

**K241608 nordicMEDiVA**Jun 28, 2024  
24 days to decisionK241608 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k241608/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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