# FDA Seeks Public Feedback to Inform Regulatory Approach for Generative AI-Enabled Medical Devices

## Discussion Paper Supports FDA's Innovation and Global Leadership Strategic Pillar; Public Docket Opens on Regulations.gov

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FDA News Release

For Immediate Release:

The U.S. Food and Drug Administration today issued a discussion paper on considerations for the regulation of generative artificial intelligence (GenAI)-enabled medical devices, seeking feedback from interested parties on risk assessment, premarket evaluation, postmarket monitoring, and other topics relevant to the regulation of GenAI-enabled medical devices. This effort aligns with one of the Trump Administration's key priorities to harness AI to accelerate the delivery of innovative medical products to market.

“Artificial intelligence is transforming medicine, and the United States must lead in shaping how this technology is developed and used safely and responsibly,” **said Acting FDA Commissioner Kyle Diamantas, J.D.** “Today’s announcement reflects the FDA’s commitment to advancing innovation for health care professionals and leveraging AI to improve care and patient health outcomes.”

The Digital Health Center of Excellence (DHCoE), within the FDA’s Center for Devices and Radiological Health, is leading this discussion paper which supports the FDA’s Public Health Pillar on Innovation and Global Leadership. This strategic pillar includes key priorities to advance regulatory frameworks for AI and digital health technologies.

“Patients and clinicians deserve a regulatory approach that keeps pace with the rapid innovation of digital health technologies,” **said FDA Center for Devices and Radiological Health Director Michelle Tarver, M.D., Ph.D.** “By inviting input from the public, we are launching a transparent process to inform the development of an approach that safeguards patients and consumers, advances innovation, and serves as a potential model for regulators around the world.”

GenAI-enabled medical devices hold transformative promise for patient care and the broader health ecosystem. At the same time, these devices may introduce unique risks when

compared to traditional software and AI-enabled medical devices.

"Generative AI-enabled medical devices are poised to reshape the health technology landscape, and the FDA has an important responsibility to provide thoughtful leadership for this new era," **said DHCoE Director Rick Abramson, M.D.** "This discussion paper advances the frontiers of regulatory science and propels a critical conversation about how to enable beneficial innovation, protect public health, and preserve trust."

The discussion paper begins by outlining a possible two-axis framework for risk assessment that might be used to inform regulatory expectations. It then discusses a potential approach to premarket evaluation built on the concept of competency assessment, inspired at a high level by how physicians are trained and evaluated, consisting of non-clinical device benchmarking and clinical confirmation to evaluate whether a GenAI-enabled medical device performs as intended before reaching patients. The paper also describes several potential approaches to risk-proportionate postmarket monitoring and discusses considerations around foundation models and agentic AI systems. For each of these areas, the FDA poses targeted questions to inform the development of a regulatory framework that is scientifically rigorous, prioritizes patient safety, and aligns with the novel

capabilities of GenAI-enabled medical devices.

The FDA encourages feedback on the discussion paper from device manufacturers, clinicians, consumers, researchers, the public, and other interested parties, to be submitted under the docket FDA-2026-N-7874 on Regulations.gov by October 19, 2026.

The discussion paper supports the FDA's efforts to advance health care by fostering the responsible innovation of safe, effective, and high-quality digital health technologies.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, radiation-emitting electronic products, and for regulating tobacco products.

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