FDA 510(k) Premarket Notification

K233582 Rapid

CLEARED

Apr 22, 2024
172 days to decision

K233582 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k233582/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 2, 2023
Decision date	Apr 22, 2024
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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