

K221248 Rapid LVOMay 31, 2022
29 days to decisionK221248 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k221248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	May 2, 2022
Decision date	May 31, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ischemaview, Inc.
Location	Irvine, CA, US
Contact	James Rosa
510(k) history	21 submissions · 21 cleared · 2013-2025

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