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## FDA Regulation of Wearable Medical Technology: It's Not Just a Mobile Medical App

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Even as the Food and Drug Administration (FDA) finalized its long-awaited guidance on mobile medical applications (or apps), wearable medical technology has emerged as a growing trend, presenting a new challenge for both the regulated industry and regulators. While this trend initially focused on wearables to monitor fitness, there already has been a natural progression towards development of technology that captures other physiologic information. Novel wearable devices under development that were featured at the 2014 Consumer Electronics Show and similar venues included, for example:

- wrist bands to monitor heart rate and calories burned;
- contact lenses to monitor glucose/insulin levels;
- tee shirts that monitor heart rate, respiration rate, and skin temperature;
- patches to monitor cardiac arrhythmias;
- electroencephalography (EEG) headsets to monitor brain activity; and
- "onesies" to monitor respiration in infants.

Other innovative wearable products on the horizon may include sensors that monitor how often a person coughs, identify and track erratic behavior, and even provide advance warning of heart attacks. Wearable cameras may be used to help read laboratory test results. Because many wearables will involve new and unique technologies, they will present different regulatory challenges for companies seeking to develop and market these innovative devices, as well as for the FDA, which is responsible for regulating medical devices. Thus far, in the health IT area, the FDA has tackled the issue of remote display of information from medical devices (referred to as "medical device data systems" or MDDS) and mobile medical apps, which are software programs that can be run on a mobile phone, tablet computer, or similar mobile platform. Although the wearables that are being developed for medical applications are mobile and may be accompanied by software apps to monitor and track the data collected, most wearable medical technology also will include hardware, such as sensors, to capture the desired physiological

information. Wearables, therefore, are not just another mobile medical app. FDA's regulatory guidance on mobile medical apps may be informative when assessing regulatory strategies for wearable technologies, however, the analysis does not end there, as the FDA regulatory status of the hardware and other sensors must also be considered.

### **FDA's Guidance on Mobile Medical Apps**

FDA issued the final version of its guidance document on mobile medical applications (Final Guidance) on September 25, 2013, more than two years after issuing its draft version of the guidance.[\[1\]](#) FDA's guidance was the subject of significant discussion both within and outside the FDA, and the industry was particularly concerned about what it viewed as potential over-regulation of low risk apps. In the final guidance, the FDA answered industry's concern by significantly expanding the category of apps that would not be subject to active regulation, on the basis that these apps presented only minimal risk to patients. Notwithstanding its decision to actively regulate only a subset of higher risk mobile medical apps, the FDA confirmed that all such products are within its regulatory authority.

The Final Guidance defines a regulated "mobile medical app" as a mobile app that (1) meets the definition of a "device" in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)[\[2\]](#) and (2) is intended either to be used as an accessory to a "regulated medical device" or to transform a mobile platform into a "regulated medical device." Categories of apps that are subject to active FDA regulation include:

- mobile apps that connect to an existing medical device for the purposes of controlling its operation, function, or energy source;
- mobile apps that display, transfer, store, or convert patient-specific medical device data from a connected medical device;
- mobile apps that transform the mobile platform into a regulated medical device; and
- mobile apps that perform patient-specific analysis and provide patient-specific diagnosis or treatment recommendations.[\[3\]](#)

The primary substance of the Final Guidance, however, is set forth in extensive lists of examples of mobile medical apps that are grouped into one of three categories, based on risk: (1) apps that are actively regulated as medical devices, (2) apps that are subject to enforcement discretion (i.e., not regulated), and (3) apps that are not considered "devices" under the FD&C Act (also not regulated).[\[4\]](#)

### **Why Wearable Medical Technology May Not Be Just a Mobile Medical App**

Because wearable medical technology has emerged as the latest health IT development, it has been viewed by many in industry as being addressed by FDA's guidance on mobile

medical apps. As described below, however, although the software accompanying a wearable might be a mobile medical app, the wearable itself (i.e., the “platform”) will not be considered a mobile medical app. Most, if not all, wearable medical technology includes sensors to detect or capture physiologic information, many of which are novel technologies. These sensors, which are hardware rather than software, may be used to detect or monitor body temperature, glucose levels, heart rate, cardiac arrhythmias, body movement, and a wide variety of other physiologic parameters.

