

**K251533 Rapid Obstructive Hydrocephalus, Rapid OH**Sep 4, 2025  
108 days to decisionK251533 · Product code: **QAS** · Radiology  
Source: <https://www.510kdatabase.net/k251533/>**SUBMISSION DETAILS**

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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**

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Company	<b>Ischemaview, Inc.</b>
Location	Irvine, CA, US
Contact	James Rosa
510(k) history	21 submissions · 21 cleared · 2013-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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