

K221456 Rapid ICHSep 12, 2022
116 days to decisionK221456 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k221456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	May 19, 2022
Decision date	Sep 12, 2022
Days to decision	116 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221456/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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