

The 510(k) Process: Myth vs. Fact

FDA's premarket notification, or 510(k), process has been both misunderstood and mischaracterized by critics almost since its inception. Most criticisms, however, are attributable to misinformation disseminated by a relative few who do not understand or appreciate the flexibilities of the program and its strengths. Over the years, several myths have been spread about the 510(k) process which have no basis in reality.

Myth: The 510(k) program is a “loophole” or “rubber stamp” that provides companies a quick and easy way to get their products onto the market without adequate FDA review.

Fact: As evidenced by the extensive amount of supporting documentation companies must submit to FDA, the 510(k) program is anything but a quick and easy path to market.

Rather, it is vital component of the robust, risk-based regulatory framework FDA has developed for ensuring the safety and effectiveness of a vast range of medical devices, calibrating regulatory requirements to the risk of the device.

The 510(k) review process is well designed to assess the safety and effectiveness of low- and moderate-risk medical devices whose risks are well understood from years, or even decades, of experience with similar devices and to foster rapid innovation with corresponding improvements in patient care.

It is common for 510(k) submissions to include hundreds or thousands of pages of documentation, based on: bench testing (batteries of non-clinical tests – durability; shelf-life, shock and vibration, temperature cycling, etc.); biocompatibility; animal studies; usability; and data demonstrating conformance with national and international standards.

FDA alone has total authority to require whatever evidence is necessary to assure a product's safety and effectiveness, including clinical studies when it deems this data to be necessary to assess the risks and benefits of the product, i.e., to determine whether it raises “new questions of safety and effectiveness.”

In addition, the 510(k) process has evolved over three decades through continual process improvement – resulting from legislation and from internal FDA evaluations – to meet the needs of patients and the diversity of medical technology.

Myth: Substantial equivalence involves showing that a new device is similar to an old and outdated product on the market before enactment of FDA device law (May 28, 1976).

Fact: In reality, it is extremely unusual for a new device to go to market with a comparison to anything but today's state-of-the-art technology.

Since the Safe Medical Devices Act of 1990 (SMDA), companies have been free to choose any "legally marketed device" as a 510(k) predicate. Additionally, the FDA Modernization Act of 1990 (FDAMA) authorized FDA reliance on national and international consensus standards which usually reflect the latest test methods developed to assess the most recent advances in device technology.

This evolution in the 510(k) program, coupled with FDA's authority to require virtually any data necessary for decision-making, has made the 510(k) process one of the agency's most progressive premarket review methods.

A company seeking a substantial equivalence determination for a new device based on an older or outdated predicate would naturally cause questions to be raised by FDA reviewers. Additionally, good business sense motivates companies to market a device that meets patient and user requirements and expectations and that provides the latest technological innovation.

Myth: The 510(k) process allows unsafe products to market based on comparisons to defective or recalled predicate devices.

Fact: First of all, the 510(k) process has an extraordinary record of safety. Multiple studies have shown that less than 0.5 percent of 510(k)-cleared devices are subject to a serious recall.

Since SMDA, as a matter of law a new device cannot be found substantially equivalent to a device that has been deemed misbranded or adulterated and removed from the market. Furthermore, it is highly unlikely a recalled device would be used as a predicate as FDA's database flags any 510(k) under recall so that a submitter knows that predicate should not be used.

Myth: Adverse patient impacts that result from devices undergoing 510(k) review prove that all devices should undergo PMA approval to ensure their safety and effectiveness.

Fact: Again, the 510(k) process has an extraordinary record of safety. This is due to the care and rigor of the medical technology development process companies undertake, and to the regulations and FDA scrutiny that apply to devices during the review process and after they are marketed.

Although devices that go to market via 510(k) undergo significant testing, it is extremely difficult, if not impossible, to identify or predict all problems that may occur when a device is made commercially available, placed in widespread distribution and used by large numbers of health care providers and patients. Requiring excessive information on low-to moderate-risk devices with which FDA has extensive experience does not benefit the public health, delays patient access to new treatment options, and consumes valuable resources that could be focused on higher-risk public health activities.

Most importantly, the 510(k) program is only part of a complex regulatory framework FDA has in place to ensure the safety and effectiveness of medical devices. In addition to premarket review, manufacturers must comply with quality system regulations to ensure consistent manufacturing, complaint investigation and reporting, as well as any special controls imposed on the device type. Special controls may include performance standards, guidance documents, post-market surveillance, device tracking, and other activities as determined by FDA to provide a reasonable assurance of safety and effectiveness.

Medical device companies also must follow additional post-market requirements including mandatory adverse event reporting to detect issues in a timely manner and report them to FDA, and recall procedures so that if a device experiences a serious problem on the market, it can be addressed quickly and effectively.