July 3, 2014

mHealth Regulatory Coalition
Accessory Policy White Paper

Problem statement

Understanding the scope of FDA regulation is the first key to business planning in the mHealth space. One of the areas greatest in need of clarity is FDA's reach over accessories to medical devices.

Further, classification is the language of medical device regulation. It is the cornerstone of understanding FDA expectations for a new medical device.

Fundamentally, the problem we want to solve is getting guidance so that the industry knows:

1. When a potential accessory, by virtue of its relationship to a parent medical device, is itself a medical device, and
2. If it is an accessory, how it is classified?
3. How are claims about accessory compatibility regulated?

For ease of reference, let's refer to the two products as the "parent medical device" and the "potential accessory."

General classification rule

We propose the following approach to classifying potential accessories.

A. Definition of an accessory

A potential accessory will become an actual accessory when the following four criteria are met:

1. The intended use – as demonstrated by words and deeds (for example by promotion and design) – of the potential accessory includes use together with either:
   a. a specific branded medical device or
   b. a generic category of medical device.

   Automatic data transfer between the devices is not required. Manual data entry can still occur as a part of the system intended to be used together.

2. The intended use is not a general purpose, but specific to being used together with that medical device (below we explain how general purpose articles retain their status as general purpose articles even if a particular use is with a medical device);

1

3. The potential accessory is distributed to the end user without being integrated into the parent device and is "suitable for use or capable of functioning." (A product that does not meet this criterion might instead be a component); and

4. The relationship between the potential accessory and parent medical device is such that the potential accessory is intended to enable or assist the parent device to be used in accordance with the parent's intended use.

If those three conditions are met, then the item is an accessory and FDA regulates it.

B. Classification process

The next question, then, is how to classify the accessory. There are at least three possibilities.

1. First analyze whether the accessory fits within an existing device classification found in the regulations other than the classification for the parent medical device. If so, that classification determines the classification of the accessory. If not,

2. Second, analyze whether the accessory fits within one of the enforcement discretion accessory categories (defined below). If so, the accessory is exempt from active regulation. If not,

3. The accessory is classified in the same classification regulation as the parent medical device.

Note that if the potential accessory is excluded from accessory status because it actually changes the intended use of the parent medical device, the software or hardware would itself become a parent medical device and would need to be classified wherever it fits.

The idea here is for FDA to create explicit, new classifications for common accessories, because the default for an accessory otherwise, if there is no express classification already, is either class III or the classification of the parent device, both of which would result in overregulation of the accessory. So expressly granting lower classification to common, low risk accessories is an extremely important step for FDA to take.

Medical device accessories should not cause general purpose hardware and software to be regulated

It is already clear that where software constitutes a medical device and is intended by the software manufacturer to be used with general purpose computing or communication hardware (such as a cell phone) or software (such as an operating system or standard

communication protocols), the general purpose computing or communication hardware or software (sold separately by a separate manufacturer) is not a medical device. The same would be true when a specialized accessory that itself has medical device functionality (such as a blood glucose test strip reader) is intended to be used with a general purpose computing or communication product (sold separately by a separate manufacturer).

We propose that FDA go a step further and clarify that the general purpose hardware or software does not need to be sold separately by a separate manufacturer. Further, FDA should clarify that the general purpose computing or communication hardware or software remains unregulated even when the manufacturer of the general purpose hardware or software intends that the hardware is to be used with any suitable software, *and in its promotion specifically includes medical device software*. In other words, the fact that a general hardware or software company explicitly identifies a specific piece of medical software, among others, that can be used with its product should not cause the general article to become regulated. For example, a general purpose cell phone should remain unregulated even when it is specifically promoted for use with a medical device app, is sold preloaded with the medical device app or contains general purpose communication protocols that meet the needs of medical apps.

Of course, if the manufacturer of the general purpose computing or communications equipment adds specific hardware or software functionality that serves a medical device functionality and adds material risk, that functionality would be regulated. Taking a risk-based approach, there are functionalities that FDA should permit without regulation such as an app that retrieves, stores and forwards data, using standard communication protocols, from a medical device to a mobile medical app to enable the mobile medical app to apply algorithms to/manipulate the forwarded data for use in a non-acute situation.

Application of accessory rules to systems

One of the areas most in need of guidance is the application of the accessory rules to systems. Systems can be quite complex, such that items might be an accessory to an accessory to an accessory of a medical device. We need some clarity from FDA regarding at which point that article no longer would be viewed as an accessory to the medical device.

