Digital Health Insights

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Orthopaedic Surgical Manufacturers Association
Fall 2024 Meeting

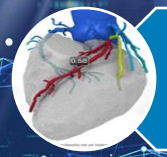
U.S. FOOD & DRUG ADMINISTRATION

CDRH Digital Health Center of Excellence

Digital Health Technologies (DHTs) and FDA's Regulatory Oversight of DHTs

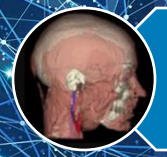
Digital Health Technology (DHT)

"A system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses"*

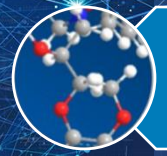


Used as a medical product

Incorporated into a medical product



Used to develop a medical product

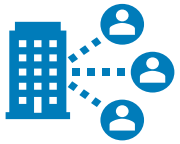


Used to study a medical product

Used as a companion or adjunct to a medical product, including diagnostics and therapeutics

*Definition from FDA-NIH BEST Glossary. Available at https://www.ncbi.nlm.nih.gov/books/NBK338448/

DHTs can transform how we study medical products



Enable Remote Data Collection in Decentralized Clinical Investigation

- More frequent or continuous monitoring compared to traditional methods
- Longitudinal view of participant's health status
- Improved recruitment and retention of participants leading to less missing data
- Final Guidance: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

Improve Access to Clinical Investigations

- Meet a participant where they are at for a clinical investigation
- Fewer visits to a study site places less burden on participants
- Reach a more diverse population, advancing health equity

Facilitate Innovative Clinical Investigation Endpoints

- New types of data to inform novel endpoints
- Complementary to other forms of data used to support a regulatory submission

Capture Real-World Data (RWD) and Patient-Generated Health Data (PGHD)

- Data reflects a participant's daily life
- Remote and longitudinal follow-up with participants beyond the clinical investigation
- More detailed picture of the impact of a medical product on a participant

FDA's risk-based approach to regulatory oversight of devices, including DHTs

Not a Device

Software functions that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health, or wellness, with no reference to a disease or condition

Intention to Exercise Enforcement Discretion

Software functions that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women

Focus of FDA's Oversight

Software functions that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG)

Increasing Risk

Interactive Overview of Digital Health Policies

The **Digital Health Policy Navigator** helps manufacturers consider whether a software function is potentially subject to or the focus of FDA's regulatory oversight as a device.

Interactive questions guide product developers to one of four different outcomes, reflecting policies described in relevant digital health guidances.

Interactive Questions

Step 1: Intended for a medical purpose?

Step 2: Intended for administrative support of a health care facility?

Step 3: Intended for maintaining or encouraging a healthy lifestyle?

Step 4: Intended to serve as electronic patient records?

Step 5: Intended for transferring, storing, converting formats, or displaying data and results?

Step 6: Intended to provide clinical decision support?

Step 7: Does the Device Software Function and Mobile Medical Application Guidance apply?

Navigator Outcomes

Icon	Outcome
	LIKELY NOT A MEDICAL DEVICE
	LIKELY FDA INTENDS TO EXERCISE ENFORCEMENT DISCRETION
FDA	**LIKELY THE FOCUS OF FDA'S REGULATORY OVERSIGHT**
	Your product may be a device. Go to Step #.

Relevant Guidances for DHTs that are Devices

Contains Nonbinding Recommendations

Multiple Function Device Products: Policy and Considerations

Guidance for Industry and Food and Drug Administration Staff

Document issued on July 29, 2020.

The draft of this document was issued on April 27, 2018.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact the Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