The text of the FDA’s mobile medical apps guidance makes clear that the guidance generally does not apply to wearable medical technology. As noted above, FDA’s mobile medical apps guidance applies to mobile apps that connect to an existing medical device (e.g., stethoscope) in order to control the device; apps that display, transfer, store, or convert data from a connected medical device; and apps that transform a mobile platform into a medical device. For wearables, it is generally the case that there is no connection to an existing medical device, such as a blood pressure or glucose monitor, that captures the physiological data used by the software. Rather, the wearable itself is stand-alone technology that detects or captures the intended physiologic information. Thus, the wearable hardware technology may be functioning as a medical device.

Although the Final Guidance on mobile medical apps is informative when evaluating the regulatory status of wearables, particularly with respect to software intended for use on or with the wearable device, the regulatory requirements must still be assessed for the wearable sensors and other hardware, and for the device as a whole (hardware plus software). Given that many wearable technologies are innovative and may be the first of their kind, the regulatory pathway for these devices may not be straightforward.

### **What Are the Potential FDA Regulatory Pathways for Wearable Medical Technology?**

Because the mobile medical apps guidance does not, by itself, establish the regulatory pathway for wearable medical technology, innovators in this area must turn to the existing FDA regulatory framework for medical devices to determine the pathway to market. The first threshold issue is to assess whether the wearable product would qualify as a “device” as defined in Section 201(h) of the FD&C Act.[\[5\]](#) The definition of a “device” under the Act hinges on the *intended use* of the product, which is determined by the product’s labeling and promotional statements. A product will be considered an FDA-regulated device under the FD&C Act if it is *intended for use* in the diagnosis, cure, mitigation, treatment, or prevention of disease or *intended to* affect the structure or any function of the body. For wearable technologies, it is sometimes difficult to determine whether the product is intended for these medical purposes or for more general health and fitness purposes. The distinction is critical, however, because FDA often exercises

enforcement discretion for lower-risk devices that are only intended for health and fitness purposes.

For example, the FDA has cleared 510(k)s for wearable bands that are intended for use by health care professionals to monitor limb and body movements. The intended use for these devices indicates that they are intended to document physical movement “associated with applications of physiological monitoring.” Wearable bands using the same or similar technology (i.e., an accelerometer), however, also are marketed for consumer health and fitness purposes (e.g., Nike+ FuelBand, Jawbone UP) and these products have not been regulated as medical devices as a matter of FDA’s enforcement discretion. In addition, the FDA has exercised enforcement discretion for some wearables that include sensors to monitor heart rate (e.g., fitness watches). Although monitoring heart rate arguably is monitoring of a medical condition, the FDA has taken the position that it will not exercise its regulatory authority over such devices, if they are intended to monitor heart rate solely for health and fitness purposes. Given that the FDA regulatory status of a product is tied to the specific intended use of the product, companies developing wearable technologies should establish in advance the intended use of their product and the intended user population.

Wearables that meet the definition of “device” under the FD&C Act (and are not subject to enforcement discretion) will be regulated based upon their risk classification. Medical devices are classified as Class I, II, or III based on risk, with Class I representing the lowest risk devices and Class III representing the highest risk devices. Class I devices are generally exempt from premarket submission requirements, but are subject to other FDA requirements, referred to as “general controls,” which include registration, listing, labeling, quality system requirements, adverse event reporting, and reporting of recall and other corrective actions taken in the field. Class II devices are moderate risk devices. Manufacturers of these devices are subject to general controls and “special controls,” which include compliance with industry standards and/or FDA guidance documents. Class II device manufacturers also must submit a premarket notification (known as a “510(k) notification”) to the FDA that establishes that the device is “substantially equivalent” to a Class II device that was previously reviewed and cleared by the FDA for marketing. Class III devices include the highest risk devices, as well as novel device technologies that have not been previously classified by FDA. Class III devices are subject to general controls and also require FDA approval of a premarket approval application (PMA), which is a much more burdensome submission than a 510(k) notification. For example, a PMA generally requires the results of a clinical trial establishing that there is “reasonable assurance” of the device’s safety and effectiveness.

