

mHealth Regulatory Coalition
MRC’s Proposed Guidance for Industry and FDA Staff
Regulation of mHealth Technology

Foreword to the Proposed Guidance Document

2 The mHealth Regulatory Coalition (MRC or Coalition) is a diverse group of mobile health (“mHealth”)¹
4 non-governmental representatives, non-profit associations, patient advocacy organizations, health care
6 payors, and individual health care professionals. Industry members also include traditional medical device
manufacturers, mobile app developers, online marketplaces for mobile apps, mobile platform
manufacturers, telecommunications service providers, and information and communications technology
companies.

8 The MRC formed in July 2010 with the goal of answering *two fundamental questions*: 1) *what mHealth*
10 *products should the U.S. Food & Drug Administration* (FDA or Agency) *regulate* and 2) if such
12 products are regulated, *in what device classification* should the FDA place them? The Coalition chose to
14 address these questions because its members believe that the interests of the public health and patient
16 safety demand appropriately tailored FDA oversight. With those goals in mind, the Coalition concluded
that only those mHealth technologies that reach a moderate or high level of risk warrant scrutiny.
Moreover, the development of *a clear, predictable, and targeted regulatory framework will promote*
innovation and discovery of new ways to improve the delivery of care, *reduce the cost of health care,*
facilitate private investment in large and small businesses in the mHealth industry, and *stimulate job*
creation in the United States.

18 As the Coalition set its course for answering these fundamental questions, we established two major work
20 products: a whitepaper that identifies the open regulatory issues that exist in the mHealth space; and a
22 proposed guidance document that describes the regulatory framework that we believe properly balances
24 the interest of the public, the FDA, and the industry. In December 2010, we published the whitepaper²
after having spent nearly five months meeting internally along with external stakeholders (e.g.,
entrepreneurs and the medical device industry) to learn about their mHealth regulatory positions and
business plans.

We are now publishing our second work product—this proposed guidance—after nine months of internal
26 deliberation and public comment.³ The outcome is a document that specifically addresses the two
28 fundamental questions we identified at the outset. More specifically, this proposed guidance addresses: 1)
30 the types of intended uses that a product may have and associated claims that a manufacturer can make
32 about a product without it being regulated as a medical device; 2) the framework for addressing products
that have traditionally been regulated as accessories to other medical devices; and 3) a framework for
software in an mHealth system. As each of these involves evaluation of risk, the proposed guidance
describes a risk model that the Coalition believes can be used as a means of assessing risk associated with
specific products in an mHealth system.

¹ We use the term *mHealth* as a short form of *mobile health*, which encompasses the use of mobile technology in a wide array of health care settings, including in-hospital, in-home, and on-the-go.

² BRADLEY MERRILL THOMPSON ET AL., A CALL FOR CLARITY: OPEN QUESTIONS ON THE SCOPE OF FDA REGULATION OF MHEALTH (2010), available at <http://mhealthregulatorycoalition.org/wp-content/uploads/2010/12/mrcwhitefinal122210.pdf>.

³ Working drafts of this proposed guidance were made available via the MRC’s website, links to which were published in social media forums (e.g., LinkedIn and MobiHealthNews.org) as well as in traditional news outlets. In addition, the Coalition held an open meeting at the Continua/ATA Policy Summit in July 2011 to discuss a draft of this proposed guidance.

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2 Ultimately, the Coalition's purpose is to propose a means by which FDA can tailor its existing regulatory
3 framework to mHealth technologies at a level of specificity that would be meaningful. Therefore, in
4 drafting this proposed guidance we have tried to step into the shoes of the Agency and written this in a
5 way that the Coalition believes the FDA could reasonably implement the proposed principles through
6 their good guidance practices. In certain instances, however, we have made recommendations to FDA that
7 would need to be accomplished through a means outside this guidance. In particular, we believe that
8 FDA needs to engage in rulemaking to develop new classifications for accessories and mHealth software,
9 which we describe in Appendix B. To be clear, the Coalition is not proposing to establish a new
10 classification scheme for mHealth products; instead, our proposal tailors the existing regulatory
11 framework to mHealth products, including identifying a number of product types that might fall within an
12 mHealth system for which there does not currently exist a classification regulation.

DRAFT – September 30, 2011

THIS HAS BEEN PRODUCED BY THE MRC AS A PROPOSAL FOR FDA'S CONSIDERATION.
THIS IS NOT AN FDA DOCUMENT.

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MRC's Proposed Guidance on Regulation of mHealth Technologies

Submitted by the mHealth Regulatory Coalition
to the Food and Drug Administration

DRAFT

September 30, 2011

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I. Introduction

2 With the rapid growth and diversification of mobile health (mHealth) technologies, there is a need for
4 guidance from FDA on what types of intended use claims subject mHealth products to the Agency's
6 regulatory authority. Certain mHealth products technically fall within FDA's jurisdiction but are
8 intended for uses that present very low risk to patient safety. FDA is choosing to exercise its
10 enforcement discretion with respect to these types of claims. For other mHealth products, FDA
jurisdiction is unclear due to ambiguity in the language of the statute and associated claim terminology.
This guidance is intended to clarify FDA's current thinking on what types of "ambiguous" mHealth
products fall outside of the agency's jurisdiction. More specifically, this guidance describes what types
of mHealth products are regulated and how a classification determination should be made.

II. Scope

12 This guidance document describes the types of mHealth products that are excluded from FDA regulation
14 as well as the process that FDA recommends to determine an mHealth product's regulatory status. The
16 scope is limited to intended use claims relating to mHealth products and does not address questions
18 regarding evidence of intended uses for a given product. This guidance document is further limited in
scope to the process by which FDA recommends to determine whether a particular mHealth product,
based on its intended use claims, would be regulated. This document does not, however, describe to
what extent a *particular product* will be regulated (if regulated).

This guidance document also describes the accessory rule and its application to mHealth products, as
well as the regulation of software products used in mHealth systems. The software regulatory framework
is not intended to apply to all software used as part of a medical device. Instead, this document focuses
on the types of software that an mHealth system might incorporate. Unless otherwise specified, the
principles developed in this guidance document apply equally to hardware and software within an
mHealth system.

III. Definitions

26 The following terms are used throughout the guidance document.

28 *Accessory:* A finished medical device that is distributed separately but intended to be attached to
or used in conjunction with another finished medical device.⁴

30 *Caregiver:* An individual who is not a health care professional but who provides personal care for
32 another individual. An example of a caregiver is a family member or professional health
educator (e.g., lifestyle/health coach or educator). An individual who would otherwise be
considered a health care professional may also be a caregiver if the individual is acting in
a caregiver-capacity.

⁴ 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>.

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2 *Cloud Computing:* Cloud computing is the use of distributed and/or virtual computing platforms
to perform specific analytical or administrative functions. The term “software as a
4 service” is often used to describe software programs that are hosted and/or performed in
the “cloud” (i.e., the network of distributed computing platforms).

6 *Component:* A component is 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.⁵ A
8 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.⁶

10 *Consumer:* A consumer is an individual who is not diagnosed or being treated for an illness by a
health care professional through the mHealth product. Examples of a consumer include
12 an individual who utilizes a medical device for personal use or who obtains specific
wellness advice from a caregiver.

14 *Disease:* For purposes of this guidance, a disease is damage to an organ, part, structure, or system
of the body such that it does not function properly (e.g., cardiovascular disease), or a state
16 of health leading to such dysfunction (e.g., hypertension). Behavioral activities (e.g.,
general lack of exercise or poor nutritional habits) are not included in this definition.

18 *Disease Claim:* A disease claim is any claim, not including a health claim, made on the label or in
labeling of a product that demonstrates, expressly or impliedly, that the intended use of
the product is to diagnose, treat, or prevent a disease.

20 *Electronic Health Record (EHR):* An EHR is an electronic record of health-related information
for a patient that contains information captured from a variety of sources (e.g., during
22 clinical visits from various health care professionals), including vital statistics, lab and
imaging studies, and other information important to the patient’s medical history.

24 *Electronic Medical Record (EMR):* An EMR is an electronic record of health-related information
used exclusively by one or more health care providers (e.g., hospital or ambulatory care
26 facility) as the legal record of a patient’s health information.

28 *Firmware:* Firmware is fixed, embedded programs and/or data structures that internally control
the proper functioning of the device.

30 *General Purpose Article:* A general purpose article is a product that is not labeled or promoted
for medical uses but which, by virtue of its application in health care, meets the definition
32 of a medical device. These products either pose little or no risk, or are appropriately the
sole responsibility of the health care professionals who have used them in medical
34 applications. Examples of a general purpose article include a personal computer that has
been programmed by a clinical chemist to display values from tests on human specimens;
and a database management system, with no medical claims, that is used by a health care

⁵ 21 C.F.R. § 820.3(c).

⁶ In some cases, a component that is sold directly to an end user as a replacement part is regulated as a finished medical device. *See, e.g.,* 21 C.F.R. § 890.3920 (designating wheelchair components sold as replacement parts as Class I devices).

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professional to identify patients at risk for a given medical procedure.⁷ A general purpose article may also include a software application design for home-use by a caregiver to record medical information.

Generally Recognized Health Claim: A generally recognized health claim is a health claim for which there is general recognition, among qualified experts, that the product has been adequately shown to be safe under the conditions of its intended use. The source of evidence to support a claim of general recognition may include current, published, authoritative support from certain federal scientific bodies (e.g., NIH, CDC, the Surgeon General), the National Academy of Sciences, the American Medical Association, or other similar professional organization.

Health Care Professional: A health care professional is a physician or other medical professional 1) who is licensed under State law to prescribe drugs or devices,⁸ or 2) whose primary purpose is to examine, evaluate, and treat or refer patients for examination, evaluation, or treatment by another physician or medical professional. Examples of a health care professional include medical doctors, dentists, chiropractors, optometrists, nurse practitioners, case managers, school nurses, and veterinarians.⁹ A health care professional acts in his or her professional capacity when the individual examines, evaluates, or treats (or refers for examination, evaluation, or treatment of) an individual for a specific disease or medical condition.

Health Claim: A health claim is any claim made on the label or in labeling of a product that expressly or impliedly characterizes the relationship of the product to a disease or health-related condition. Implied health claims include third party references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol or •), or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the mHealth product and a disease or health-related condition.

Level of Concern: Level of concern refers to an estimate of the severity of injury that a device could permit or inflict, either directly or indirectly, on a patient or operator as a result of device failures, design flaws, or simply by virtue of employing the device for its intended use. Level of Concern is not related to device classification (Class I, II or III) or to hazard or risk analysis per se.¹⁰

⁷ CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., DRAFT POLICY FOR THE REGULATION OF COMPUTER PRODUCTS 2 (1989); *see also* 21 C.F.R. § 807.65(c).

⁸ *See* 21 C.F.R. § 99.3 (defining *health care practitioner* for purposes of dissemination of information on unapproved uses for marketed drugs, biologics, and devices).

⁹ *See* 21 C.F.R. § 803.3 (defining *physician's office* in the medical device reporting context).

¹⁰ CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR THE CONTENT OF PREMARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN MEDICAL DEVICES 4–8 (2005), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf>; *see also* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, FDA REVIEWERS AND COMPLIANCE ON OFF-THE-SHELF SOFTWARE USE IN MEDICAL DEVICES (1999), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf>.

