Digital Health Regulatory Pathways

Navigate Digital Health Regulations in the U.S.

Digital Health Regulatory Pathways — DiMe Digital Medicine Society

STARTING POINT

Before you go through the tool, think about 5Ws for your digital health product

- **WHO?** Who is/are the end user(s) of your product?
- **WHAT?** What does your product do?
- **WHEN?** When should the end user (s) utilize your product?
- **WHERE?** Where will your product be used?
- **WHY?** Why should end user(s) use your product?

Are you interested in understanding which FDA regulations may apply to your digital health product?

YES / NO → *Stop now* — *This flowchart is created to help innovators navigate FDA regulations for digital health products in the U.S.*

For your product, have you:

- Identified a **single** intended use
- Identified **multiple** intended use(s)
- **Not** identified intended use(s)

Use this template to create your intended use statement and indication of use for your digital health product.

Digital health products may have multiple components (referred to as "functions" in FDA's lexicon) and may be regulated differently. Please complete the following steps for each component (or function) of your digital health product. Learn more.

What is the intended use of this component (or function) of your digital health product?

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans.
- Intended to maintain or encourage a healthy lifestyle (e.g. wellness, fitness, etc.) **and is unrelated** to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition. Check this guide for examples or learn more.
- None of them. *(If the product is intended for clinical research **only** continue to the next question, otherwise stop here.)*

For your product, FDA likely exercises FDA enforcement discretion. However, continue to the next question to determine the FDA oversight

Do any of the following three statements apply to your product?

1. Has an intended use that relates the role of a healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions?
2. Has an intended use that relates between healthy lifestyle and disease specifically expressed as "may help to reduce the risk of" or "may help living well with" a chronic disease or condition?
3. Has a product with low risk as defined by the FDA guidance? Learn more.

If your answer is no to any of the 3 choices, select "No." Otherwise, select "Yes."

NO / YES

Do any of the following four statements apply to your product?

1. The product is invasive.
2. The product is an implant.
3. The product is an intervention or technology that poses more than "a low risk" to the safety of users and other persons if specific regulatory controls are not applied Learn more.
4. A product of the same type is already actively regulated by FDA.

If your answer is no to all of the 4 choices, select "No." Otherwise, select "Yes."

NO / YES → *Your product is likely a "general wellness" product that will not be the focus of FDA's regulatory oversight.*

It is important to know that even if the product may be used by both individual patients/caregivers and HCPs, it is key to differentiate who your end user is (or will be) as that may affect your regulatory pathway.

Who is the end user for your product?

- Individuals/patients or caregivers
- Healthcare provider (HCP)
- Both

Where (or in what environment) would your product be used in?

- Clinical research setting **only**
- Care setting including traditional care (in-clinic, hospital, etc.), and Non-traditional care setting (virtually, at home, etc.)
- Clinical research and care setting

Do you envision your product to be used **only** in the exploratory research setting?

NO / YES

Do any of the following statements apply to your product?

1. The product is Intended to be an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
2. The product is represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.
3. The product is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health, and presents a potential for serious risk to the health, safety, or welfare of a subject.
4. The product presents a potential for serious risk to the health, safety, or welfare of a subject.

If your answer is yes to any of the 4 choices, select "Yes". Otherwise, select "No"

YES / NO

- *Your product is likely to pose a significant risk and classified by FDA as a "Significant Risk Device". Learn more*
- *Your product is likely to pose non-significant risk and classified by FDA as a "Non-Significant Risk Device". Learn more*

Do you envision your product to be used in clinical research and care setting at some point?

YES / NO

Do any of the following three statements apply to your product?

1. The product provides or facilitates supplemental clinical care (by coaching or prompting) to help patients manage their health in their daily environment, without providing specific treatment or treatment suggestions.
2. The product helps patients communicate with healthcare professionals by supplementing or augmenting data or information through capturing an image for patients to convey to their healthcare professionals about potential medical conditions.
3. The product performs simple calculations routinely used in clinical practice.

If your answer is yes to any of the 3 choices, select "Yes". Otherwise, select "No"

NO / YES → *Your product is likely not the focus of FDA's regulatory oversight. Learn more*

Do any of the following three statements apply to your product?

1. The product is an extension of one or more medical products by connecting to such product(s) for the purposes of controlling the product(s) or analyzing medical product data.
2. The product transforms a mobile platform or general-purpose computing platform into a regulated medical device by using attachments, display screens, or sensors, or by installing functionalities similar to those of currently regulated digital health products.
3. The product performs patient-specific analysis and provides specific output(s) or directive(s) to users for use in the diagnosis, treatment, mitigation, cure, or prevention of a disease/condition.

If your answer is yes to any of the 3 choices, select "Yes". Otherwise, select "No"

NO / YES → *Your product is likely the focus of FDA's regulatory oversight. Learn more*

Does your product provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions?

NO / YES

Does FDA product classification exist for your digital health product?

YES / NO / IDK PAGE

What is your FDA product classification?

