March 20, 2026

NordicNeuroLab AS
Chandana Gurung Bhandari
VP Quality
Møllendaslveien 1
Bergen, 5009
Norway

Re: K251937
Trade/Device Name: nordicAudio (1.0)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH,
Dated: February 13, 2026
Received: February 17, 2026

Dear Chandana Gurung Bhandari:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251937

Please provide the device trade name(s).

nordicAudio (1.0)

Please provide your Indications for Use below.

Intended use

The nordicAudio allows auditory signals from a source in the control room to enter the Magnet room and to be presented to the subject. The system consists of headphones connected through an access point. From this unit the system is connected to an audio hub unit in the control room, through a fiber cable. Standard audio sources can be connected to the audio hub and by this bring the audio to the subject.

Indications for use

The device is used to present audio to a subject during an MRI examination. It also facilitates communication between the operator and subject during the examination. The nordicAudio is intended to be used by trained professionals within the MRI environment.

Population

nordicAudio is intended to be used by subjects and operated by trained professionals such as radiographers or technologist performing functional, clinical or interventional MRI scans. The Headset is designed for children above the age of 4 years.

Environments for use
The nordicAudio is intended to be used in functional, clinical or interventional MRI environment.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251937

510(k) Summary

Prepared on: 2026-02-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NordicNeuroLab AS
Applicant Address	Møllendalsveien 1 Bergen 5009 Norway
Applicant Contact Telephone	+4755707095
Applicant Contact	Mrs. Chandana Gurung Bhandari
Applicant Contact Email	chandana@nordicneurolab.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	nordicAudio (1.0)
Common Name	Magnetic resonance diagnostic device
Classification Name	System, Nuclear Magnetic Resonance Imaging
Regulation Number	892.1000
Product Code(s)	LNH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K232680	fMRI Hardware System (AudioSystem)	LNH

Device Description Summary

21 CFR 807.92(a)(4)

nordicAudio is an MR conditional audio System used to reduce acoustic noise, present auditory stimuli and enable subject operator communication during MR imaging.

nordicAudio consisting of an MR compatible headset with optical data transmission, Battery unit for powering the headphones, Audio Hub for interfacing between commercial audio and optical transmission to headset.

The device shall be deigned to fit into commonly used head coils from the main OEMs and provide noise attenuation during common MRI sequences .

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Intended use

The nordicAudio allows auditory signals from a source in the control room to enter the Magnet room and to be presented to the subject. The system consists of headphones connected through an access point. From this unit the system is connected to an audio hub unit in the control room, through a fiber cable. Standard audio sources can be connected to the audio hub and by this bring the audio to the subject.

Indications for use

The device is used to present audio to a subject during an MRI examination. It also facilitates communication between the operator and subject during the examination. The nordicAudio is intended to be used by trained professionals within the MRI environment.

Population

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Environments for use
The nordicAudio is intended to be used in functional, clinical or interventional MRI environment.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The primary medical purpose conveyed in the intended use for both the predicate and the subject device is the same.

Although the wording of the intended use statements is slightly different from the predicate device, the primary intention is the same.

nordicAudio has the same functional characteristics i.e. auditory signals from the audio sources to enter the scanner room and to be presented to the patient.

We identified no difference in the intended use statements that impacts the safety and effectiveness of the subjective device.

Technological Comparison 21 CFR 807.92(a)(6)

nordicAudio has the same functional characteristics i.e. auditory signals from the audio sources to enter the scanner room and to be presented to the patient.

The subject device differs from the predicate device in its technological characteristics where the AudioSystem(Predicate device) is based on Electrostatic technology while the nordicAudio is based on MEMS (Micro electro mechanical systems) technology.

The differences do not raise additional questions about the safety or effectiveness of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No clinical testing was required to demonstrate substantial equivalence.
nordicAudio underwent performance testing as well as electrical, mechanical, structural testing. In addition electrical safety and electromagnetic compatibility testing has been conducted . All testing of the nordicAudio support the determination of substantial equivalence.

Conclusion:
The nordicAudio has the similar intended use and similar basic technological characteristics as AudioSystem (K232680, fMRI Hardware system, predicate device). While there are some differences in technological characteristics between the proposed and predicate device, the differences were tested and verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device.

NordicNeuroLab AS has concluded that the nordicAudio is substantially equivalent to the currently marketed predicate device AudioSystem (fMRI Hardware system).