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Accessory Regulation in mHealth

To clarify what types of mHealth technologies FDA will regulate, the mHealth Regulatory Coalition (MRC) is drafting a guidance document it plans to propose to the agency. Our proposed guidance document will specifically address three areas: (1) intended use claims, (2) accessory products, and (3) software applications. Having previously developed and published part one on our website, attached is part two.

Regulation of accessories involves two different but quite related issues: (1) classification of the accessories and (2) substantiation of compatibility claims involving accessories. Understanding how those two different requirements fit together indeed is a cornerstone of this proposal. In some cases, accessories might remain in a relatively low classification, but at the same time any company wanting to make a claim of compatibility may have a rather significant obligation to validate that claim. It is through both of those requirements that FDA can assure the safety and effectiveness of accessories used in mHealth.

Note that in this portion of the guidance document, we need to rely upon an appropriate risk model just as we explained in Part 1. Our plan is to study risk models being developed elsewhere in the connected health space for suitability here. Suggestions with regard to appropriate risk models are welcomed.

We look forward to hearing your thoughts and recommendations with regard to our proposed approach to accessories. Comments should be directed to Bradley Merrill Thompson at BThompson@EBGLaw.com. We will be publishing on our website in the coming months the third and final part of our proposal, addressing software. At that point we will make revisions to all three parts in response to comments we are receiving. We then will propose all three parts to FDA.

mHealth Regulatory Coalition
FDA Regulation of mHealth
Proposed Draft Guidance Outline

Part 3--Accessories

1. Introduction

1.1. Historically, the "accessory rule" has been thought of as an overarching rule, broadly applicable to nearly all so called *parent device-accessory* connections.

1.1.1. Under that rule, in certain situations, FDA regulates a product that is an "accessory" to a medical device as if in the same regulatory classification as the "parent" medical device.

1.1.2. The burgeoning mHealth industry has generated significant questions about the scope of the accessory rule, due to the inherent interconnectedness of mHealth products. These questions are likely to only get more complicated, as many products will be marketed in the future with broad system claims, rather than one-to-one pairing claims.

1.1.3. In this document, we describe the general boundaries of the accessory rule and how the rule is applied to mHealth products.

1.2. Here are the general rules that describe when this approach applies to a given article:

1.2.1. FDA must determine whether the article is a medical device based on its intended use.

1.2.2. If the article is a medical device, FDA must determine whether it fits into a specific existing classification. If so, that classification stands so long as the use of the device does not exceed the parameters of the classification, including the 8xx.9 regulations.

1.2.3. If the article does not fall within a specific existing classification, there are a couple options. An applicant may use the *de novo* process to petition FDA to regulate the device as a Class I or II medical device independent of the *parent device*. If the applicant does not pursue that route, and the article is intended to be used with another device, the product takes on that *parent device*'s classification.

1.3. Separate from this regulatory pathway, it is important to recognize that, as with all claims, claims associated with *accessories* and their *parent devices* must be substantiated.

1.3.1. For example, if either the *parent device* manufacturer or the *accessory* manufacturer makes a claim of compatibility, the claim maker must substantiate it. Substantiation must take the form of validation testing.

1.3.2. Claim substantiation does not change the classification of either article. The lower class device does not get up-regulated.

1.3.3. Consider the following claims of compatibility:

1.3.3.1. The product manufacturer claims that its product is compatible with:

1.3.3.1.1. All major blood glucose meters or that meet a particular standard;

1.3.3.1.2. A specific brand of blood glucose meters;

1.3.3.1.3. A specific blood glucose meter;

1.3.3.1.4. A specific blood glucose meter and the manufacturer of the blood glucose meter claims that its device is compatible with the product.

1.3.3.2. For each of these scenarios, the evidence required to substantiate the claims of compatibility may change, but the classification of the product should not.

1.4. In addition to validation testing, the claim maker should establish a quality system that will ensure revalidation of the claim whenever changes to either article are made.

1.4.1. At a practical level, that means the company either needs to control the design of both devices (e.g., by ownership), or there needs to be an agreement between the two companies that give assurances that notification will be given for any changes.

