

K251027 cvi42 Coronary Plaque Software ApplicationOct 27, 2025
208 days to decisionK251027 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k251027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 2, 2025
Decision date	Oct 27, 2025
Days to decision	208 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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