We propose that each link in the system be examined using the approach outlined in the first section, that is applying the five criteria to the article to see if it is an accessory *to an article that would be considered a freestanding medical device*. The analysis should always focus on the relationship between the potential accessory and the parent medical device. This is instead of considering whether an accessory somehow supports another accessory, which is too attenuated to declare a product regulated.

Further, the guidance should consider software modules or software add-ons to the parent software device. FDA also should address system testing and the separation of modules/units that is required before such modules might be treated differently for regulatory purposes. It is typically difficult to draw regulatory lines between two connected software modules. In a separate position paper, we will recommend a specific approach to drawing lines between modules.

Claims of interoperability

A claim that an accessory meets certain standards that are recognized as relevant to medical device functionality does not automatically mean the product is a regulated accessory. For example, the claim that an accessory is interoperable and/or compatible with a particular type piece of medical device software or hardware does not make the accessory any less of a general use item. Claims of interoperability and compatibility are commonly used to describe complex systems and underlying platforms. Because something is compatible or interoperable does not necessarily mean it has been optimized for use solely with medical devices and thus it can retain its general use status and should not be regulated. Only items of software or hardware that add or mitigate material risk and for which the seller makes medical device claims should be regulated.

Freestanding regulatory device classifications

FDA already has a few classifications in its regulations for products that can serve an accessory function. Examples include:

1. 862.2100   Calculator/data processing module for clinical use
2. 864.4010   General purpose reagent
3. 890.3710   Powered communication system
4. 892.2050   Picture archiving and communications system

With regard to these existing classifications, we would like to see four improvements in FDA's approach.

1. When interpreting the scope of those classification regulations, FDA should not be unduly narrow in its interpretation and should not, for example, exclude new products that reasonably fit within those classifications on the basis of the so-called "8xx.9 regulations." FDA should not use those 8xx.9 regulations to exclude products from the classification simply because the new product connects to another medical device or the new product has novel features that do not impact risk. For example, we think the regulations should be revised to make clear that SaMD, as that term has been defined by IMDRF, should not be excluded from a 510(k) exemption on the basis of the 8xx.9

4

regulations just because it uses data from an in vitro diagnostic device. The classification should be based upon the function of the SaMD (what is done with the data), not the data source. This is consistent with the FDA Mobile Medical Application Guidance and the Food and Drug Administration Safety and Innovation Act Health IT Report where there is a clear focus on the health IT functionality and not the platform(s) on which such functionality resides or the product name/description of which it is a part.

2. FDA also should establish additional classification regulations that define and characterize the risk associated with the most common mHealth accessories that it intends to regulate. The purpose here would be to establish more appropriate, risk-based classifications specific to the accessories. We have included some specific classifications we would propose in Appendix A. We believe that FDA should leverage FDA's recently proposed revised reclassification procedures, in accordance with FDASIA, to facilitate the creation of these new classifications.

3. FDA should document its use of enforcement discretion in a manner that can be consistently and confidently relied upon by industry. For example, FDA recently made the decision to deregulate diabetes data management software products. We think that's a good decision, as such systems are so safe and so well characterized that there was no benefit to subjecting them to regulation. We were pleased that FDA publicly announced that on the agency's website in a manner that all could see. We would like to see FDA use that same transparency for other categories that the agency has decided not to regulate.

4. And finally, we would like to see FDA make greater use of the de novo reclassification process for novel mHealth technologies that plainly do not create undue risk. We would like to see greater flexibility by the agency for assembling the necessary information for a de novo submission, and we would also like to see clearer guidance on applying the de novo process to mHealth technologies, and an expedited process.

Enforcement discretion accessory categories

Knowing which accessory categories FDA agrees are general purpose enough and low risk enough to be not regulated would greatly help industry innovate in this space. We would like to see FDA spell out in a guidance document some of the more important and common categories of accessories that the agency agrees are either not medical devices, or if they technically meet the definition, are categories where FDA has no intention to regulate. We have assembled a preliminary list of these categories in the attached Appendix B.

Regulatory requirements applicable to accessories

Regardless of the classification of an accessory, the following rules would apply to any intended use as an accessory.

1. Claims that certain products are compatible or interoperable with a medical device must be adequately substantiated and
2. The company making the claim must assure the claim remains accurate as the accessory or parent medical device changes over time.

