FDA 510(k) Premarket Notification

K243989 Second Opinion® 3D

CLEARED

May 23, 2025
148 days to decision

K243989 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k243989/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 26, 2024
Decision date	May 23, 2025
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Pearl, Inc.**
Location	Beverly Hills, CA, US
Contact	Ashley Brown
510(k) history	8 submissions · 8 cleared · 2022-2025