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# Medical Device News and Insights

## [Pre-Market Clearance Changes – 510\(k\) Update](#)

Written by: MDCI Blogging Team

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At MDCI we have been keeping a close eye on the upcoming changes that could be made to the current 510(k) clearance process for licensing medical devices through the FDA. As we have stated in the past, although these types of changes may at first seem daunting to companies which have an established licensing process in place, brand new medical device manufacturers can take heart that at least some of the new practices and requirements being introduced by the FDA should make certain aspects of 510(k) clearance less of a headache. retweet

Obviously the full details of the 510(k) changes won't be revealed until much closer to the actual implementation date – a date which has also yet to be formally announced, despite a report on the issue which is slated to be released in June of 2011 from the Institute of Medicine. However, there are some indications that highlights from the revised process will include an increased focus on the level of evidence required to substantiate device claims, as well as new definitions for predicate devices and the concept of substantial equivalence. Change reporting over a device's lifecycle might also be required to adopt a much more formal protocol.

There is no question that increasing the evidence demands for 510(k) clearance will add an extra burden to medical device companies attempting to bring a product to market. However, the formalization of processes, which until now have been sometimes confusing and arcane, will go a long way towards making the outcome of a device's approval application more predictable. The introduction of clear standards will help medical device organizations better prepare for the 510(k) process, and also streamline what has been an intimidating, complex, and confusing regulatory aspect of the health industry.

If, in the final analysis, the trade-off of increased evidence burden for a more clearly-delineated process does come to pass, then the outcome of the FDA's pre-market approval revision might be more positive than has initially been perceived by the industry at large.

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