1.4.1.1. In the absence of such an agreement, the company claiming compatibility would need to do a risk assessment to show that an agreement with the other manufacturer is not necessary.

1.5. To summarize, this process for *accessory* regulation can be broken down into two steps:

1.5.1. Device Classification; and

1.5.2. Present and Future Claim Substantiation.

1.5.2.1. Present substantiation requires validation of the claim by the claim maker.

1.5.2.2. Future substantiation requires an established quality system and on-going validation by the claim maker.

2. Scope

2.1. This document describes the accessory rule and its application to mHealth products.

3. Definitions

3.1. ***[This section will be updated as necessary and incorporated with the definitions of the other parts of the guidance document.]***

3.2. *Accessory* – a finished device that is distributed separately but intended to be attached to or used in conjunction with another finished device.[1]

3.3. *Component* – a product (finished or unfinished) that is intended to be purchased by the manufacturer of the finished device in which the product will be incorporated. A *component* is distinguished from an *accessory* based on the purchaser of the product—an end-user buys an accessory, while a manufacturer buys a component. The exact same piece of equipment could, therefore, be either an *accessory* or a *component* depending on the target purchaser.

3.4. *Parent device* – a finished device to which an *accessory* is attached or with which an *accessory* is used.

[1] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FOOD & DRUG ADMIN., PUB. NO. FDA 97-4179, MEDICAL DEVICE QUALITY SYSTEMS MANUAL: A SMALL ENTITY COMPLIANCE GUIDE (1996), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/default.htm.

4. The Accessory "Rule"

4.1. Under the accessory rule, in certain situations, FDA regulates an *accessory* as if in the same regulatory classification as the *parent device*. Below is a detailed explanation of when the accessory rule applies.

4.2. The accessory rule applies if and only if there is not an existing classification for the device in question.

4.2.1. The first step for determining whether a product is subject to the accessory rule is to consider whether the product is a device at all. If it is not, the analysis ends and we do not even reach the question of whether the accessory rule applies.

4.2.2. FDA classifies medical devices into three classifications, generally based upon the potential risks associated with the device's intended use and its indications for use.

4.2.2.1. When considering the appropriate classification of a new device, classification is evaluated by first determining whether FDA has previously classified and described a similar device type in the Code of Federal Regulations (CFR).[2]

4.2.2.2. **If a device falls within one of the device type descriptions, the device will be subject to that classification and the relevant controls contained within the relevant section of the CFR. The existence of a regulatory classification of a medical device type is the agency's recognition that a given device type should fall within a pre-defined Class, <u>even if</u> that device happens to be an *accessory* or compatible with other devices.**

4.2.3. The medical device data systems (MDDS) Final Rule recognizes this fundamental principle of FDA regulation:

4.2.3.1. "If the product meets the definition of an MDDS because it is limited to the intended uses of an MDDS, FDA will regulate such a product as an MDDS, not as an accessory to or component of another device, regardless of how many particular devices or device types the product supports. FDA recognizes that some devices that meet the definition of an MDDS may have been previously cleared as accessories to other device types. Through enactment of this regulation, devices that are considered MDDSs will now be classified as class I, Exempt, whether they are existing devices or new/modified devices that are now defined as MDDS."[3]

4.2.4. The device will fall within the existing classification as long as the design and intended use of the device does not exceed the boundaries of the classification, including any 8xx.9 regulations, if applicable.

4.2.4.1. For those regulatory classifications that are exempt from 510(k) requirements, an mHealth accessory will remain in that classification category and exempt from 510(k) requirements if the accessory:

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[2] The classification and descriptions of device types are organized by medical specialty panels in 21 CFR Parts 862 through 892.

[3] *Medical Devices; Medical Device Data Systems*, 76 Fed. Reg. 8637, 8644 (Feb. 15, 2011) (to be codified at 21 C.F.R. § 880.6310), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-02-15/pdf/2011-3321.pdf.

4.2.4.1.1. Has existing or reasonably foreseeable characteristics of other devices in the classification category; and

4.2.4.1.2. Has the same intended use and fundamental scientific technology as another device in the classification category.

