

K243234 Second Opinion® CSJun 12, 2025
245 days to decisionK243234 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k243234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Oct 10, 2024
Decision date	Jun 12, 2025
Days to decision	245 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243234/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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