

**K243350 Rapid Neuro3D**Jan 22, 2025  
86 days to decisionK243350 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k243350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 28, 2024
Decision date	Jan 22, 2025
Days to decision	86 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	Patricia Setti-LaPerch
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/k243350/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026