FDA 510(k) Premarket Notification

K232436 Rapid SDH

CLEARED

Oct 25, 2023
72 days to decision

K232436 · 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