4.2.4.2. An mHealth accessory to an in vitro diagnostic device is subject to additional exemption limitations under the 8xx.9 regulations.

4.2.4.2.1. In addition to the requirements above, an mHealth accessory of this type will remain in its existing classification and exempt from 510(k) requirements if:

4.2.4.2.1.1. The accessory is a low-risk device as determined under the risk model described in Part 1 of this guidance document; and

4.2.4.2.1.2. The accessory does not change the risk profile of the in vitro diagnostic device.

4.2.4.2.2. A low-risk mHealth accessory is not *per se* restricted from exemption under the 8xx.9 limitation, even if the intended use is any of the following:

4.2.4.2.2.1. For assessing the risk of cardiovascular disease;

4.2.4.2.2.2. For use in diabetes management;

4.2.4.2.2.3. For identifying or inferring the identity of a microorganism directly from clinical material; or

4.2.4.2.2.4. For near-patient testing (point of care).

4.2.4.3. The 8xx.9 limitations should be used judiciously. They should not be used to exclude a product from a classification simply because that product connects to another medical device or the product at issue has different characteristics than other devices.

4.2.4.4. In determining whether the 8xx.9 regulation will exclude a device from a classification, a manufacturer should conduct a risk assessment. If the risk assessment supports the Class I or II exempt classification, the device should remain within the boundaries of the existing classification.

4.2.5. Appendix A of this document lists current regulatory classifications that are useful for mHealth accessories. Appendix B suggests classifications that the agency should consider for future development.

4.3. If there is not an existing classification for the device in question, there are a couple options.

4.3.1. An applicant may petition FDA to regulate the device as a Class I or II medical device independent of the *parent device*.

4.3.1.1. The *de novo* review process is an opportunity for a device automatically designated as Class III to be reclassified if appropriate. The *de novo* process is particularly appropriate for low risk devices.

4.3.1.2. Applicants should support their *de novo* submission by a risk assessment

that demonstrates the low risk profile of the device. The existing guidance on the *de novo* process also should be used to guide application content; however, FDA should include specific guidance for mHealth products in the guidance on the *de novo* process that CDRH expects to publish by September 30, 2011.

4.3.1.3. The *de novo* process will be useful for mHealth accessories and the creation of needed regulatory classifications. FDA should use this process more frequently for mHealth products to create consistency and predictability in the regulation of mHealth accessories.

4.3.1.4. FDA or any stakeholder may also employ any other available route to reclassification.

4.3.2. If the applicant does not pursue the *de novo* route or any other form of reclassification, and the article is intended to be used with another device, the product takes on that *parent device*'s classification. Thus, a product is an accessory when it:

4.3.2.1. Otherwise meets the definition of a medical device—i.e., it is used in a health-related context (but not, for example, in a billing or administrative context);

