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Medical Device News and Insights

[Smaller Medical Device Companies Facing Extended 510\(k\) Review Periods](#)

Written by: MDCI Blogging Team

Monday, October 3rd, 2011 | [FDA Medical Device Regulations](#), [International Medical Device Requirements](#)

Smaller [medical device companies](#) aren't imagining things – it really does take longer to receive 510(k) approval for medical device developers with fewer than 100 employees than it does for larger industry players. This startling information comes from a study published this summer by researchers at Northwestern University, which took a hard look at how much time companies of various sizes spent in the pre-IDE process. 3 retweet

[According to an article published by MDDI Online](#), on average small medical device companies found themselves in the pre-IDE stage 3.4 months longer than their larger counterparts. Even more startling is the fact that larger companies faced close to 50 percent less 510(k) review time (330 days for organizations with fewer than 100 employees, 177 days for those with more than 100 employees).

The Medical Device Manufacturer's Association (MDMA) claims that this disparity in approval times is driving more and more product launches to the European market, where well over 60 percent of small [medical device companies](#) are successful in their pursuit of initial clearance. Exported product launches bring with them exported jobs and a brain drain of institutional knowledge that could end up staying in Europe in order to continue to benefit from the more welcoming regulatory environment that it has to offer.

The FDA has publicly stated that [one of the biggest reasons for increased delays during the 510\(k\) medical device approval process](#) has to do with the amount of time that companies take to respond to information requests on the part of the Administration. This reality affects both large and small medical device manufacturers, but larger companies have greater resources to draw on in addressing these requests, which puts them in a better position to move through the [pre-IDE process](#) more quickly. Big medical device manufacturers are also typically more capable of absorbing the financial burden of medical device approval delays due to their more diversified cash flow situations.

[The FDA argument regarding the quality of 510\(k\) submissions](#) and the increased need for additional information to clarify incomplete or confusing applications [is nothing new](#). The unbalanced effect that current FDA review and clearance practices has on smaller medical device companies, however, is alarming. Smaller companies spearhead innovation, and given that the industry is currently up in arms over regulatory hurdles that are pushing more and more researchers out of the U.S. and into Europe and Asia where product approval is quicker and more efficient, the impact of these 510(k) delays cannot be overstated. The FDA might call for higher quality submissions as a solution for rectifying the situation, but the focus on this one particular symptom of what is currently wrong with the pre-market approval process runs the risk of missing the bigger picture implications of maintaining the status quo in the American market.

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