

**K232156 Rapid ASPECTS (v3)**Jan 19, 2024  
183 days to decisionK232156 · Product code: **POK** · Radiology  
Source: <https://www.510kdatabase.net/k232156/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Jul 20, 2023
Decision date	Jan 19, 2024
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232156/> 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