

K251151 Rapid CTA 360Jul 16, 2025
93 days to decisionK251151 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k251151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Apr 14, 2025
Decision date	Jul 16, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ischemaview
Location	Golden, CO, US
Contact	James Rosa
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251151/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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