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# Medical Device News and Insights

## [Congress Questions 510\(k\) Regulatory Changes](#)

Written by: MDCI Blogging Team

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Regulatory transparency is a hot topic in Washington, and the [proposed changes to the 510\(k\) medical device approval process](#) by the FDA have been subject to scrutiny from federal lawmakers intent on addressing what are considered to be “controversial” aspects of the Administration’s initiative. retweet

Although the updates to the [510\(k\) premarket notification](#) and clearance regulations for [medical devices](#) have been public since August 3, [12 members of Congress](#) have now stepped forward to specifically question the implementation of certain components of the overhaul. The bi-partisan group, which is composed of 50 percent Republicans and 50 percent Democrats, made their concerns public to the [Food & Drug Administration](#) in the form of a letter earlier this October.

In their missive, the Congress members outlined several ways that they felt the 510(k) process changes could negatively impact the American medical device industry if they were implemented according to what the FDA has proposed. The concerns voiced by the group were organized into several key categories. First, the group of Congress members took issue with the FDA’s desire to tighten its predicate device requirements for [medical devices](#) and the decision to broaden its authority to revoke 510(k) clearance for medical devices already on the market.

The letter also adopted a negative viewpoint regarding the potential creation of a new ‘IIb’ medical device class which would require clinical evidence for effectiveness outside the framework of a [pre-market approval](#) submission. Other issues broached by the group included worries that proprietary information held by medical device manufacturers could be made public knowledge as the result of the proposed FDA changes.

From MDCI’s perspective, it can only help medical device companies to have members of government openly questioning the recommendations and proposals made by the FDA regarding the 510(k) process. According to the group which penned the letter in question, there is a contingent of both industry members and government lawmakers who feel that without careful attention, the implementation of the 510(k) changes runs the risk of derailing the current medical device pipeline, incurring additional costs in financial investment as well as in the time it takes for new treatments to make it to market.

The 12 Congress members are arguing for two concessions from the FDA: a detailed economic analysis of how the proposed regulatory changes could affect the medical device industry, and an in-depth look at the most effective ways to implement and administrate these new policies so as to minimize any damages to the integrity of the current approval system. It is difficult to see how either of these requests represent anything but a positive for medical device companies faced with the changes proposed by the most recent FDA plans.

Benjamin Hunting  
MDCI Blogging Team



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