

K243378 Rapid MLSMay 28, 2025
210 days to decisionK243378 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 30, 2024
Decision date	May 28, 2025
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ischemaview, Inc.
Location	Irvine, CA, US
Contact	James Rosa
510(k) history	21 submissions · 21 cleared · 2013-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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