

K243989 Second Opinion® 3DMay 23, 2025
148 days to decisionK243989 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243989/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026