If FDA product classification does not exist for your digital health product, the following explanations and solutions may apply:

- If your product is exempt (Class I and II) from FDA regulatory oversight, there may be no applicable product classification.
- If your product is a novel digital health solution, you may benefit from a de novo program or file a pre-submission to determine your product classification. Learn more
- If you are still unsure, check out the Product Classification Toolkit or visit FDA's "Classify your medical device" webpage.

Class I and II Exempt	Class I	Class II	Class III	Unclassified/ Unknown risk

Your product is likely exempt from the FDA oversight

Have any similar product(s) been legally marketed in the U.S.? *Note: FDA calls that a "predicate device". Learn more.*

NO / YES / IDK → *Check out this guide (Step 3) to walk you through how to identify your predicate device.*

Comparison of your product to an already marketed product

- Does your product have the same intended use? NO / YES
- Does your product have the same technological characteristics? NO / YES
- Do different technological characteristics of your product raise different questions of safety and effectiveness? Yes / No
- Are the scientific methods acceptable? NO / YES
- Do the performance data demonstrate substantial equivalence? NO / YES

Your product is likely to undergo FDA's De novo Pathway

Your product is likely to undergo FDA's 510(k) pathway

De Novo	De Novo	De Novo	De Novo
As-a-Glance	Prep Guide	Checklist	FAQs

510(k)	510(k)	510(k)	510(k)
As-a-Glance	Prep Guide	Checklist	FAQs

Is your product intended to treat or diagnose a disease/condition that affects <8000 individuals in US annually?

NO / YES

Does your product expose patients to an unreasonable or significant risk of illness or injury?

YES / NO

Does the probable benefit to health from use of your product outweigh the risk of injury or illness from its use compared to alternative forms of treatment from other digital health products?

YES / NO

Is there a comparable product available to treat or diagnose such disease/condition or another product approved under a Humanitarian Device Exemption (HDE) or Investigational Device Exemptions (IDE)?

YES / NO

Your product is likely to undergo FDA's Premarket Approval (PMA) pathway

Your product is likely to qualify for the Humanitarian Device Exemption (HDE) Program

PMA	PMA	PMA	PMA
As-a-Glance	Prep Guide	Checklist	FAQs

HDE	HDE	HDE	HDE
As-a-Glance	Prep Guide	Checklist	FAQs

Is your product intended for interpretation or analysis of patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition?

YES / NO

- The product is intended to be used for administrative support of a healthcare facility. → *Your product is likely not the focus of FDA's regulatory oversight Learn more*
- The product is intended to be used for administrative support of laboratories and/or for transferring, storing, converting formats of, or displaying clinical laboratory test data and results. → *Your product is likely not the focus of FDA's regulatory oversight. Learn more*
- The product is intended to serve as electronic patient records, or to transfer, store, convert formats of, or display electronic patient records that are the equivalent of a paper medical chart.
- None of the above.

Is your product **solely** intended to transfer, store, convert formats of, or display medical device data and results, including medical images, waveforms, signals, or other clinical information?

NO / YES

Do any of the following statements apply to your product?:

1. The product controls or alters the functions or parameters of any connected medical product?
2. The product generates alarms or alerts or prioritizes patient-related information on multi-patient displays, or provides for active patient monitoring to enable immediate clinical action?
3. The product analyzes or interprets digital health product data?

If your answer yes to any of the 3 choices, select "Yes". Otherwise, select "No"

YES / NO → *Your product is likely not a medical device and will not be the focus of FDA's regulatory oversight. Learn more*

Does your product intend to acquire, process, or analyze a medical image or a signal from an in-vitro diagnostic device or a pattern or signal from a signal acquisition system?

YES / NO

Do any of the following three statements apply to your product?:

1. The product displays, analyzes, or prints medical information normally communicated between healthcare professionals.
2. The product provides recommendations (information/options) to a healthcare professional rather than providing a specific output or directive for preventing, diagnosing, or treating a disease or condition.
3. The product provides the basis of recommendations so that the healthcare professional does not rely primarily on any recommendation to make a decision regarding an individual patient.

If your answer is no to any of the 3 choices, select "No". Otherwise, select "Yes"

NO / YES → *Your product is likely not a medical device and may not be the focus of FDA's regulatory oversight. Learn more.*

Are your product records certified under a program of voluntary certification kept or recognized by the Office of the National Coordinator for Health Information Technology (ONC)?

YES / NO

- *Your product is likely not the focus of FDA's regulatory oversight. Learn more*
- *Your product is likely not a medical device and may not be the focus of FDA's regulatory oversight. Learn more*

Are your product's health records created, stored, transferred, or reviewed by healthcare professionals or by individuals working under their supervision?

YES / NO → *Your product is likely not a medical device and may not be the focus of FDA's regulatory oversight. Learn more*

Does your product:

1. Represent a breakthrough technology;
2. Have no cleared or approved alternative device;
3. Offer a significant advantage over existing approved or cleared alternatives to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), and establish long-term clinical efficiencies; or
4. Claim its availability to be in the best interest of patients?

If your answer is no to any of the 4 choices, select "No". Otherwise, select "Yes"

NO / YES → *Your product is likely to qualify for FDA's Breakthrough Devices Program. Learn more.*

Use this guide to determine the product class for your digital health product.