

Digital Health Product Categorization Guide

This guide is intended to help guide individuals, teams, and organizations to help classify their digital health products as a part of their design, development, and deployment processes. Ultimately, the final product class designation is determined by the FDA. But before we dive in, it's important to know this:



The FDA doesn't regulate
healthcare practice,
only health products.

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An overview

Over the last 47 years, since the passage of the [Medical Device Amendments to the FD&C Act](#), the inception of the FDA's current regulatory framework, digital health products have evolved from traditional hardware devices to newer, broad-spectrum digital health solutions. In the FDA's early days, regulations were crafted for hardware products (MRI scanners, laser cataract surgicals, and more) almost 20-25 years before the [1990s software dot-com bubble](#) came into the picture. The rise of the Internet and laptop computers in the 1990s, smartphones in the mid-2000s, and cloud computing, AI, and the Internet of Things (IoT) in the 2010s have all impacted how software is used in various medical products.

Today, modern-day software products are often quite sophisticated and highly connected. The rapidly evolving landscape of digital health technologies include clinical decision support systems, digital diagnostics and therapeutics, extended reality, SaMD (Software as Medical Devices), BioMeTs, AI/ML tools, digital endpoints for medical product development, remote monitoring technologies, and more. Therefore, there are many factors and nuances when it comes to classifying a digital health product under current FDA regulations.



PRO TIP

Regulatory oversight of a digital health technology does **not** necessarily indicate it being *fit-for-purpose*.

FDA clearance, grant, or approval of a technology should not be used in place of the evaluation processes to determine the suitability of a technology for a given context of use. A rigorous clinical, technical, operational, and economic evaluation should be conducted.

Source: [DiMe-VHA The Playbook: Healthcare team analysis](#)



What are the factors determining how the FDA classifies a digital health product?

The FDA uses a number of factors to determine which category a digital health product falls into, including the intended use of the product, the potential risks and benefits to patients, the performance of the product, and the potential for the product to interact with other digital health products or drugs.



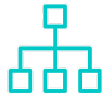
Intended Use & Indication of Use

“**Intended use**” refers to the general purpose of the digital health product or its components. Intended use includes “**indications of use,**” which describe the disease or condition the product will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.



Device Risk

The FDA regulates digital health products based on the potential risk a digital health product poses to human health during its intended use (e.g. to patients or users, providers, etc.).



Product Class

Based on what type of risk a digital health product poses, the FDA determines the product class (Class I, II, III). Sometimes, low risk products are exempt from the FDA’s regulatory oversight.



Regulatory Controls

The class of the digital health product then determines the extent of regulatory controls that are necessary to provide responsible assurance of the device safety and effectiveness.

How will the FDA classify your digital health product?

1,700

As of today, various types of digital health products are classified by the FDA into approximately **1,700 different generic types**.

16

All of these different kinds of digital health products are grouped into **16 medical specialties**, AKA “[Panels](#).”


3

Each of these products are assigned one of **three product classes** based on the level of control necessary to assure the safety and effectiveness of the device.



What are the different classes of digital health products?


The FDA product classification (aka medical device classification) for digital health products is based on the level of risk the products pose to patients. The classification determines the regulatory requirements and processes that the manufacturer must follow to bring the device to market, including premarket notification, testing and clinical trials, and post-market surveillance.

Digital Health Regulatory Pathways 

FDA Classification Overview for Digital Health Products

CLASS	RISK	POTENTIAL HARM	REGULATORY CONTROLS	% DEVICES IN CLASS*	EXAMPLES
I	Lowest risk	Lowest risk products Subject to only general controls Most Class I products are "exempt" from premarket notification	General	35%	Podimetrics SmartMat™ , Visibly Digital Acuity Product
II	Moderate risk	Higher risk than Class I but lower risk than Class III Subject to general controls and special controls Requires premarket notification	General and special (if applicable)	53%	reSET-O , DeepRhythmAI , Tidepool Loop , Eko Murmur Analysis Software , BlueStar
III	Highest risk	Highest risk to patients - usually life-supporting, life-sustaining, or used to prevent unreasonable risk of illness or injury Subject to general controls and special controls Requires premarket notification	General and Premarket Approval (PMA)	9%	Freestyle Libre 14-day Flash CGM , VNS software , Pacing system analyzer by Abbott

Source: FDA, US RegPath Project team analysis *3% of devices are unclassified



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**FDA Classification Overview
for Digital Health Products**



The classification is divided into three main classes:

1. **FDA CLASS 1** - Low risk digital health products
2. **FDA CLASS 2** - Moderate risk digital health products
3. **FDA CLASS 3** - High risk digital health products

Note: In addition to these three classes, the FDA also has a category called "preamendment devices" for products that were on the market prior to the passage of the Medical Device Amendments Act in 1976. These products may include traditional products such as x-ray machines.



