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5-minute guide:

FDA discussion paper: Considerations for the regulation of GenAI-enabled medical devices

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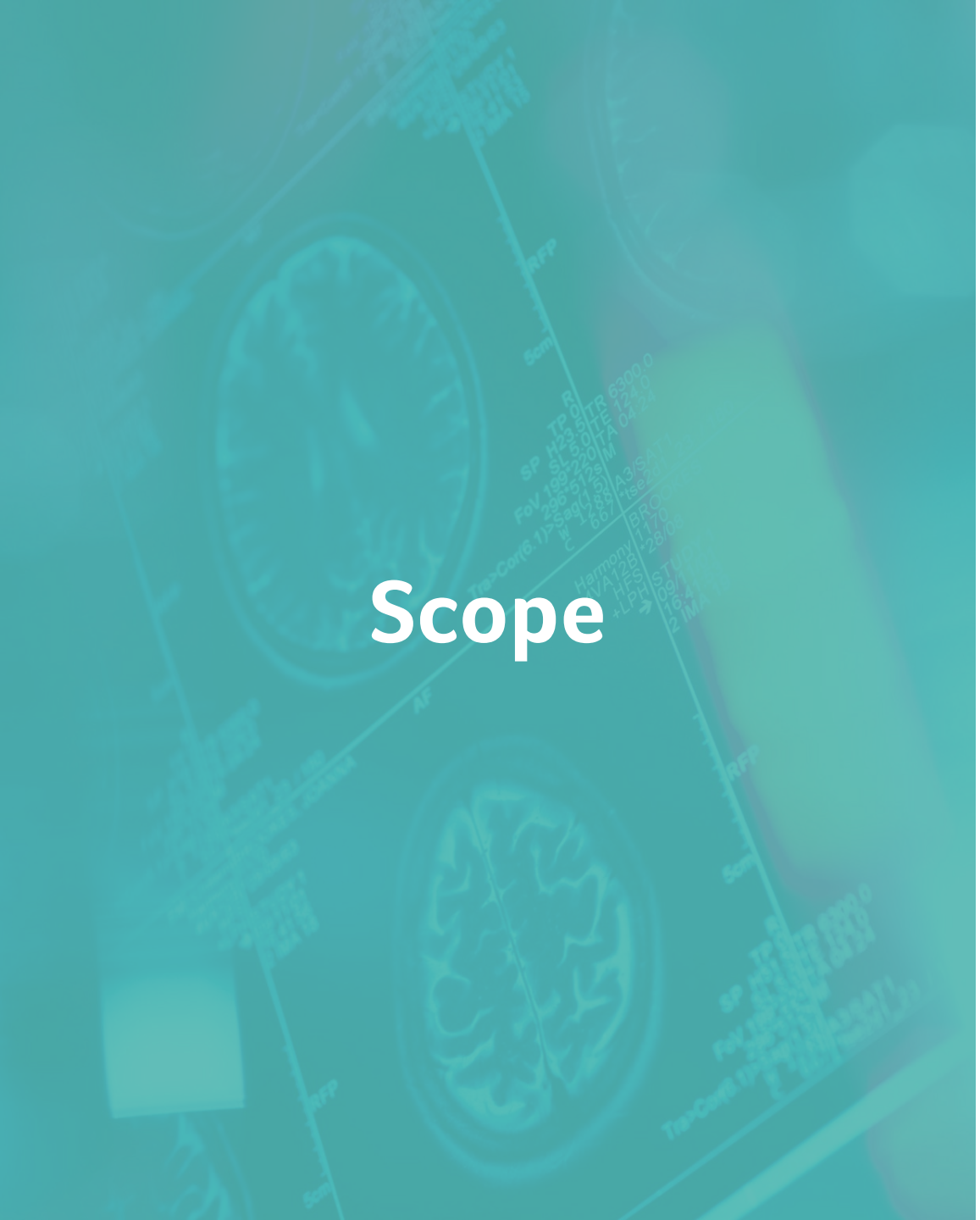
On 18 August 2026, the FDA's CDRH published "Considerations for the Regulation of Generative AI-Enabled Medical Devices", a discussion paper with an open request for feedback.

As acknowledged by the FDA, whilst GenAI-enabled medical devices have the potential to improve patient outcomes, they come with their own set of risks and challenges currently unaddressed by existing policies for software-based devices including those enabled by predictive AI.

The discussion paper is the next logical step for the FDA after the November 2024 public advisory committee meeting, during which total product lifecycle considerations for GenAI-enabled devices were discussed.

In this 5-minute guide, our Head of Regulatory Richie Christian outlines the scope of the discussion paper, highlights five key components and insights, and looks ahead to next steps…



Scope

What does the discussion paper cover?

The discussion paper focuses on device software functions enabled by generative AI, including multi-turn conversational and agentic functions.

The focus is solely on GenAI-enabled device software functions and not the entire device.

The discussion paper does not cover other software functions (device or non-device) that are already addressed in current policies and guidance.

What are the key components of the discussion paper?