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2 *Medical Advice:* Medical advice is a health-related recommendation that is provided to a patient
by a health care professional in furtherance of an examination, evaluation, or treatment of
the patient.

4 *Medical Device:* A medical device (or device) is “an instrument, apparatus, implement, machine,
6 contrivance, implant, in vitro reagent, or other similar or related article, including any
component, part, or accessory, which is . . . intended for use in the diagnosis of disease or
8 other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or
other animals, or . . . intended to affect the structure or any function of the body of man
10 or other animals, and which does not achieve its primary intended purposes through
chemical action within or on the body of man or other animals and which is not
12 dependent upon being metabolized for the achievement of its primary intended
purposes.”¹¹

14 *Medical Device Data:* Medical device data are any information generated from a medical device
or manually entered into a medical device for use or analysis by the medical device.

16 *Medical Data:* Medical data are any patient-specific information generated as a result of a
18 medical examination, evaluation, or treatment ordered or conducted by a health care
professional.

20 *Mobile Application:* A mobile application (or mobile app) is software that is designed for use on
in a mobile setting (e.g., hardware or software-based virtual machine on a smartphone,
tablet computer, laptop computer, or other similar mobile product).

22 *Parent device:* A parent device is a finished device to which an accessory is attached or with
which an accessory is used (e.g., via wireless communication).

24 *Patient:* A patient is an individual who seeks the assistance of a health care professional for the
examination, evaluation, or treatment of a disease or health-related condition.

26 *Personal Health Record (PHR):* A PHR is an electronic record of health information that is
28 maintained, controlled, and shared by a consumer. A PHR consists of health-related data
that are generated and entered by the consumer and can incorporate data from both EMRs
and EHRs.

30 *Software:* Software is programming code (e.g., instructions or machine commands) that employs
32 a machine or multiple machines, any of which can be real or virtual, to perform certain
analytical tasks not specifically traceable to the operation of any particular physical
34 product. Software is inherently non-physical in nature. Common terms include
“software”, “software application”, “software app”, “software program”, “app”, or
36 “program”. Examples include stand-alone programs for use on a computer or mobile
phone, including mobile apps; web-based applications; programs that perform functions
38 on multiple machines (e.g., “cloud computing”); and modularized, third-party software
that performs discrete functions (e.g., “software-as-a-service”).

¹¹ Food, Drug, and Cosmetic Act, § 201(h), 21 U.S.C. § 321(h).

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2 *Software device:* A software device is software that meets the definition of a medical device.
3 Software that would otherwise be a general purpose article, but which is modified by the
4 user outside of the original manufacturer's specifications, would constitute a software
5 device.

6 *Software manufacturer:* A software manufacturer is any person or entity who creates, designs,
7 develops, labels, re-labels, remanufactures, or modifies software or who creates a
8 software system from multiple components, including someone who might commonly be
9 called a "software developer". In addition, anyone who initiates specifications or
10 requirements for software or who procures product development/manufacturing services
11 from other individuals or entities for subsequent commercial distribution is a software
12 manufacturer. This term does not include a person or entity who solely distributes or
13 markets software or who provides a service for others to distribute or market software on
14 the Internet.

15 *Software module:* A software module is a discrete element of a software application that performs
16 a specific function upon request by the core software code or by another software
17 module. Software modules are used as part of a software architecture as a means of
18 partitioning specific sub-functions that, when combined in a larger package or "wrapper",
19 create the software application. The specific functions performed by a software module
20 can be analytical (e.g., calculating daily averages of medical device data) as well as
21 procedural (e.g., using standard or proprietary protocols for transmitting and/or
22 converting data streams).

23 *Wellness Data:* Wellness data are consumer-specific, health-related information. Examples of
24 wellness data include health information that is not medical data or that is generated by a
25 consumer and/or a caregiver.

26 *Wellness Advice:* Wellness advice is a health-related recommendation that is provided via any
27 mechanism to a consumer by a caregiver or by an individual who is not a health care
28 professional acting in their professional capacity. An example of wellness advice is a
29 recommendation by a person or company via a software or web-based program to
30 increase exercise activity or reduce calorie consumption.

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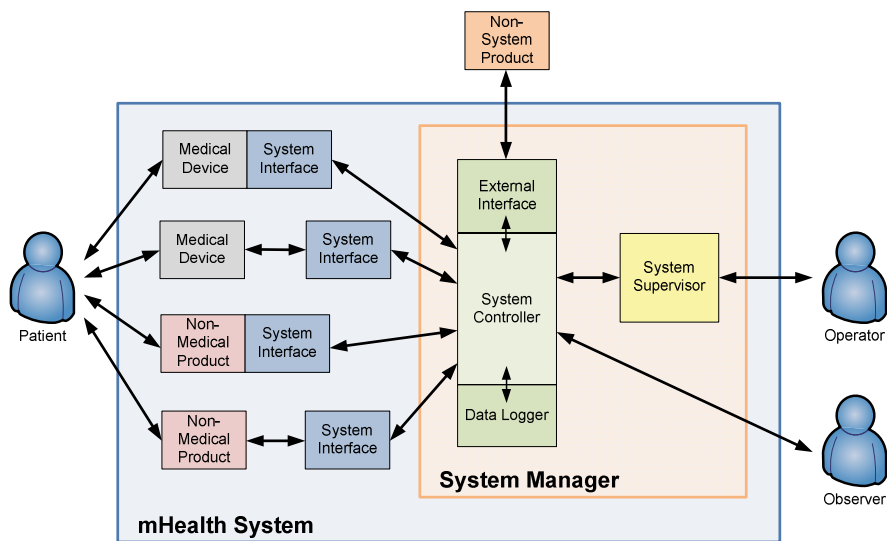
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IV. Risk Model

2 The following mHealth System risk model has been developed based on ASTM F-2761-2009 *Medical*
 4 *Devices and Medical Systems—Essential Safety Requirements for Equipment Comprising the Patient-*
 6 *Centric Integrated Clinical Environment (ICE)—Part 1: General Requirements and Conceptual Model*
 8 and its adaptation to connected health technologies by the Medical Device Interoperability Safety
 10 Working Group (MDISWG).¹² The fundamental premise of the mHealth System risk model is that each
 12 stand-alone product should be classified (i.e., unregulated or Class I, II, or III) based on the risk
 14 associated with that specific product. By using standard interface protocols, each product can be
 evaluated without identifying, at the time of the regulatory review, the numerous devices that may be
 included in the mHealth System. Furthermore, any product that complies with these standard interfaces
 can be added or replaced (by a product with equivalent functionality and intended use) without affecting
 the risk profile of the system.¹³ This risk model applies to both hardware and software in an mHealth
 system. Figure 1 illustrates a generic mHealth System and the potential connections between devices,
 non-device products, system controllers, and system users.

Figure 1: Illustration of a Generic mHealth System and the Various Components/Interfaces



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¹² The ASTM F-2761-2009 standard “establishes the general principles for the design, verification, and validation of a model-based integration system that enables the creation of an integrated clinical environment intended to facilitate cross-manufacturer medical device interoperability.” The standard embraces the concepts developed in ISO 14971, IEC 60601-1, IEC 62304, and IEC 80001. The focus of the ASTM standard is “for the care of a single high acuity patient.” The Medical Device Interoperability Safety Working Group (MDISWG), part of the broader Medical Device “Plug-and-Play” (MD PnP) Interoperability program, adapted the terminology and requirements of the ASTM standard for use in any interoperable health care environment. Separately, Sandy Weininger (Sr. Electrical Engineer at FDA’s Center for Devices and Radiological Health) in conjunction with Michael Robkin (President, Anakena Solutions and technical lead for the NIH Quantum Grant for medical device interoperability), are working to develop a risk model for interoperable medical device systems. We are adapting the ASTM standard and MDISWG’s work products for use with mHealth systems. Furthermore, we reference and support the work of Sandy and Michael as a basis for evaluating risk in an interoperable mHealth system.

¹³ This concept extends to software modularization, discussed in Section VII.F.1 of this guidance document.

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A. General Risk Assessment

2 Generally, the level of FDA regulation of medical devices is determined by the overall risk associated
 4 with the device. Overall risk is a function of inherent product risk and ambiguity in the claims
 6 terminology. Inherent product risk associated with a specific mHealth product is determined by
 evaluating the likelihood of an adverse event to the *patient* or *consumer* and the severity of harm from
 that event on the individual's well-being. Table 1 describes the generic inherent risk chart based on the
 following definitions of likelihood and severity.

8 Likelihood can be defined as:

- *Improbable*: so unlikely to occur that it can be assumed that this hazard will not occur.
- *Remote*: unlikely to occur but possible.
- *Occasional*: likely to occur sometime in the life of the product.
- *Probable*: likely to occur more than once in the life of the product.
- *Frequent*: likely to occur several times in the life of the product.

14 Severity can be defined as:

- *Negligible*: will not result in injury or illness to the patient or user; no damage to the user
 environment (e.g. physical, contamination, EMC).
- *Minor*: could result in minor injury to the patient or user; little or no damage to the user
 environment.
- *Moderate*: could result in moderate injury or illness to the patient or user; may cause
 moderate damage to the user environment.
- *Major*: could result in death or serious injury or illness to the patient or user without
 intervention; may cause significant damage to the user environment.
- *Catastrophic*: could result in death to more than one patient or user; may cause severe
 damage to the user environment.

26 **Table 1:** Relationship Between the Likelihood and Severity of Risk in an mHealth System

		Severity				
		Negligible	Minor	Moderate	Major	Catastrophic
Likelihood of Failure	Improbable	Minimum	Minimum	Minimum	Minimum	Low
	Remote	Minimum	Low	Low	Low	Medium
	Occasional	Minimum	Low	Medium	Medium	High
	Probable	Minimum	Low	Medium	High	High
	Frequent	Low	Medium	High	High	High

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B. *mHealth-Specific Risk Considerations*

1. Influence of Product Functionality

For specific products within mHealth Systems, inherent risk may be influenced by evaluating the specific functionality of the product. The categories of functionality involved in mHealth systems include:

- *Data display*: representation of data (including alarms) generated by the various products in the system.
- *Generation of alarms*: creation of alarms based on data generated by the various products in the system.
- *Virtual control*: commands that allow control of specific products in the system by other products in the system.
- *Automatic control*: control commands automatically initiated according to pre-determined thresholds or algorithms based on data generated by the various products in the system.
- *Programming control*: clinician-established algorithms that control specific activity of any of the various products within the system.

2. Other Influential Factors

Additional factors that should be considered when determining the inherent risk of a specific product include:

- Intended use of the product as demonstrated by the claims and design features;
- The level of involvement of the consumer, a caregiver, and/or a health care professional in the proper use of the product;
- The degree of data analysis performed by the product or the product's underlying system;
- The level of involvement of the product's manufacturer or a third party in communicating results of the product's function to the consumer, patient, caregiver, or health care professional;
- The degree of influence the use of the product will have on clinical decisions by a health care professional;
- The need for immediate review of the product's results; and
- The potential for significant harm associated with the product's failure.

The greater significance of these factors in the product, the greater the inherent risk involved. Table 2 illustrates the degrees of risks for each of these risk factors.

