FDA 510(k) Premarket Notification

K241608 nordicMEDiVA

CLEARED

Jun 28, 2024
24 days to decision

K241608 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k241608/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 4, 2024
Decision date	Jun 28, 2024
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nordicneurolab AS**
Location	Bergen, NO
Contact	Chandana Gurung Bhandari
510(k) history	7 submissions · 7 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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