FDA 510(k) Premarket Notification

K213165 Rapid

CLEARED

Feb 8, 2022
133 days to decision

K213165 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k213165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 28, 2021
Decision date	Feb 8, 2022
Days to decision	133 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