

**K252298 ANDI 2.0**Oct 22, 2025  
91 days to decisionK252298 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k252298/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 23, 2025
Decision date	Oct 22, 2025
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Imeka Solutions, Inc.</b>
Location	Sherbrooke, CA
Contact	Valerie Lacroix
510(k) history	2 submissions · 2 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252298/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026