FDA CLASS 1 - Low risk digital health products

Definition	<p><u>As defined by the FDA</u>, Class I products are “not intended for use in supporting or sustaining life or of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury.”</p>				
Prevalence	<p>Currently, ~ 35% of all digital health products are in this category (out of which 74% are exempt from the regulatory process). <i>Source: #1, #2</i></p>				
Characteristics	<p>FDA Class I products are considered to have the lowest level of risk to patients and present minimal potential for harm. Therefore, they are subjected to the least amount of regulatory controls. Characteristics of Class I products include:</p> <ul style="list-style-type: none">• Generally simple products that do not require a lot of technical expertise to use.• Typically used for diagnostic or therapeutic purposes, but do not pose a significant risk to the patient if used improperly.• Typically do not require premarket clearance or approval by the FDA. They are subject to general controls such as registration and listing, labeling, and good manufacturing practice.• Can be exempt from certain requirements, such as Premarket Notification (510(k)) and Device Master Record (DMR), in some cases.• Subject to inspection and enforcement by the FDA to ensure compliance with general controls.• Do not require a clinical trial or testing, but the manufacturers should be able to demonstrate that the product is substantially equivalent to a predicate device that is already on the market.				
Examples	<table><tr><td>Traditional products</td><td>Plasters, Electric toothbrushes, Enema kits, Bedpans, Manual stethoscopes, Tongue depressors, Oxygen masks, Hospital beds</td></tr><tr><td>Modern-day digital health products</td><td><ul style="list-style-type: none">• SmartMat™ Remote Temperature Monitoring System by Podometrics• Visibly Digital Acuity Product by Visibly Inc</td></tr></table>	Traditional products	Plasters, Electric toothbrushes, Enema kits, Bedpans, Manual stethoscopes, Tongue depressors, Oxygen masks, Hospital beds	Modern-day digital health products	<ul style="list-style-type: none">• SmartMat™ Remote Temperature Monitoring System by Podometrics• Visibly Digital Acuity Product by Visibly Inc
Traditional products	Plasters, Electric toothbrushes, Enema kits, Bedpans, Manual stethoscopes, Tongue depressors, Oxygen masks, Hospital beds				
Modern-day digital health products	<ul style="list-style-type: none">• SmartMat™ Remote Temperature Monitoring System by Podometrics• Visibly Digital Acuity Product by Visibly Inc				



FDA CLASS 2 - Moderate risk digital health products

Definition	<u>Defined by the FDA</u> as “devices for which general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device.”	
Prevalence	~ 53% of all digital health products fall into this category. <i>Source: #1</i>	
Characteristics	<p>FDA Class II digital health products are considered to have a moderate level of risk to patients and are subject to more regulatory controls than Class I products. Characteristics of Class II products include:</p> <ul style="list-style-type: none"> • Generally more complex than Class I products but less complex than Class III products. • Subject to Premarket Notification [510(k)] requirements, which means that manufacturers must notify the FDA and provide information about the product’s safety and effectiveness before it can be marketed. • Required to meet general controls and special controls, including clearance, registration and listing, and product good manufacturing practices (GMPs). • Subject to FDA's premarket review process, but are not required to undergo the more stringent Premarket Approval (PMA) process. • Subject to more regulatory oversight than Class I products, but less than Class III products. • May be subject to special controls, such as performance standards, postmarket surveillance, patient registries, and/or guidance documents, in addition to the general controls. • Subject to less frequent inspections and less rigorous post-market surveillance than Class III products. 	
Examples	Traditional products	Powered wheelchairs, Pregnancy test kits, Catheters, Blood pressure cuffs, Blood transfusion kits, Surgical gloves, Absorbable sutures, Syringes, Contact lenses
	Modern-day digital health products	<ul style="list-style-type: none"> • reSET-O by Pear Therapeutics • DeepRhythmAI by Medicalgorithmics S.A. • Tidepool Loop by Tidepool • BlueStar by Welldoc • Eko Murmur Analysis Software (EMAS) by Eko Devices • EndeavorRx by Akili Interactive Labs Inc. • ProstatID by ScanMed





