

K261405 ANDI 2.2May 28, 2026
29 days to decisionK261405 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k261405/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 29, 2026
Decision date	May 28, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imeka Solutions, Inc.
Location	Sherbrooke, CA
Contact	Valerie Lacroix
510(k) history	3 submissions · 3 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Eversana
Contact	Kory Dillman

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

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