FDA 510(k) Premarket Notification

K243350 Rapid Neuro3D

CLEARED

Jan 22, 2025
86 days to decision

K243350 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k243350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 28, 2024
Decision date	Jan 22, 2025
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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