FDA 510(k) Premarket Notification

K223396 Rapid RV/LV

CLEARED

Feb 1, 2023
85 days to decision

K223396 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k223396/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 8, 2022
Decision date	Feb 1, 2023
Days to decision	85 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