Reclassification to a Lower Risk Class

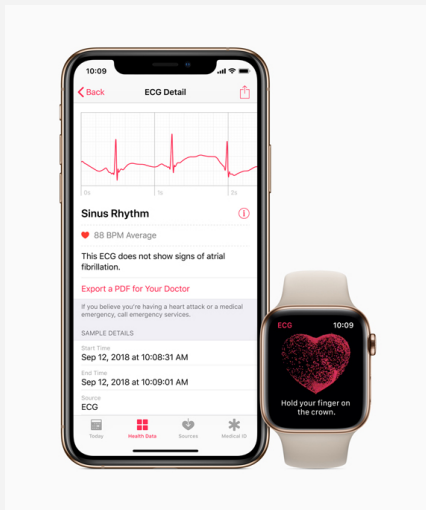


Image Source: [Apple](#)

The ECG feature on the Apple Watch Series 4

A digital health product that underwent reclassification and became the first ECG app for over-the-counter use

In September 2018, the [FDA reclassified the Apple ECG app as a Class II medical device](#), which means it has a lower level of regulatory oversight than Class III devices. The reclassification was based on the ECG app's ability to be used to determine the presence of atrial fibrillation (AFib) or sinus rhythm.

AFib is a serious heart condition and the [most common type of heart arrhythmia](#) (when the heart beats too slowly, too fast, or in an irregular way). The FDA noted that the ECG feature on the Apple Watch Series 4, when used with the appropriate instructions and warnings, is intended for over-the-counter use as a screening tool for atrial fibrillation among adult users (not under the age of 22 years), though the ECG app is not recommended for users with other known arrhythmias.

The implications of the reclassification meant that as a Class II medical device, the Apple ECG app can be used by consumers without a prescription. However, it still requires clearance from the FDA before it can be marketed. The reclassification also allowed the product to be marketed with scaling capability without going through the FDA approval process, which would have increased the cost and timelines, and required clinical testing. The app is intended to be used as an aid for detecting AFib, but it is not intended to be used as a substitute for traditional diagnostic methods or to replace consultation with a doctor or other healthcare professional.

FDA CLASS 3 - High risk digital health products

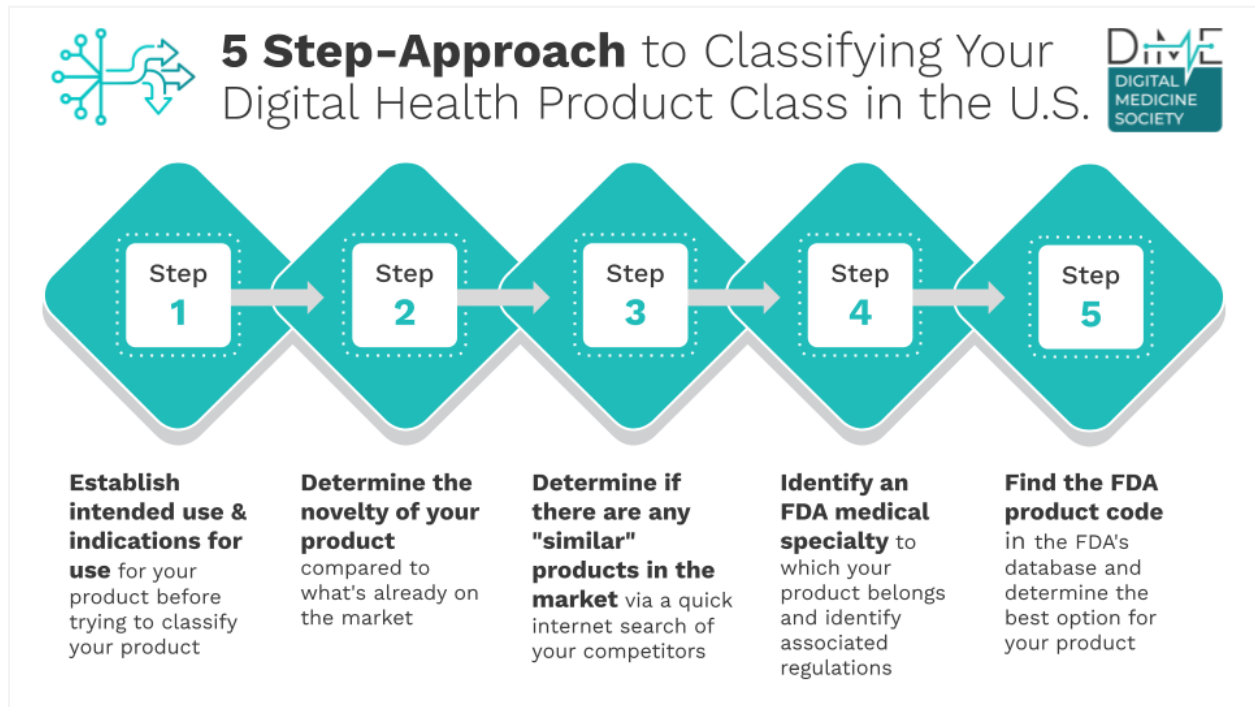
Definition	Defined by the FDA as products that “usually sustain or support life, are implanted or present a potential unreasonable risk of illness or injury.”	
Prevalence	Only ~ 9% of all digital health products fall in this category. Source: #1	
Characteristics	<p>FDA Class III products are considered to have the highest level of risk to patients and are subject to the most amount of regulatory controls. Characteristics of Class III products include:</p> <ul style="list-style-type: none"> • Generally complex products that are intended to sustain or support life or be used in a life-sustaining or life-supporting capacity. • Subject to Premarket Approval (PMA) requirements, the most stringent type of product marketing application required by the FDA. • Required to meet general controls and special controls, which include PMA, clearance, registration and listing, and product good manufacturing practices (GMPs). • Subject to the FDA's premarket review process, which includes clinical trials to demonstrate safety and efficacy. • Subject to the most regulatory oversight and pose the highest level of risk to patient safety. • Required to have more stringent controls, such as clinical trials to demonstrate safety and efficacy. • Subject to more frequent inspections and more rigorous post-market surveillance to ensure the safety and effectiveness of the product over time. 	
Examples	Traditional products	Implantable pacemakers, Defibrillators, High-frequency ventilators, Fetal blood sampling monitors, etc.
	Modern-day digital health products	<ul style="list-style-type: none"> • Freestyle Libre 14-day Flash CGM by Abbott • Orchestra, Orchestra Plus, And SmartTouch Programming Software Modules by MicroPort CRM • Minimed CGM by Medtronic • VNS therapy system programming software by LivaNova • Pacing system analyzer by Abbott