The FDA has provided their thinking on five key topics (26 questions in total), with much of the discussion paper dedicated to the first three topics:

1. Risk assessment

(6 questions)

2. Competency-based pre-market evaluation approach

(11 questions)

3. Post-market monitoring

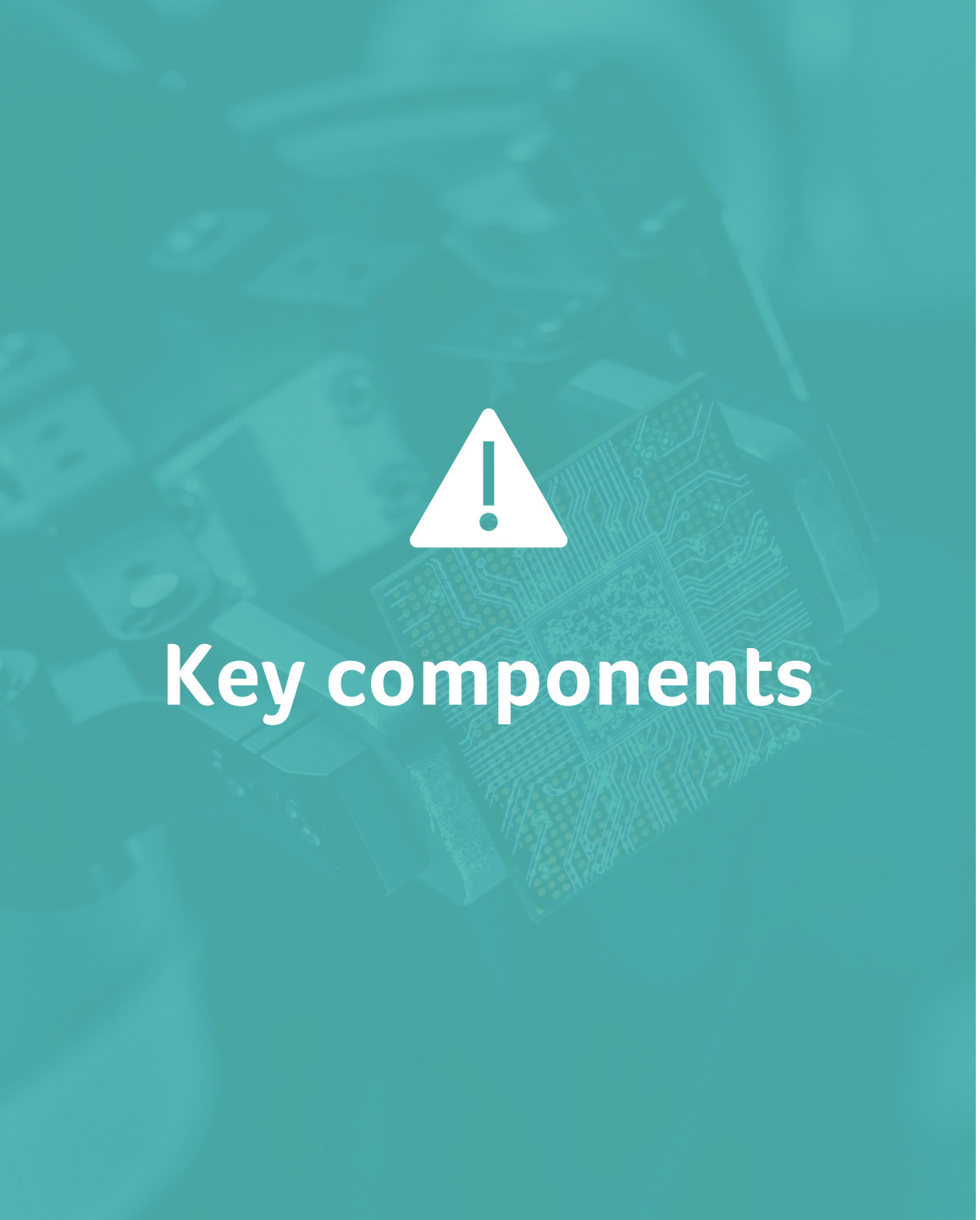
(7 questions)

4. Foundation model device master files

(1 question)

5. Agentic AI systems

(1 question)



Key components

Risk assessment

The FDA has proposed a **two-axis risk heuristic** that considers the risk of the GenAI software function depending on its independence to direct or take action, and consequences that consider the severity of the harm resulting from relying on and using incorrect output.

Key components

Competency-based pre-market evaluation approach

This new approach would include **competency-based benchmarking** across safety, clinical proficiency, generalisability, and agentic capability.

The FDA has also proposed using **risk-based clinical confirmation approaches**, such as shadow deployment and clinician adjudication of real cases.

Key components

Post-market monitoring

The paper discusses **shared responsibility** from stakeholders when it comes to post-market monitoring.

The FDA is considering several approaches, such as **periodic device benchmarking** and **periodic sample-based clinical review**.

What’s next?

The FDA is requesting feedback on some of or all 26 questions by the 19 October 2026. Stakeholders can submit feedback via docket FDA-2026-N-7874.

After the deadline, the FDA’s Digital Health Center of Excellence (DHCoE) will review and categorise all submitted public comments to identify areas of industry consensus, technical roadblocks, or ethical concerns.

Although the FDA has not yet announced a standalone public meeting or workshop dedicated to this discussion paper, the topic may be discussed through public forums given the FDA's historical approach to transformative technologies.

The FDA will use outputs from the discussion paper and any public forums to shape policy and future guidance on GenAI-enabled devices. We’ll be staying tuned, ready to share our insights on further developments.

Should you require regulatory support regarding your AI-enabled medical device, contact our experts today.

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