Can AI Medical Devices Receive De Novo Classification?

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Abstract

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Introduction

Artificial intelligence (AI) is rapidly transforming the healthcare landscape, with AI-powered medical devices offering unprecedented opportunities for improving diagnosis, treatment, and patient care [1]. As these innovative technologies emerge, a critical question arises: how are they regulated? Specifically, can these novel AI medical devices, which often lack a clear predicate on the market, navigate the U.S. Food and Drug Administration (FDA) regulatory pathways? The De Novo classification request offers a potential route to market for such devices [2]. This article explores the De Novo pathway and its applicability to AI medical devices, providing health professionals with an understanding of the evolving regulatory framework.

The De Novo Pathway: A Route for Novel Medical Devices

The De Novo classification request is a risk-based classification process for novel medical devices for which there is no legally marketed predicate device. In essence, it provides a regulatory pathway for new types of devices to obtain marketing authorization as class I or class II devices, which have low to moderate risk. The De Novo pathway was introduced to provide a more efficient route to market for innovative devices that would otherwise be automatically classified as Class III, the highest-risk category, requiring the most stringent premarket approval (PMA) process [1].

For a device to be eligible for the De Novo pathway, it must be demonstrated that general controls or a combination of general and special controls are sufficient to provide a reasonable assurance of safety and effectiveness. General controls are the baseline requirements for all medical devices, while special controls are additional measures, such as performance standards, post-market surveillance, or specific labeling, that can be implemented to

mitigate risks associated with a particular device [1].

AI Medical Devices and the De Novo Pathway

AI and machine learning (ML) technologies are increasingly being integrated into medical devices, particularly in the realm of Software as a Medical Device (SaMD). These technologies have the potential to analyze vast amounts of data, identify complex patterns, and provide valuable insights to clinicians [4]. However, the adaptive nature of some AI/ML algorithms presents a unique challenge for traditional regulatory frameworks. The FDA has acknowledged that its traditional paradigm of medical device regulation was not designed for these adaptive technologies and has been actively developing a new regulatory framework [2].

The FDA has stated that AI/ML-based SaMD is subject to the same regulatory oversight as other medical devices and that the agency reviews these devices through appropriate premarket pathways, including 510(k) premarket clearance, De Novo classification, and premarket approval (PMA). For novel AI medical devices that lack a predicate, the De Novo pathway is a particularly relevant option. By successfully navigating the De Novo process, a new AI medical device can be classified as Class I or II, and it can then serve as a predicate for future 510(k) submissions from other, similar devices [2]. A 2023 study published in *The Lancet Digital Health* highlighted the successful use of the De Novo pathway for an AI-based device for pediatric autism screening, demonstrating the viability of this route for complex AI technologies [3].

The Evolving Regulatory Landscape

The FDA is actively working to create a regulatory framework that is tailored to the unique characteristics of AI/ML-based medical devices. In recent years, the agency has published several key documents, including the "Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan" and a series of guiding principles on topics such as Good Machine Learning Practice (GMLP), predetermined change control plans, and transparency. These documents signal the FDA's commitment to fostering innovation while ensuring the safety and effectiveness of AI-powered medical devices [2].

A key aspect of the evolving framework is the concept of a "predetermined change control plan." This would allow manufacturers to pre-specify certain modifications to their AI/ML algorithms and to manage these changes without requiring a new premarket review for each modification. This approach is intended to provide a more streamlined and efficient process for updating and improving AI-powered devices while maintaining appropriate regulatory oversight [2, 3].

Conclusion

The De Novo classification pathway provides a viable and increasingly important route to market for novel AI medical devices. As the field of AI in medicine continues to evolve, the FDA is adapting its regulatory framework to accommodate the unique challenges and opportunities presented by these innovative technologies. Health professionals should stay informed about

these regulatory developments, as they will play a crucial role in shaping the future of AI-powered healthcare. The ongoing dialogue between the FDA, industry, and the healthcare community will be essential for ensuring that patients can benefit from the transformative potential of AI medical devices while being protected from potential risks.
