Digital Health
Regulatory
Pathways

5-Step Approach

to Classifying Your Digital Health Product in the U.S.

SHOW, DON'T TELL

Classifying a digital health product as a certain risk class is important in the US because it determines the level of regulatory oversight that the product will be subject to. The Food and Drug Administration (FDA) classifies digital health products into three risk classes: **Class I** (low risk), **Class II** (moderate risk), and **Class III** (high risk). This system helps to ensure that products that pose the greatest risk to patients are subject to the most rigorous oversight, while products that pose a low risk can be brought to market more quickly.

But as an innovator, how would you know what FDA class your product fits into? Well, this guide is intended to help guide individuals, teams, and organizations to help classify their digital health product as a part of their development process. Ultimately, the final decision of the risk class is up to the FDA.

To learn more about the FDA's approach to classifying digital health products, including various factors, types of product class, risk assessment for product development, case studies and more, check out the guide below:

DOWNLOAD Digital Health Product Categorization Guide

5 STEPS TO CLASSIFYING DIGITAL HEALTH PRODUCTS IN THE US

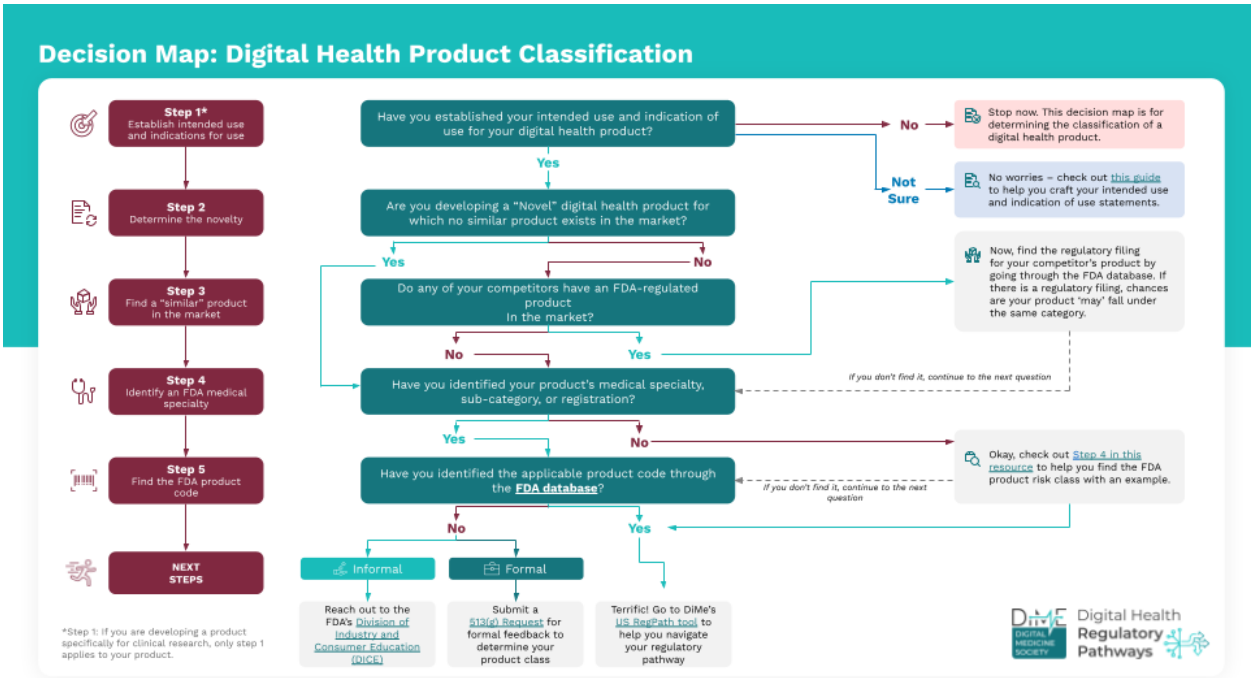
Establish intended use & indications for use for your product before trying to classify your product

Determine the novelty of your product compared to what's already on the market

Determine if there are any "similar" products in the market via a quick internet search of your competitors

