

K230913 ANDIJul 25, 2023
116 days to decisionK230913 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k230913/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 31, 2023
Decision date	Jul 25, 2023
Days to decision	116 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	2 submissions · 2 cleared · 2023-2025

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