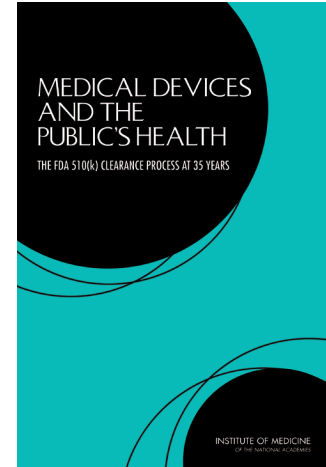


Medical Devices and the Public's Health

The FDA 510(k) Clearance Process at 35 Years



Medical devices play a critical role in the health care of Americans. They can range from simple tools, such as tongue depressors and bandages, to complex or life-saving equipment, such as pacemakers, magnetic resonance imaging machines, and heart–lung machines. Devices are used in healthcare facilities—such as hospitals, physicians’ offices, and nursing homes—and at home.

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires a “reasonable assurance of safety and effectiveness” before a device can be marketed. The U.S. Food and Drug Administration (FDA) is responsible for enforcing this requirement. Devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the 510(k) process, named for Section 510(k) of the FFDCA. Devices that are subject to the 510(k) process include such devices as blood pressure cuffs as well as some types of contact lenses and pacemakers. The FDA received about 4,000 510(k) submissions in 2009.

Some policymakers and patients have expressed concern about the ability of the 510(k) process to ensure that medical devices on the market are safe and effective. Other policymakers and patients, as well as the medical-device industry, have asserted that the process has become too burdensome and time-consuming and that it is delaying important new medical devices from entering the market.

The FDA turned to the Institute of Medicine (IOM), which appointed a committee to review the 510(k) process and answer two questions:

- Does the current 510(k) process protect patients optimally and promote innovation in support of public health?

Devices that are deemed to have a moderate risk to patients generally cannot go on the market until they are cleared through the 510(k) process, named for Section 510(k) of the FFDCA.

- If not, what legislative, regulatory, or administrative changes are recommended to achieve the goals of the 510(k) process optimally?

The Legislative Framework of the 510(k) Process

Regulation of medical devices began in 1938 and reflected the relatively simple devices on the market at that time. By the 1970s, the original regulatory system no longer was adequate or flexible enough to deal with the growing array of device types and increasing sophistication of new devices. Sporadic public-health disasters associated with a few devices generated substantial public concern. Consequently, Congress passed the *Medical Device Amendments of 1976*, which established the framework for the current regulatory system, including the 510(k) process. Then, in 1990 and 1997, Congress passed sets of substantial changes to the 1976 statute. These three enactments serve as the basis of the legislative framework for the 510(k) process.

The law states that a moderate-risk device that is *substantially equivalent*, or similar, to any previously 510(k)-cleared device or any device that was on the market when the Medical Device Amendments were enacted—referred to as a *predicate device*—can be cleared for marketing with some exceptions. When the FDA assesses the substantial equivalence of a device, it generally does not require evidence of safety or effectiveness; and when a device is found to be substantially equivalent to a predicate device, the new device is assumed to be as safe and effective as the predicate because of its similarity. Devices that were on the market before the Medical Device Amendments were never systematically assessed for safety and effectiveness—but they are being used as predicate devices. This leads the committee to find that 510(k) clearance is not a determination that the cleared device is safe or effective. The committee concludes that the 510(k) process lacks the

legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices and, furthermore, that it cannot be transformed into one.

The committee is not suggesting that all, many, or even any medical devices cleared through the 510(k) process and currently on the market are unsafe or ineffective. The continual use of many of these devices in clinical practice provides reason for a level of confidence in their safety and effectiveness.

Innovation and the 510(k) Process

The committee defines innovation as something that improves the quality of, efficiency of, or access to health care. The 510(k) process does not require a moderate-risk device to be innovative, nor does it reward innovation. However, the 510(k) process can facilitate innovation by making new devices available to consumers in a timely manner.

It is unclear—and the committee concludes that it is indeterminable, given current information—whether the 510(k) process over the last 35 years has had a positive or negative effect on innovation. To answer this question, the FDA should commission an assessment to determine this effect.

The Medical Device Regulatory System

The 510(k) process does not operate in isolation. Premarket review, including the 510(k) process, and postmarket oversight—from product labeling regulations to the reporting of adverse events associated with use of a device—make up a comprehensive medical device regulatory system. All the components of the system need to be functioning well in order to provide a reasonable assurance of the safety and effectiveness of medical devices.

The committee concludes that the 510(k) process lacks the legal basis to be a reliable premarket screen of the safety and effectiveness of moderate-risk devices and, furthermore, that it cannot be transformed into one.

No premarket regulatory system for medical devices can guarantee that all new medical devices will be completely safe and effective when they reach the market. Robust postmarketing surveillance is essential. The committee identified substantial problems in the current postmarketing surveillance of devices. The FDA should develop and implement a comprehensive strategy to collect, analyze, and act on medical device aftermarket performance information.

It is important for the FDA to use postmarket enforcement tools, such as seizing or banning a device, when necessary. The FDA has stated that there are limitations to the use of these tools but has not identified the limitations. The agency should review its postmarket regulatory powers to identify these limitations and address them.


The committee recommends that the FDA develop and implement a program of continuous quality improvement to increase predictability, transparency, and consistency in all regulatory decisions for devices and to address emerging issues that affect decision making.

Moving Forward

The committee finds that the current 510(k) process is flawed based on its legislative foundation. Rather than continuing to modify the 35-year-old 510(k) process, the committee concludes that the FDA's finite resources would be better invested in developing an integrated premarket and postmarket regulatory framework that provides a

reasonable assurance of safety and effectiveness throughout the device life cycle. This new framework should:

- be based on sound science;
- be clear, predictable, straightforward, and fair;
- be self-sustaining and self-improving;
- facilitate innovation that improves public health by making medical devices available in a timely manner and ensuring their safety and effectiveness throughout their lifecycle;
- use relevant and appropriate regulatory authorities and standards throughout the life cycle of devices to ensure safety and effectiveness; and
- be risk-based.

Current information is not adequate to design a new framework, and the FDA should begin to obtain the needed information. Once adequate information is available to design an appropriate medical-device regulatory framework, Congress should enact legislation to do so. A new regulatory framework will benefit everyone—patients, healthcare providers, the medical device industry, payers, and the FDA. 



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510(k) Clearance Process**

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