



DIAGNOS Advances Regulatory Strategy with US FDA Submission for CARA System

BROSSARD, Quebec, Canada – September 28, 2026 - Diagnos Inc. (“DIAGNOS” or the “Corporation”) (TSX Venture: ADK, OTCQB: DGNOF, FWB: 4D4A), a Corporation dedicated to the early detection of eye-related health using Artificial Intelligence (AI) techniques, is pleased to announce that it has submitted a Section 513(g) Request for Information to the U.S. Food and Drug Administration (“FDA”) regarding the classification and applicable regulatory requirements for its CARA System.

The submission follows DIAGNOS’ FDA Pre-Submission filing. DIAGNOS filed this submission to address a specific recommendation received from the FDA. This represents another important step in DIAGNOS’ U.S. regulatory and commercial strategy for the CARA System.

CARA System is the logical progression of DIAGNOS’ existing Medical Image Management and Processing System (MIMPS). The new device combines an updated deterministic retinal image enhancement algorithm (CARA-Enhancement), a dedicated interface for clinician-lead annotations related to retinal conditions, and AI-powered analytic modules that support optometrists in the analysis of retinal images.:

- **CARA-AMDdetect** – *Age-related macular degeneration indicators detection*
- **CARA-DR** – *Diabetic retinopathy indicators detection*
- **CARA-MVA** – *Retinal microvascular analysis*

By combining image enhancement, supplementary AI findings, and retinal image and retina microvascular analytics, CARA System helps clinicians unlock more clinically relevant information from every fundus photograph while ensuring that the optometrist remains in full control of every clinical decision.

“This submission represents another milestone in our strategy to bring CARA System to the U.S. market,” said **André Larente, President of DIAGNOS**. Building on its established license in Canada, for the optometry market, DIAGNOS is pursuing a separate regulatory pathway in the U.S. to access a market of approximately 49,500 optometrists, seeing strong commercial potential in both markets for its AI-assisted solution designed to streamline clinical workflows, ensure diagnostic consistency, and support early detection in everyday optometric practice.

About DIAGNOS

DIAGNOS is a public Canadian corporation dedicated to the early detection of critical eye-related health problems. DIAGNOS manufactures CARA System, a software platform which assists health specialists in the detection of retinal eye pathologies. CARA System is currently licensed for commercialization in Canada and Saudi Arabia. By developing innovative products based on AI technologies, DIAGNOS' solutions provide healthcare clinicians with valuable information that refines diagnostic accuracy, streamlines workflows, and improves patient outcomes.

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

For further information, please contact:

Mr. André Larente, President
DIAGNOS Inc.
Tel: 450-678-8882 ext. 224
alarente@dignos.ca

This news release contains forward-looking information. There can be no assurance that forward-looking information will prove to be accurate, as actual results and future events could differ materially from those anticipated in these statements. DIAGNOS disclaims any intention or obligation to publicly update or revise any forward-looking information, whether as a result of new information, future events or otherwise. The forward-looking information contained in this news release is expressly qualified by this cautionary statement.

Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.