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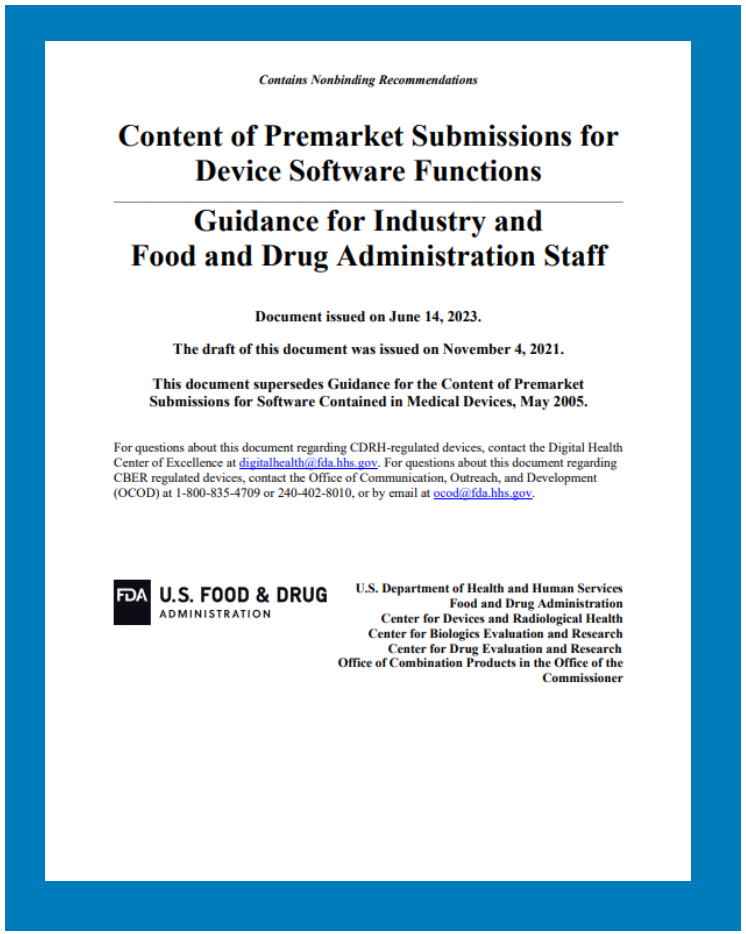

Contains Nonbinding Recommendations

Content of Premarket Submissions for Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

Document issued on June 14, 2023.

The draft of this document was issued on November 4, 2021.

This document supersedes Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 2005.

For questions about this document regarding CDRH-regulated devices, contact the Digital Health Center of Excellence at digitalhealth@fda.hhs.gov. For questions about this document regarding CBER regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

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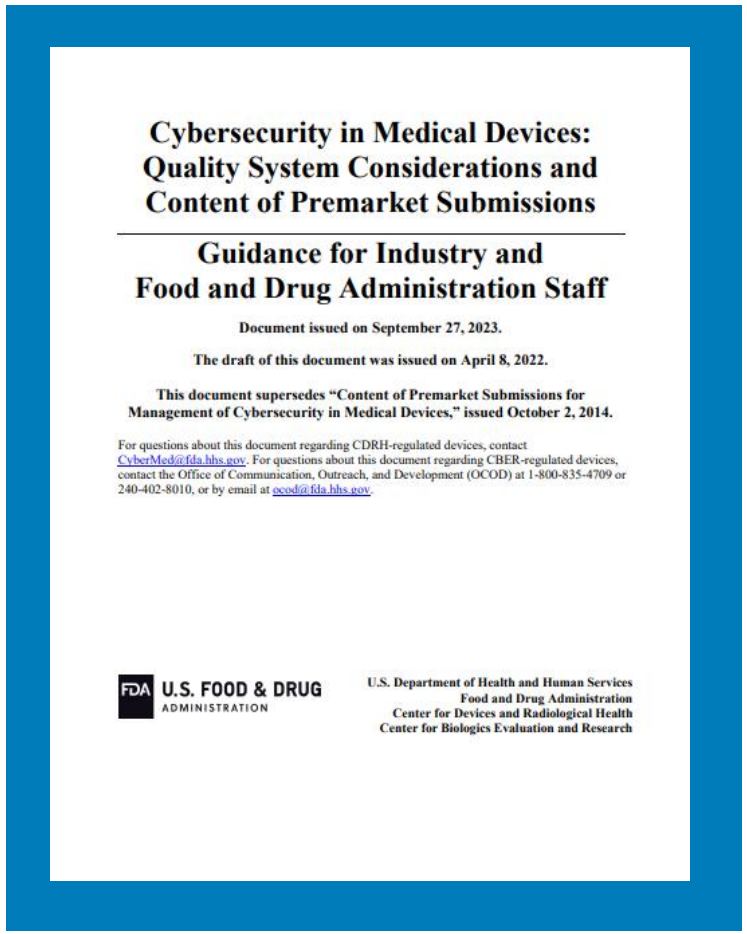

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 27, 2023.