Identify an FDA medical specialty to which your product belongs and identify associated regulations

Find the FDA product code in the FDA's database and determine the best option for your product



DOWNLOAD **Decision Map: Digital Health Product Classification**

A STEP-BY-STEP METHOD TO DETERMINE YOUR DIGITAL HEALTH PRODUCT CLASS IN THE US

5-step approach to classifying your digital health product

According to the FDA classification process, as of today, all types of digital health products are classified by the FDA into approximately 1,700 different generic types that are grouped into 16 medical specialties, AKA "Panels." The products are then assigned one of three regulatory classes (i.e., Class I, II, or III) based on the risk and level of controls needed to ensure device safety and effectiveness.

Keeping that in mind, here are some steps to show you how you can get an idea or your digital health product class:

STEP 1: ESTABLISH YOUR PRODUCT'S INTENDED USE AND INDICATION FOR USE

Before trying to classify your product, one of the key steps is to articulate your general statements regarding its intended use and indications for use. As these statements inform the product classification, carefully craft your intended use and indications for use statements – even though they sound similar, they are different.

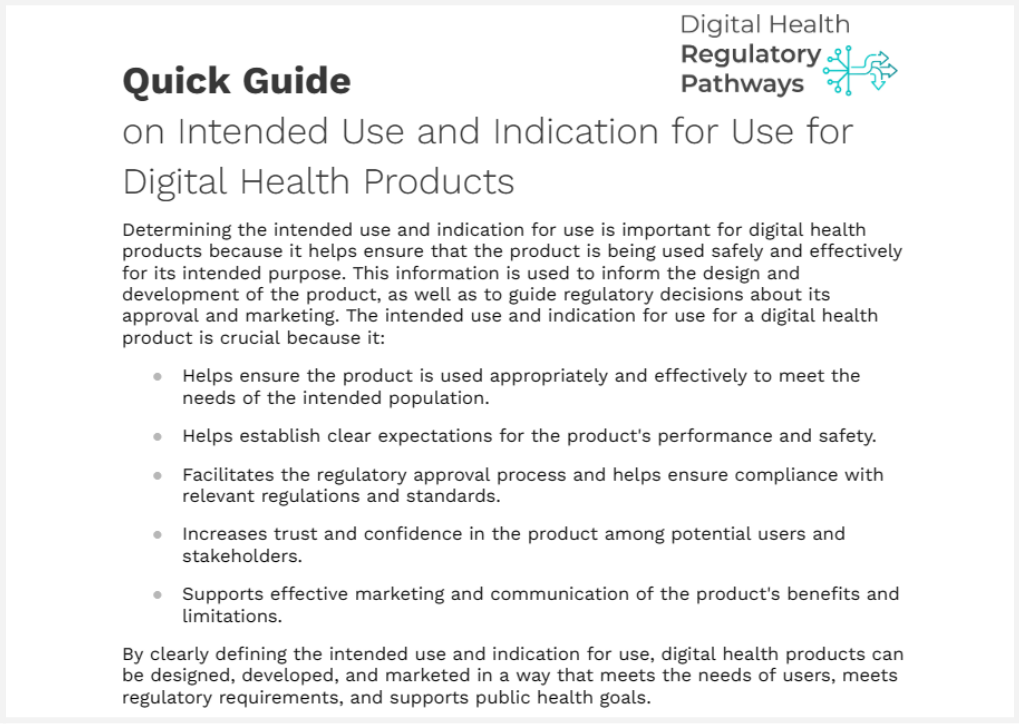
- **Intended use** - The general purpose of the device or its function, which includes its indications for use. A real-world example:

Photoplethysmograph analysis software for over-the-counter use: A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.

- **Indications for use** - Describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended. A real-world example:

  The Atrial Fibrillation (AFib) History Feature is an over-the-counter ("OTC") software-only mobile medical application intended for users 22 years of age and over who have a diagnosis of atrial fibrillation (AFib). The feature opportunistically analyzes pulse rate data to identify episodes of irregular heart rhythms suggestive of AFib and provides the user with a retrospective estimate of AFib burden (a measure of the amount of time spent in AFib during past Apple Watch wear).

