What Are the FDA-Approved AI Devices for Eye Disease?

Rasit Dinc

Rasit Dinc Digital Health & AI Research

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Abstract

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By Rasit Dinc

Artificial intelligence (AI) is rapidly transforming the landscape of healthcare, and ophthalmology is at the forefront of this revolution. The integration of AI into diagnostic processes promises to enhance efficiency, accuracy, and accessibility of eye care. However, for these technologies to be safely integrated into clinical practice, they must undergo rigorous evaluation and receive approval from regulatory bodies like the U.S. Food and Drug Administration (FDA). This article provides an overview of the key FDA-approved AI devices for eye disease, with a focus on those that have demonstrated the potential to reshape ophthalmic care.

The Rise of AI in Ophthalmology

The application of AI in ophthalmology primarily focuses on the automated analysis of retinal images to detect signs of disease. Diabetic retinopathy, a leading cause of blindness in adults, has been a major target for AI-driven diagnostic tools. Early detection and treatment of diabetic retinopathy are crucial to preventing vision loss, but the increasing prevalence of diabetes has placed a significant strain on healthcare systems. AI-powered screening tools offer a solution by enabling rapid and accurate detection of the disease, often without the need for a specialist's interpretation.

Key FDA-Approved AI Devices

Several AI-based devices have received FDA clearance for the detection of eye diseases, particularly diabetic retinopathy. These devices are designed to be used in primary care settings, making eye screenings more accessible to a

wider population.

IDx-DR (LumineticsCore)

In 2018, the FDA approved IDx-DR, now known as LumineticsCore, developed by Digital Diagnostics. This was a landmark decision, as it was the first autonomous AI diagnostic system to be authorized for marketing. LumineticsCore is designed to detect more than mild diabetic retinopathy in adults with diabetes. The system uses an AI algorithm to analyze images of the retina captured by a retinal camera. The device provides a binary result: either refer to an eye care professional or rescreen in 12 months. This allows for on-the-spot screening and referral, streamlining the diagnostic process and ensuring that patients who need further evaluation are identified quickly [1]. A 2024 study highlighted the role of such FDA-approved AI-powered devices in modernizing diabetic retinopathy diagnostics [2].

EyeArt

The EyeArt system by Eyenuk is another autonomous AI system that received FDA clearance in 2020 for the detection of more than mild diabetic retinopathy. Similar to LumineticsCore, EyeArt analyzes fundus images to identify signs of the disease. The system is designed to be used by healthcare providers to automatically detect diabetic retinopathy in adults diagnosed with diabetes. The EyeArt system has been shown to have high sensitivity and specificity, making it a reliable tool for screening and early detection. A 2023 review on the development and deployment of AI for diabetic retinopathy screening highlighted the importance of autonomous AI models like EyeArt [3].

AEYE-DS

AEYE-DS, developed by AEYE Health, is a more recent addition to the list of FDA-cleared AI devices for diabetic retinopathy screening. AEYE-DS is an AI-powered system that can be used with both tabletop and handheld retinal cameras, increasing its versatility and accessibility. The system is designed to provide a diagnosis in under a minute, making it a highly efficient tool for use in primary care and other point-of-care settings. AEYE-DS has also received FDA clearance for use with a portable handheld camera, a first for a fully autonomous AI for diabetic retinopathy screening. A 2023 paper in *Diabetes Care* discussed the framework and validation of such AI systems, emphasizing their role in the future of diabetic retinopathy management [4].

The Impact of FDA-Approved AI on Eye Care

The FDA's approval of these AI-powered devices marks a significant step forward in the integration of AI into clinical practice. By automating the detection of diabetic retinopathy, these devices can help to alleviate the burden on ophthalmologists and ensure that patients receive timely and appropriate care. The use of these devices in primary care settings can also help to improve access to eye care, particularly for underserved populations.

Conclusion

The FDA-approved AI devices for eye disease are revolutionizing the way we screen for and diagnose conditions like diabetic retinopathy. As AI technology continues to evolve, we can expect to see even more innovative solutions that will further enhance the quality and accessibility of eye care. These devices are not intended to replace ophthalmologists, but rather to serve as powerful tools that can assist in the early detection and management of eye diseases, ultimately leading to better patient outcomes.

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