The draft of this document was issued on April 8, 2022.

This document supersedes "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," issued October 2, 2014.

For questions about this document regarding CDRH-regulated devices, contact CyberMed@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

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Multiple Function Device Products

A product with multiple functions that contains at least one function that:

(A) meets the definition of device under section 201(h) in the Federal Food, Drug, and Cosmetic Act that is the focus of FDA's regulatory oversight; and

(B) is considered an "other function"

***Function* is a distinct purpose of the product,** which could be the **intended use or a subset of the intended use** of the product

- "Other functions" are not the subject of the FDA's review simply because they are part of a multiple function device product
- However, the FDA may assess the impact of "other functions" when assessing the safety and effectiveness of the device functions-under-review of a multiple function device product

"Other Function"

- Does not meet the definition of a device;
- Meets the definition of device, but is not subject to premarket review (for example, 510(k)-exempt); or
- Meets the definition of device, but for which FDA has expressed its intention not to enforce compliance with applicable regulatory controls

For more information regarding multiple function device products, please see FDA's guidance

Multiple Function Device Products: Policy and Considerations

Software Submission Content

- Provides recommendations on the information to provide in a **premarket submission for a device that includes a device software function(s)**
- Recommended documentation for a premarket submission depends on the **device's risk to a patient, a user of a device, or others in the environment of use**
- FDA intends to take a **risk-based approach** to help determine the **device's Documentation Level**, which is either ***Basic*** or ***Enhanced***

Software Documentation	
Documentation Level Evaluation	**Software Design Specifications**
Software Description	**Software Development, Configuration Management, and Maintenance Practices**
Risk Management File	**Software Testing as a part of Verification and Validation**
Software Requirement Specifications	**Software Version History**
Software System and Architecture Design	**Unresolved Software Anomalies**

For more information regarding software submission content, please see FDA's guidance

Content of Premarket Submissions for Device Software Functions

Cybersecurity Submission Content

Section 524B(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines "**cyber device**" as a device that "**(1) includes software validated, installed, or authorized by the sponsor as a device or in a device**; **(2) has the ability to connect to the internet**; and **(3) contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats**." If your **device meets the definition of a cyber device**, as defined under section 524B(c) of the FD&C Act, you are **required to submit information to ensure that cyber devices meet the cybersecurity requirements under section 524B(b) of the FD&C Act.**

Security Risk Management

1. Threat Modeling
2. Cybersecurity Risk Assessment
3. Interoperability Considerations
4. Third-Party Components
5. Security Assessment of Unresolved Anomalies
6. Total Product Lifecycle Risk Management

Security Architecture

1. Implementation of Security Controls
2. Security Architecture Views

Cybersecurity Testing

1. Security Requirements
2. Threat Mitigation
3. Vulnerability Testing
4. Penetration Testing

Cybersecurity Transparency

1. Labeling Recommendations for Devices with Cybersecurity Risks
2. Cybersecurity Management Plans

For more information regarding cybersecurity submission content, please see FDA's guidance **Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions**

Predetermined Change Control Plans (PCCPs)

Predetermined Change Control Plans for Devices: Section 515C of the FD&C Act

2022 Omnibus Appropriations Bill

Added section 515C to the Federal Food, Drug and Cosmetic Act (FD&C Act), which has provisions regarding PCCPs for devices that would otherwise require a PMA supplement or a new 510(k).

