

K233582 RapidApr 22, 2024
172 days to decisionK233582 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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