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CDS Coalition Proposal for an HIT-Type Medical Devices Master Classification Plan

Classification is the language of medical device regulation. For software that meets the statutory definition of a medical device and therefore is subject to FDA regulation, the starting point for any regulatory analysis is the determination of the classification in which the software fits.

From a big picture perspective, classification is key because it determines the level of FDA regulation. For example, the classification determines whether the particular medical device can go right to market based on an effective quality system, or needs to wait potentially years and millions of dollars to get FDA approval.

But more than that, from a more tactical perspective, determining the precise classification regulation in which a piece of software fits determines the exact requirements. FDA has approximately 1700 device classification regulations that typically either contain a listing of the specific regulatory requirements for that specific type of device or are linked to a discussion of regulatory requirements in an FDA guidance document.

Simply put, any manufacturer of medical device software needs to first determine the specific classification regulation(s) that applies to identify the requirements they face, including the pathway to market. For innovators bringing a new product to market, these issues frequently determine whether the company can proceed.

Problem

Congress intended the classification regulations to be organic, to evolve as technology evolves. Unfortunately, the system has ossified, struggling mightily to keep up with changes in technology. Citing a lack of resources, the agency explains that it cannot devote the time and energy necessary to come up with new classifications that address new technology.[1] The result is a lot of manufacturers trying to figure out how to fit a new square peg into an old round hole.

Of late, to address this issue, FDA seems to be relying on a process generally referred to as the de novo classification process.[2] The de novo process places the burden on manufacturers to come up with new classifications in the context of getting individual products approved. In the

[1] Because FDA was struggling to keep up with the need for new classifications, in 2012 Congress enacted section 608 of FDASIA which streamlined some of the classification procedures. The early implementation of this new authority is focusing on old technology that has not yet found a classification home.

[2] FDA Draft guidance, Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types, proposed on January 20, 2015.

de novo process, a manufacturer submits a proposed classification to FDA together with a request to approve that manufactures product. The submission also typically includes a draft of the regulatory requirements that the manufacturer proposes be applied to the new category. FDA can take up to a couple of years to respond to a de novo petition.[3]

More than just the delay in getting a response, the de novo process has limitations. For example:

1. The de novo process requires manufacturers to act against their own financial interest. Putting together a de novo submission requires collecting data on the safety and effectiveness of the technology, and often generating new data to justify a lower classification. That costs money. By itself, that is a deterrent, but the real problem is--reclassification helps everyone who wants to sell a given product. Pursuing reclassification means directly helping your competitors, without the competitors having to financially support the reclassification. That's why even though the de novo process has been around for almost 18 years, only 135 companies have used it.[4] The only rational use for the de novo process is by manufacturers that believe they will be repeatedly improving their product over time, and thus want to lower the regulatory obligations that subsequent submissions will encounter. And that benefit must be so great that it outweighs making life easier for the company's competitors.
2. De novo submissions represent a very inefficient way to develop new classifications for entire categories of medical devices.
    a. Companies may duplicate efforts because each de novo submission is developed secretly. That means two different companies could be working on the same subject unbeknownst to each other, collecting and developing duplicative data.
    b. Proposed regulatory requirements for a given category lack timely public input. The proposed regulatory requirements are developed unilaterally by the company submitting them. Not surprisingly, the company submitters typically propose a narrow definition that focuses on their particular technology. It's only after FDA decides to accept the proposal that the particular regulatory requirements are publicly vetted. So obtaining broad stakeholder input is delayed until the FDA rules on the company's petition.
3. Reliance on de novo submissions produces a disjointed mosaic of individual classifications. Imagine the goal is to paint a mural of the White House. Hundred artists

[3] For the 10 de novo petitions granted in 2015 thus far, the average time from receipt of the submission to an FDA decision is just over 12 months. For a stand-alone software category covering cerebral assessment systems, the duration was two years.

[4] These numbers are as of June 29, 2015 according to the FDA de novo database. There are also various procedures for reclassification petitions that could be filed jointly by industry stakeholders, but these are rarely used because they have proven very cumbersome.

are told that they can each contribute to the painting, but they need to work in complete isolation from each other and submit their individual contributions. No artist knows what portion of the picture others are painting. What kind of picture do you think you would get? That's the de novo classification process. FDA could get 10 submissions that all cover the same basic small portion of the medical device mural, but none of the 10 look exactly the same, and there are huge gaps in the rest of the mural. There has to be a better way.

The bottom line is these limitations have led to a classification system that is hopelessly out of date and disjointed. That's a problem, because without a vibrant classification system innovators cannot identify the regulatory pathways their new technologies face.

Solution

On the one hand, there is certainly logic behind having industry drive the classification process. They know what technology lies on the horizon. On the other hand, FDA in some ways has broader vision, seeing all the new technologies that industry brings to the agency. As the federal regulator, FDA also plays a leadership role, which would allow the agency to serve as a natural coordinator, offering guidance on the submission of classification requests.

In urban planning, experts often develop what they refer to as a "master plan." The purpose of such a plan is to bring a holistic vision to how a city should develop, solicit public input on that vision and the completed plan then encourages private development in a coordinated fashion.

We need FDA to develop a master plan for the classification of health information technology (HIT) type medical devices. Specifically, we would like to see FDA take the following steps:

1. Draft a master plan for the classification of HIT-type medical devices. Conceptually the plan would include three interrelated sections:
    a. A high level risk stratification of HIT-type medical devices, the proverbial big picture. This is arguably the piece that is most conspicuously absent. Building on the agency's discussion with the FDASIA working group in 2013 as well as the work that FDA has done with the International Medical Device Regulators Forum, FDA could construct a risk-based model for the portion of HIT the agency regulates. The FDA's 2014 FDASIA report focuses mostly on software that FDA does not regulate, which was the essential starting point. But this master plan would go a step further to focus on the software that FDA does regulate.
    b. An inventory of the existing hardware and software classifications relevant to HIT-type medical devices. For each of those existing classifications, FDA ought

to offer its perspective on the types of hardware and/or software that fit within it.

c. An inventory of the gaps in the classification regulations for HIT- type medical devices. In this inventory, FDA should not only identify useful classifications for primary medical devices, but also categories of useful accessory medical devices.

2. Obtain public input on the master plan. Rather than simply publish the master plan for comment, we think that a document such as this could benefit from more interactive public involvement.

This master plan would help those innovators seeking to properly classify their HIT-type medical devices, and industry trade groups and coalitions that wish to collectively pursue new classifications.