4.3.2.2. Is distributed separately to an end user; and

4.3.2.3. Is intended to be attached to or used in conjunction with another finished device by, for example:

4.3.2.3.1. Accepting data from a user and modifying it for input into the finished device;[4]

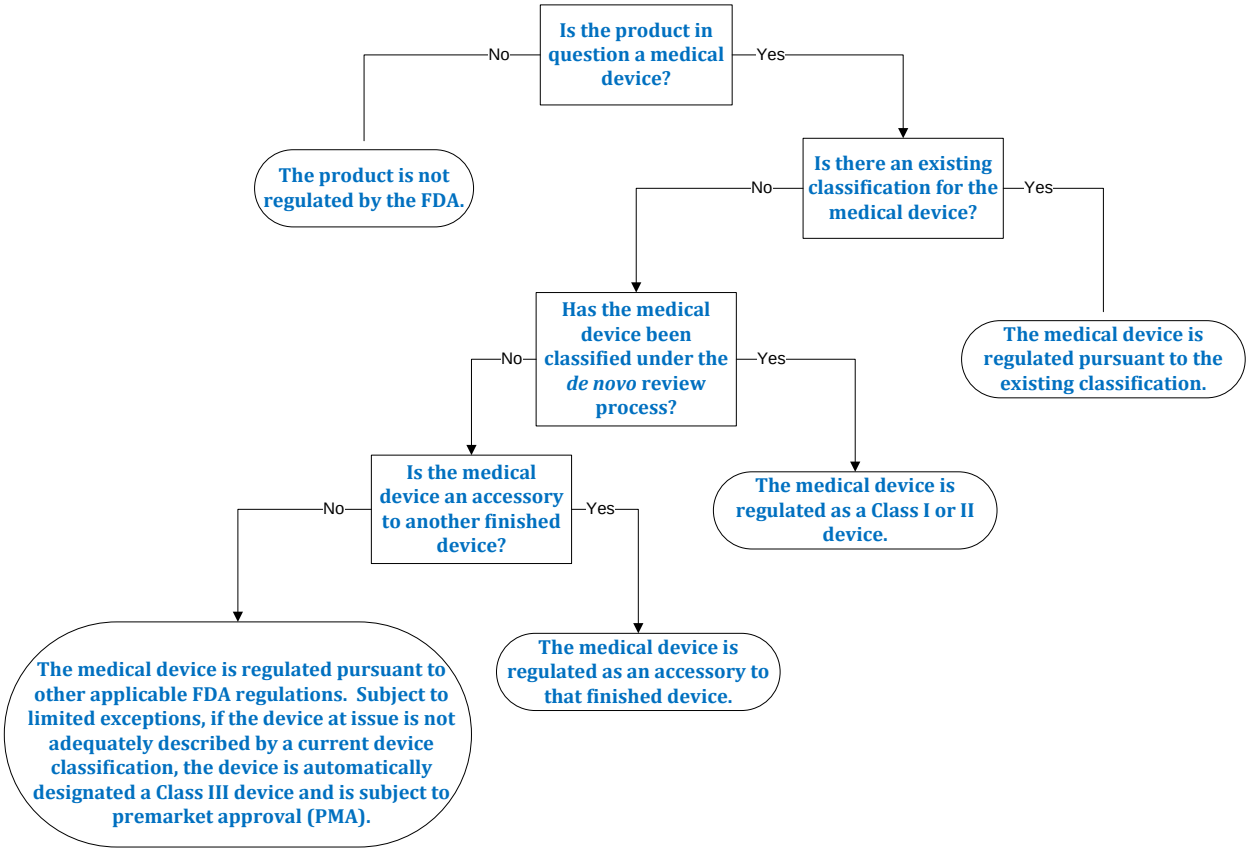
4.3.2.3.2. Taking data from the finished device and modifying it for presentation to a user;[5] or

4.3.2.3.3. Otherwise enhances the performance of the separately distributed finished device.[6]

4.3.3. If the device is not classified or regulated as an accessory and the applicant does not pursue the *de novo* process, the device will be regulated as a Class III device.

[4] *See* E. Stewart Crumpler & Harvey Rudolph, *FDA Software Policy and Regulation of Medical Device Software*, 52 FOOD & DRUG L.J. 511 (1997).
[5] *Id*.
[6] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FOOD & DRUG ADMIN., PUB. NO. FDA 95-4158, PREMARKET NOTIFICATION 510(K): REGULATORY REQUIREMENTS FOR MEDICAL DEVICES (1995), *available at* http://www.fda.gov/cdrh/manual/510kprt1.html (last visited May 17, 2005).

4.3.4. **In summary, the analysis goes like this:**



5. Application of the Accessory Rule in mHealth

5.1. Given the diversity of mHealth products, a number of additional aspects of the accessory rule are worth exploring to understand how the rule applies in this context.

5.2. The difference between an *accessory* and a *component* is important because it determines the applicable regulatory requirements for a particular product.

5.2.1. *Components* are exempt from most FDA regulatory requirements, with the regulatory burdens being borne by the finished device manufacturer.

5.2.2. *Accessories*, on the other hand, because they go right to the end user, must meet the FDA requirements before they leave the hands of the *accessory* manufacturer.

