Voler SYSTEMS

WHITE PAPER

Are You Making a Medical Device?

There are lot of exciting and innovative advances in fitness and healthcare. Startups and established firms have introduced thousands of new software and hardware solutions–and more are being developed every day. But some of these companies may think they are making a fitness or home health device when they are actually introducing a medical device without realizing it.

If you make a medical device and don't register it with the FDA, you risk getting a letter from the FDA with an injunction and a notice to stop selling your product. To be ready to register with the FDA can take tens or hundreds of thousands of dollars of regulatory work for a simple device.

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What is a medical device?

The FDA provides the following definition for a medical device [1].

A medical device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or 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 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 dependent upon being metabolized for the achievement of any of its primary intended purposes."

1 https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm510630.htm

It is often difficult to apply this definition. Often it takes advice from the FDA to be sure. There are a lot of people making consumer devices that may in fact be medical devices. Every wearable startup should consider whether their device might be a medical device. Intended use of the device matters a great deal to determine if it is medical device or not.

A thermometer is a medical device if its purpose is to take people's temperature. However, if you sell it to take air temperatures, it is not a medical device. The Internet is not a medical device, since the intended use is to transmit data without modifying it. These devices have known use cases and have FDA rulings on them.

As simple as instructions

Choicemed makes a pulse oximeter that's being sold as a medical device [2] with a high price. The same device is being sold to consumers for fitness and is not a medical device [3].The difference is in the instructions. The one for consumers is not for diagnosis. But, when they sell it to doctors for use in hospitals, it's for diagnosis. By changing the Instructions for Use it becomes not a medical device.

Is it a medical device?

The FitBit[4] measures activity. The wearable band has an accelerometer and tracks your movement, calories, distance and time. With the app, you can compete with yourself or share results with your friends. Since it's just for personal information on your activity level, it is not a medical device.

Pill reminders like MedCenter's Talking Alarm Clock[5] is not a medical device. Neither is EZ-Twist's Timer Cap[6]. Some pill reminders have sensors attached to pill bottles can indicate if a person is taking their medicines.

Smart Caregiver® Cordless Exit Alarm[7] monitors an elder person's activity. Alerts from sensors like this can alert remote family members to changes in normal activity. Since it is just monitoring activity, it is not a medical device, but it can depend on exact wording in the Instructions for Use.

Zosano's[8] transdermal dosing patch transmits drugs through the skin. This is a medical device used in the treatment of diseases.

Azumio[9] has introduced an instant heart rate monitor as an app on a cell phone. It's nothing but software. You place the tip of your index finger on the phone's camera and the app measures your heart rate using a technique similar to a pulse oximeter. It may be a medical device depending upon how they market it (marketing material, including a web site is part of the Instructions for Use). They may have created it without thinking about it being a medical device.

2 http://www.whichmedicaldevice.com/by-manufacturer/217/514/oxywatch-pulse-oximeter-md300c63

3 https://www.walgreens.com/store/c/choicemmed-oxywatch-c18-fingertip-pulse-oximeter/ID=prod6064149-product

4 https://www.fitbit.com/home

5 https://www.medcentersystems.com/

6 https://www.amazon.com/Timer-Caps-Std-oz-Vials/dp/B00EZ6TL2S/ref=sr_1_3_a_it?ie=UTF8&qid=1521774986&sr=8-3&keywords=pill+reminder+cap

7 http://smartcaregiver.com/

8 http://www.zosanopharma.com/

9 http://www.azumio.com/

image sources:
FitBit: https://www.fitbit.com/home
MedCenter Systems https://www.medcentersystems.com/
Smart Caregiver http://smartcaregiver.com/
Zosano http://www.zosanopharma.com/
Azumio http://www.azumio.com/

FDA Update on Mobile Apps

Sourced from the FDA site
https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm [10]

"The FDA issued the Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff [11] (PDF – 269KB) on December 13, 2016, which explains the agency's oversight of mobile medical apps as devices and their focus only on the apps that present a greater risk to patients if they don't work as intended and on apps that cause smartphones or other mobile platforms to affect the functionality or performance of traditional medical devices. "

"The FDA will apply the same risk-based approach the agency uses to assure safety and effectiveness for other medical devices. The guidance document [11] (PDF – 269KB) provides examples of how the FDA might regulate certain moderate-risk (Class II) and high-risk (Class III) mobile medical apps. The guidance also provides examples of mobile apps that are not medical devices, mobile apps that the FDA intends to exercise enforcement discretion and mobile medical apps that the FDA will regulate in Appendix A [12], Appendix B [13] and Appendix C [14]. "

A good article with more information is "The FDA Releases Final Guidance for Mobile Medical Applications [15]. "

Mobile medical apps that the FDA will regulate

"The FDA takes a tailored, risk-based approach that focuses on the small subset of mobile apps that meet the regulatory definition of "device" and that:

- are intended to be used as an accessory to a regulated medical device, or
- transform a mobile platform into a regulated medical device.

