

K261085 Rapid Vessel Occlusion (Rapid VO)

Jul 13, 2026
103 days to decision

K261085 · Product code: **QAS** · Radiology
Source: <https://www.510kdatabase.net/k261085/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer-assisted Triage And Notification Software (QAS)
Date received	Apr 1, 2026
Decision date	Jul 13, 2026
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ischemaview
Location	Golden, CO, US
Contact	James Rosa
510(k) history	2 submissions · 2 cleared · 2025-2026