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What's a 510(K)?

Editorial

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Stewart Michael Sharp
Editor-In-Chief, Regulatory Consulting, Inc, USA

Correspondence: S Michael Sharp, FRAPS, Regulatory Consulting, Inc, USA, Email drsnsharp@aol.com

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More than four decades since the implementation of the Medical Device Amendment (MDA) to the Food, Drug and Cosmetic Act (FDCA)I still get asked that question. The answer is important to understanding the regulatory status of many medical devices. As legislators and congressional staff worked to develop the text of the MDA there was recognition that the regulation of medical devices (powerfully articulated by a legion of special interests and lobbyists) would need to differ in many ways from the approach utilized for pharmaceuticals.

The diversity of medical devices, ranging from urine specimen collection bottles to intraocular lenses, lasers, MRI Imaging and other high-tech modalities, was a starting place to think about the overall approach. The outcome was based on a risk management approach, establishing three risk categories. Class I devices are low-risk devices requiring general controls, such as Good Manufacturing Practice, to ensure safety. Class I devices do not require FDA Clearance or Approval prior to marketing. Class II devices may have a higher risk profile and be more complex, require general and special controls to ensure safety and effectiveness. Special controls may include, for example, mandatory performance standards, patient registries for implantable devices, and post-market surveillance. In addition Class II devices must be cleared by FDA prior to marketing unless specifically exempted. Clearance is obtained by demonstrating substantial Equivalence to a predicate device which has been cleared under the 510(k) process. Finally, Class III devices are defined as those that are life-sustaining, life supporting or pose significant potential for risks to patients. These devices require general controls, special controls and Pre-market approval is specifically required. In the majority of cases a clinical trial is required. Having established the paradigm for risk based regulation, FDA created classification panels with expertise in a wide variety of devices, therapeutic area, etc. to evaluate devices for risk assignment. The outcome of this process was the establishment of product categories which describe the devices included in that category.

So now we have some idea of how the FDA's process for bringing new devices to market works. But what is that pesky thing the 510(K) remains an open question. But the fact is that there is no such "thing" as a 510(k). Section *510(k)* of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify *FDA* of their intent to market a medical device at least 90days in advance. This is known as Premarket Notification.

Technically the term 510(k) describes the section of the FDCA that includes the requirements for Premarket Notification, over time the regulatory community has adopted "510(k)" as shorthand for the actual citation. Over time the use of the term "510(k) as a noun has expanded, being used by both regulators and sponsors. But wait, the regulations have evolved since the promulgation of the device regulations. Not only do we have the "Traditional 510(k)" (which is the fallback approach for most devices), but also Abbreviated 510(K)s which are used when there are is an FDA guidance for the product type, a special control already has been established and FDA has recognized a relevant consensus standard.Finally, there is the Special 510(k) which may be used if a new 510(K) is required for device modification and the modification does not affect the device's intended use or alter its fundamental scientific technology.

Given all that it's no wonder that confusion about 510(k). For example: when to use which format, is there an available predicate device and can the predicate be convincingly shown to be substantially equivalent to the new device.

Yes, when we follow the 510(k) crumbs into the regulatory forest it turns out to be just as dark and confusing we fear. But wait there is a light in the forest but it isn't the gingerbread house. It is really the library of guidance documents created by the FDA. There is a guidance for the contents, format etc. for all four types of 510(k) submission. Then there is a document helping us to determine when a new submission is required and one to assist with questions regarding substantial equivalence. You can also get copies of the 510(K) summary for already cleared 510(k), not the full submission of course, but often a very helpful source of information. Even more helpful is the "ACCEPTANCE CHECK LIST FOR TRADITIONAL 510(k) S. Yes, the FDA will provide the actual criteria that reviewers use to determine whether or not your device will be accepted for filing. All of the guidance documents mentioned here are readily available on-line.

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Conflicts of interest

The author declares that they have no conflicts of interests.