How to determine the risk class of your digital health product

With sophisticated modern-day digital health technologies, classifying a digital health product can feel daunting. But in the US, the risk classification of your product is important to determine the level of regulatory oversight that the product will be subject to.

Follow the simple 5-step approach to classifying your digital health product:



DOWNLOAD

5-Step Approach to Classifying your Digital Health Product Class in the US



Where to consider the "risk" during the product life cycle

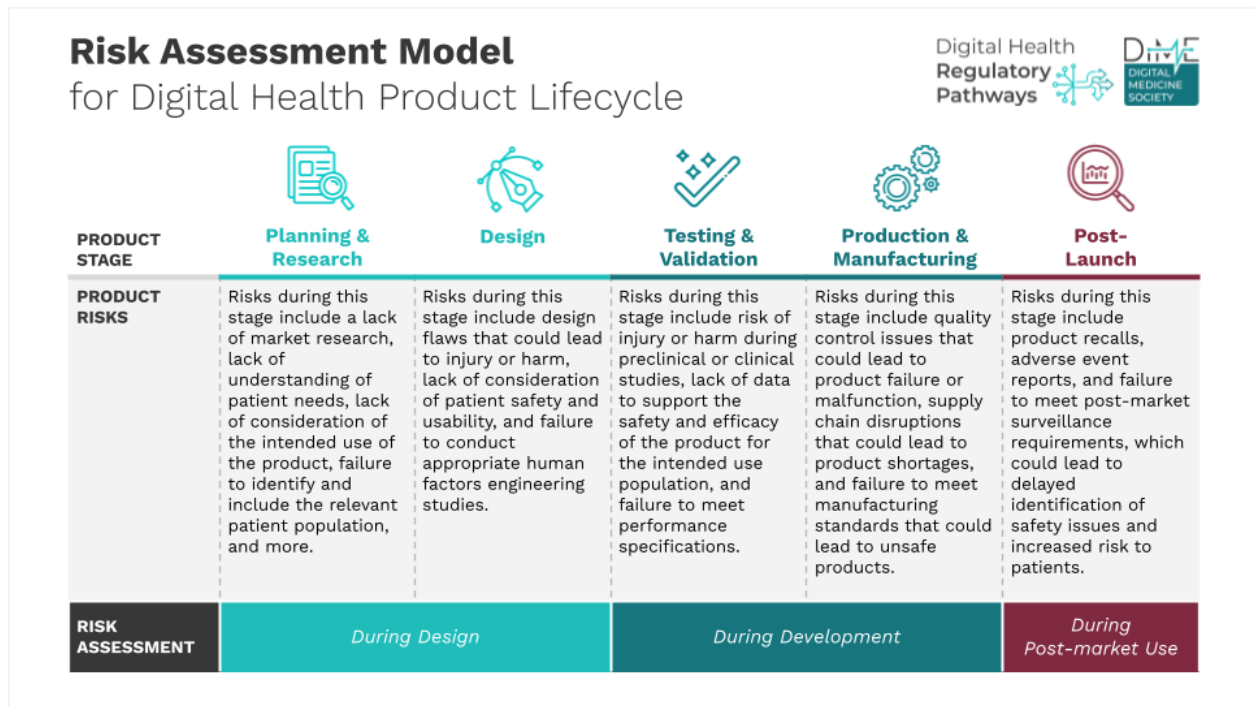
The FDA uses a [Total Product Life Cycle \(TPLC\)](#) approach for digital health products. The risks across the product lifecycle may vary, which may include the following stages:

