

K200760 Rapid ASPECTSJun 26, 2020
94 days to decisionK200760 · Product code: **POK** · Radiology
Source: <https://www.510kdatabase.net/k200760/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer-assisted Diagnostic Software For Lesions Suspicious For Cancer (POK)
Date received	Mar 24, 2020
Decision date	Jun 26, 2020
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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