

K191032 fMRI Hardware SystemNov 27, 2019
223 days to decisionK191032 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191032/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026