5.3. Human intervention may affect the application of the accessory rule, and the resulting classification.

5.3.1. Human intervention may impact whether a device is intended to be attached to or used in conjunction with another finished device and is therefore an *accessory*. As discussed above, a device may be an *accessory* if it operates in conjunction with a finished device by, for example: accepting data from a user and modifying it for input into the finished device; taking data from the finished device and modifying it for presentation to a user; or otherwise enhancing the performance of the separately distributed finished device. As such, introducing human intervention between the

medical device and the putative accessory may interrupt the connection between the device and the would-be accessory, meaning that the product at issue does not qualify as an *accessory*.

5.3.1.1. Manual data entry can be a form of human intervention. A weight scale and a software app that communicates manually entered data to a personal health record is a simple example where human intervention interrupts the connection between the finished device and the would-be accessory. Although the weight scale is a medical device and the software app operates in conjunction with and enhances the performance of the weight scale, the software app is not an accessory in this example because the manually entered data constitutes human intervention that breaks the connection between the two products.

5.3.2. Human intervention that renders a product a non-*accessory* may have important implications for the regulatory status of the would-be *accessory*.

5.3.2.1. Remember, if you are considering whether a device is an *accessory* means you have already concluded that the device does not have an existing classification.

5.3.2.2. Subject to limited exceptions, if the device at issue is not adequately described by a current device classification, the device is automatically designated a Class III device and is subject to premarket approval (PMA).[7] A Class III device designation may be changed to Class I or II through the de novo review process, or any other form of reclassification.

5.4. The following are examples of relationships that could potentially form a *parent device-accessory* link.

5.4.1. Class III connected to Class I or II

5.4.1.1. Device-to-accessory: Implantable cardioverter defibrillator (device) connected to a body area network sensor for blood pressure (accessory). The link is created here because the blood pressure sensor is a medical device but falls outside of an existing classification. The sensor would be regulated as an accessory to the defibrillator (i.e., Class III).

5.4.1.2. Device-to-non-accessory: Pacemaker (device) connected to a smartphone (non-accessory) for communication of medical device data. The link is not created here because the existing MDDS classification would apply to the smartphone, which would be regulated at that classification (i.e., Class I).

5.4.2. Class II connected to Class I

5.4.2.1. Device-to-accessory: Blood pressure cuff (device) connected to software app for reporting of blood pressure data (accessory). The link is created here because the software app analyzes the blood pressure cuff data and generates a report of that data. The software app is a medical device and does not fall within an existing classification. The app would, therefore, be regulated at as an accessory to the blood pressure cuff (i.e., Class II).

[7] In certain cases, the sponsor of such a device may request a Class I or Class II determination through the de novo process established in § 513(f)(2) of the Federal Food Drug & Cosmetic Act.

5.4.2.2. Device-to-non-accessory: Pulse oximeter (device) connected to a computer (non-accessory) for communication of medical device data. The link is not created here because the computer would fall into the existing MDDS classification (i.e., Class I).

5.4.3. Device connected to non-device

5.4.3.1. Pulse oximeter (device) connected to a wrist watch (non-accessory). The link is not created because the wrist watch is not a device and is, therefore, not regulated.

5.5. It is important to understand what happens *to* "*access*ories to accessories". Consider the following:

5.5.1. In mHealth, there may be a configuration where a device transmits data to Product A; Product A transmits information to a Database (stored on Product B); and Product B transmits data to Product C. The mere existence of the original *parent device* and its transmission of data to Product A does not necessarily mean that Product A is a medical device.

5.5.1.1. The status of Product A depends upon whether it is a medical device in its own right. If it is, then you analyze whether there is an existing classification for it. If there's not, then you ask whether it is an *accessory* to the original *parent device*.

5.5.1.2. For the same reason, the fact that Product A is a medical device does not necessarily render the Database or Product B a device.

5.5.1.3. A break in the chain (i.e., if one of the Products is not a medical device or an *accessory* to a medical device) does not necessarily render the remainder of the products in the chain unregulated. Each product in the chain must be evaluated independently.

5.5.2. The bi-directional flow of data (i.e., both from the patient/device to the *healthcare professional* and from the *healthcare professional* to the patient/device) may impact classification.

5.5.2.1. This particular factor does not impact the general framework (i.e., the questions that we ask) for deciding whether a particular item is a medical device or an *accessory*.