- **Planning and Research:** Risks during this stage include a lack of market research, unclear or unrealistic product goals, and inadequate funding or resources.
- **Design and Development:** Risks during this stage include design flaws, inadequate testing, and failure to meet regulatory requirements.
- **Testing and Validation:** Risks during this stage include failure of preclinical or clinical studies, lack of data to support safety and efficacy, and failure to meet performance specifications.



- **Production and Manufacturing:** Risks during this stage include quality control issues, supply chain disruptions, and failure to meet manufacturing standards.
- **Post-Launch:** Risks during this stage include product recalls, adverse event reports, and failure to meet post-market surveillance requirements.

A product risk assessment should not be a one-stop-shop but rather an ongoing, interactive process. The risks should be considered throughout the entire product lifecycle, including during the planning and research phase, the design and development phase, the testing and validation phase, the production and manufacturing phase, and the post-launch phase. It is important to identify and assess potential risks at each stage of the product life cycle, and to develop strategies to mitigate or manage those risks. This process can help to ensure that the product is developed and launched successfully, and that any issues that arise are addressed in a timely and effective manner.



DOWNLOAD Risk Assessment Model for Digital Health Product Lifecycle 

For every digital health product, the key is to remember that the risks may change as the product life cycle progresses and new information becomes available. Therefore, it's important to continually assess risks and update risk management plans as needed. Additionally, at each stage, the FDA requires a certain level of documentation, such as design control and risk management documentation, to ensure proper management of risks and compliance with regulatory requirements.

In the case below, the FDA reclassified the product due to safety and effectiveness concerns and the need for additional regulatory oversight and special controls to mitigate the risks associated with the product.



Reclassification to a Higher Risk Class

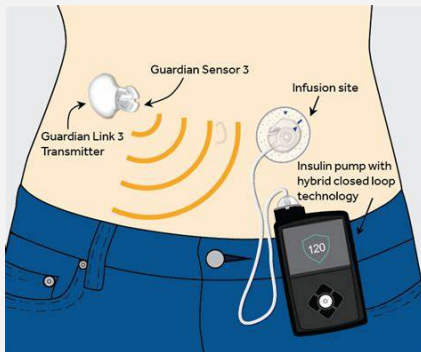


Image source: [Medgadget](#)

The Medtronic MiniMed 670G is an insulin pump system that includes a continuous glucose monitoring sensor and an algorithm that automatically adjusts insulin delivery based on glucose levels. In September 2016, the FDA cleared the device as a Class II medical device. However, in June 2017, the FDA reclassified the device to Class III (high risk) due to safety concerns related to the device's automatic insulin dosing algorithm. The FDA noted that the device could cause dangerously low blood sugar levels if the algorithm did not properly adjust insulin delivery in response to changes in glucose levels.

As a result, Medtronic was required to submit a premarket approval (PMA) application, which is the most stringent type of device marketing application, and go through more extensive testing and clinical trials before the device could be marketed again. Medtronic submitted its PMA application in October 2017 and received FDA clearance for the device in September 2018.

This case study illustrates how the FDA's TPLC approach can help to ensure the safety and effectiveness of medical devices and how even a product that is already on the market may be re-evaluated and reclassified if new safety concerns are identified. Additionally, it highlights the importance of continuous monitoring and risk management throughout the product life cycle.

The Medtronic MiniMed 670G Insulin Pump System

A digital health product that underwent reclassification from Class II to Class III by the FDA for safety and effectiveness reasons

Access DiMe's Digital Health Regulatory Pathway Resources



Identify your regulatory pathway



Build your regulatory strategy



Interact with regulators