  - *The feature also tracks and trends estimated AFib burden over time, and includes lifestyle data visualizations to enable users to understand the impact of certain aspects of their lifestyle on their AFib. It is not intended to provide individual irregular rhythm notifications or to replace traditional methods of diagnosis, treatment, or monitoring of AFib.*
  - *The feature is intended for use with the Apple Watch and the Health app on iPhone.*



Digital Health Regulatory Pathways

Quick Guide

on Intended Use and Indication for Use for Digital Health Products

Determining the intended use and indication for use is important for digital health products because it helps ensure that the product is being used safely and effectively for its intended purpose. This information is used to inform the design and development of the product, as well as to guide regulatory decisions about its approval and marketing. The intended use and indication for use for a digital health product is crucial because it:

- Helps ensure the product is used appropriately and effectively to meet the needs of the intended population.
- Helps establish clear expectations for the product's performance and safety.
- Facilitates the regulatory approval process and helps ensure compliance with relevant regulations and standards.
- Increases trust and confidence in the product among potential users and stakeholders.
- Supports effective marketing and communication of the product's benefits and limitations.

By clearly defining the intended use and indication for use, digital health products can be designed, developed, and marketed in a way that meets the needs of users, meets regulatory requirements, and supports public health goals.

Need help crafting intended use and indication for use statements?

DOWNLOAD **Quick Guide for Intended Use and Indication for Use for Digital Health Products**

STEP 2: DETERMINE THE NOVELTY

To get started, ask yourself a question, “Am I developing a digital health product that is truly novel, meaning no similar products currently exist in the market?”

Note: The FDA has a full database repository of all products on the market, and very few products are completely “novel.” If you are confident you are developing a novel solution, please skip to Step 4.

STEP 3: FIND A “SIMILAR” PRODUCT IN THE MARKET

You know your product best, and you likely also know your competitors in the field. You may be able to avoid going through the full FDA database search by doing a good old-fashioned internet search of your competitors:

1. Compile a list of your competitors and/or potential competitors
2. Use the internet to check if any of your competitors have an FDA regulated product:
    - If **no** → go to Step 4
    - If **yes** → find the regulatory filing for their product by going through the FDA database (as below). If there is a regulatory filing for their product, there is a chance your product may fall under the same category.

Quick Tips for Searching the FDA Database

- Search by a company → Type in the "**Applicant Name**" or "**Requester Name**" field
- Search by product name → Type in the “**Device Name**” field
- Search by application no. → Type in the “**510(k) Number**,” “**De Novo Number**,” etc., field based on the application
- Search by timeline → Type in the “**Decision Date**” field
- Search by code → Type in the “**Product Code**” field
- Search by FDA division → Type in the “**Center**” field

DOWNLOAD **FDA Databases for Digital Health Products**

STEP 4: IDENTIFY AN FDA MEDICAL SPECIALITY

Sometimes, identifying the right regulatory class of your product may take some more time and grit. Your next step is to identify the FDA medical specialty that best applies

to your product, keeping your product's intended use and indications for use in mind. The full list of FDA medical specialities is available in CFR Title 21: Parts 862 to 892.

Let's say the intended use of your product is to help identify Atrial Fibrillation, so click **"870 Cardiovascular devices"** (as per the below image).

Once you select a medical speciality category (in this case, "**870 Cardiovascular devices**"), the link will take you to a list of various subcategories and specialities. Search through the list to find the subcategory/specialty that appears to be the closest fit to your product and click the associated link for additional information.

