

K242781 cvi42 Software ApplicationOct 15, 2024
29 days to decisionK242781 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k242781/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 16, 2024
Decision date	Oct 15, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Circle Cardiovascular Imaging, Inc.
Location	Calgary, Alberta, CA
Contact	Omar Naimi
510(k) history	9 submissions · 9 cleared · 2008-2025

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