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Medical Device News and Insights

[FDA Announces Changes To Medical Device 510\(k\) Approval Process](#)

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The heat was on this past Tuesday when [President Barack Obama made it clear in a piece published by The Wall Street Journal](#) that the Food and Drug Administration would be making changes to the current [medical device approval process](#) in order to streamline the pathway between innovation and market availability. After calling an all-hands meeting this morning, the FDA has made public several of the new policies that will affect the [510\(k\) clearance programs](#) and stated that by the end of 2011 [as many as 25 changes in total will be made to the medical device approval process](#). retweet

Some of the most important changes involve the FDA backtracking on policies that had been proposed in 2010. In August of last year the Centers for Devices and Radiological Health (CDRH) [released a report from its 510\(k\) working group](#) that contained 55 recommended changes to the medical device premarket notification program. As of today, a substantial portion of these recommendations have been put on hold, including the proposed 510(k) clearance revocation process that sent waves of discontent rippling through the industry. [The CDRH has also decided to freeze plans to require increased clinical evidence for certain classes of medical devices](#) as well as bump up post-market surveillance efforts. One of the key factors behind the FDA and the CDRH backing away from these particular proposed changes was the number of negative public comments concerning their impact on the future of the medical device industry in terms of being able to adequately serve American health interests.

There is no doubt that increased industry regulation in some ways impedes the desire of the Obama administration to knock down barriers in terms of cost and time between new technologies which can provide a boost to healthcare in the United States and the medical device companies which are poised to offer them. At [MDCI](#), we feel that a balance between regulatory safeguards and creating an environment in which medical devices can be developed and marketed rapidly enough to play an important role in national health policy is the most prudent path to follow.

News that the FDA will not be dramatically altering the 510(k) premarket approval process is particularly important, [as 90 percent of medical devices approved between 2003 and 2007 used this regulatory path](#). Several of the most restrictive previously proposed policies will be re-examined in the coming months, and the FDA will seek out additional comment from medical device industry participants as part of that process.

The FDA has put a positive spin on its revised 510(k) changes, stating that by slowly rolling out a series of less drastic medical device approval changes it will be able to manage both innovation and safety in an appropriate fashion. The Administration plans to create a Center Science Council that will be composed of FDA-appointed experts who will contribute to accelerating and normalizing the decisions made in the approval process. The new Council will also audit the [existing 510\(k\) regulations](#) and present a fresh report June 15, 2011.

Other changes that the FDA discussed this morning included streamlining the review process for lower risk medical devices [by making reforms to the current "de novo" process](#) by the third quarter of 2011, a plan to increase transparency through the additional publication of guidance regarding clinical data submissions and the creation of a database encompassing as much information as possible surrounding the clearance decisions of devices approved for the market. The FDA will also now ask higher risk devices to be accompanied by an explanation of the scientific evidence concerning their safety and efficacy.

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