

US

Is Your Wearable a Regulated Medical Device?

Determining if your product falls under FDA oversight



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One of the biggest challenges for companies in the general wellness space is understanding how and when their technology might encounter FDA regulatory scrutiny.

The US FDA recognizes that they need to strike the right balance between regulation and innovation. Many products intended to promote a healthy lifestyle are so low risk that the FDA will not view them as regulated medical devices. The FDA does not intend to regulate low-risk general wellness products, which include products like the Nike Fuelband and Fitbits, as well as apps like MyFitnessPal and MapMyRun.



In July 2016, the FDA issued a guidance document dealing with this topic. It is of particular importance to the rapidly growing market of wellness products, which includes activity trackers, smart watches, exercise equipment, mobile health apps, and other products intended to help monitor and improve consumers' physical fitness, nutrition, or other lifestyle and wellness goals. This white paper examines the FDA guidance document on "general wellness products" and discusses the nuances that determine if a product intended to improve health and fitness is a regulated medical device.

How does the FDA define General Wellness Product?

In the final FDA guidance [*General Wellness: Policy for Low Risk Devices*](#), the FDA defines "general wellness product" as one that meets two criteria:

- 1) intended for only general wellness use, as defined in this guidance, and
- 2) presents a low risk to the safety of users and other persons.

The guidance goes on to describe a general wellness product's intended use as:

- 1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or
- 2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

Sounds fairly straightforward, but it can get a bit murky in the analysis when considering how these play into the definition of "medical device," which is an:

"instrument, apparatus, implement, machine, 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 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..."

Some general wellness products could be viewed as preventing disease in man or affecting the structure of any function of the body. However, the FDA maintains that they will not regulate products solely intended to benefit an individual's overall health and wellness as medical devices, as long as the products do not make claims about disease prevention, treatment, mitigation, or cure, but rather claim to sustain or offer general improvement to conditions and functions associated with a general state of health.

This means that the FDA's Center of Devices and Radiological Health (CDRH) does not plan to enforce compliance with medical device regulations, including registration, device listing, premarket notification, labeling, and Good Manufacturing Practice requirements, for general wellness products.

This should be great news to the fitness and general wellness industries that are exploding the market with devices and applications designed to promote a healthy lifestyle. Smartphone apps that track steps and count calories are readily available and becoming more sophisticated every day. Stress reduction and mental acuity programs, as well as devices for monitoring heartrate during fitness-related activities, are becoming more prevalent. As technology continues to proliferate in this area, questions about regulations naturally arise.



Developers of these “widgets” have long wondered how to market their products as beneficial to health — that is, to claim that their calorie counter might help someone to lose weight, or that their UV ray tracker might help avert skin cancer — without incurring FDA scrutiny.

The FDA guidance document, when read carefully and understood properly, can assist manufacturers of wellness products and applications to determine whether their products will be regulated by the FDA as medical devices.

What claims are you making?

Claims are critical. If you market the product in relation to a “general state of health,” rather than specific diseases or conditions, you should be fine. (So, *yes* to “relaxation or stress management”; *no* to “treating or preventing hypertension.”)

However, you can still market in relation to specific diseases and conditions if your claims refer to specific lifestyle choices that might abate the risk of said condition, and those claims are reasonable and generally accepted. For example, one can claim a product that alerts over-exposure to UV intensity may mitigate the chance of developing skin cancer, but not make a claim that a product will prevent skin cancer. Remember, the product has to be “low risk” — if it's just, say, listening to some brain-stimulating music, it's okay; if it's applying electrical stimulation to your brain, it's probably not.

The FDA published the guidance document to provide manufacturers with guidelines and examples to determine if their product meets the FDA's threshold criteria of a low-risk general wellness product. But, as is the case for most FDA guidance documents, it covers a multitude of various product types, so it isn't necessarily cut-and-dried.

First, does your product meet the 'general wellness product' definition above in terms of intended uses?

The FDA created two categories of General Wellness Intended Uses:

Category One: intended uses involve claims about sustaining or offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions.

That one is easy because it draws a hard line: It entirely excludes wellness products not intended to address specific diseases or conditions from FDA oversight. This category includes uses and claims that relate to non-specific health areas such as weight, stress, and sleep management. Arguably, even without this guidance document, many such products would clearly fall outside the statutory definition of a medical device. A few examples that the FDA gives are:

- Claims to improve mental acuity, concentration, problem-solving, decision-making, pattern recognition or eye-hand coordination;
- Claims to promote physical fitness, such as to help log, track, or trend exercise activity, measure aerobic fitness, and develop or improve endurance, strength or coordination;
- Claims that address a specific body structure or function, such as to increase or improve muscle size or body tone, or enhance or improve sexual performance.

On the contrary, a few examples of unacceptable claims that would push the product into the regulated 'medical device' realm include:

- A claim that a product will treat an eating disorder, such as anorexia;
- A claim that a computer game will diagnose or treat autism;
- A claim that a product will cure muscle atrophy or erectile dysfunction.



