

K253535 Ligence HeartFeb 27, 2026
106 days to decisionK253535 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k253535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 13, 2025
Decision date	Feb 27, 2026
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Ligence Uab
Location	Kaunas, LT
Contact	Alvaro Perez-Moreno
510(k) history	2 submissions · 2 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Arazy Group Consultants, Inc.
Contact	Raymond Kelly

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

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