5.5.2.2. However, this feature/functionality may impact whether the particular item qualifies (i.e., based on the answers to the framework questions) as a medical device or operates as an *accessory*.

5.6. Consider a device–non-device–device connection (e.g., a Class III device–computer/smartphone–Class I or II device). Take, for example, the following: ICD–computer or smartphone–weight scale.

5.6.1. The classification of the Class III device is not necessarily imputed to all products in the chain, including the non-devices.

5.6.2. The same analysis applies, meaning that the first step for analyzing the status of the non-device is to consider whether it is a device at all. If it is not, you don't even need to reach the accessory question.

5.6.3. Even if instead of going through a chain, the products were connected through a web, with the sensor transmitting to multiple products, the framework still applies.

6. Claims of Compatibility

6.1. A claim of compatibility between two regulated articles does not necessarily render a *parent device-accessory* relationship between the two articles.

6.1.1. If an existing classification applies to the product, the product is regulated under that classification rather than as an *accessory* to the parent.

6.1.2. The claim of compatibility, however, must be substantiated through adequate validation.

6.1.3. Take, for example, an MDDS that claims compatibility with a specific brand of blood glucose meters.

6.1.3.1. The MDDS device is regulated as a Class I device under 21 C.F.R. § 880.6310.

6.1.3.2. The blood glucose meter is regulated as a Class II device under 21 C.F.R. § 862.1345.

6.1.3.3. The MDDS device is not regulated as an *accessory* to the blood glucose meter because the MDDS has its own classification.

6.1.3.4. However, the manufacturer of the MDDS device must validate its claims of compatibility with the blood glucose meter.

6.1.3.4.1. If the manufacturer of the blood glucose meter claims compatibility with the MDDS device, the manufacturer must validate that its blood glucose meter is compatible with the MDDS device.

6.1.3.4.2. The burden lies on the manufacturer making the claim of compatibility to substantiate that claim through adequate validation.

6.1.4. FDA should also consider using a feasibility test to determine the significance of the validation.

6.1.4.1. If it is feasible for the manufacturer (at the time the product is created) to self-assess the product as a low-risk device, the validation requirements should be minimal.

6.2. Claims of compatibility must be substantiated to demonstrate that the associated risk is recognized and minimized. Even though an *accessory* is not up-regulated, the claim substantiation process ensures the risk associated with the *parent device-accessory* relationship is low.

6.2.1. Claim substantiation is separate and apart from the determination of whether an *accessory* is a device or the appropriate classification.

6.2.2. Claim substantiation requires both present and future validation by the claim maker.

6.2.2.1. Present substantiation consists of validation testing to ensure that the claim of compatibility is accurate and to clarify the design specifications that

support the claim.

6.2.2.2. Future substantiation consists of the establishment of a quality system and on-going validation testing.

6.2.2.2.1. This may involve an agreement between the claim maker and the manufacturer of the product that design specifications will not change or that notification will be given in advance of any changes to allow the claim maker to adequately address the impact of such changes on the future substantiation of the claim.

6.2.2.2.2. In the absence of such an agreement, the claim maker would need to assess the risk to show that an agreement is not necessary.

6.3. Some types of *parent device-accessory* relationships trigger additional regulatory obligations. Consider the following three scenarios:

6.3.1. A *parent device* manufacturer makes a claim that its product will work with a PrickAxe Brand *accessory* and only a PrickAxe Brand *accessory*.

6.3.1.1. The *parent device* manufacturer must substantiate the claim through validation testing.

6.3.1.2. The *accessory* manufacturer has no obligations to substantiate the claim made by the *parent device* manufacturer.

6.3.1.3. The *parent device* manufacturer carries the burden of maintaining adequate design controls to respond to changes that occur in the *accessory*.

6.3.2. An *accessory* manufacturer makes a claim that its *accessory* will work with a PawPrick Brand *parent device* and only a PawPrick Brand *parent device*.

6.3.2.1. The *accessory* manufacturer must substantiate the claim through validation testing.

6.3.2.2. The *parent device* manufacturer has no obligations to substantiate the claim made by the *accessory* manufacturer.

