Take Control Of Your Medical Device's FDA Classification

By Michael Drues, Ph.D., President, Vascular Sciences

If you're developing a medical device that's "substantially equivalent" to an existing device (i.e., a device currently on the U.S. market with similar labeling), then the FDA classification process can seem straight forward. Simply head over to the classification database on the CDRH website, enter the relevant information about your product, hit the search button, and *viola!* You can quickly determine whether your device fits into the Class I, II, or III category. At least, that's what most people think. Reality, however, is far more complicated, and there are exceptions to every rule. The best regulatory professionals know how to use the exceptions – not just the rules.

Recently I was asked by a venture capitalist to evaluate some new medical device technologies at an investor conference. One of the young entrepreneurs told me his new medical device was Class II. When I asked why, he said "because that's what I read on FDA's webpage." If you needed surgery, would you want it done by someone who learned to do it by reading a website? Like medicine, regulation should not be practiced from a textbook — or worse, from a website! I handed him my business card and am now designing his regulatory strategy, including the classification determination.

Many people think device classification is determined by the design of the device or the riskiness of the device. That's what the regulatory textbooks say, but it's not nearly so simple. What it really comes down to is what you *say* your device will do. In the regulatory vernacular, that's called *intended use*. Many think intended use means "what your device is designed to do" or "what your device could be used for" — but that's not what intended use means! Intended use comes down to one thing: what you *say* your device is to be used for.

You don't have to change the device itself — the design of the device, the packaging, or anything else — to move your product to a different class. By simply adjusting or tweaking the label, you can actually have a major impact on the classification.

The classic example of this is a scalpel, a device used to cut through tissue. If you bring a scalpel onto the market with a general label of cutting tissue, then it is considered a Class I device. However, if you label the exact same scalpel for ophthalmology and eye surgery use, then the scalpel becomes a Class III device. From a regulatory perspective, why would a device manufacturer want to do that — it is clearly not in their best interest. So the challenge becomes getting your scalpel onto the market for general use (i.e., the "least burdensome" path), then encouraging surgeons to use it for other uses, like eye surgery. Suffice it to say, there are subtle and not-so-subtle ways this can be done.

According to the regulatory textbooks, classification depends on risk. While not factually incorrect, it's not that simple either. And there are many connotations of risk. So which are we talking about here? This is where classification strategy and risk mitigation strategy intersect, and it is one of the two critical components of a successful 510(k) submission — the other being a strong substantial equivalence argument. A savvy regulatory professional will design (not write!) a successful 510(k) submission that will achieve both components simultaneously.

Another commonly held belief is that once classification is determined, it is set in stone. But this is simply not the case! For an existing device, you can go through a request for reclassification to either increase or decrease the class of your device. CDRH does this from time to time, and manufacturers can do it too. We must always look for similarities (i.e., precedent) even when no similarities seem to exist. Down-classification for medical devices is similar to moving a drug from prescription to OTC, and much of the underlying regulatory logic is the same.

One of the most important lessons I learned long ago as a graduate student was "you don't get if you don't ask." When it comes to *negotiating* with regulatory bodies, however, I take a slightly different approach: "don't ask — tell" ... but politely of course! (I will discuss tactics like this in more detail in my upcoming webinar *Communication With FDA: What Do We Say And How Do We Say It?)*

If you are bringing a device to market that is truly new and novel — different than anything we already have — you certainly have the opportunity to influence the FDA to set the classification bar where you want it to be. One obvious example is the de novo process, a form of down-classification. But there are many other examples of down-classification and up classification as well. (For additional information on the *de novo* pathway, read parts one and two of my recent Med Device Online guest column *Secrets Of The De Novo Pathway*.)

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Regardless of whether your device is novel or a "me-too," you can take charge of your product classification and use it to your advantage. This is one of several examples of what I call competitive regulatory strategy.

It may be very tempting to set the class of a device as low as you possibly can. After all, it will make your job easier. On the other hand, it will also make your competitors' jobs easier. For this reason, you may want to set the classification for your device higher than necessary — to make it more difficult for competitors to follow in your footsteps.

And when it comes to reimbursement, the Centers for Medicare and Medicaid Serves (CMS) often has a different take than the FDA on classification. So the best regulatory professionals will use classification to their advantage, not just from a regulatory perspective, but from a reimbursement perspective as well. This is especially true when it comes to labeling. After all, is there any rule that says you can only get reimbursed if your product is used

Speaking of money, since we compete in a global economy, classification strategies need to be considered in terms of international regulatory strategy as well. Although most regulatory authorities use a classification system of some kind, where and how classification lines are drawn can differ greatly. Suffice it to say, my regulatory friends in the EU have a much different connation of the word "risk" than my friends in the U.S. Manufacturers would be wise to take these differences into account in determining which markets they should enter first, second, fifth, or tenth. Considering these factors in advance can minimize the overall regulatory burden tremendously and greatly mitigate the risk of having to repeat expensive and time-consuming benchtop, animal, or clinical testing to collect "new" information for marketing in another part of the globe.

Finally, if regulation is a science — and that is certainly a debatable topic — I would like to think it is an evolutionary science, constantly changing and evolving based on what we learn. To use a regulatory metaphor, it's like the design controls where the outputs become the inputs. To that end, the FDA recently issued a proposed rule that would amend its device classification and reclassification regulations. The move represents another attempt by the agency to provide additional clarification guidelines to industry, to help manufacturers navigate the U.S. regulatory maze. And in many cases, this is a good thing. Savvy regulatory professionals will not wait to see how others use these new rules — they will just to be among the first to use them to their advantage.

In a nutshell, regulation is constantly changing, constantly evolving. It is incumbent upon manufacturers to keep up with what's going on — not just what has already changed but what is being discussed and, most importantly, why. It's not always easy to take the reins on matters like device classification and reclassification, but you have to try — if you want to be competitive in an increasingly complex and challenging medical device market.

Editor's Note: Dr. Drues will go into much further detail on the topic of device classification/reclassification during a 90-minute online course called *Understanding the Medical Device Classification System: Best Practices for Selecting the Best Fit*. The course will take place on July 15, 2014, at 1 pm EDT time. For more information or to register, visit the Life Science Training Institute website.

About The Author

Michael Drues, Ph.D., is president of Vascular Sciences, an education, training, and consulting company offering a broad range of services to medical device, pharmaceutical, and biotechnology companies. He has worked for — and consulted with — leading medical device, pharmaceutical, and biotechnology companies ranging in size from start-ups to Fortune 100s.

Drues works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the U.S. and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS), and other regulatory and governmental agencies around the world. He is also an adjunct professor of medicine, biomedical engineering, and biotechnology at several universities and medical schools, teaching graduate courses in regulatory affairs and clinical trials, clinical trial design, medical device regulatory affairs and product development, combination products, pathophysiology, medical technology, translational medicine, and biotechnology.

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