Category Two: intended uses that relate to sustaining or offering general improvement to functions associated with a general state of health while making reference to diseases or conditions.

This one presents more interpretive challenges. The FDA tries to make it easier by breaking this group into two subcategories:

- 1) Products that may help reduce the risk of certain chronic diseases or conditions;
- 2) Products that may help someone live well with certain chronic diseases or conditions.

But, again, the FDA is clear that it must be generally accepted and understood that the healthy lifestyle choices may impact health outcomes associated with the chronic disease or condition. For example, it is common knowledge that regular glucose monitoring is important to glycemic control for diabetics, so a mobile app that reminds you to monitor your glucose levels at specific times could claim to help in living well with type 2 diabetes. However, if it is intended to monitor glucose levels or manage a patient's data, it may be a regulated medical device.



The primary distinction between a general wellness product and a regulated medical device is that the intended use of a general wellness product is either to maintain or encourage a general state of health or healthy activity or to support a healthy lifestyle to help reduce the risk or impact of certain chronic conditions where there is a well-known connection.

We anticipate that many companies seeking to promote products related to specific diseases or conditions must carefully consider whether their products and the claims they want to make meet the definition of a general wellness product under this category. After all, at what point does a particular wellness activity's contribution to the prevention of a specific disease or condition become "well understood?"



Second, is your product “low risk?”

This could be considered a rather subjective decision, as “risk” is often in the eye of the beholder. Thankfully, the FDA provided three questions that must all be answered “No” to meet the “low risk” criterion:

- 1) Is the product invasive? (Does it penetrate or pierce the skin or mucous membranes of the body?)
- 2) Is the product implanted?
- 3) Does the product involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied, such as risks from lasers or radiation exposure?

A device that uses electrical stimulation claiming to reduce appetite would probably not be considered a low-risk device because of potential safety risks associated with the electrical current. It would therefore be regulated as a medical device by the FDA, and subject to pre-market clearance or approval and myriad regulations, depending on its classification. The FDA generously provides examples of both low-risk and non-low risk products in the guidance.

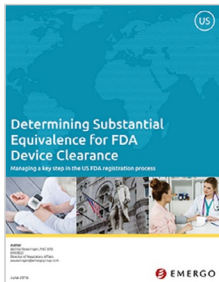
Finally, the FDA offers a user-friendly decision framework in Section VI of the guidance document that summarizes the above-described process for determining whether an item may be classified as a low-risk general wellness product. The decision flowchart walks the reader through the questions addressed above related to intended use and risk to hopefully arrive at a determination.

On a related note, a manufacturer of a mobile medical software application should also consult the 2015 FDA Guidance Document, Mobile Medical Applications, which explains FDA’s current policy for overseeing only those mobile apps that are defined as medical devices AND whose functionality could pose a risk to the patient’s safety if the app does not function as intended. While many mobile apps are indeed medical devices and make medical claims, FDA intends to exercise enforcement discretion if they pose low risk to the public. A mobile medical app may not be a ‘general wellness’ product, but still fall under FDA’s enforcement discretion.



As you can see, this can be a very foggy pathway to tread. The guidance document provides a good starting point for assessing whether a proposed product could fall within the FDA's enforcement. However, as manufacturers develop innovative tools with novel features and functionalities, more questions are certain to arise about the limits of the FDA's enforcement discretion policy with respect to general wellness devices. For companies developing new products or adding new features to existing general wellness tools (such as mobile wellness or lifestyle apps), a comprehensive analysis of the regulatory status and basis for marketing and, where the regulatory status is ambiguous, obtaining input from the FDA prior to launching the product, is advisable. Absent careful analysis, such companies could find themselves inadvertently facing the same level of onerous regulation as more traditional medical device manufacturers.

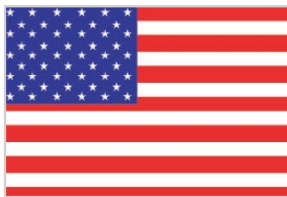
Manufacturers and distributors of general wellness products also need to scrutinize advertising and promotional materials to ensure they carefully articulate intended uses and avoid disease or condition-specific claims that could bring scrutiny or enforcement from the CDRH. Thus, companies should consider monitoring relevant websites or promotional claims created by third party vendors or downstream retailers that could be attributed to the company. Employees and vendors should also be trained to understand the types of claims and statements they can make on behalf of the company through websites, social media presence, press releases, etc.



Learn more about US FDA medical device classification?

If you found this information useful, you might enjoy our white paper about how to determine substantial equivalence. Substantial equivalence is the key to getting your Class II medical device cleared for sale by the US Food and Drug Administration. In this white paper, we answer your biggest questions about substantial equivalence and its role in the FDA regulatory process.

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About the Author

Audrey Swearingen is Director of Regulatory Affairs at Emergo's Austin, Texas headquarters. With over 20 years of experience in regulatory affairs, Audrey's areas of expertise include US FDA medical device registration as well as European and Canadian device registration.