What Is a 510(k) and a PMA?

Lillian L. Yin

Prior to marketing a device in the United States, manufacturers or initial distributors of imported devices must obtain Food and Drug Administration (FDA) marketing clearance. There are two routes to the market: premarket notification [510(k)] and premarket approval (PMA).

The premarket notification program is meant to:

- identify new devices that must be placed automatically into class III and undergo premarket approval or reclassification before they are marketed;
- classify new devices; a not substantially equivalent (NSE) new device is in class III, and a substantially equivalent (SE) new device is in the same regulatory class as the device to which it is found equivalent; and
- achieve marketing equity by allowing manufacturers of new devices that are SE to pre-amendments devices to market their devices without facing any greater regulatory burdens than faced by manufacturers of the pre-amendments devices.

The Medical Device Amendments (the act) were enacted on May 28, 1976. They direct the FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories, class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that must be met before a manufacturer may distribute the device in interstate commerce.

Class I devices are subject to a comprehensive set of regulatory authorities applicable to all classes of devices, e.g., premarket notification, registration and listing, prohibitions against adulteration and misbranding, and rules for good manufacturing practices. Class II devices also need performance standards, and class III devices need premarket approval.

The act also specifies how a new device, i.e., a post-amendments device, is to be classified. A post-amendments device is automatically in class III and must undergo premarket approval or reclassification before it can be
Section 510(k) of the act requires a person who wishes to introduce a device into commerce to notify the Center for Device and Radiological Health (CDRH) at least 90 days in advance. This premarket notification is referred to as a “510(k).” The agency uses 510(k)s to determine if new devices are, or are not, SE to either a pre-amendments device or a reclassified post-amendments device.

The 510(k) rules were incorporated into the registration and listing regulation because the 510(k) requirements apply only to those persons required to register for establishment registration and device listing for manufacturers of devices.

A person required to register must submit a 510(k) at least 90 days before marketing a device that (1) is being introduced into distribution for the first time by that person, or (2) is in distribution but is being significantly modified in design, material, chemical composition, energy source, manufacturing process, or intended use.

A 510(k) must contain:

- proposed labeling sufficient to describe the device’s intended use;
- a description of how the device is similar to or different from other devices of comparable type, or information about what consequences a proposed device modification may have on the device’s safety and effectiveness; and
- any other information the CDRH needs to determine whether the device is SE.

A new device can be SE to one of two type of devices (from hereon referred to as a “predicate device”). A predicate device is one that was in distribution prior to enactment of the amendments, or it is a post-amendments device that was subject to reclassification from class III to class I or II. The CDRH requires submitters to provide information that compares the new device to a legally marketed device of a similar type.

The CDRH normally approaches the review of 510(k)s by considering the following points:

- Does the new device have the same intended use as a predicate device? Does the new device have the same technological characteristics, i.e., same materials, design, energy source, etc.? If it has new technological characteristics, could they affect safety or effectiveness?
- If the new device has a new intended use (what constitutes a new intended use is discussed below), it is considered NSE. If the new device...