Mobile apps span a wide range of health functions. While many mobile apps carry minimal risk, those that can pose a greater risk to patients will require FDA review.

Visit the mobile medical apps example page[16] for a list of examples of mobile medical apps that have been cleared or approved by the FDA.

Visit the Examples of MMAs the FDA regulates[17] webpage for a more detailed list of examples of mobile apps that would require FDA review.

For a list of what is considered a mobile medical application, manufacturers and developers of mobile applications can search FDA's database of existing classification[18] by type of mobile medical application (for example diagnostic). Approved or cleared mobile medical applications will also be listed in FDA's 510(k)[19] and PMA databases [20] and on the FDA's Registration & Listing Database [21]. "

10 https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm
11 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf
12 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf#page=21
13 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf#page=22
14 https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf#page=28
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17 https://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368743.htm
18 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm
19 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
20 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
21https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

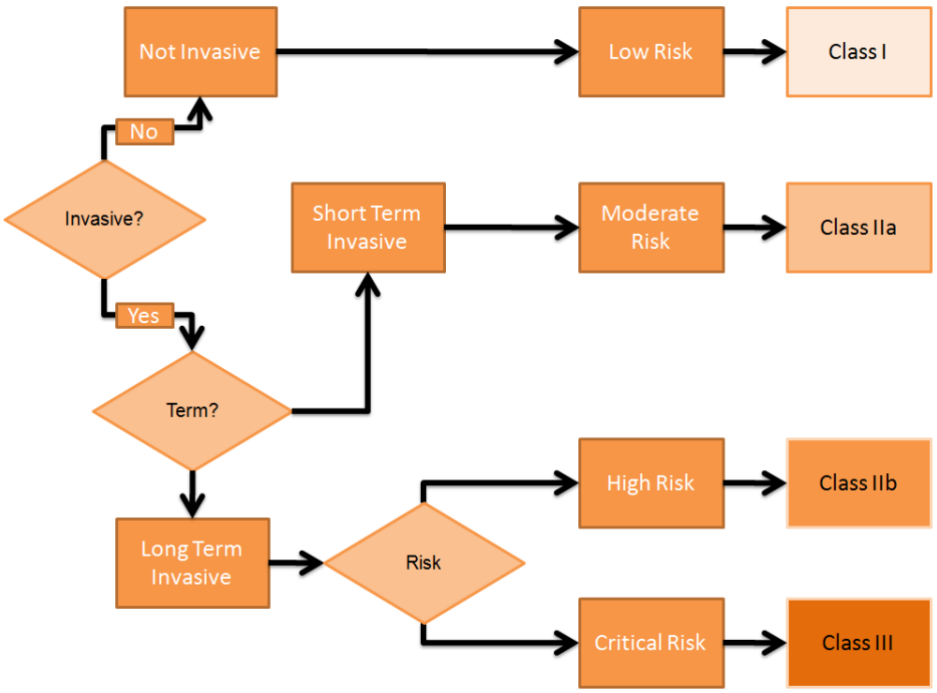
Digging deeper

If you are building a medical device then you will need to dig deeper into their classifications. University of Cincinnati is a useful source for this. Below is some text, the flowchart and diagrams that originally came from the University of Cincinnati. Source (Oct. 2013): http://www.ece.uc.edu/POC-CENT/funding/Additional%20Information/fda-classification [22]

Classification of Medical Devices

The FDA is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States. "There are 3 FDA regulatory classifications of medical devices: Class I, Class II and Class III. The classifications are assigned by the risk the medical device presents to the patient and the level of regulatory control the FDA determines is needed to legally market the device. As the classification level increases, the risk to the patient and FDA regulatory control rises. Accessories to medical devices and devices used with a medical device to support use of the device are considered the same classification as the medical device.

The flow chart provided below provides the decision making process used by the FDA when determining the class of a medical device."



Class I Medical Devices

"Class I Medical Devices have the least regulatory control. They present minimal potential harm to the user. Class I devices are typically simple in design, manufacture and have a history of safe use.

