

K213998 cvi42 Auto Imaging Software ApplicationJul 28, 2022
219 days to decisionK213998 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k213998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 21, 2021
Decision date	Jul 28, 2022
Days to decision	219 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	Sydney Toutant
510(k) history	9 submissions · 9 cleared · 2008-2025

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