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Table 2: Risk Factors in mHealth Systems and Examples of Degrees of Risk¹⁴

Risk Factor	Degrees of Risk		
	← Less Risk	More Risk →	
Intended Uses	Consumer uses	Disease-specific uses	Life-sustaining uses
User Involvement	Personal monitoring	Health care professional long-term monitoring	Health care professional acute care
Manufacturer's Role	Device Assessment	Infrastructure/service provider	Clinical evaluation
Data Analysis	Displaying data	Evaluating data via predictive algorithms	Triggering alerts/notifications
Role in Clinical Decisions	No role; personal use only	Informative; limited data points among many	Essential; only data source
Acuity of Results	Long-term monitoring only	Short-term monitoring, but not real-time	Real-time monitoring
Significance of Failure	Minimal harm	Reversible, physical injury possible	Irreparable, physical injury

2

a) Human Intervention

4 One factor that influences the risk associated with an mHealth system is the level of involvement of the
 6 consumer, a caregiver, and/or a health care professional in the proper use of the product. As with other
 8 medical devices, hardware and software components in an mHealth system may or may not involve
 human interaction or intervention. Human interaction or intervention can be categorized into three types
 of activities:

- 10 1. **Manual data entry** – keyed entry of data that is stored, transmitted, analyzed, or manipulated
 in some other way by the software;
- 12 2. **Assessment of data** – visual assessment of data stored in, received from, analyzed by, or
 manipulated in some other way by an mHealth system; and
- 14 3. **Manual manipulation** – electronically generated data that is manually modified prior to or to
 facilitate assessment of the data.

16 Historically, FDA has generally believed that human intervention reduces the risk associated with medical
 devices. Based on the advancement of technology and the common use of electronically generated data,

¹⁴ This table is not intended to describe the entire spectrum of degrees of risk for a given risk factor.

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FDA is no longer focusing on the means by which the data is generated. FDA now believes that electronically generated data involves no more inherent risk than manually-entered data. In line with this thinking, a hardware or software device that requires, for example, manual data entry of personal health information or medical device data (e.g., a blood glucose measurement) should be viewed as having comparable risk as a similar device that automates these activities. On the other hand, an mHealth system that involves human intervention as an intermediate step (e.g., by the product's manufacturer) between data generation (manual or automatic) and assessment (e.g., by a health care professional) should be viewed as having additional risk when compared to a system that directly transmits the data to the end user.¹⁵ An intermediate step that has no effect on the assessment (e.g., for billing purposes) should have no impact on the associated risk.

b) Relationship Between Hardware and Software

Software may involve additional risk as a result of the associated hardware. For example, a software app designed for use on a proprietary, wireless hardware device may involve less risk than the same software app that is designed for a general purpose smartphone because the general purpose smartphone involves features and functions that are not specific to the software app, but that may cause the software app to malfunction. A proprietary hardware device, on the other hand, should involve less risk because the design features are limited to the specific intended use and functionality of the software app.

A software app that uses a cloud computing platform should not be viewed as involving additional risk when compared to a software app that relies on a dedicated hardware device. More specifically, FDA believes that, if you compare two devices of a specific type, one device that executes a software app locally involves no more significant risk than another device that executes the same software app on a cloud server.¹⁶ Compare, for example, an app that is designed to be executed on a smartphone with another version of the same app that is designed to be accessed and executed on a cloud server using the same smartphone. While the risks may be different, FDA does not believe that the risks are significantly greater in either of these situations.

3. Examples of Products and the Associated Risk Categories

As described above, risk assessment for a given mHealth product is dependent on a number of different factors. While it is difficult in this guidance document to evaluate risk for a specific product, the following are a number of examples that the Agency believes demonstrate varying degrees of risk. Examples of products that fall into the **low-risk category** based on these factors include:

- A software app intended to reduce the risk of heart disease by the promotion of exercise and/or a well-balanced diet through health coaching advice on a smartphone.
- A software app intended to reduce the risk of pregnancy-related disorders through the promotion of relaxation and stress management by playing soothing music on an MP3 player or radio.

¹⁵ For mHealth systems that communicate information directly to the consumer, assessment of data by a health care professional prior to provision of the information to the consumer may reduce the associated risk (e.g., by modifying the behavior of the consumer who might otherwise have taken different action associated with greater risk).

¹⁶ Other considerations (e.g., security and privacy) must be well-controlled.

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- A proprietary hardware device and software app intended to enable self-monitoring of personal health or vital statistics.

Examples of products that fall into the **moderate- or high-risk category** based on these factors include:

- An activity sensor device and software app intended to alert a health care professional of deviations from prescribed exercise activity using system-analyzed data.
- A software app with predictive algorithms intended for use as a weight management device to monitor congestive heart failure.
- A pill-bottle sensor intended to alert a health care professional of the delivery of medication or other therapy.

C. Risk Considerations for Exemption/Exclusion Criteria

Section V describes specific exemption/exclusion criteria for low-risk devices. Additional risk criteria for eligibility of the exemption/exclusion within this guidance document include:

1. The risk associated with a potential failure of the product should be sufficiently attenuated in time between the use of the product and the onset of the health-related condition such that failure of the product would not be considered to have an immediate or long-term, cumulative negative effect on the consumers' health; and
2. The product should not be used for life-sustaining purposes or to diagnose or treat an immediately life-threatening condition.

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V. Intended Use Claims

A. *Socially Beneficial, Low Risk (SBLR) Devices*

This section categorizes the types of claims associated with mHealth products with intended uses that technically fall within the definition of a medical device but that should not be regulated because their social benefit outweighs their inherent low risk. Regulation of SBLR devices would removed the potential benefit to public health that such devices will undoubtedly deliver. FDA believes that the claims associated with SBLR devices pertain to medical issues that are so well-resolved that inclusion in the product claim should be exempt from regulation because: 1) the claims serve as an essential and powerful educational tool for consumers to learn about the benefit of lifestyle and behavioral modification; 2) education is a proven method of effectively modifying human behavior; and 3) the nature of the SBLR claims will greatly improve public awareness and subsequent education on the benefits of proactively preserving health.

The purpose of this section is to establish criteria by which FDA would make a “not regulated” decision about a product with one of these types of intended uses. A “not regulated” decision can be achieved for products associated with at least two general categories of claims: 1) Impact Claims; and 2) Information Claims. These two categories of claims are not mutually exclusive of each other but depend on the type of claim being evaluated. For example, a product may be considered “not regulated” based on the associated impact claims, yet be “regulated” as a result of the associated information claims.

1. Impact Claims: Criteria for Exemption

Impact Claims include statements that suggest the product can: 1) “reduce the risk of” a particular disease or medical condition; or 2) “improve” or “maintain” a particular aspect of an individual’s health or medical condition. To be eligible for this exemption, the Impact Claim must meet each of the following:

1. The claim is a generally recognized health claim and not a disease claim;
2. The claim language is adequately qualified by *may*, *might*, or other similar language;
3. The mechanism by which the product functions to “reduce the risk of”, “improve”, or “maintain” the specified health-related condition does not involve invasive procedures.

Examples of Impact Claims include:

- “A software app that may reduce the risk of heart disease by actively monitoring and trending exercise activity on a daily basis.”
- “A cloud-based personal health storage system that may improve your quality of life by allowing friends and family to review your behavioral activities in order to support you in your effort to quit smoking.”

2. Information Claims: Criteria for Exemption

Information Claims, which include statements that suggest the product is designed to: 1) “collect” or “aggregate” diagnostic information; 2) “capture” or “detect” changes in an individual’s health or medical condition; or 3) “alert” or “notify” a consumer, patient, caregiver, or health care professional of a non-acute health or medical condition.

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To be eligible for this exemption, the Information Claim must meet each of the following:

- 2 1. The information collected or analyzed must be either:
 - 4 a) Medical data that are manually or electronically collected and entered or
 - 6 b) Wellness data;
- 6 2. The results of the function performed on the information must not be transferred to a medical device for further analysis or to control the medical device;
- 8 3. The monitoring and/or notification functions must be intended only for use by:
 - 8 a) A consumer or caregiver;
 - 10 b) A health care professional not acting in their professional capacity; or
 - 12 c) A health care professional performing record-keeping or non-acute monitoring activities; and
- 14 4. The condition that the product is intended to monitor and/or about which the product is intended to notify the consumer or caregiver must not warrant the involvement of a health care professional to actively monitor the person's medical condition.

16 The use of these data by a health care professional does not automatically exclude a product from this exemption. The determination depends on the manufacturer's claims as to the intended use of the data by a health care professional.

18 Examples of Information Claims include:

- 20 • "A sensor system and web-based software app to collect, monitor, and store sleep parameters (e.g., duration and frequency of REM and non-REM sleep, etc.) for review by a behavioral/health coach."
- 22 • "A sensor system and smartphone app for use by a school nurse to monitor and alert the user of allergens in the school cafeteria and/or air pollen/pollutants on the school playground."

24 *B. Ambiguously Defined, Low Risk (ADLR) Products*

26 FDA believes that certain wellness purposes fall outside of the definition of a medical device and, therefore, are excluded from (i.e., not subject to) regulation because either the product is not acting to diagnose, treat, or prevent or the associated wellness condition is not a disease. For products in the "gray zone", inherent risk should be considered.

30 The purpose of this section is to establish criteria by which FDA would make a regulatory decision about a product associated with one of these types of intended uses. To that end, this section categorizes the types of claims associated with products where it is unclear whether the intended uses fall within the definition of a medical device because of the ambiguity in the statutory language as applied to an mHealth product. The statutory definition of a medical device is "an **instrument**, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory that is **intended for use in the diagnosis . . . , treatment, or prevention of disease**, in man or

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other animals.”¹⁷ The task here is to resolve the ambiguity in the interpretation of the statutory definition. In the mHealth space, the ambiguity involves the terms *diagnosis, treatment, prevention, and disease*.

These ambiguities result from the use of general language as well as degrees of interpretation of specific terms used in the claims. Below is an example of several claims and the associated sources of ambiguity.

Table 3: Examples of Claims that Create Ambiguity in Regulatory Status

		Statutory Language	
		Diagnosis, Treatment, or Prevention	Disease
Claims Language	General Terms	To help manage your health	To improve heart health not associated with a diagnosed condition
	Specific Terms	To remind a patient to take medication or to complete some aspect of treatment (e.g., attend a doctor's appointment)	To allow patients to perform cognitive/audio/visual/motor/sensory challenges/games

To resolve these ambiguities, the decision-making process should consider risk associated with the intended uses and types of health-related conditions being targeted.

To be eligible for the ADLR exclusion, the intended use claim must not be a disease claim, as demonstrated by one of the following being true:

1. The condition for which the product is intended to be used is not a) specifically identifiable, or b) a specific disease recognized by the American Medical Association or similar medical professional organizations (e.g., general health, weight, pain/discomfort, stress, stress-related hair loss, etc.);
2. The intended use of the product targets behavioral activities (e.g., exercise, sleep, nutrition, relaxation, smoking cessation, play games, etc.) not generally associated with a specific disease; or
3. The product is intended for use by a caregiver and/or a consumer.

In addition, this exclusion requires that:

1. For products that involve a health care professional, the product must not be intended for real-time or daily monitoring purpose of behavioral activities that are specifically identified to diagnose, prevent, or treat a disease. An example of a product that would fall outside of this exclusion is a product intended to allow a health care professional to monitor daily exercise activity of a patient being treated for morbid obesity.