Scope

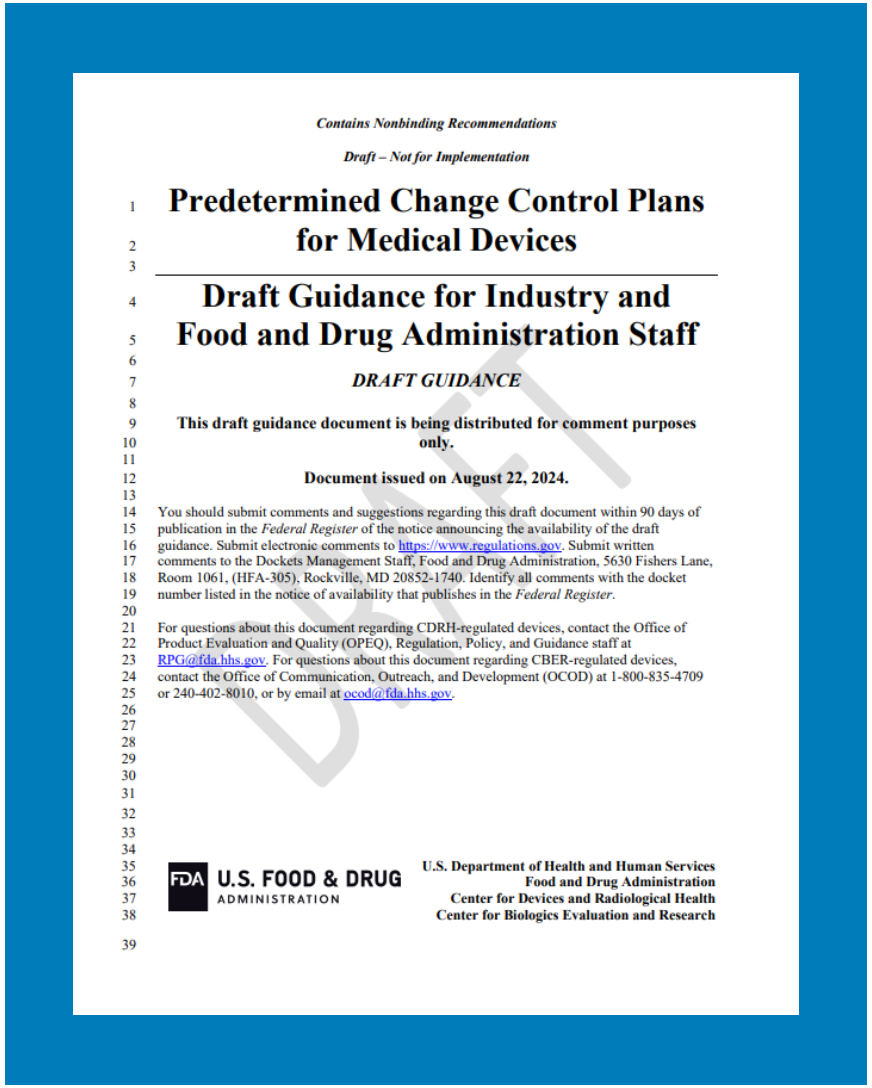
This provision applies to all device types—it is not specific to software or AI/ML-enabled devices. It applies to both premarket approvals and 510(k) submissions.

Predetermined Change Control Plans

PCCPs are planned changes that may be made to the device (and that would otherwise require a supplemental application) if the device remains safe and effective without any change.

- ✓ 515C is in effect and self-executing
- ✓ Manufacturers may submit, and FDA may approve or clear, a PCCP for a device at this time

Recent Draft Guidances on PCCPs



Contains Nonbinding Recommendations

Draft – Not for Implementation

Predetermined Change Control Plans for Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on August 22, 2024.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact the Office of Product Evaluation and Quality (OPEQ), Regulation, Policy, and Guidance staff at RPG@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