Going back to our example of the product to identify Atrial Fibrillation, under the “870 Cardiovascular devices,” you would select the option, “**§ 870.2790 - Photoplethysmograph analysis software for over-the-counter use**” (as per the image), because:

1. Our example has a mobile medical application software based on a non-prescription purpose
2. The photoplethysmograph helps identify irregular heart rhythms (which is helpful for identification of Atrial Fibrillation)

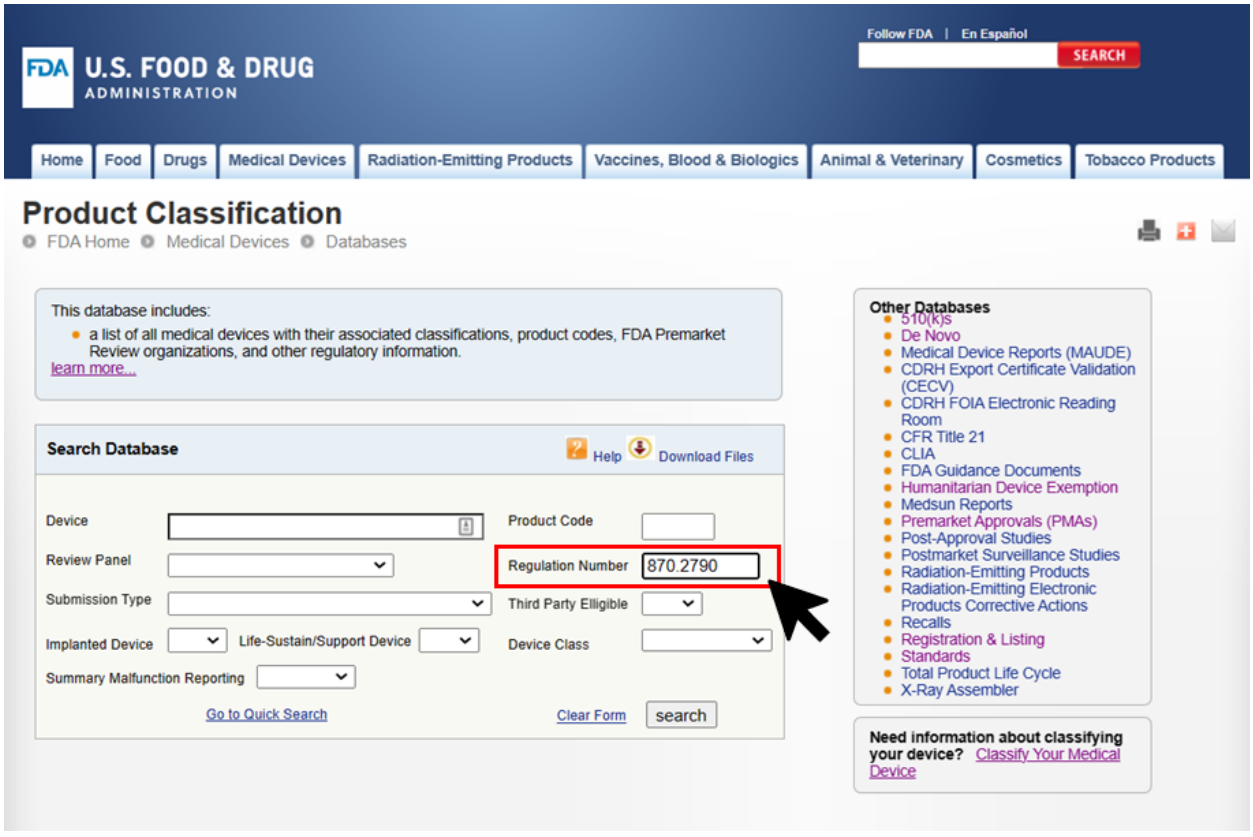
Once you select the link, it will lead you to the CFR Title 21 page (image below). Read through this information and compare it with your intended use and indication of use to find similarities that align with this specific regulation.

As you read through this information, you will find that your product may be an **FDA "Class II" device** and it would require "**special controls,**" along with the general controls.

