

K212261 StrokeSENS LVOOct 14, 2021
86 days to decisionK212261 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k212261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Jul 20, 2021
Decision date	Oct 14, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Circle Neurovascular Imaging, Inc.
Location	Calgary, CA
Contact	Kyle Mayr
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Circle Cardiovascular Imaging, Inc.
Contact	Kyle Mayr

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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