

Emerging Medical Device Regulations at the FDA

On August 4, 2010 U.S. FDA issued two comprehensive evaluations addressing changes underway that will impact the manner in which the agency will regulate the premarket notification process for medical devices, i.e. the 510(k) process. This recent announcement is essentially a progress report on the work of two committees formed in September 2009 to address long-standing concerns about the 510(k) regulatory track affecting the great majority of medical devices. The workings of these two committees has generated keen interest among device suppliers, and their reported work-in-progress has already created a firestorm of concern, much of it unwarranted in my view.

The August news release can be found [here](#), and that document contains links to additional detail: Highlights of recommendations made to date and detailed reports from each of the two committees. Your regulatory staff and/or advisors should have already seen these documents and digested their contents; this is important because the time for comment on these preliminary recommendations is now, before they are converted to specific guidance and regulations.

My purpose here is to recount the highlights of the ten recommendations published in August by the Director of CDRH, Dr. Jeffrey Shuren, and to offer my views on these recommendations. To fully understand any of these topics I suggest you consult the full published detail. But here's the 10,000-foot view:

1. Streamline the premarket pathway for lower-risk novel devices.

This recommendation recognizes the current deficiencies of the tortuous *de novo* pathway available to devices that cannot use the 510(k) pathway for lack of a predicate device but whose risks don't warrant a PMA pathway. Reform of the *de novo* pathway is long overdue. Let's see if FDA can really come up with an improved protocol. Kudos for trying.

2. Enhance science-based professional development for CDRH staff.

Given FDA's statutory responsibilities, this is a no-brainer. It's all about personnel qualifications and money. FDA funding has been given short shrift before. Is there any real hope now?

3. Establish a network of external experts to better inform the review of cutting-edge technologies.

This seems to be a worthy idea. What could be wrong with building a bigger tent of expertise? Well, are these experts going to be compensated? How can we be assured that they will be objective and not influenced by industry relationships? FDA says that these folks would not serve in an "advisory capacity". What does that mean? I really like this idea but I think implementation will be fraught with difficulties. Good luck.

4. Increase the predictability of 510(k) data needs by establishing a new “class IIb”.

This recommendation has received the most attention so far; many call it PMA-lite. It actually makes great sense as the goal is to make certain 510(k) requirements and processes more predictable by developing guidance for certain subsets of class II devices “for which clinical or manufacturing information would typically be necessary to support a substantial equivalence determination”. Of course the devil’s in the details, especially defining the subsets and adequately defining the additional data requirements. If this works it will at least reduce the occurrence of nasty surprises, but I don’t think it will measurably reduce review times.

5. Create a new “Notice to Industry” tool to more rapidly communicate changes in premarket expectations.

Of course this can be nothing but good for suppliers, and it’s probably long overdue. But which industry sectors will receive these notices? Will all registered suppliers receive all the notices? If not, how will the industry sectors be defined, and who decides which suppliers are in which sectors? How does one deal with a supplier who is contemplating entering a new sector? These details can be worked out. This is a good idea.

6. Clarify the meaning of key terms in the 510(k) “substantial equivalence” review standard to improve the consistency, transparency, and timeliness of the review process.

I’ve never been a fan of “substantial equivalence”, and it’s becoming ever more meaningless. There are better ways to skin this cat. But I guess we’re stuck with it for now. FDA has had many opportunities to clarify its definitions over many years. Why should we believe it can be successful now? I’m pessimistic that this recommendation can be implemented satisfactorily.

7. Establish a Center Science Council as a new governance model to assure quality and consistency in CDRH’s science-based decision making.

Fancy, bureaucratic language. Worthy goal. Hard to know if it could really make a difference. I’m skeptical.

8. Require the up-front submission of more complete safety and effectiveness information to support the review of 510(k) devices.

This one has suppliers the most worried. CDRH would revise existing regulations to “explicitly require 510(k) submitters to provide in their 510(k)s a summary of all scientific information known or that should be reasonably known to the submitter regarding the safety and/or effectiveness of the device under review”. On the surface this makes great sense as it efficiently informs FDA reviewers of available data. But some of that data may be proprietary to the submitter. Will that data later be made public? If so, that’s a big problem.

I have a better, albeit much more radical, solution. Forget about demonstrating device effectiveness. Focus exclusively on demonstrating safety. Let clinicians determine device effectiveness as evidenced by postmarket refereed publications over time. And, if a device is ultimately proven ineffective in its intended use, FDA could require its removal from the U.S. market. Exceptions to this solution would have to be made for devices used exclusively by patients without clinician involvement.



9. Create a searchable online public database to provide more detailed, up-to-date medical device information to industry, the health care community, and patients.

I really like this idea. The resulting database would be helpful to all. Can proprietary information be appropriately omitted? Are the FDA's IT resources up to the job, and how long would it take?

10. Clarify CDRH's 510(k) rescission authority and the circumstances under which a device should not be used as a predicate.

Makes sense to me. For example, previously cleared devices that are proven to be unsafe should not be cited as predicates. It should be possible to define the agency's rescission authority without stepping on industry toes too much.

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