FDA 510(k) Premarket Notification

K243239 Lung AI (LAI001)

CLEARED

Apr 24, 2025
196 days to decision

K243239 · Product code: **MYN** · Radiology
Source: https://www.510kdatabase.net/k243239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Oct 10, 2024
Decision date	Apr 24, 2025
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Exo, Inc.**
Location	Walker, MI, US
Contact	Murray Jacqueline
510(k) history	5 submissions · 5 cleared · 1983-2025