

**K252105 Ligence Heart**Sep 26, 2025  
85 days to decisionK252105 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k252105/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Arazy Group Consultants, Inc.</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252105/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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