

K210365 Second OpinionMar 4, 2022
389 days to decisionK210365 · Product code: **MYN** · Radiology
Source: <https://www.510kdatabase.net/k210365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Feb 8, 2021
Decision date	Mar 4, 2022
Days to decision	389 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Boston Medtech Advisors
Contact	Zvi Ladin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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