FDA 510(k) Premarket Notification

CLEARED

K251533 Rapid Obstructive Hydrocephalus, Rapid OH

Sep 4, 2025
108 days to decision

K251533 · Product code: **QAS** · Radiology
Source: https://www.510kdatabase.net/k251533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	May 19, 2025
Decision date	Sep 4, 2025
Days to decision	108 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