6.3.2.3. The *accessory* manufacturer carries the burden of maintaining adequate design controls to respond to changes that occur in the *parent device*.

6.3.3. Both occur at the same time, such that there is a uniquely one-to-one relationship between the *parent device* and *accessory*.

6.3.3.1. The unique "one-to-one" relationship between the *parent device* and the *accessory* requires that the manufacturers work together to ensure that the claims are substantiated and that any changes made to either device are validated.

6.3.3.2. Both manufacturers must ensure that adequate design controls are in place to account for changes that occur in the future.

6.3.3.3. If the manufacturers cease cooperating together such that the changes to either of the devices are not validated, they can no longer make claims of one-to-one compatibility.

6.3.3.4. Although not required by regulation, having an agreement in place to exchange information regarding product complaints and safety events is generally considered good practice.

7. Conclusion

Appendix A—Current Regulatory Classifications and Product Codes for Accessories in mHealth Systems

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
862.1345	Glucose test system	II	CFR, CFW, CGA, CGD, CGE, LFR, MRV, NBW
862.2050	General purpose laboratory equipment labeled or promoted for a specific medical use	I	GLE, JBS, JJP, JQC, JQO, JQQ, JQY, JQZ, JRB, JRC, JRG, JRI, JRJ, JRK, JRL, JRM, JRO, JRQ, JRR, JRS, LCI
862.2100	Calculator/data processing module for clinical use	I	JQP, NVV
864.2240	Cell and tissue culture supplies and equipment	I	KIY, KIZ, KJA, KJB, KJC, KJD, KJE, KJF, KJH, NVG
864.3600	Microscopes and accessories	I	IBJ, IBK, IBL, IBM, KEG, KEH, KEI, KEJ
864.4010	General purpose reagent	I	HZI, IAL, IAM, IAT, IAW, IAY, IBB, IER, IEX, IEZ, IFF, IFH, IFI, IFJ, IFL, IFN, IFO, IFP, IFQ, IFS, IFT, IFY, IFZ, IGB, IGC, IGD, IGE, IGF, IGG,IGK, IGM, IGN, IJZ, JCB, JCC, JCE, KDX, KDY, KEE, KEF, KEL, KEM, KEO, KEP, KEQ, LDT, LDW, LDX, LDY, LDZ, LEA, LEB
870.1025	Arrhythmia detector and alarm	II	DSI, MHX, MLD, MXD

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
870.1100	Blood pressure alarm	II	DSJ
870.1110	Blood pressure computer	II	DSK
870.1120	Blood pressure cuff	II	DXQ, NPP, OED
870.1130	Noninvasive blood pressure measurement system	II	DXN
870.1875	Stethoscope	I/II	DQD, LDE, OCR
870.2340	Electrocardiograph	II	DPS, MLC, OEY
870.2360	Electrocardiograph electrode	II	DRX, MLN
870.2390	Phonocardiograph	I	DQC
870.2400	Vectorcardiograph	II	DYC
870.2700	Oximeter	II	DQA, MUD, NLF, NMD, OCH
870.2710	Ear oximeter	II	DPZ
870.2810	Paper chart recorder	I	DSF
870.2860	Heart sounds transducer	II	JOO
870.2880	Ultrasonic transducer	II	JOP
870.2910	Radiofrequency physiological signal transmitter and receiver	II	DRG
870.2920	Telephone electrocardiographic transmitter and receiver	II	DXH
876.1300	Ingestible telemetric gastrointestinal capsule imaging system	II	NSI, NEZ, NYZ*
876.1725	Gastrointestinal motility monitoring system	II	FES, FFX, KLA
876.1735	Electrogastrography system	II	MYE
880.2400	Bed-patient monitor	I	KMI
880.2700	Stand-on patient scale	I	FRI