¹⁷ Food, Drug, and Cosmetic Act, § 201(h), 21 U.S.C. § 321(h) (emphasis added).

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2 2. For products that involve the exchange or display of patient health information, the product
must not be intended for review by a health care professional as a means of diagnosing,
treating, or preventing a disease or medical condition.

4 Health claims for products that are eligible for exclusion may include certain terms that distinguish the
intended use from that of a disease claim, such as those listed in Figure 2.

6 **Figure 2:** Example “Health” Terms that Should Not Automatically Trigger FDA Regulation¹⁸

• Health, wellness or well-being	• Stress or stress management
• Satisfaction or happiness	• Hospitalization
• Heart health	• Challenge or game
• General health	• Personal use
• Overall health	• Non-diagnostic-quality
• Unhealthy	• Sleep deprivation

Examples of ADLR claims include:

- 8 • “A tablet and web-based software app that provides mind challenging games and tracks
scores and other parameters for review by a life coach for the elderly.”
- 10 • “A SMS text system that provides daily motivational tips to reduce stress and promote a
positive mental outlook.”

12 C. *Decision-Making Process*

14 This section describes the process that FDA recommends in order to decide whether a particular mHealth
product is regulated based on its intended use claims. The process results in a determination that a
product, based on the intended use claims, either is regulated or not regulated by FDA. If regulated, FDA
16 intends to indicate to what extent the product is regulated based on existing classifications.

18 The two categories of products require separate decision-making processes. The existing 513(g) process
can resolve the ADLR Product claims because the existing process allows FDA to make a determination
as to whether the product is a medical device based on information provided by the manufacturer. The
20 existing 513(g) process does not help to resolve the SBLR Device claims because 1) the information
collected in the process is not sufficient to making the kind of judgment that needs to be made, and 2)
22 these claims technically meet the literal definition of a medical devices and, therefore, the result of the
513(g) determination would always be that the product is regulated. FDA must be able to exercise
24 enforcement discretion for those claims that pose little risk and for which it is in the public interest to not
regulate. The additional information required to convert 513(g) into a process that covers SBLR Device
26 claims will likely overburden the process, making review of ADLR Product claims more difficult.

¹⁸ This list is not exhaustive; instead, these are examples to demonstrate the general principle that references to general health or personal wellness do not per se constitute disease claims.

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1. Review of ADLR Product Claims

FDA will generally use the 513(g) process to resolve ADLR Product claims because the existing process results in determination as to whether the product, based on the information provided, is a medical device subject to agency regulation. If the product is determined to be a medical device subject to regulation, FDA will generally provide the following information consist with the current 513(g) process:

1. The generic type of device (e.g., classification regulation) (if any) that applies;
2. The Class within that generic type of device (and if more than one Class within that generic type, the particular Class that applies);
3. Whether a guidance document has been issued regarding the exercise of enforcement discretion over the particular Class of devices within that generic type; and
4. Whether additional requirements apply.¹⁹

2. Review of SBLR Device Claims

FDA will generally use its authority to make product-specific determinations regarding enforcement discretion. Enforcement discretion should be based on the criteria established above and, therefore, should be based on evidence that the product meets these criteria. In addition, risk may be determined based on a "primary mode of action" approach, whereby the significance of the wellness or non-medical purposes of the product weighs in favor of enforcement discretion for products that do not clearly meet the criteria above but are sufficiently low risk to warrant the exercise of enforcement discretion.

The manufacturer should submit specific information, including:

1. A product description and concise summary of the product's uses;
2. Samples of proposed marketing materials (e.g., instructions and other reference guides);
3. Evidence that the appropriate criteria are met; and
4. A recommended determination.

FDA will generally issue a confidential letter to the manufacturer within 60 days of receipt of the request for determination.

¹⁹ CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICAL EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF: FDA AND INDUSTRY PROCEDURES FOR SECTION 513(G) REQUESTS FOR INFORMATION UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 4 (2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209851.pdf>.

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VI. Accessories

2 In the future, everything that produces or receives medical device data, whether therapeutic or
4 diagnostic, is likely to be connected to a network. So, for example, a blood glucose meter will be
6 connected to a cell phone, which will connect to a cell tower, which will connect to a local area network,
which will connect to a server, which will dump data in an EMR, which a physician will view on a tablet
or smartphone.

8 Historically, the “accessory rule” has been thought of as an overarching rule, broadly applicable to
nearly all so-called *parent device-accessory* connections. Under that rule, in certain situations, FDA
10 regulates a product that is an “accessory” to a medical device as if in the *same regulatory classification*
as the “parent” medical device. The theory has been simply: if an accessory malfunctions, the risk to the
12 patient would be the same as if the parent medical device malfunctioned. So, for a modern example,
take an EMR that is indirectly connected to a blood glucose meter by way of three other low risk Class I
14 medical devices that are interconnected and passing data among one another. If one of those devices
ultimately connects to the glucose meter, the EMR receiving data from the Class II blood glucose meter
16 would receive a Class II designation—as would the other medical devices in this example. This results
in regulatory excess, as harmless widgets would obtain the highest regulatory scrutiny just because they
utilize data from a medical device with a higher classification.

18 The developing mHealth industry has raised significant questions about the scope of the accessory rule,
due to the inherent interconnectedness of mHealth products. These questions are likely to become more
20 complicated, as many products will be marketed in the future with broad system claims, rather than one-
to-one pairing claims. This section describes FDA’s current thinking on the regulation of traditional
22 accessories in an mHealth system.

A. Policy Overview

24 Instead of deriving the regulatory classification from the data-generating parent device, FDA proposes a
different conceptual approach, with two key prongs:

- 26 1. FDA intends to publish classification regulations for commonly used accessories. Much like
28 with FDA’s recent MDDS rule, the purpose here would be to establish more appropriate,
risk-based classifications specific to the accessories that make up the various “families”
30 within the family tree of connected products. The specific classification that defines a
generic family of accessories should trump any classification derived from the data generator
within a given tree.
- 32 2. FDA intends to regulate claims of compatibility between accessories in a family and the data-
generating medical devices (traditionally treated as *parent* devices) by requiring that the firm
34 making the claim provide adequate support to underpin the claim. If the device made by the
manufacturer making the claim is Class II or III, the claim substantiation would need to be
36 included in the submission to FDA. The manufacturer making the compatibility claim will
also need to have some assurance that the claim will remain true (e.g., by agreements
38 between manufacturers, through its quality system, or by compliance with key standards).

The following sections describe this proposed policy in more detail.

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B. Regulation of Accessory Devices in an mHealth System

2 Under the traditional accessory rule, in certain situations, FDA regulates an *accessory* as if in the same
4 regulatory classification as the *parent device*. As described above, the Agency is modifying its policy to
the regulation of accessories. The fundamental concept is that the accessory rule applies if and only if
there is not an existing classification for the device in question.

6 The first step for determining whether a product is subject to the accessory rule is to consider whether the
8 product is a device at all based on the product's intended use. If it is not, the analysis ends because the
accessory rule does not apply. If the product is a device, the next question is whether it meets an existing
10 classification regulation based on its intended use.²⁰ If a device falls within an existing classification
regulations, then the device will be subject to that classification and the relevant controls contained within
12 the applicable section of the CFR.²¹ To meet the definition of the classification regulation, the design and
intended use of the device must not exceed the boundaries of the generic product type, including any
applicable limitations (e.g., 8xx.9 regulations).

14 For those classification regulations that are exempt from 510(k) requirements, an mHealth device will
remain exempt if the device:

- 16 1. Has existing or reasonably foreseeable characteristics of other devices in the classification
category; and
- 18 2. Has the same intended use and fundamental scientific technology as another device in the
classification category.

20 An mHealth device associated with an in vitro diagnostic device is subject to additional exemption
22 limitations under the 8xx.9 regulations. In addition to the requirements above, an mHealth device of this
type will remain in its existing classification regulation and exempt from 510(k) requirements if: 1) the
24 device is a low-risk device as determined under the risk model described in Section IV of this proposed
guidance document; and 2) the device does not change the risk profile of the associated in vitro diagnostic
device.

²⁰ 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). The classification and descriptions of device types are organized by medical specialty panels in 21 CFR Parts 862 through 892.

²¹ 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 specified device classification, even if that device happens to be an accessory or compatible with other devices. The medical device data systems (MDDS) Final Rule recognizes this fundamental principle of FDA regulation:

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.

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>.

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

1. For assessing the risk of cardiovascular disease;
- 4 2. For use in diabetes management;
3. For identifying or inferring the identity of a microorganism directly from clinical material; or
- 6 4. For near-patient testing (point of care).

8 FDA intends to use the 8xx.9 limitations judiciously and not to exclude a product from a classification regulation simply because that product connects to another medical device in an mHealth system or the product at issue has different characteristics than other devices. 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.²²

14 If the device does not fit within an existing classification, the device manufacturer may avoid the accessory rule by requesting that FDA determine the device classification through the *de novo* review process. The *de novo* review process is an opportunity for a device automatically designated as Class III to be reclassified as a Class I or II device, if appropriate.²³ Applicants should support their *de novo* submission by a risk assessment that demonstrates the lower risk profile of the device.²⁴ FDA or any stakeholder may also employ any other available route to reclassification.

20 If the device manufacturer does not pursue the *de novo* review process (or any other form of reclassification) and the device is intended to be used with another medical device in an mHealth system, the device becomes an accessory and takes on that device classification of the other medical device.²⁵

22 If the device is not intended to be used with another medical device in an mHealth system, the device is not an accessory and, instead, will be automatically subject to a premarket approval submission as a Class III device.²⁶ Figure 3 summarizes this analysis.

²² Appendix A of this document lists current regulatory classifications that are useful for mHealth accessories. Appendix B suggests classifications that FDA should consider for future development.

²³ A device manufacturer may petition FDA to regulate the device as a Class I or II medical device independent of the other products in the mHealth system. The *de novo* process, established in § 513(f)(2) of the Federal Food Drug & Cosmetic Act, is particularly appropriate for low risk devices. The *de novo* process will be useful for mHealth devices 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 devices.

²⁴ 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.

²⁵ Inherent in this analysis is the assumption that the device is a finished product rather than a *component* to another finished product. The difference between an accessory and a component is important because it determines the applicable regulatory requirements for a particular product. Components are exempt from most FDA regulatory requirements, with the regulatory burdens being borne by the finished device manufacturer. 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.

