FDA 510(k) Premarket Notification

# K191032 fMRI Hardware System

**CLEARED**

Nov 27, 2019
223 days to decision

K191032 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k191032/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received | Apr 18, 2019 |
| Decision date | Nov 27, 2019 |
| Days to decision | 223 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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