So for accessories that are in fact regulated medical devices, instead of up classifying accessories, we recommend FDA use its authority under the general controls to assure that companies are adequately validating accessory type claims. Thus, instead of premarket review, we are proposing that FDA use the agency's inspection powers to make sure that the validation has been done.

Conclusion

Our goal in providing this comprehensive assessment of how accessories should be regulated is the acknowledgment that accessories often should be regulated independently of the medical devices they accessorize. If an accessory fits into its own classification regulation, or fits into one of the enforcement discretion categories, it should be regulated independently and not as part of a particular system or configuration. This has tremendous practical consequences, not the least of which is that these accessories would not need to be included in premarket notifications for the parent device. Instead, as just explained, they would have their own classification status and claims of compatibility would be addressed under the quality system, and not through premarket notification.

We include in Appendix C examples of accessories in the market today which demonstrate the issues identified above.

Appendix A—Proposed New Regulatory Classifications

for mHealth Accessories

Data aggregators and report generators	A data aggregator and report generator is a hardware or software device intended to produce an electronic report of health-related and/or medical device data generated from one or more sources connected via an mHealth system. An example of a data aggregator and report generator is a software device that electronically generates a report of data collected from a weight scale, blood pressure cuff, and a proprietary device that manually prompts the user to respond to predetermined, health-related questions.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Appendix B—Proposed Unregulated, mHealth Accessory Categories

Description	Definition
General Purpose communication equipment labeled or promoted for a specific medical use	General Purpose communication equipment labeled or promoted for general use but including an explicit, specific medical use consists of products that are used for telecommunications purposes to transmit data in an mHealth system and that comply with applicable standards for such products. These include wireless routers, modems, switches, Bluetooth transmitters/receivers, cables, connectors, adaptors, and any other similar product used for basic connectivity purposes, as well as equipment used to support, test, and maintain such equipment.
Device controllers for Class I exempt devices	A device controller (for Class I exempt devices) is a hardware or software device used to electronically control the functionality of a Class I device exempt from premarket notification requirements that is part of an mHealth system. An example of a device controller is a software device that electronically triggers a sensor device in an mHealth system to perform a task (e.g., to collect health-related information, or to notify the user to respond to predetermined, health-related questions).
Adapted general purpose communication software	Software allows consumer to enter vital sign and other data, or retrieves data from a medical or fitness device via standard wireless communication in lieu of manual entry of the vital sign data. This software may temporarily store data on mobile device; use standard SSL, encrypt data; and, using a standard mobile data connection, transmit data at a scheduled time to a secure data center. This software does not issue real-time alerts to healthcare providers and is not intended for individuals in acute care facility, or high-risk individuals requiring active, real time monitoring by a healthcare provider. This software may deliver to the consumer certain content (may be educational, motivational or instructional) that is configured for the consumer by separate software domiciled at the data center (that may be regulated) and transmitted to the mobile device for display. May or may not have the same brand name as one of the regulated devices or software with which it communicates.
Secondary display hardware and software	In certain care settings, caregivers and patients find it convenient to use a secondary display for collected data, sometimes to simultaneously display data taken from multiple sources. Secondary displays include any hardware or software intended for displaying health or medical device data where the user has reasonable access

to another, primary display. This does not change the regulatory classification of that primary display.

Appendix C—Examples of Accessories in the Market Today

mHealth Accessory Issue	Example	Current regulatory treatment
General purpose hardware and software used with a medical device	A Patient Management system allows implanted defibrillator data to be recorded and forwarded via Plain Old Telephone System (POTS) to a Webserver that is manufactured by the Implant Defibrillator manufacturer.	When sold by a class III manufacturer, the Web server is treated as an accessory and classified in class III. Indeed the entire Web server system including power cords and disk drives are treated in class III. This is over regulation.
General purpose hardware and software used with a medical device	A standard cell phone may well in the future be sold with a mobile medical app, regulated by FDA, preinstalled.	FDA likely would treat the cell phone as a medical device but choose not to regulate it under enforcement discretion. More accurately, the cell phone should not be considered a medical device at all.
Application of accessory rule to systems	An in-home device capable of reading implant data can then send the data to a physician. The data is non-urgent and having the home monitor is primarily for convenience. The in-home device has no decision making capability and does not close any therapy loop by reprogramming settings. The in-home device functionality could be alternatively accomplished with a standard cell phone and custom interrogation interface to collect the data. The data would flow from the implant to a custom telemetry device	Under current regulatory approaches that FDA, any of these in-home devices would be class III. This is over regulation.

via a Bluetooth connection to
a cell phone.