III, which is reserved for devices classified by the FDA as posing the greatest risk (e.g., life-sustaining or implantable devices, or devices that are not substantially equivalent to a predicate device). For these devices, the product must be approved via the premarket application (“PMA”), which requires that the safety and effectiveness of the device be established with valid scientific evidence, normally high-quality clinical data..

3. De Novo review

FDA will consider the de novo pathway for novel devices when the de novo requester either determines that there is no predicate device (“direct de novo”) or has its device found not substantially equivalent. To be eligible, the device must be low to moderate risk, such that general or special controls would provide reasonable assurance of the safety and effectiveness of the device.

4. Humanitarian device exemption (HDE)

The HDE program encourages device companies to bring treatments onto the market for conditions that affect small populations. Humanitarian use devices (HUDs) are limited to treating or diagnosing conditions that affect fewer than 4,000 people in the U.S. per year. The approval process is similar to a PMA except that the application is only required to demonstrate safety and probable benefit of the therapy.

5. Investigational device exemption

An Investigational Device Exemption (IDE) allows a manufacturer to provide an investigational device to be used in a clinical study in order to collect safety and effectiveness data. All investigational clinical studies, unless exempt, must have an approved IDE. An IDE can be obtained through submission of an IDE application, which includes, for example, a clinical protocol and informed consent documents. Some studies that present nonsignificant risk may proceed without an IDE if approved by the Institutional Review Board (IRB)..

6. Expanded access; Compassionate use & emergency

The expanded-access option allows an investigational device to be used, outside of a clinical trial, where a physician determines that a seriously ill patient requires use of the device and there are no generally accepted alternatives. Under the Emergency Use provision, a device that is needed immediately is exempted from FDA approval. Under the Compassionate Use provision, FDA approval is still required.

7. Custom device exemption (CDE)

The custom device exemption allows manufactures to provide a device(s) to meet a particular patient or surgeon need in treating a unique condition in the absence of a commercially available medical device. No more than five custom devices within a device type may be manufactured per year.