### *510(k) Pathway*

Many wearables in development are intended to provide a patient-friendly, wearable version of an existing Class II medical device used in physicians' offices or hospitals (e.g., blood pressure cuff, heart rate monitor). As noted above, a manufacturer filing a 510(k) for a Class II device must submit a 510(k) premarket notification demonstrating that the device is "substantially equivalent" to a legally marketed "predicate" device (e.g., a Class II device that was previously cleared via the 510(k) process by the FDA or a device legally on the market prior to enactment of the Medical Device Amendments of 1976). The data and information required to support a 510(k) is generally less burdensome than required for Class III devices. FDA must provide an initial decision on a 510(k) within 90 days,<sup>[6]</sup> but the Agency often requests additional data and/or information, causing average review times to be in the range of 130 to 160 days over the last few years.

However, the same 510(k) pathway may not be available for a wearable, if it uses novel technology for which there is no predicate device. Most glucose monitors, for example, are regulated as Class II devices subject to 510(k) premarket notification requirements. Wearable medical technology intended to monitor glucose levels may use novel, non-invasive technologies to monitor glucose (e.g., optical, thermal, ultrasonic) that differ from those currently regulated by FDA. To date, there are no FDA-cleared non-invasive glucose monitoring devices.<sup>[7]</sup> If there is no predicate device to which a wearable could claim "substantial equivalence," the device is automatically considered a Class III device subject to PMA approval requirements.<sup>[8]</sup> Accordingly, the 510(k) pathway may not be available for a novel, non-invasive wearable glucose monitor.

### *De Novo Pathway*

The FD&C Act provides an alternative pathway for novel, lower risk devices that lack a predicate. If the manufacturer of a novel wearable device cannot identify a legally marketed predicate device that is substantially equivalent to its wearable, the manufacturer can submit a request to FDA to have the device downclassified from Class III to Class II, if certain criteria are met.<sup>[9]</sup> These are:

- There is no legally marketed predicate device.
- The new device is not of a type for which there is an existing Class III classification regulation or an approved premarket approval application.
- The new device is low to moderate risk and likely to meet the statutory standards for classification into Class I or Class II under Section 513(a)(1) of the FD&C Act, *i.e.*, that general and/or special controls would provide reasonable assurance of the safety and effectiveness of the device.<sup>[10]</sup>

Depending on the level of risk presented by a device utilizing novel technology, the *de novo* pathway may be an alternative route to market for certain wearable medical technologies. For example, if a novel monitoring device is intended to monitor trends, but is not intended to affect medication decisions, it is possible (depending on the specific intended use) that the FDA would consider downclassifying the device from Class III to Class II.

If seeking a *de novo* classification, a manufacturer must prepare and submit a request for classification. Pursuant to changes enacted as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), manufacturers are no longer required to first submit a 510(k) and receive a “not substantially equivalent” decision (on the basis that there is no predicate), prior to seeking *de novo* classification.<sup>[11]</sup> Pursuant to FDASIA, the FDA is accepting direct *de novo* petitions. FDA is required to classify the device within 120 days of receipt of the request for classification.<sup>[12]</sup>

#### *Premarket Approval Application (PMA)*

If neither the 510(k) nor *de novo* pathways to market are available for a novel wearable device subject to active regulation, the company seeking to market such a device would need to submit a PMA. A PMA is a substantially more burdensome submission, and must demonstrate that there is “reasonable assurance” that the device is safe and effective “under the conditions of use prescribed, recommended or suggested in the proposed labeling.”<sup>[13]</sup> PMAs generally must be supported by both preclinical studies and well-controlled clinical studies establishing the safe and effective use of the device. Additionally, the manufacturing site must undergo a successful FDA inspection before a PMA will be approved.

Companies whose devices require a PMA will need to take into account the cost and time associated with the development and analysis of nonclinical and clinical data required for the submission, and the FDA review time for PMAs. By statute, the FDA has 180 days to review a PMA,<sup>[14]</sup> but it often has additional questions for PMA sponsors, which lengthen the review time. The average review time for a PMA in FY 2012 was approximately 270 days.