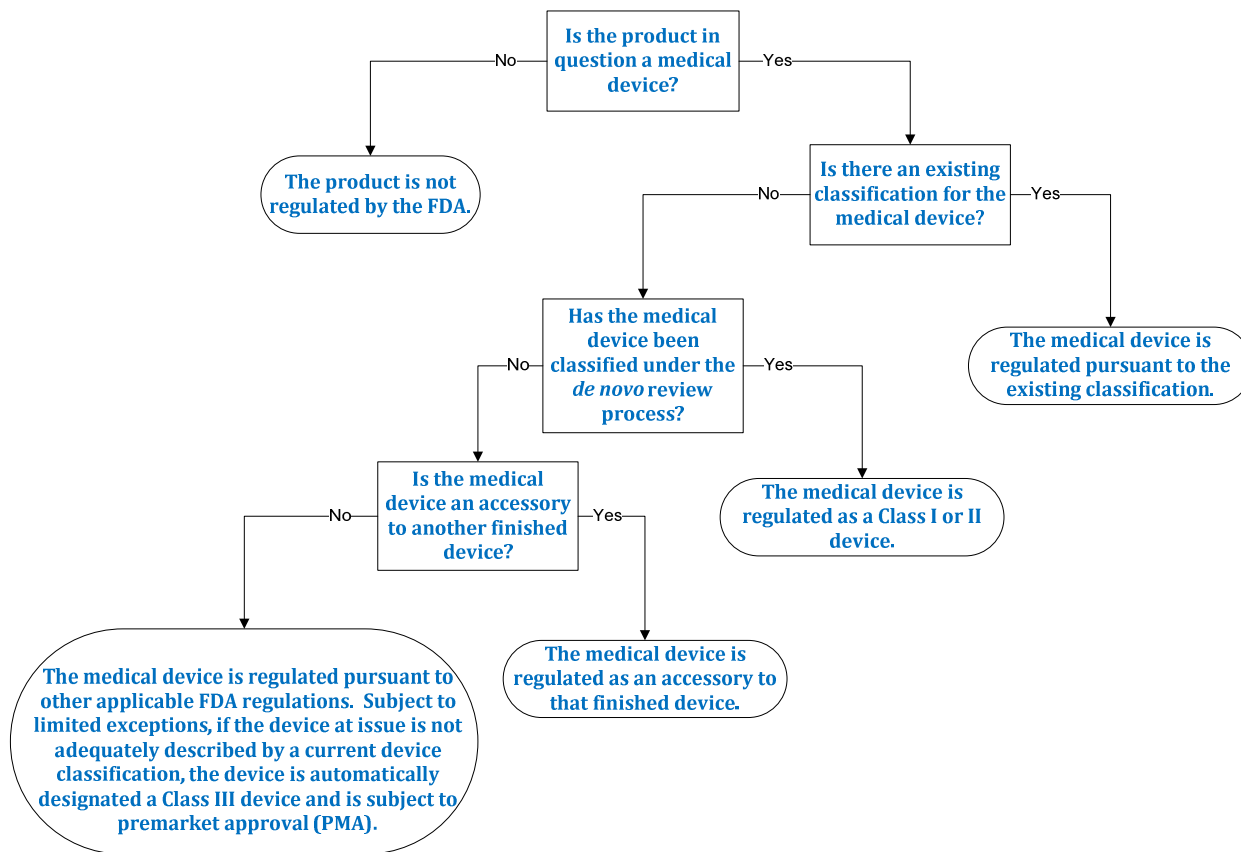
²⁶ Appendix C describes other considerations that may impact this analysis.

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Figure 3: Framework for Regulation of Accessories in an mHealth System



2

C. Claims of Compatibility

4 A claim of compatibility between two medical devices in an mHealth system does not render a parent
 6 device-accessory relationship between the two products. The analysis described above determines
 whether a device is an accessory. The claim of compatibility, however, must be substantiated through
 adequate validation.

8 Take, for example, a weight scale that claims compatibility with a specific brand of blood glucose meters.
 10 The scale is not regulated as an accessory to the blood glucose meter because the scale has its own
 classification.²⁷ However, the manufacturer of the scale must validate its claims of compatibility with the
 12 blood glucose meter. If the manufacturer of the blood glucose meter claims compatibility with the scale,
 the manufacturer must validate that its blood glucose meter is compatible with the scale. The burden lies
 14 on the manufacturer making the claim of compatibility to substantiate the claim through adequate
 validation.

16 FDA should also consider using a feasibility test to determine the significance of the validation. If it is
 feasible for the manufacturer (at the time the product is created) to self-assess the product as a low-risk

²⁷ The scale is regulated as a Class I device under 21 C.F.R. § 880.2700. The blood glucose meter is regulated as a Class II device under 21 C.F.R. § 862.1345.

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device, the validation requirements should be minimal.

- 2 Claims of compatibility should be substantiated to demonstrate that the associated risk is recognized and
minimized. Even though a lower-class device is not up-regulated, the claim substantiation process
4 ensures the risk associated with the two products is low. Claim substantiation is separate and apart from
the determination of whether a device is an accessory or its appropriate classification.
- 6 Claim substantiation requires both present and future validation by the claim maker.²⁸ Present
substantiation consists of validation testing to ensure that the claim of compatibility is accurate and to
8 clarify the design specifications that support the claim. Future substantiation consists of the establishment
of a quality system and on-going validation testing whenever changes to either article are made. This
10 may involve either control of the design of both devices (e.g., by ownership) or an agreement between
the claim maker and the manufacturer of the product that design specifications will not change or that
12 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. In the absence of such an agreement,
14 the claim maker would need to assess the risk to show that an agreement is not necessary.

²⁸ Some types of device relationships trigger additional regulatory obligations. Appendix D describes three scenarios that demonstrate the degrees of regulatory obligations that may arise.

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VII. Software

2 Software is of particular importance to mHealth technologies because the data collected by sensors,
4 wireless medical devices, and other physical products—most of which have their own internal software—
6 are being stored, analyzed, and routed by software apps. It is common in mHealth systems that these
functions are conducted remotely across interconnected networks via local networks and the Internet. As
with any other product, FDA regulates software if an app meets the definition of a medical device.

8 Software in the mHealth world can come in all shapes and sizes and can perform a variety of functions.
Although software is purely non-physical, association with a tangible piece of hardware is required at
10 some point throughout the web of interconnected hardware technology comprising the mHealth system.
Software can be found in any of the following mHealth system components:

1. Medical devices;
- 12 2. Patient-centered communications technologies;
3. Provider-centered communications technologies;
- 14 4. Intermediary-centered communications technologies; and
5. Network infrastructure technologies.

16 Software in a medical device can come in two forms: the first is called *firmware*, while the second uses
the generic *software* term. Software also can be found outside of the medical device and at any point
18 along the information pathway from the patient to the health care professional.

20 Patient-centered communications technologies (e.g., a personal computer, smartphone, tablet, or
proprietary communications device) can utilize software to perform analytical tasks or to control the
transmission of patient data.

22 Provider- and intermediary-centered communications technologies may be any of the same types of
communications technologies used by the patient but instead are used by a health care professional or a
24 third-party intermediary. These technologies can employ any of the types of software that are designed
for patient use. The software also could be used for the same or different purposes as the patient-centered
26 devices.

28 The network infrastructure of an mHealth system can include any number of servers, mainframe
computers, data storage devices, wireless routers, and telephone service switches, among other things.
These products are distinct from the patient-, provider-, and intermediary-centered communications
30 technologies in that the network infrastructure technologies function independently of the other
technologies and require no involvement from the patient, clinician, or intermediary. Software that
32 resides on these components may or may not be specific to the mHealth system.

34 The software, however, need not “reside” on a network infrastructure component in the way that software
is traditionally downloaded onto a computer. Cloud computing, which is becoming more common in the
consumer marketplace as well as the mHealth sphere, distributes software algorithms and functionality
36 over a number of different networked hardware components. The fluidity of this type of software system
is technically powerful, promoting advanced algorithmic capabilities but makes identifying where the
38 software “resides” increasingly difficult. Similarly, aspects of software that once were bundled in a

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specific software program are now being “outsourced” across the Internet to various developers who provide “software services”. These software services perform standard functions (e.g., a search or payment function) across the network infrastructure and separate from any specific mHealth component.

A. *General Approach to Software Regulation*

Software is treated in the same way that other products are treated for purposes of determining whether and how FDA would regulate. Any software that does not meet the definition of a medical device is not regulated by FDA. Therefore, to be considered for regulation, the software product must be intended by the manufacturer for use in the diagnosis, treatment, or prevention of disease according to 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).²⁹ Refer to Section V of this guidance document for further discussion of the intended use analysis for mHealth products.

Any software device that falls into an existing classification regulation should be subject to the regulatory requirements established in that classification regulation. If no classification regulation exists, the software device may be evaluated under the de novo review process for classification purposes.³⁰

Any software device that meets the definition of an accessory should be regulated based on the accessory framework described in Section VI of this guidance document. Software apps that are intended to be purchased by a manufacturer of the finished device in which the product will be incorporated should be treated as components. The software manufacturer of a component software app should not be regulated by FDA unless the app is sold as a reusable software module or to an end user as a replacement part.

The manufacturer of a finished software device, however, should be subject to regulation appropriate for the finished device. Any software device that is not an accessory or a component and that is not adequately described by an existing classification regulation or has not been evaluated under the de novo review process should be a Class III device subject to premarket approval requirements.

A software manufacturer must comply with all applicable regulations, including the Quality System Regulations (21 C.F.R. Part 820), premarket notification/approval submissions, establishment registration, and product listing, as are appropriate for the designated device classification.³¹

²⁹ Products that are built with or consist of hardware and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&C Act. That provision defines a device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent . . .” that is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . or . . . intended to affect the structure or any function of the body of man or other animals . . .” 21 U.S.C. § 321(h). Thus, software applications that run on a desktop computer, laptop computer, remotely on a website or “cloud,” or on a handheld computer may be subject to device regulation if they are intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man. The level of regulatory control necessary to assure safety and effectiveness varies based upon the risk the device presents to public health.

³⁰ Appendix A lists the current classification regulations and associated product codes that may apply to software in an mHealth system. Appendix B presents a number of proposed classification regulations that should be implemented to adequately address regulation of mHealth software.

³¹ Software that is manufactured outside of the United States is subject to FDA regulation if the manufacturer intends for its product to be marketed in the United States.

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B. Unregulated mHealth Software

2 Software that fall into the ADLR Product exclusion do not meet the definition of a medical device and are
not subject to FDA regulation. See Section V.B for a description of the ADLR Product exclusion.
4 Examples of ADLR Products include:

- 6 • Software that alerts a caregiver of a low-risk health event because the product does not
diagnose, treat, or prevent a specifically identifiable disease or medical condition and is
intended for use by a caregiver.
- 8 • Software that facilitates the monitoring of behavioral activities or basic health information
10 (e.g., food consumption, weight trends) to evaluate general wellness of an individual because
the product does not diagnose, treat, or prevent a specifically identifiable disease or medical
12 condition and is intended to target behavioral activities not generally associated with a
specific disease or medical condition.
- 14 • Software that helps a consumer manage personal health information because the product does
not diagnose, treat, or prevent a specifically identifiable disease or medical condition.

16 FDA believes that there are a number of software devices for which the associated risk is sufficiently low
that regulation is not warranted. At this time, FDA is choosing to exercise its enforcement discretion for
these software devices that are part of an mHealth system. FDA reserves the right to reevaluate any
18 enforcement discretion decision.

20 Software devices that meet the SBLR Device exemption (described in Section V.A) or that have any of
the following functions fall into this unregulated category:

- Automates a function for ease-of-use;
- 22 • Performs library functions;
- Stores or transmits personal health information in EMR, EHR, or PHR systems;³²
- 24 • Analyzes for non-diagnostic purposes personal health information stored in an EMR (or other
similar EHR or PHR system); or
- 26 • Performs general IT functions³³ or business functions (i.e., general purpose articles).