STEP 5: FIND THE FDA PRODUCT CODE

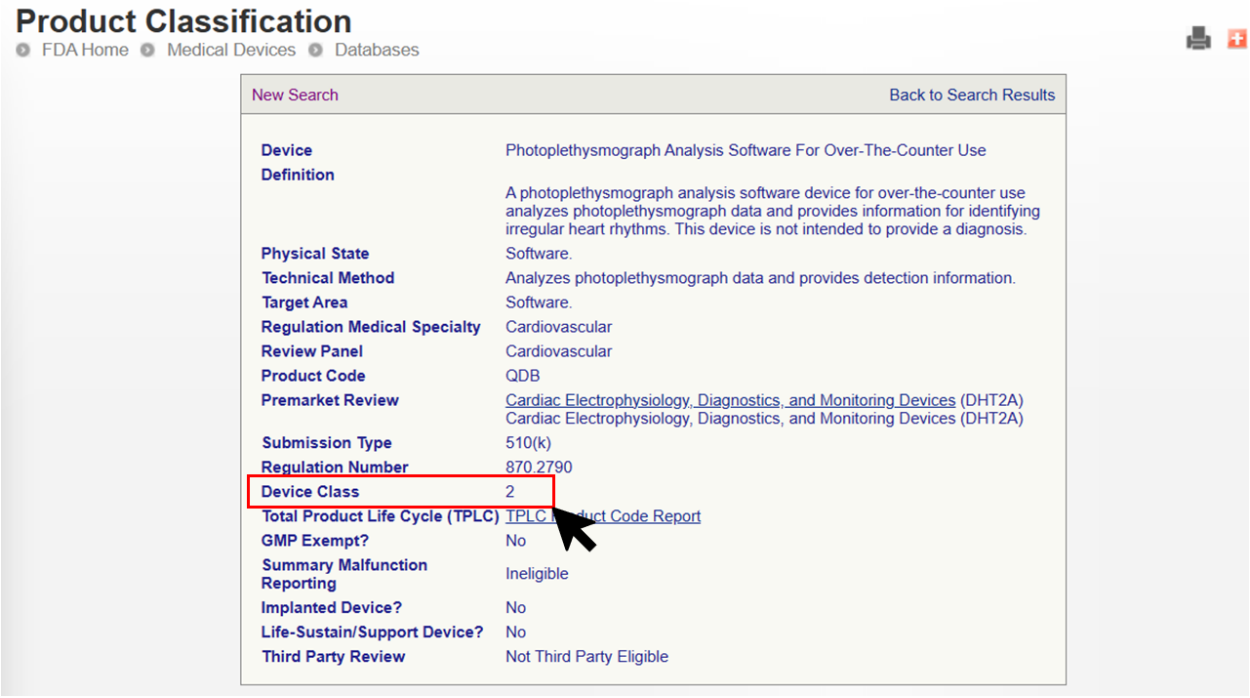
Once you find appropriate regulations for your digital health product and potential classification of the product, you will need to identify your product's applicable product codes by conducting a search in the FDA Product Classification database.

Go to the "Registration Number" and input the 7-digit code. For the example we identified above, the code is **"870.2790"** for photoplethysmograph analysis software for over-the-counter use.



Once you click the search button, you will go either:

- Directly to the product classification page (as in the image below), and you can see your FDA product class -> **Class II**, OR
- Indirectly to a series of product codes and corresponding device classifications. In such a case, review the links of each product code, and choose the option that best applies to your product.



NEXT STEPS

This process may look (and feel) time-consuming, overwhelming, and unnecessary, but it's not impossible – you just went through it. Going through the process by reviewing regulations and product codes will be beneficial in the long run for developing a regulatory strategy, product decision-making, and communicating with regulatory authorities.

As a next step:

- If you identified your product classification, your next step is determining which FDA regulatory pathway you need to pursue for your product. Use DiMe's US RegPath tool to help you navigate the regulatory pathways.
- If you weren't able to identify your product's classification, no worries. You can choose one of two routes to communicate with the FDA to help you with your product's classification:

INFORMAL PATHWAY	FORMAL PATHWAY
Reach out to the Division of Industry and Consumer Education (DICE) at DeviceDetermination@fda.hhs.gov. Things to include: • Intended use of your product • Physical description of your product and its mechanism of action • Any claims you intend to publicly make about the product • Your contact information	If you would like a formal device determination or classification from the FDA, consider submitting a 513(g) Request. Learn more about 513(g).

Access DiMe's Digital Health Regulatory Pathway Resources

Identify your regulatory pathway

Build your regulatory strategy

Interact with regulators