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.

Contents of the guide:

At-a-glance

	INTENDED USE	INDICATIONS FOR USE
FDA Definition	*The general purpose of the device or its function. This includes the 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.*
In other words	Provides a **general description** of what your digital health product does.	Provides more **specific information** about the disease, condition, environment, and patient population that your digital health product will address.
Things to include	• Name of your digital health product • Medical purpose of your product and what it's trying to do for the user	• Name of your digital health product • Specific condition or disease state the product is addressing • Age group the product is being used for • Patient population the product will be targeting • What the features of the product do • If there other technology components or products that are going to be used with/paired/connected with this product (e.g. a mobile application on a phone) • Whether your product will be for “prescription” or “over-the-counter” use
Hypothetical example	A CardiacPC is intended to be used to treat patients with heart rhythm disorders. This product is not intended to provide a diagnosis.	A CardiacPC is intended to be used to treat patients above the age of 18 with heart rhythm disorders. It would be used to treat conditions such as bradycardia (slow heart rate) or tachycardia (fast heart rate). The healthcare provider may be expected to follow the manufacturer's instructions for implantation and programming of the device, as well as any follow-up care and maintenance.

Things to consider for the product's intended use and indication for use

Clinical Scale: General to Specific

As the indication for use of the digital health product can vary from being wide and general to being targeted or specific, the FDA notes that a change in a product's indication for use from general to specific usually results in an indication for use that is narrower than the approved or cleared general use. Such a change or additional indication will typically narrow the indication for use with respect to function, target population, therapeutic area or disease entity, organ or organ system effect, etc.

Levels of Specificity

The FDA defines levels of specificity as a qualitative ranking of the proposed indications for use of a digital health product. Levels of specificity for diagnostic and therapeutic products can be categorized as follows (listed in order of increasing specificity, from more general to more specific).

Levels of Specificity for Measurement and Diagnostic Digital Health Products

- Identification or measurement of a physical parameter (e.g., heart rate, frequency of sleep, gait measurements, heart rate variability, etc.)
- Identification of a new or specific target population (e.g., women, pediatrics)
- Identification of the clinical use of the measurement (e.g., diagnosis, screening)
- Identification of or implication of an effect on the clinical outcome (e.g., screening mammography reduces breast cancer mortality)

Levels of Specificity for Therapeutic (Including Preventive) Digital Health Products

- Identification of function (e.g., cut)
- Identification of an organ system or specific organ (e.g., liver)
- Identification of a particular disease entity (e.g., resection of hepatic metastases) or target population
- Identification of an effect on the clinical outcome (e.g., use of product improves the rate of durable complete remissions with chemotherapy)

Users and Usage Context

- Characterize the users who will be using your software, e.g. by age, knowledge (education), or language.

- Describe in which setting your software is used, e.g., on a hospital ward, in an emergency room, on workstations, etc. If it is used on workstations, is it pre-installed on those workstations or is it a web-based application? Is it an app? If so, how and when is this app typically used? Are any specific lighting conditions necessary, such as when looking at x-ray images, which require dark rooms?

Sample Template for the product's intended use and indication for use

Intended use

The **[Product name]** is intended to be used **[intentions for use]** in order to **[achieve intended use]**.

Indication for use

The **[Product name]** is an **[over-the-counter ("OTC") / Prescription]** only [**technology function/components**] intended for users **[x]** years of age and for the **[diagnosis/cure/mitigation/management/ treatment]** of **[disease/disorder/therapeutic area]**.

The **[Product name]** is intended for **[include clinical capabilities, usage context, how does this product diagnose a disease, etc.]**. It is not intended for **[include clinical capabilities, usage context, how this app diagnoses a disease, etc.]**.

The **[Product name]** is intended for use with **[other technology components or devices]**.

Please note: The sample template is for informational purpose only. As you craft your statements please check out the above mentioned factors and reference examples below.

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Example 1: Mobile Medical Application

Intended use

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.

Indication for use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213971

Device Name
Atrial Fibrillation History Feature

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Example 2: Continuous Glucose Monitoring

Intended use

FreeStyle Libre software is intended for use by individuals and healthcare professionals to aid in the review, analysis, and evaluation of information such as sensor glucose readings, blood glucose test results, and other data uploaded from the FreeStyle Libre Flash Glucose Monitoring System, in support of an effective diabetes health management program.

FreeStyle Libre software is not intended for the diagnosis of or screening for diabetes mellitus. Users should be aware that FreeStyle Libre software is merely an information management tool and it is therefore not intended to substitute for the support of a healthcare professional. Individuals should always consult their healthcare professional if they have any queries or concerns about diabetes management.

Indication for use

The FreeStyle Libre Flash Glucose Monitoring System is a continuous glucose monitoring (CGM) device indicated for the management of diabetes in persons aged 18 and older. It is designed to replace blood glucose testing for diabetes treatment decisions.

The System detects trends and tracks patterns aiding in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments. Interpretation of the System readings should be based on the glucose trends and several sequential readings over time. The System is intended for single patient use and requires a prescription.

Example 3: Virtual Reality Behavioral Therapy for Pain Relief

Intended use

EaseVRx is a virtual reality behavioral therapy device for pain relief intended to provide behavioral therapy for patients with pain. Therapy is administered via a virtual reality display which utilizes a software program containing the behavioral therapy content.

Indication for use

EaseVRx is a prescription-use immersive virtual reality system intended to provide adjunctive treatment based on cognitive behavioral therapy skills and other evidence-based behavioral methods for patients aged 18 and older with a diagnosis of chronic lower back-pain (defined as moderate to severe pain lasting longer than three months).

The device is intended for in-home use for the reduction of pain and pain interference associated with chronic lower back pain.

Example 4: Remote Temperature Monitoring System

Intended use

Foot examination tool used for potential inflammatory changes.

Indication for use

The Podimetrics Remote Temperature Monitoring System™ (RTM System™) is intended to be used by a patient in conjunction with a healthcare professional or caretaker for periodic evaluation of the temperature over the soles of the feet for signs of inflammation. It will provide information indicating when the patient and healthcare provider should communicate for further evaluation and treatment regarding any persistent localized inflammation observed on the feet via the electronic sensing system and remote visualization of its data.

The Podimetrics RTM System™ is intended to be used under the direction of a healthcare professional as an adjunct to, and not in replacement of, self-examination and periodic foot care and examination conducted by a healthcare professional, and does not diagnose any specific disease state.

Example 5: ECG Analysis System

Intended use

DeepRhythmAI is intended for use by a healthcare solution integrator to build web, mobile, or other types of applications to let qualified healthcare professionals review and confirm the analytic result.

Indication for use

DeepRhythmAI is a cloud-based software for the assessment of cardiac arrhythmias using two lead ECG data in adult patients. It is intended for use by a healthcare solution integrator to build web, mobile, or other types of applications to let qualified healthcare professionals review and confirm the analytic result. The product supports downloading and analyzing data recorded in the compatible formats from dedicated ambulatory ECG devices such as Holter, event recorder, Mobile Cardiac Telemetry, or other similar devices when the assessment of the rhythm is necessary.

The product can be electronically interfaced and perform analysis with data transferred from other computer-based ECG systems, such as an ECG management system. DeepRhythmAI can be integrated into medical devices. In this case, the medical device manufacturer will identify the indication for use depending on the application of their device.

DeepRhythmAI is not for use in life-supporting or life-sustaining systems or ECG Alarm devices. Interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in

conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms and other diagnostic information.

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