

K243230 Second Opinion® BLEMay 9, 2025
213 days to decisionK243230 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 8, 2024
Decision date	May 9, 2025
Days to decision	213 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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