

DIAGNOS Advances Regulatory Strategy for CARA in Key Markets: Updates on Health Canada, FDA, and SFDA Progress

written by Raj Shah | January 13, 2026

January 13, 2026 ([Source](#)) – Diagnos Inc. (“DIAGNOS” or the “Corporation”) (TSX Venture: ADK, OTCQB: DGNOF, FWB: 4D4A), a pioneer in applying techniques in Artificial Intelligence (AI) for the early detection of eye-related health issues, is pleased to provide an update on the regulatory pathway for its AI platform, CARA. This follows the acceleration plan announced on October 8, 2025.

The Corporation continues to execute its strategy to secure approvals in three targeted jurisdictions:

- Saudi Arabia (SFDA): DIAGNOS has formally submitted CARA for marketing approval to the Saudi Food and Drug Authority (SFDA).
- Canada (Health Canada): The Corporation is actively engaged with Health Canada to ensure full alignment with applicable medical device regulations. DIAGNOS confirms it is on track to submit its formal application for CARA in the course of this current quarter.
- United States (FDA): Following strategic meetings with the U.S. Food & Drug Administration (FDA), DIAGNOS has clarified the specific requirements to secure 510(k) clearance, paving the way for commercialization in the US market.

A Word from the CEO “Navigating the regulatory landscape for medical AI requires precision and expertise. Our team is fully focused on meeting the rigorous standards of Canada, the U.S., and Saudi Arabia,” stated André Larente, CEO of DIAGNOS. “Securing these authorizations is a priority milestone that we believe will serve as a significant catalyst for commercial growth and shareholder value.”

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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