

K243209 nordicMEDiVAOct 22, 2024
21 days to decisionK243209 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k243209/>**SUBMISSION DETAILS**

| | |
|-----------------------|----------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Oct 1, 2024 |
| Decision date | Oct 22, 2024 |
| Days to decision | 21 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

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