

**K213165 Rapid**Feb 8, 2022  
133 days to decisionK213165 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k213165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 28, 2021
Decision date	Feb 8, 2022
Days to decision	133 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/k213165/> 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 14, 2026