FDA 510(k) Premarket Notification

K252105 Ligence Heart

CLEARED

Sep 26, 2025
85 days to decision

K252105 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k252105/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 3, 2025
Decision date	Sep 26, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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