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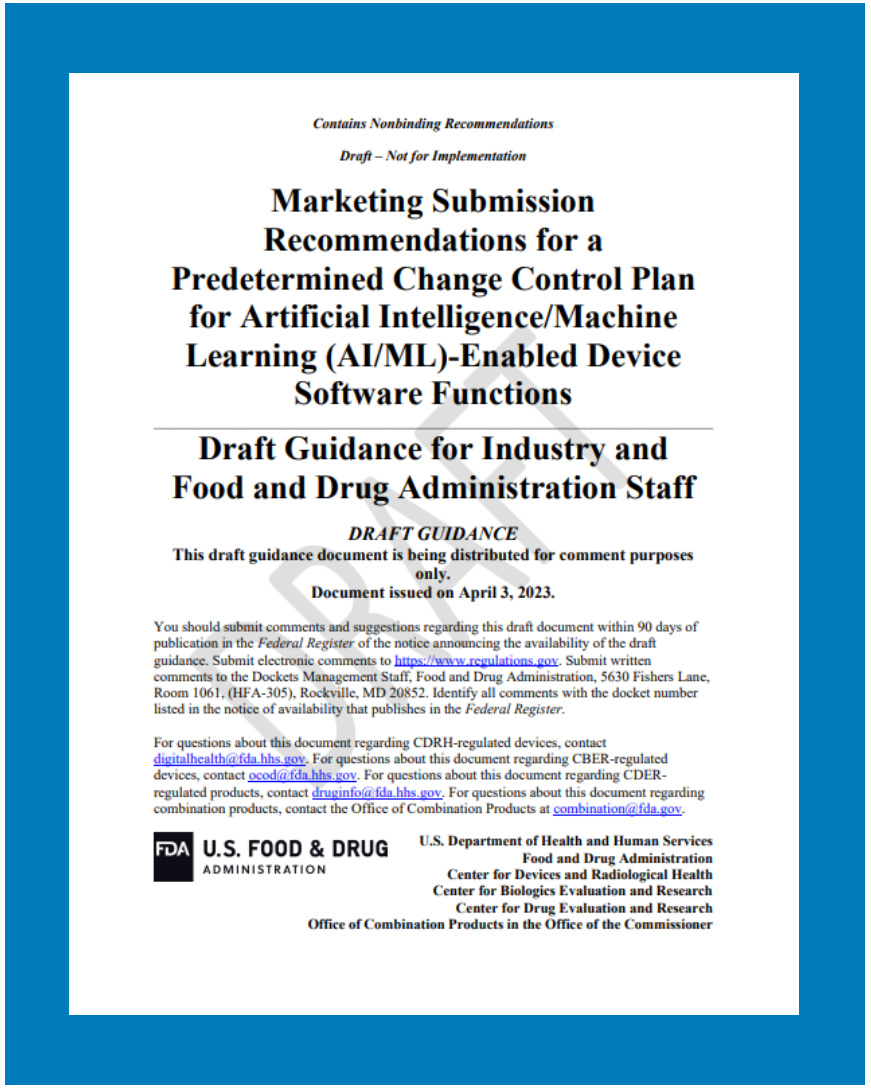

Contains Nonbinding Recommendations

Draft – Not for Implementation

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on April 3, 2023.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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Proposed Components of a PCCP

A PCCP is the documentation for a device that includes a description of the planned device modifications; the associated methodology to develop, validate, and implement those modifications; and an assessment of the impact of those modifications

Description of Modifications

- Detailed description of the specific, planned modifications that may be made to the device, including:
  - Device specifications
  - Performance characteristics

Modification Protocol

- Verification and validation activities, including pre-defined acceptance criteria, that will support each modification to ensure the device remains safe and effective

Impact Assessment

- Assessment of the benefits and risks of implementing a PCCP for a device
- Documentation of the risk mitigations

Proposed Types of Modifications

Modifications that are appropriate for inclusion in a PCCP include those that:

- Are intended to maintain or improve the safety or effectiveness of the device
- Are specific
- Can be verified and validated

Modifications included in a PCCP must maintain the device within the device's intended use *(sections 515C(a)(2) and 515C(b)(2) of the FD&C Act)*

FDA believes that most modifications to the **indications for use** included in a PCCP would be **difficult for FDA to assess prospectively** to determine whether the device would remain safe and effective

Proposed Types of Modifications related to DHTs

Modifications that are appropriate for inclusion in a PCCP include those that:

- Are intended to maintain or improve the safety or effectiveness of the device
- Are specific
- Can be verified and validated

Certain changes in device design, including dimensions, performance specifications, wireless communication, components or accessories, or the patient/user interface

Certain changes in software related to device compatibility and/or interoperability (e.g., changes to support device use on additional operating system(s), new data vendors and/or sources, or compatibility with additional devices)

Certain changes in software consistent with the intended use to improve device performance

FDA Feedback on PCCPs

We encourage manufacturers to engage early with FDA by submitting a Pre-Submission to discuss a proposed PCCP!

