

K250221 StrokeSENS ASPECTS Software ApplicationJul 1, 2025
158 days to decisionK250221 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k250221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Jan 24, 2025
Decision date	Jul 1, 2025
Days to decision	158 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	Kyle Mayr
510(k) history	9 submissions · 9 cleared · 2008-2025

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