FDA 510(k) Premarket Notification

K243378 Rapid MLS

CLEARED

May 28, 2025
210 days to decision

K243378 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k243378/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 30, 2024
Decision date	May 28, 2025
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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