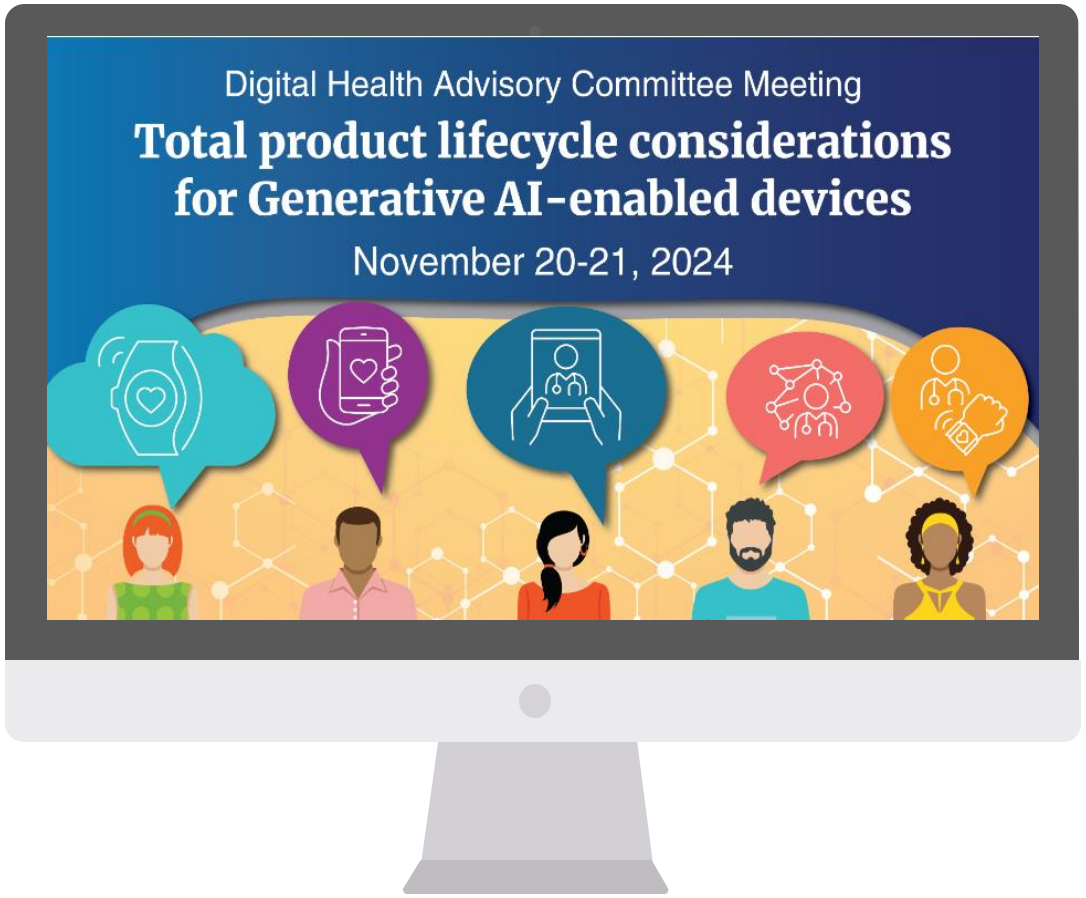
Pre-Subs can be a helpful way to obtain feedback on:

- ✓ A proposed PCCP for a device prior to submitting a marketing submission
- ✓ A proposed submission type for a device and PCCP
- ✓ Specific, proposed modifications for a device
- ✓ Proposed modifications to a PCCP

Digital Health Advisory Committee (DHAC) will advise FDA on DHTs

On November 20-21, 2024, the Digital Health Advisory Committee will discuss:

- Total product lifecycle considerations for generative AI-enabled medical devices
- How the use of generative AI may impact safety and effectiveness of medical devices enabled with this technology
- Premarket performance evaluation, risk management, and postmarket performance monitoring for generative AI-enabled devices



Further Questions or Feedback

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