

DIAGNOS Files FDA Pre-Submission for its CARA System: Strategic Entry into the U.S. Optometry Market with Support from ORA LLC

written by Raj Shah | July 16, 2025

July 16, 2025 ([Source](#)) – Diagnos Inc. (“DIAGNOS” or the “Corporation”) (TSX Venture: ADK, OTCQB: DGNOF, FWB: 4D4A), a Canadian leader in artificial intelligence (AI) for the early detection of retinal and systemic diseases, is proud to announce that it has formally submitted a Pre-Submission (Q-sub) to the U.S. Food and Drug Administration (FDA) for its flagship CARA System. This filing marks the first strategic step toward regulatory clearance and commercial deployment in the U.S. optometry market.

The CARA System—DIAGNOS’ cloud-based platform—is designed to inform optometrists by providing AI-assisted analysis of retinal images to detect indicators of Diabetic Retinopathy (DR), Hypertensive Retinopathy (HR), Age-Related Macular Degeneration (ARMD), and other vascular or macular anomalies.

The United States hosts approximately 49,300 actively practicing optometrists, according to the U.S. Bureau of Labor Statistics (May 2023) who, to the American Optometric Association, perform an estimated 88 million comprehensive eye exams annually. Given this high volume of routine evaluations, DIAGNOS sees a strong market for its AI assisted solution which is designed to enhance efficiency, ensure greater consistency, and support early detection in everyday optometric practice.

Enhancing Optometry Through AI-Driven Microcirculation Analysis

The CARA System also enables evaluation of the retina's microcirculation—an important window into systemic vascular health—by analyzing subtle vascular changes that may indicate early disease.

“CARA has been designed to perform image analysis and provide informative results at the fingertips of optometrists, giving them more time to focus on meaningful patient interactions and recenter the patient at the heart of the visit,” said Yves-Stéphane Couture, Chief Operating Officer of DIAGNOS.

By delivering fast, AI-driven insights through a streamlined, intuitive interface, CARA not only accelerates documentation—it also enhances the role of the optometrist by providing tools to detect early signs of Age-Related Macular Degeneration (ARMD), Diabetic Retinopathy (DR), and Hypertensive Retinopathy (HR), supporting more accurate referrals and timely intervention for systemic conditions.

The eye is a window into your heart—and DIAGNOS gives optometrists the clarity to see through it. We are proud to take this significant step toward entering the U.S. market. We would like to express our sincere appreciation to [ORA](#) for their outstanding regulatory support and ophthalmic device expertise, which have been instrumental throughout the pre-submission process.”

CARA's dataset is the result of screenings conducted in 16 countries, encompassing retinal images from over 450,000 patients. This global foundation ensures the robustness and adaptability of the system across diverse populations, enabling more reliable detection and information for clinical decision-making in various healthcare settings.

About DIAGNOS

DIAGNOS is a publicly traded Canadian corporation dedicated to early detection of critical eye-related health problems. By leveraging Artificial Intelligence, DIAGNOS aims to provide more information to healthcare clinicians to enhance diagnostic accuracy, streamline workflows, and improve patient outcomes on a global scale.

Additional information is available at www.diagnos.com and www.sedarplus.com.

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