³² FDA is currently exercising its enforcement discretion, but is considering several possible approaches to
regulation of EMRs, including:

- 1) Focusing on post-market safety by requiring HIT device establishments to electronically
register and list their HIT devices, and to submit Medical Device Reports (MDRs) to the FDA;
- 2) Focusing on manufacturing quality and post-market safety by requiring HIT device
manufacturers to comply with the above requirements and also to adhere to FDA's Quality
Systems Regulation (QSR); and
- 3) Applying the traditional regulatory framework, in which HIT device manufacturers would be
required to meet all the same regulatory requirements as other, more traditional devices, including
risk-based premarket review.

Testimony of Jeff Shuren, Director of Ctr. for Devices & Radiological Health, U.S. Food & Drug Admin., before the
Adoption/Certification Workgroup of the HIT Policy Committee (Feb. 25, 2010), *available at*
http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_910717_0_0_18/3Shuren_Testimony022510.pdf
f.

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2 The intended use and design functions of these software devices must not exceed the functional limits described here. Examples of software devices that should remain unregulated at this time include:

- 4 • Software that sends notifications to a patient to take a pill or to remind them to visit their health care professional because such software automates a function of the health care professional or caregiver for ease-of-use.
- 6 • Software that prompts the consumer to answer pre-determined, health-related questions because such software performs library functions typically associated with the activities of a health care professional or caregiver. Similarly, software that transmits this information to a health care professional or caregiver in a report is unregulated because such software automates the report-writing and record-keeping function of a health care professional or caregiver for ease-of-use. The location where the software executes or is used (i.e., on a device in the consumer's home or a health care professional's office, on a third-party cloud server) does not affect the regulatory status.
- 10 • Software that stores or transmits personal health information (e.g., EMR, EHR, or PHR software) even if automatically obtained from a Class I medical device (e.g., data obtained from an electronic blood pressure cuff). More specifically, EMR software that stores or transmits (e.g., to another EMR software system) personal health information (including data from a Class I device, e.g., blood pressure measurements) is unregulated such that once the information enters the EMR software, it can be stored and transmitted freely throughout the EMR system and to other EMR systems without triggering FDA regulation. Similarly, software that allows an individual to manually enter personal health information (including medical device data) is unregulated.
- 14 • Software that calculates and graphically displays trends in personal health incidents (e.g., hospitalization rates or alert notification rates). Similarly, software that generates a report based on data stored in an EMR, EHR, or PHR system is unregulated.
- 16 • Software that controls the equipment used to communicate health-related information from one location to another because such software performs general IT functions.
- 18 • Software that allows a "face-to-face" high-definition (HD) video conversation with a health care professional if marketed as a general purpose IT product.
- 20 • Software that monitors a consumer's use of the mHealth system for billing purposes because such software performs a general business function.
- 22
- 24
- 26
- 28
- 30

32 As with any product, software that does not meet the definition of a medical device is not regulated as a software device. Examples of products that do not meet the definition of a medical device and could be easily confused with regulated software devices include:

- 34 • Software that stores, analyzes, and transmits calorie consumption and/or exercise activity for personal use.
- 36

³³ This exemption applies to a general purpose IT product that is used in an mHealth system and that is not altered or reconfigured outside of its manufactured specifications. Modifications within the off-the-shelf parameters of operation are still considered exempt.

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- Software that provides educational information related to medical diseases or conditions.
- 2 • Software that provides educational information, advice, or motivational guidance related to behavioral activities that may be associated with a medical disease or condition (e.g., to help
4 quit smoking or to improve medication compliance).
- 6 • Software that allows “face-to-face” HD video conversations (or other means of communication, e.g., instant messenger, email, SMS text, etc.) between a consumer and a caregiver.
- 8 • Software that allows a patient or health care professional to manage administrative activities associated with the delivery of health care (e.g., electronic appointment scheduling,
10 prescription writing/filling, billing, etc.).
- Software that allows a consumer to play “mind challenging” games.
- 12 • General communication software that are used for telecommunications purposes to transmit data in an mHealth system and that comply with applicable standards for such products.
14 These include wireless routers, modems, switches, Bluetooth transmitters/receivers, cables, connectors, adaptors, and any other similar product used for connectivity purposes. This also
16 includes software drivers and accessories associated with the basic functionality of these devices.
- 18 • General purpose health applications that are used in an mHealth system to electronically collect, store, transmit, display, or analyze (e.g., trend, aggregate, or generate reports) health-
20 related data for educational purposes or as a tool to affect normal behavioral activity (e.g., food consumption or exercise activity). An example of a general purpose health application
22 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
24 purposes.

C. *Class I Exempt mHealth Software*

26 FDA believes that certain software devices have sufficient risk associated with their intended use that enforcement discretion is inappropriate; however, there also exist a number of software devices for which
28 general controls will adequately address the associated risk. FDA intends to regulate these software devices as Class I devices exempt from premarket notification requirements.

30 Software devices that meet any of the following should be Class I exempt from premarket notification:

1. Firmware associated with a Class I exempt medical device;
- 32 2. Software that fall into an existing Class I exempt regulation (e.g., medical device data systems (MDDS) under 21 CFR § 880.6310, laboratory information systems (LIS) under
34 § 862.2100, or medical image management systems (MIMS) under §§ 892.2010 and 892.2020) and that do not fall within the 8xx.9 limitations on exemption); or
- 36 3. Low-risk software that do not meet the SBLR Device exemption or ADLR Product exclusion criteria.

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D. Class II or III mHealth Software

2 FDA believes that, for a number of software devices, the associated risk requires additional regulatory
4 controls to ensure safety and effectiveness of the devices. These software devices are regulated as Class
II or III devices.

6 FDA applies its long-standing Level of Concern and inherent risk analysis to determine the appropriate
regulatory controls for the following:

- Firmware associated with a Class II or III medical device; and
- 8 • Software that fall into an existing Class II or III regulation as a stand-alone product, a
component, or an accessory; and
- 10 • Software that does not fall into an existing classification but involves moderate to high risk.

12 The Level of Concern analysis focuses on the severity of an injury. The categories in which a given
software device can fall is as described in Figure 4.

Figure 4: Definitions of Level of Concern for Software Risk Assessment

Level of Concern	Major: The software directly affects the patient or anyone else such that a failure could result in death or serious injury.
	Moderate: The injuries would be non-serious.
	Minor: Failures would not be expected to result in any injury.

14 The Level of Concern analysis is independent of the device classification determination and is used to
16 establish the depth and degree of hazard analysis and mitigation that is expected, the depth and degree of
documentation, what needs to be submitted as opposed to simply documented, the rigor applied to the
18 verification and validation of the software, and the degree to which the device manufacturer's software
development process is scrutinized.³⁴

20 Generally, the inherent risk analysis involves the likelihood and severity of an injury occurring. The
association between inherent risk and the intended use forms the basis of the total risk. For software,
22 however, FDA believes the focus should be on the severity of harm because likelihood of risk related to
software cannot easily be estimated.³⁵

³⁴ CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., *supra* note 10.

³⁵ CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, FDA REVIEWERS, AND COMPLIANCE ON OFF-THE-SHELF SOFTWARE USE IN MEDICAL DEVICES 2 (1999), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf>; CTR. FOR DEVICES & RADIOLOGICAL HEALTH & CTR. FOR BIOLOGICS EVALUATION & RESEARCH, *supra* note 10, at 17.

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E. Categories of mHealth Software

2 At a high-level, mHealth software can be broken into the following three product types:

1. Hardware drivers and software accessories;
- 4 2. Communication device apps; and
3. Stand-alone and web apps.

6 For each of the product types, a software product can fall into any of the following classification
8 categories: Class II or III; Class I (exempt from premarket notification); or unregulated software. The
following describes each of the product types in more detail with examples of software and their
associated classification category.

10 1. Hardware Drivers and Software Accessories

12 Generally, software that fall into this product type includes firmware or other device controllers (e.g.,
operating systems). Class II or III devices that fall into this product type include:

- Firmware for a Class II or III device (e.g., blood glucose meter or pacemaker);
- 14 • Software that sends signals to a Class II or III device to control device operation (e.g.,
establishing a set-point for a control parameter or “waking up” the device).

16 Devices that are Class I exempt from premarket notification and that fall into this product type include:

- Firmware for a Class I device (e.g., MDDS or weight scale);
- 18 • Software that sends signals to a Class I device to control device operation (e.g., establishing a
set-point for a control parameter or “waking up” the device).

20 Unregulated software products that fall into this category include general purpose device operating
systems.

22 2. Communication Device Apps

24 Generally, software that fall into this product type receives and/or transmits data (e.g., a smartphone app).
Class II or III devices that fall into this product type include a smartphone app that is intended:

- 26 • To alert a health care professional or emergency service of a moderate- or high-risk medical
event;
- To facilitate real-time diagnosis or treatment; or
- 28 • To facilitate monitoring patient activity associated with a moderate- or high-risk disease.

Devices that are Class I exempt from premarket notification and that fall into this product type include:

- 30 • MDDS software (21 CFR § 880.6310);
- MIMS communication software (21 CFR. § 892.2020);

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- A smartphone app intended to alert a health care professional of a low-risk medical event or to facilitate monitoring patient activity associated with a lower-risk disease.

Unregulated software products that fall into this category include:

- A smartphone app intended to alert a caregiver of a low-risk health event, or to facilitate monitoring activity to evaluate general wellness.
- Apps that perform general IT functions (e.g., e-mail or SMS text messaging).

3. Stand-Alone and Web Apps

Generally, software that fall into this product type perform data analysis (e.g., for professional decision support or personal health management). Class II or III devices that fall into this product type include PC, smartphone-, or web-based apps intended:

- To analyze patient data for medical diagnosis or treatment;
- To allow a health care professional to monitor Class II or III device data or patient activity for diagnosis or treatment of a moderate- or high risk-disease; or
- To track and report activity for treatment of a moderate- or high-risk disease.

Devices that are Class I exempt from premarket notification and that fall into this product type include PC-, smartphone-, or web-based apps intended:

- To allow a health care professional to monitor Class I device data or patient activity for diagnosis or treatment of a low-risk disease; or
- To track and report activity for treatment of a low-risk disease.

Unregulated software products that fall into this category include PC-, smartphone-, or web-based app intended:

- To manage personal health information;
- To track, display, or report basic health information (e.g., daily/monthly exercise activity, food consumption, weight trends, etc.) to evaluate general wellness;
- To automate manual office and/or record-keeping functions (e.g., EHRs).

F. *Other Considerations*

1. Software Modularization and Reusable Software

It is possible—in fact, quite probable—that a single software product may involve functionality that places it in more than one of these product types. Under the current regulatory approach, in the event that a software product involves different product types and classification categories, the highest classification would apply. Alternatively, the software manufacturer may choose to separate these functionalities so that a single product type is applicable. To achieve this modularization, each software functionality should be marketed as separate products with the specific intended use described in one of the product types and associated classification categories. As yet another alternative, the software manufacturer may

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2 choose to separate the software app such that specific modules that fall into a lower classification or that
are unregulated and unaffected by functionalities that fall into a higher classification.

