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The evolution of the medical device 510 (k) process and impending changes

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Medical devices play a critical role in the health care of Americans. They span a range from simple tools, such as dental floss and bandages, to complex or life-saving equipment, such as pacemakers, magnetic resonance imaging machines, and heart-lung machines. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires a "reasonable assurance of safety and effectiveness" before a device can be marketed, and 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.

This is the process by which most medical devices reach the market. Also known as “premarket notification,” the 510(k) process has been subject to a considerable amount of criticism in the last several years. Claims that it is both too rigorous and not rigorous enough have been made, and legislators are ordering the US Food and Drug Administration (FDA) to scrap planned changes to the 510(k) process in favor of one yet to be built. This session discusses the legislative evolution of the 510(k) process, the perceived need for major change to the process and the controversy resulting from the impending change.

Biography

Jacqueline McCulloch, RAC, is a senior consultant with Clarkston Consulting and has over 25 years of experience working in quality systems compliance, regulatory submissions & strategy. She has experience leading projects for regulatory submissions and quality systems. She is experienced in working under remediation and consent decree.

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