

K232436 Rapid SDHOct 25, 2023
72 days to decisionK232436 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k232436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Aug 14, 2023
Decision date	Oct 25, 2023
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232436/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026