4 While the traditional boundaries for software development are currently being broken, FDA recognizes
that software the mHealth system of the future may involve modules develop from a variety of sources
and based on novel architectures. In that way, the software would be much like a system of software that
6 comprises a larger software product.³⁶ For example, a software product may be composed of multiple
modules that are created by various manufacturers and that span a range of device classifications.
8 Alternatively, the manufacturers may choose to independently market only specific modules rather than
the entire app. These software units and subunits should be regulated based on the principles outlined in
10 this guidance.³⁷

12 When manufacturers employ the various software architecture standards described below, modules can be
regulated independently from the rest of the app, so long as the module fits squarely within an existing
classification.³⁸ FDA encourages the use of standard software design principles in the development of
14 mHealth software and system architectures. Use of standard design principles reduces inherent risk and
enables modularization of discrete functions within a software app (i.e., software modules) as well as
16 within an mHealth system that involves more than one hardware or software element. FDA believes the
use of software modularization principles will ensure that the entire product is not subject to unnecessary
18 regulation.

a) Example of App-level Modularization

20 An MDDS device is an example of how data can be transmitted from one software app to another without
affecting the regulatory status of either software app. Assume for this example that App A collects
22 medical device data within a blood pressure cuff. App A transmits the blood pressure data to a separate
software app (App B). App A is regulated based on its intended use (i.e., Class II under 21 C.F.R.
24 § 870.1120), while App B is regulated as a Class I exempt MDDS device (assuming for the sake of this
example that App B fits squarely within the MDDS rule). Even though Apps A & B communicate and
26 share information with each other, each is regulated independently. Use of standard design principles
should ensure the inherent risk associated with each app and with the communication between each app is
28 minimized. Apps A & B in this example need not be separate products. At a minimum, there should be
separation in the software architecture such that the functions are independent (see example below).

³⁶ The Agency recognizes that the term *app* may become obsolete over time. Nonetheless, the principles established in this guidance document should still apply.

³⁷ While portions of this guidance specify regulation at the app-level, the principles apply to any unit, subunit, or system of units. For example, while this guidance describes modularization at an app and sub-app level, the principles nonetheless apply to at the level of a system of apps or any other unit or subunit.

³⁸ The FAA regulates *reusable software*, allowing for reuse of software such as a Global Positioning System (GPS). The FAA has used this approach in all types of aviation systems, including the highest risk classification. See FED. AVIATION ADMIN., U.S. DEP'T OF TRANSP., FAA ORDER 8110.49: SOFTWARE APPROVAL GUIDELINES 75–78 (2003), available at [http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgOrders.nsf/0/640711b7b75dd3d486256d3c006f034f/\\$FILE/Order8110.49.pdf](http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgOrders.nsf/0/640711b7b75dd3d486256d3c006f034f/$FILE/Order8110.49.pdf). According to FAA, if properly planned and packaged, software life cycle data (including software code) can be reused from one project to the next, with minimal rework. *Id.* at 75. For example, the software plans, requirements, design, and other software life cycle data may be approved on the original project and reused on subsequent projects. *Id.* By following similar planning and packaging methods, FDA can allow mHealth systems to reuse software modules that fit squarely within an existing classification and avoid unnecessary regulation of the entire mHealth system under the reusable module's classification.

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2 The principle presented in this example should not be limited to MDDS devices. App B in this example
3 could be replaced with other Class I devices or unregulated devices. The software modularization
4 principle remains the same. It is important to note the distinction between firmware and software in
5 relation to this principle. Firmware is the code that controls the basic functionality of a traditional medical
6 device (e.g., controlling the timing of a pacemaker). The software modularization principle is not
7 intended to apply to firmware. Instead, this principle applies to software used, for example, in mobile
8 apps or a store-and-forward system that involves back-end software for use by a health care professional
or some third-party intermediary.

b) Example of Module-level Modularization

10 Now consider a single software app that is designed using multiple software modules to perform discrete
11 functions within the app. Module A receives and stores medical device data transmitted from a Class II
12 blood pressure cuff. For the sake of this example, assume that Module A fits squarely within the Class I
13 MDDS regulation. Module B compiles the blood pressure data into a trend graph and displays the trend
14 upon request. If appropriate software design principles are employed in the development of the software
15 app (including Modules A & B), the risk that Module B will influence Module A should be low, such that
16 Module A should be regulated under the MDDS classification regardless of the fact that Module A is
17 packaged in a software app that also includes non-MDDS functions in Module B. Module B should be
18 regulated based on the risk associated with its functionality and intended use.

c) Approaches to Software Modularization

20 A variety of approaches can be used to achieve modularization of software such that 1) a single software
21 app, comprised of software modules created by one or more manufacturers, can be separated into distinct
22 device classifications based on the intended use of the discrete modules within the software app and 2) a
23 single software app can be separated from other software apps not associated with the mHealth
24 functionality (e.g., other software apps on a smartphone that perform non-medical functions and that are
not intended to influence the mHealth system). These approaches include the use of:

- 26 1. Library standards (e.g., DLLs or COMs);
- 27 2. Privileged sections of controlled execution environments (e.g., for memory, task managing,
28 etc.);
- 29 3. Other object-oriented programming approaches, including information hiding (i.e., protecting
30 software components from external entities), decoupling (i.e., ensuring two separate software
31 components are not tightly dependent on each other), and encapsulation (i.e., hiding inner
32 workings of software component behind the public interface);
- 33 4. Harmonized standards for medical devices (e.g., IEC 62304 – for medical device software;
34 IEC 60601 – for medical electrical equipment; IEC 61010-1 – for safety requirements for
35 electrical equipment for measurement, control, and laboratory use; ISO 13485 – for medical
36 device quality management systems; and ISO 14971 – for medical device risk management);
and
- 37 5. Defensive programming techniques (e.g., input/output validation, error handling, memory
38 management, and data management).

40 When using these approaches, the manufacturer(s) should, at a minimum, design the module such that it
does not affect other modules within the app/system, create reusable modules for use across all intended

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systems, and validate and verify the modules' performance in key scenarios.³⁹

2 d) Environmental Considerations

4 FDA recognizes that the use of a software app on a platform (e.g., a smartphone) alongside other software
6 apps that are not intended to function with the mHealth system involves some additional inherent risk that
8 platform-based functions (e.g., communication protocols) may become affected by the non-medical app. FDA believes, however, that using standard software design principles for the mHealth app with standard off-the-shelf (OTS) platforms (e.g., smartphones, tablets, etc.) minimizes this risk. Compliance with ISO 14971 and the Quality System Regulation (21 C.F.R. Part 820) will further reduce this risk.

10 In some situations, the relationship between software and hardware is inseparable (e.g., device operating
12 systems), while in others the software is not hardware-dependent (e.g., stand-alone software app). Where
14 software cannot be divorced from the hardware on which it executes, the software should take on the
16 classification of the hardware unless the software itself would result in a higher classification. Where the
18 software is not hardware-dependent, the software should be regulated separately from the underlying
20 hardware. More specifically, a smartphone that is intended for use in the execution of a software app should not by default be regulated at the same classification as the software app (or regulated at all) and vice versa. For example, a software app that allows the user to enter blood glucose readings and weight measurements and that transmits the data to the health care professional for monitoring of the patient's diabetes should be regulated as a Class II medical device. The smartphone on which the software app resides should not be regulated as a medical device (unless it otherwise meets the definition of a medical device).⁴⁰

2. 8xx.9 Regulations

22 As with any medical device, software devices that are Class I exempt from premarket notification are also
subject to the 8xx.9 regulation restricting the exemption to certain types of devices.

24 FDA recognizes the importance of creating a long-lasting regulatory framework for medical device
26 software, particularly software apps used in an mHealth system. The rapid evolution of mHealth
28 technologies and software system architectures poses a significant challenge. FDA intends to apply the
following general principles to future technology to determine whether the technology is included in the
scope of the current classifications and exemptions. A technology fits within an existing classification
and any associated exemption if:

- 30 1. The new technology fits squarely within the wording of the classification regulation and any
32 associated exemption, which was written with a focus on basic operating principles and
intended uses rather than specific technology types; and
- 34 2. One of the following is true:
 - a) The technology is reasonably foreseeable at the time the classification/exemption
was created, as demonstrated by literature that existed at that time; or

³⁹ This concept is analogous to testing in the aviation industry of global positioning systems in different types of aircraft.

⁴⁰ Recall that, although a smartphone might not be regulated, the regulated software manufacturer would be required to validate claims of compatibility with the smartphone and comply with other guidance regarding security in software devices.

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- 2 b) The technology advances since the creation of the classification/exemption do not
3 create significant new risks that need to be evaluated.

4 One recent technological advancement that challenges the current regulatory framework is the use of
5 cloud computing or “software services” to perform a discrete software function. Cloud computing
6 challenges the current framework because functions that were once embedded in a single software app are
7 now being “outsourced” to external servers and other platforms to take advantage of computing power
8 and a diversity of resources. When functions (or entire apps) are outsourced to a cloud, it becomes
9 difficult to identify where a fault may have occurred.

10 A product that uses cloud computing would still fit within the existing classification regulation if the
11 product remains squarely within the wording for the regulation and there are no new risks presented.
12 Using standard software design approaches discussed for software modularization should minimize the
13 inherent risk associated with cloud-based systems. More specifically, architectural frameworks for client-
14 server systems, the simple object access protocol (SOAP) specification, representational state transfer
15 (REST) designs, and extensible markup language (XML)-based methods may be useful to perform certain
16 functions (e.g., to manage/exchange data, resources, access, or security). Risk assessment should focus
17 on software implementation approaches and design controls rather than the platform on which the
18 software performs its functions.

19 Another technological advancement that challenges the current regulatory framework is the use of over-
20 the-air (OTA) software upgrades. OTA upgrades are used to rapidly disseminate product changes. Use
21 of OTA upgrades should not affect the classification of the software app because the basic functionality of
22 OTA upgrades is not substantially different from downloading an upgrade using traditional approaches
23 (e.g., using a CD or DVD disk in a PC or connecting the device to the Internet via a telephone or cable
24 modem). Some OTA product changes may be superficial (e.g., an app icon update), while others may
25 have a significant impact on the functionality of the app (e.g., new features or patches for known software
26 bugs). Even where OTA upgrades implement significant changes to the functionality of the app, not all
27 changes involve the same level of risk. For example, an upgrade that affects a software module that does
28 not perform a medical device function (e.g., a billing module) may involve a substantial change, but may
29 not involve any risk to the medical modules within the app. Modularization approaches described above
30 should be used to mitigate any risk to software modules that perform medical functions. Whether a
31 product that uses OTA upgrades remains in an existing classification regulation will depend on the risk
32 (i.e., whether the associated risks go beyond the scope of the generic device type). Ultimately, a software
33 manufacturer must still comply with all applicable regulations, including design controls under the
34 Quality System Regulations.⁴¹

⁴¹ See 21 C.F.R. § 820.30.

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2 VIII. Conclusion

4 This guidance document describes FDA's current thinking on regulation of mHealth technologies. FDA
6 recognizes that certain mHealth products that fall within the Agency's jurisdiction are intended for uses
8 that present low risk to patient safety and should not be regulated at this time. FDA is choosing to
10 exercise its enforcement discretion with respect to these types of claims. For other mHealth products, it
is unclear whether FDA regulation is appropriate due to ambiguity in the language of the statute and
associated claim terminology. Manufacturers and FDA staff should use this document in evaluating
whether a given mHealth product is regulated and, if regulated, the process for determining what
classification.