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
880.2720	Patient scale	I	FRW
880.2910	Clinical electronic thermometer	II	FLL
880.6300	Implantable radiofrequency transponder system for patient identification and health information	II	NRV
880.6310	Medical device data systems	I	OUG
880.6315	Remote medication management system	II	NZH
882.1400	Electroencephalograph	II	GWQ, OLT, OLU, OLV, OLW ,OLX, OLY, OLZ ,OMA, OMB, OMC, ORT
882.1410	Electroencephalograph electrode/lead tester	I	GYA
882.1420	Electroencephalograph signal spectrum analyzer	I	GWS
882.1430	Electroencephalograph test signal generator	I	GWR
882.1540	Galvanic skin response measurement device	II	GZO
882.1560	Skin potential measurement device	II	HCJ
882.1570	Powered direct-contact temperature measurement device	II	HCS
882.1610	Alpha monitor	II	GXS
882.1835	Physiological signal amplifier	II	GWL
882.1845	Physiological signal conditioner	II	GWK
882.1855	Electroencephalogram telemetry system	II	GYE
882.5050	Biofeedback device	II	HCC
884.2050	Obstetric data analyzer	III	HEO
884.2600	Fetal cardiac monitor	II	KXN
884.2620	Fetal electroencephalographic monitor	III	HGO

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
884.2640	Fetal phoncardiographic monitor and accessories	II	HFP
884.2660	Fetal ultrasonic monitor and accessories	II	HEI, HEJ, HEK, HEL, HEP, HEQ, KNG, LXE, MAA
884.2730	Home uterine activity monitor	II	LQK, MOH
884.2740	Perinatal monitoring system and accessories	II	HGM
884.2800	Computerized labor monitoring system	II	NPB
890.1375	Diagnostic electromyography	II	IKN, KZM, OAL
890.3075	Cane	I	IPS, KHY
890.3150	Crutch	I	IPR
890.3710	Powered communication system	II	ILQ
890.3725	Powered environmental control system	II	IQA
890.3800	Motorized three-wheeled vehicle	II	INI
890.3825	Mechanical walker	I	ITJ, NXE
890.3850	Mechanical wheelchair	I	IOR, LBE
890.3860	Powered wheelchair	II	ITI
890.3880	Special grade wheelchair	II	IQC
890.3890	Stair-climbing wheelchair	III	IMK
890.3900	Standup wheelchair	II	IPL
890.5050	Daily activity assist device	I	IKW, IKX, ILC, ILD, ILS, ILT, ILW, IQG, NXB, NXQ, OAG, OIZ, OJL
890.5350	Exercise component	I	IOD
890.5360	Measuring exercise equipment	II	ISD

Classification Reg. (21 CFR)	Description	Device Class	Product Codes
890.5380	Powered exercise equipment	I	BXB, IOL, IRR
890.5575	Powered external limb overload warning device	II	IRN
892.1540	Nonfetal ultrasonic monitor	II	JAF
892.1550	Ultrasonic pulsed Doppler imaging system	II	IYN
892.1560	Ultrasonic pulsed echo imaging system	II	IYO, NQQ, OIJ
892.1570	Diagnostic ultrasonic transducer	II	ITX, MUI, OUJ
892.1720	Mobile x-ray system	II	IZL
892.2010	Medical image storage device	I	LMB, NFF
892.2020	Medical image communications device	I	LMD, NFG
892.2030	Medical image digitizer	II	LMA, NFH
892.2040	Medical image hardcopy device	II	LMC, NFI
892.2050	Picture archiving and communications system	II	LLZ, NFJ, NEW, OEB, OMJ

Appendix B—Proposed Regulatory Classifications for Accessories in mHealth Systems

Description	Definition	Classification
First-line communication equipment	First-line communication equipment are general 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.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.
General purpose health applications	General purpose health applications are software devices used in an mHealth system to electronically collect, store, transmit, display, or analyze (e.g., aggregate) health-related data for educational purposes or as a tool to affect normal behavioral activity. An example of a general purpose health application is a software device stored on a smartphone that electronically collects daily exercise and weight information from a variety of sensors and displays the data for personal monitoring purposes.	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.
General health information data collection devices	A general health information data collection device is a hardware or software device used in an mHealth system to manually or electronically collect general health information (e.g., normal behavioral activity) about the user of the mHealth system. An example of a general health information data collection device is a software device used on an electronic tablet device that allows 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, subject to the limitations in 8xx.9. The device also is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

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).	Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 8xx.9.
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, subject to the limitations in 8xx.9.

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