FDA 510(k) Premarket Notification

K242522 Second Opinion CC

CLEARED

Jan 16, 2025
146 days to decision

K242522 · Product code: **MYN** · Radiology
Source: https://www.510kdatabase.net/k242522/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Aug 23, 2024
Decision date	Jan 16, 2025
Days to decision	146 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