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Appendix A: Current Regulatory Classifications and Product Codes for Accessories and Software

2 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
868.2377	Apnea monitor	II	NPF
870.1025	Arrhythmia detector and alarm	II	DSI, MHX, MLD, MXD
870.1100	Blood pressure alarm	II	DSJ

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Classification Reg. (21 CFR)	Description	Device Class	Product Codes
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

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Classification Reg. (21 CFR)	Description	Device Class	Product Codes
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
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

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Classification Reg. (21 CFR)	Description	Device Class	Product Codes
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	G YA
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

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Classification Reg. (21 CFR)	Description	Device Class	Product Codes
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
884.2640	Fetal phonocardiography 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

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Classification Reg. (21 CFR)	Description	Device Class	Product Codes
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
890.5380	Powered exercise equipment	I	BXB, IOL, IRR
890.5575	Powered external limb overload warning device	II	IRN

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Classification Reg. (21 CFR)	Description	Device Class	Product Codes
892.1180	Bone sonometer	II	MUA
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

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Appendix B: Proposed Regulatory Classifications for Accessories and Software in mHealth Systems

Description	Definition	Classification ⁴²
General purpose health applications labeled or promoted for a specific medical use	General purpose health applications labeled or promoted for a specific medical use are software devices used in an mHealth system to electronically collect, store, transmit, display, and analyze (e.g., trending ⁴³) health-related data and that are labeled or promoted for a specific medical use (e.g., physical therapy, sleep monitoring, stress management, and weight management) not associated with a specific disease. An example is a software device stored on a smartphone that electronically trends daily exercise and weight information from a variety of sensors and displays the data for use in the treatment of non-morbid obesity.	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.
Physical therapy health application	A physical therapy health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data for physical therapy purposes associated with a specific medical disease. An example is a software device that collects and displays trends of data from an exercise monitoring system to evaluate improvements in joint function associated with arthritis.	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.
Sleep monitoring health application	A sleep monitoring health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data for monitoring a sleep-related medical disease or condition. An example is a software device that collects and displays trends of data from an on-body respiratory sensor, ECG monitor, and limb activity sensor for the detection of insomnia.	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.

⁴² The classification for each of these generic device types is based on an evaluation of the intended use as defined here. The evaluation of intended use includes consideration of the various factors described in Section IV. An assessment of each mHealth product must be conducted to ensure that the intended use does not fall outside of the definitions of the generic device type established in these classification regulations.

⁴³ A trend is the analysis and display/report of a specific data element (e.g., blood pressure or weight) over time for a given patient.

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Description	Definition	Classification ⁴²
Stress management health application	A stress management health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data to diagnose or treat a stress-related medical disease or condition. An example is a software device that collects and trends blood pressure, ECG, and physical activity data to diagnose or treat a stress-related disease or condition (e.g., depression).	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.
Weight management health application	A weight management health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data to diagnose or treat a weight-related medical disease or condition. An example is a software device that analyzes daily weight and physical activity data to monitor pregnancy-related medical diseases or conditions.	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.
Diabetes health application	A diabetes health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in diabetes management (e.g., a blood glucose meter, weight scale, and blood pressure cuff). This does not include data collected for real-time or active patient monitoring.	Class II (special controls).
Cardiac disease health application	A cardiac disease health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in cardiac disease management (e.g., ECG monitor, weight scale, and blood pressure cuff). This does not include data collected from an implantable cardiac device or for real-time or active patient monitoring.	Class II (special controls).
Therapy compliance health application	A therapy compliance health application is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in therapy compliance (e.g., RF-enabled pill, electronic medication dispensers, electronic pill bottles). This does not include data collected for real-time or active patient monitoring.	Class II (special controls).

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Description	Definition	Classification⁴²
Health application for monitoring activity associated with a specific medical disease or condition	A health application for activity monitoring associated with a specific medical disease or condition is a software device used to electronically collect, store, transmit, display, and analyze (e.g., trending) data generated from one or more devices used in the monitoring of an individual’s activity associated with a specific medical disease or condition. An example is a software device that analyzes data from home-based sensors that detect falls, physical movement, food consumption, and toileting for physical therapy 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.
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.

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Description	Definition	Classification⁴²
Device controllers (for Class II or III devices)	A device controller (for Class II or III devices) is a hardware or software device used to electronically control the functionality of a Class II or III device 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).	a) Class II (special controls) if associated with a Class II device. b) Class III (premarket approval) if associated with a Class III device.
General data aggregator and report generator	A general data aggregator and report generator ⁴⁴ 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 and that are labeled or promoted for a specific medical use (e.g., physical therapy, sleep monitoring, stress management, and weight management not associated with a specific disease). 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 pre-determined, health-related questions.	a) 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. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.
Diabetes data aggregator and report generator	A diabetes data aggregator and report generator is a hardware or software device intended to produce an electronic report of data generated from one or more devices used in diabetes management (e.g., a blood glucose meter, weight scale, and blood pressure cuff). This does not include data collected for real-time or active patient monitoring.	a) 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. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.

⁴⁴ A data aggregator and report generator analyses and displays/reports multiple data elements (e.g., age, sex, blood pressure, and weight) for a given patient at a specific point in time. Data aggregators and report generators may include trending functions.

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Description	Definition	Classification ⁴²
Cardiac disease data aggregator and report generator	A cardiac disease data aggregator and report generator is a hardware or software device intended to produce an electronic report of data generated from one or more devices used in cardiac disease management (e.g., ECG monitor, weight scale, and blood pressure cuff). This does not include data collected from an implantable cardiac device or for real-time or active patient monitoring.	a) 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. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.
Therapy compliance data aggregator and report generator	A therapy compliance data aggregator and report generator is a hardware or software device intended to produce an electronic report of data generated from one or more devices used in therapy compliance (e.g., RF-enabled pill, electronic medication dispensers, electronic pill bottles). This does not include data collected for real-time or active patient monitoring.	a) 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. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.
A data aggregator and report generator for activity monitoring associated with a specific medical disease or condition	A data aggregator and report generator for activity monitoring associated with a specific medical disease or condition is a hardware or software device intended to produce an electronic report of data generated one or more devices used in the monitoring of an individual’s activity associated with a specific medical disease or condition. An example is a software device that aggregates data from home-based sensors that detect falls, physical movement, food consumption, and toileting for physical therapy purposes.	a) 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. b) Class II (special controls) if the device analyzes the data for any purpose other than reporting the data in an aggregated form.

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Appendix C: Additional Considerations Regarding the Accessory Rule in an mHealth System

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.

Human intervention may affect the application of the accessory analysis and the resulting classification. Human intervention may impact whether a device is intended to be attached to or used in conjunction with another finished device and, thus, whether the device can even be regulated as an accessory.

Generally, a device may be regulated as 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 two products, meaning that the product at issue does not qualify as an accessory. 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.

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

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

1. Class III connected to Class I or II

a) 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).

b) Device-to-non-accessory: Pacemaker (device) connected to a smartphone (non-accessory) for communication of medical device data. The link is not created here

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because the existing MDDS classification would apply to the smartphone, which would be regulated at that classification (i.e., Class I).⁴⁵

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2. Class II connected to Class I

a) 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 fails to fall within an existing classification. The app would, therefore, be regulated at as an accessory to the blood pressure cuff (i.e., Class II).

b) Device-to-non-accessory: Pulse oximeter (device) connected to a weight scale (non-accessory) for storage and display of the pulse oximeter and weight measurement data. The link is not created here because the weight scale would fall into an existing classification (i.e., Class I).

3. Device connected to non-device

a) 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.

18 It is important to understand what happens to “accessories to accessories”. Consider the
20 following. In mHealth, there may be a configuration where a device transmits data to Product A;
22 Product A transmits information to a Database (stored on Product B); and Product B transmits data to
24 Product C. The mere existence of the original parent device and its transmission of data to Product A
26 does not necessarily mean that Product A is a medical device. The status of Product A depends upon
28 whether it is a medical device in its own right. If it is, FDA would analyze whether the device fits within
an existing classification regulation. If no classification regulation exists (and the device manufacturer
has not requested a reclassification), then FDA would analyze whether it is an accessory to the original
parent device. For the same reason, the fact that Product A is a medical device does not necessarily
render the Database or Product B a device. 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 should be evaluated independently.

30 The bi-directional flow of data (i.e., both from the patient/device to the health care professional and from
32 the health care professional to the patient/device) may impact classification. This particular factor does
not impact the general framework for deciding whether a particular item is a medical device or an
accessory. 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.

34 Consider a device• non-device• device connection, such as a pacemaker (Class

⁴⁵ This example assumes that the smartphone falls into the Class I MDDS device. The purpose of this example is not to suggest that smartphones are Class I MDDS devices but to say that a Class I MDDS smartphone would not be an accessory to the Class III pacemaker. In fact, not all smartphones will be regulated or will fall into the MDDS classification. For example, merely promoting a smartphone as a communication tool that is capable of running a software device app does not trigger FDA regulation. On the other hand, if the manufacturer modifies the phone or tailors the phone for the software device app, the smartphone would become a medical device and the classification determination would depend on the intended use of the smartphone based on those modifications.

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2 III)• computer/smartphone (unregulated)• weight scale (Class I) connection. The classification of
the Class III device is not necessarily imputed to all products in the chain, including the non-devices. The
4 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, it is not an accessory. Adding a software app on the
6 computer/smartphone does not affect the regulatory status of the computer/smartphone as a hardware
platform. The software app, however, may be regulated as an independent medical device or as an
8 accessory based on its intended use. 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.

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Appendix D: Claims of Compatibility and Associated Regulatory

2 Obligations

Claims of compatibility in an mHealth system require the manufacturer of the product making the claims to substantiate those claims through validation testing and quality system controls. Consider the following scenarios:

1. The PawPrick Brand software device manufacturer makes a claim that its product will work with all major blood glucose meters, all meters that meet a particular standard, or a PrickAxe Brand blood glucose meter and only a PrickAxe Brand meter. The PawPrick manufacturer must substantiate the claim through validation testing. The blood glucose meter manufacturers have no obligations to substantiate the claim made by the PawPrick manufacturer. The PawPrick manufacturer carries the burden of maintaining adequate design controls to respond to changes that occur in the blood glucose meters.
2. The PrickAxe Brand blood glucose meter manufacturer makes a claim that its device will work with a PawPrick Brand software device and only a PawPrick Brand software device. The PrickAxe manufacturer must substantiate the claim through validation testing. The PawPrick manufacturer has no obligations to substantiate the claim made by the PrickAxe manufacturer. The PrickAxe manufacturer carries the burden of maintaining adequate design controls to respond to changes that occur in the PawPrick software device.
3. Both occur at the same time, such that there is a uniquely one-to-one relationship between the PawPrick software device and the PrickAxe blood glucose meter. The unique “one-to-one” relationship between the PawPrick device and the PrickAxe device requires that the manufacturers work together to ensure that the claims are substantiated and that any changes made to either device are validated. Both manufacturers must ensure that adequate design controls are in place to account for changes that occur in the future. 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. Although not required by regulation, having an agreement in place to exchange information regarding product complaints and safety events is generally considered good practice.

Claim substantiation does not change the device classification of either product (i.e., the lower-class device does not get up-regulated). In none of the examples above does the classification of the individual devices change. Only the validation burden changes as a result of the claims of compatibility.