FDA 510(k) Premarket Notification

K232156 Rapid ASPECTS (v3)

CLEARED

Jan 19, 2024
183 days to decision

K232156 · 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	**Ischemaview, Inc.**
Location	Irvine, CA, US
Contact	Jim Rosa
510(k) history	21 submissions · 21 cleared · 2013-2025