

K251029 Vista OS, Vista AI Scan, RTHawkAug 21, 2025
141 days to decisionK251029 · Product code: **LNH** · Radiology
Source: <https://www.510kdatabase.net/k251029/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Apr 2, 2025
Decision date	Aug 21, 2025
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vista AI, Inc.
Location	Palo Alto, CA, US
Contact	James Rogers
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Heartvista, Inc. Db a Vista.Ai
Contact	James Rogers

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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