22 University of Cincinnati. Source (Oct. 2013): http://www.ece.uc.edu/POC-CENT/funding/Additional%20Information/fda-classification

Class I Devices are subject to following requirements know as General Controls:

Register manufacturing and distribution locations. List device to be marketed with the FDA. Manufacture the devices in accordance with Good Manufacturing Practices. Label medical devices in accordance with the labeling regulations, 21 CFR 801 or 21 CFR 809. Report adverse events of medical device as identified by the user, manufacturer and/or distributor. "

Examples of Class I devices include tongue depressors, arm slings, and manual stethoscopes.

Class II Medical Devices

"Class II Medical Devices have the potential to pose a mild risk to a patient if used incorrectly. General controls alone are not adequate to assure the safety and effectiveness of the device. Due to these risks, special controls must be implemented in addition to general controls. **Class II devices typically require pre-market notification by submission and FDA review of a 510(k) clearance to market submission**. Special Controls applicable to Class II Devices are as follows.

Special labeling requirements, mandatory performance standards, both International and United States, post-market surveillance, FDA medical device specific guidance. "

Examples of Class II devices include fever thermometer, powered wheelchairs, intravenous tubing, catheters, gas analyzers, and surgical drapes.

Examples of Class IIb devices include blood bags, x-ray units, and dressings for severe wounds.

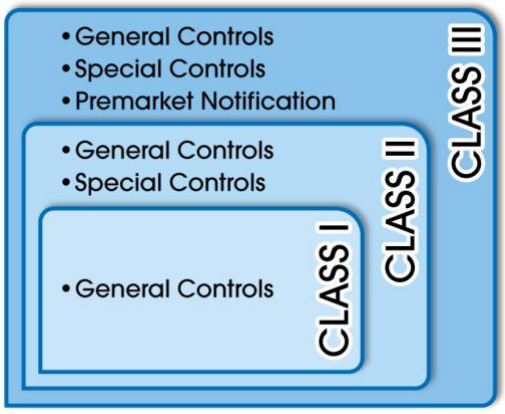
Class III Medical Devices

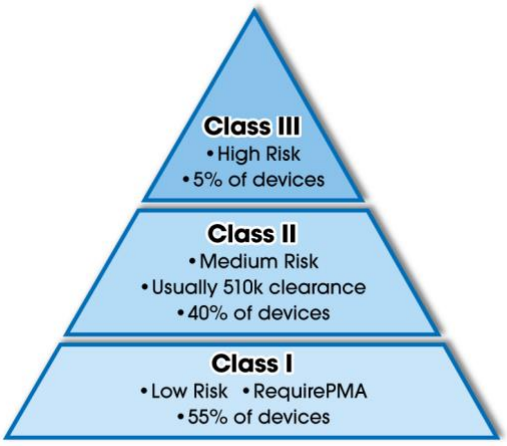
"Class III Medical Devices have the most stringent regulatory controls. Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient. For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Class III devices typically require pre market approval (PMA). PMA application content includes:

Full reports of all information, published or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective; full statement of the components, properties and principles of operation for the device; full description of the methods and the facilities used for the manufacturing, processing, packing and installation of the device; reference to any existing performance standards and adequate information to show that the device fully meets each standard; sample of the device or the location of one or more devices readily available for examination and testing in the instance that the device is burdensome to move; the labeling proposed to be used for the device."

Examples of Class III devices are pacemakers, replacement heart valves and total joint replacements.

22 University of Cincinnati. Source (Oct. 2013): http://www.ece.uc.edu/POC-CENT/funding/Additional%20Information/fda-classification





"The diagram on the left shows the relationship between class and the controls required by the FDA. As device class increases, controls become more extensive. General controls are the foundation of the FDA approval process and are present at all three levels of device classification. The image on the right depicts the relationship between device class and risk to the patient. The greater the device class, the higher the potential risk. Class I medical devices make up the majority (55%) of FDA approved medical devices. High risk, Class III devices comprise only a small percentage, 5%, of medical devices approved by the FDA. "

22 University of Cincinnati. Source (Oct. 2013): http://www.ece.uc.edu/POC-CENT/funding/Additional%20Information/fda-classification

About Voler System

Voler Systems provides full-service R&D consulting from concept to moving new products into production without problems. Since 1979, clients have turned to us for reliable new products involving sensors and measurement electronics. Our multidisciplinary team delivers high-quality products on time and on budget. We have developed medical devices, automatic test equipment, heart valve testers, RFID devices, instrumentation design, data acquisition systems, and other specialized sensor-based electronics and prototype circuits.

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