#### **Other Strategic Issues for Manufacturers of Wearable Medical Technology**

Many companies engaged in the development of wearable medical technology have not previously been subject to FDA medical device and related regulatory requirements. Such companies may be aware of the premarket review requirements, but might not consider the impact on their business of the numerous postmarket regulatory requirements, which

can be substantial. These requirements impact device manufacture, future design improvements, and marketing activities.

For example, if a wearable technology is an actively regulated medical device, the facility manufacturing the technology must be registered with the FDA and is subject to periodic inspections to assess the facility's compliance with the FDA's Quality System Regulation (QSR). The QSR sets forth detailed requirements for the manufacture and control of medical devices, and compliance with the QSR requires significant investment of resources and time. Additionally, medical device manufacturers must establish procedures for adverse event reporting, reporting of any field actions taken to reduce a risk to health presented by a medical device, and review of any modifications to the technology. If changes are made to a Class II or III device or to its manufacture, a new premarket submission may be required. Finally, device manufacturers may be subject to federal and state reporting requirements for payments or gifts to health care professionals, state license requirements, the federal device excise tax, and health care reimbursement requirements.

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Wearable medical technology is an exciting new trend that will bring a number of new companies under the FDA's jurisdiction. While FDA regulation can be daunting to companies not used to this level of regulation, there are various ways that such companies can manage these new responsibilities. An important first step is to understand the requirements and integrate them into the company's timeline for product development. For those companies that do not have the appropriate internal resources to bring a device to market and comply with FDA's medical device requirements, engaging with development partners and contract manufacturers might be an option. Alternatively, companies can consider changes to the intended use of their wearable technologies to avoid active FDA regulation.

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[\[1\]](#) FDA, Guidance for Industry and Food and Drug Administration Staff, Mobile Medical Applications (Sept. 25, 2013).

[\[2\]](#) A "device" is defined in the FD&C Act as "an instrument, apparatus, implement . . . , or other related article, which 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 . . . which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." Section 201(h) of the FD&C Act, 21 U.S.C. § 321(h).

[\[3\]](#) FDA, Guidance for Industry and Food and Drug Administration Staff, Mobile Medical Applications (Sept. 25, 2013).



[4] Similarly, the FDA's April 2014 report entitled "FDASIA Health IT Report – Proposed Strategy and Recommendations for a Risk-Based Framework," also grouped health IT products into three categories based on risk: (1) administrative health IT, (2) health management health IT, and (3) medical device health IT. Only the latter category is subject to active FDA regulation. The report also indicated that FDA may exercise enforcement discretion for most clinical decision support software that meets the definition of "device," but is considered low risk.

[5] See *supra* note 1.

[6] Section 510(n) of the FD&C Act, 21 U.S.C. § 360(n).

[7] A non-invasive watch, called the GlucoWatch Biographer, was approved by FDA via the premarket approval process in 2001, but is no longer marketed.

[8] Section 513(f) of the FD&C Act, 21 U.S.C. § 360c(f).

[9] Section 513(f)(2) of the FD&C Act, 21 U.S.C. § 360c(f)(2).

[10] Section 513(f)(2) of the FD&C Act, 21 U.S.C. § 360c(f)(2). See FDA, Draft Guidance for Industry and Food and Drug Administration Staff, *De Novo* Classification Process (Evaluation of Automatic Class III Designation (Oct. 3, 2011) (this guidance was issued prior to enactment of The Food and Drug Administration Safety and Innovation Act (FDASIA) and FDA anticipates that it will issue a new draft guidance reflecting changes to the "de novo" statute set forth in FDASIA).

[11] Section 513(f)(2) of the FD&C Act, 21 U.S.C. § 360c(f)(2)(A)(ii).

[12] Section 513(f)(3) of the FD&C Act, 21 U.S.C. § 360c(f)(2)(A)(iii).

[13] Section 515(d)(2) of the FD&C Act, 21 U.S.C. § 360e(d)(2).

[14] Section 515(d)(1) of the FD&C Act, 21 U.S.C. § 360e(d)(1).

