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Fact Sheet

Premarket Submissions for Device Software Functions:

Understanding the FDA draft guidance

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Preparing your Premarket Submission for Device Software Functions

What will you find in this fact sheet?

Earlier this month (November 2021) the FDA published draft guidance regarding the **content of premarket submissions for device software functions**. The guidance document provides information on the recommended documentation to include in premarket submissions for the FDA's evaluation of the safety and effectiveness of device software functions.

Our easy-to-read fact sheet outlines:

- **What the guidance covers**
- **What you need to consider regarding documentation level**
- **A quick comparison between this guidance and IEC 62304**

What does the guidance cover?

The recommendations in the guidance document relate to device software functions including:

- **Software in a Medical Device (SiMD) and**
- **Software as a Medical Device (SaMD)**

The guidance refers to **a software function that meets the definition of a device as a "device software function."** For example:

A device software function may control a hardware device or be part of a hardware device (SiMD) or be a device without being part of a hardware device (SaMD).

For any given product, the term "function" is a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product.

For example, a product with an intended use to analyse data has one function: analysis. A product with an intended use to store, transfer, and analyse data has three functions: (1) storage, (2) transfer, and (3) analysis.

As this example above illustrates, **a product may contain multiple functions.**

What does the guidance cover?

Which software and hardware does the guidance cover?

- Firmware and other means for software-based control of medical devices
- Stand-alone software applications
- Software intended to be operated on general-purpose computing platforms
- Dedicatated hardware/software medical devices
- Accessories to medical devices when those accessories contain or are composed of software

Which types of Premarket Submission does the guidance apply to?

- Premarket Notification (510(k)) **(see our fact sheet on 510(k))**
- De Novo Classification Request **(see our fact sheet on De Novo)**
- Premarket Approval Application (PMA) **(see our fact sheet on PMA)**
- Investigational Device Exemption (IDE)
- Humanitarian Device Exemption (HDE)
- Biologics License Application (BLA)

Which existing guidance documentation is complementary to this draft guidance?

- Multiple Function Device Products: Policy and Considerations
- Off-The-Shelf Software Use in Medical Devices
- Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices
- General Principles of Software Validation
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software

What do I need to consider regarding documentation level?

Establishing the documentation level required helps to identify the minimum amount of information required to support your premarket submission for device software functions.

The recommended documentation for a premarket submission depends on:

- **The device's risk to a patient, a user of a device, or others in the use environment**
- **The device's intended use as a whole – not the individual device function(s)**

FDA intends to consider four risk-based factors to help determine the device's documentation level, which is either classed as **Basic** or **Enhanced**.

Basic Documentation

Should be provided for any premarket submission that includes device software functions where Enhanced Documentation does not apply.

Enhanced Documentation

Should be provided for any premarket submission that includes device software functions, where any of the following factors apply:

1. The device is a constituent part of a combination product
2. The device is:
    a. *intended to test blood donations for transfusion-transmitted infections*
    b. *used to determine donor and recipient compatibility*
    c. *a Blood Establishment Computer Software*
3. The device is classified as Class III
4. A failure or latent flaw of the device software function(s) could present a probable risk of death or serious injury, either to a patient, user of the device, or others in the use environment. These risk(s) should be assessed prior to implementation of risk control measures. You should consider the risk(s) in the context of the device's intended use; the direct and indirect impacts to safety, treatment, and/or diagnosis; and other relevant considerations

The guidance includes a **useful table** which provides an outline of the documentation recommended by the FDA for each software documentation element, together with a corresponding documentation level.

Tip: The items listed in the table should demonstrate traceability practices, planning, device requirements, risk assessment, design reviews, change management, testing plans and results, plus any other aspects of good software engineering for device software functions.

Comparing this guidance with IEC 62304

FDA harmonised the terminology and recommendations in the guidance with software-related consensus standards including:

- **ANSI/AAMI/IEC 62304 |** Medical Device Software - Software Life Cycle Processes
- **ANSI/AAMI/ISO 14971 |** Medical devices - Applications of risk management to medical devices
- **ANSI/AAMI SW91 |** Classification of defects in health software

That said, there are both similarities and differences between the intents and information discussed in the guidance and IEC 62304:

Similarities

Both the guidance and IEC 62304 discuss how to document and communicate software development, maintenance, and risk management processes.

Differences

This latest guidance document focusses on documentation and communication only, as it pertains to facilitating FDA's complete and efficient review of device software functions subject to premarket submission, whereas the scope of IEC 62304 extends beyond the intent of this guidance, discussing broader perspectives that may not result in documents that are easily reviewed by the FDA.

Should you require assistance with an eHealth challenge, please don't hesitate to get in touch – we'd be happy to help.

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