



December 13, 2023

Chandana Gurung Bhandari
VP Quality
Møllendalsveien 1
Bergen, Vestland 5009
Norway

Re: K232680

Trade/Device Name: fMRI Hardware System (nordicAktiva)

Regulation Number: 21 CFR 892.1000

Regulation Name: Magnetic Resonance Diagnostic Device

Regulatory Class: Class II

Product Code: LNH

Dated: August 29, 2023

Received: September 18, 2023

Dear Chandana 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a faint, light blue background watermark of the FDA logo.

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

510(k) Number (if known)

K232680

Device Name

fMRI Hardware system (nordicAktiva)

Indications for Use (Describe)

The fMRI Hardware System is a stimulus presentation and response collection system intended to be used by trained professionals to facilitate auditory and visual stimulation to be used in functional MR Imaging (fMRI) based on BOLD contrast.

nordicAktiva is a stimulus presentation software intended to be used by trained professionals to facilitate auditory and visual stimulation to be used in functional MR imaging (fMRI) based on BOLD contrast. In addition, it records responses from the NordicNeuroLab ResponseGrips.

The device is indicated for use during BOLD fMRI examinations of individuals over 2 years of age. It is not intended for the diagnosis of disease or for the direct treatment of conditions.

nordicAktiva would be used in an MRI department of a hospital or clinic, when a functional MRI exam based on BOLD contrast is required involving the provision of visual or auditory stimulation to a subject inside the MRI scanner.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
NordicNeuroLab AS
fMRI hardware System (nordicAktiva)

K232680

510(k) Type: Traditional: Device Modification

Submission Date: 29th August 2023

Submitter: NordicNeuroLab AS
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E-mail: chandana@nordicneurolab.com

Device Name: fMRI Hardware System (nordicAktiva)

Device common Name: Accessory to MRI System, Nuclear magnetic Resonance Imaging

Basis for submission: Device modification with an update software (nordicAktiva)

Classification Regulation: 21 CFR 892.1000

Class: II

Panel: Radiology

Product Code: LNH

Trade/Proprietary Name: fMRI Hardware System

Predicate device name: **fMRI Hardware System (K191032)**

Device Description

1.1 Indication for use

The fMRI Hardware System is a stimulus presentation and response collection system intended to be used by trained professionals to facilitate auditory and visual stimulation to be used in functional MR Imaging (fMRI) based on BOLD contrast.

nordicAktiva is a stimulus presentation software intended to be used by trained professionals to facilitate auditory and visual stimulation to be used in functional MR imaging (fMRI) based on BOLD contrast. In addition, it records responses from the NordicNeuroLab ResponseGrips.

The device is indicated for use during BOLD fMRI examinations of individuals over 2 years of age. It is not intended for the diagnosis of disease or for the direct treatment of conditions.

nordicAktiva would be used in an MRI department of a hospital or clinic, when a functional MRI exam based on BOLD contrast is required involving the provision of visual or auditory stimulation to a subject inside the MRI scanner.

1.2 System Description

The system presents auditory and visual stimulus to the patient and the patient gives feedback through a pair of handheld grips. A synchronization module synchronizes the stimulus presentation software with the MR scanner. The System consists of five subsystems: AudioSystem, VisualSystem, ResponseGrip, SyncBox and nordicAktiva.

The system is used for fMRI studies. fMRI stands for functional Magnetic Resonance Imaging. This technique is primarily used for determining which area of the brain is responsible for specific processes controlling essential functions such as movement, speech, hearing, and vision. This information can form part of the pre-operative planning process in patients with brain tumors, for example. Functional MRI can also be used for research into specific neurological or psychological conditions or investigating cognitive function and networks in general.

The System is used to present the stimulus necessary to provoke physiological processes in the brain. Visual [VisualSystem] and auditory [AudioSystem] stimulus and manual responses from the patient [ResponseGrips] are of primary interest. The timing of the visual and auditory stimulation is critical to make sure that the correct MR image of the activated brain is linked to the stimulus presented. A synchronization unit [SyncBox], connected between the MR-scanner and the stimulus presentation software [nordicAktiva], is included in the system to make sure that the synchronization is correct.

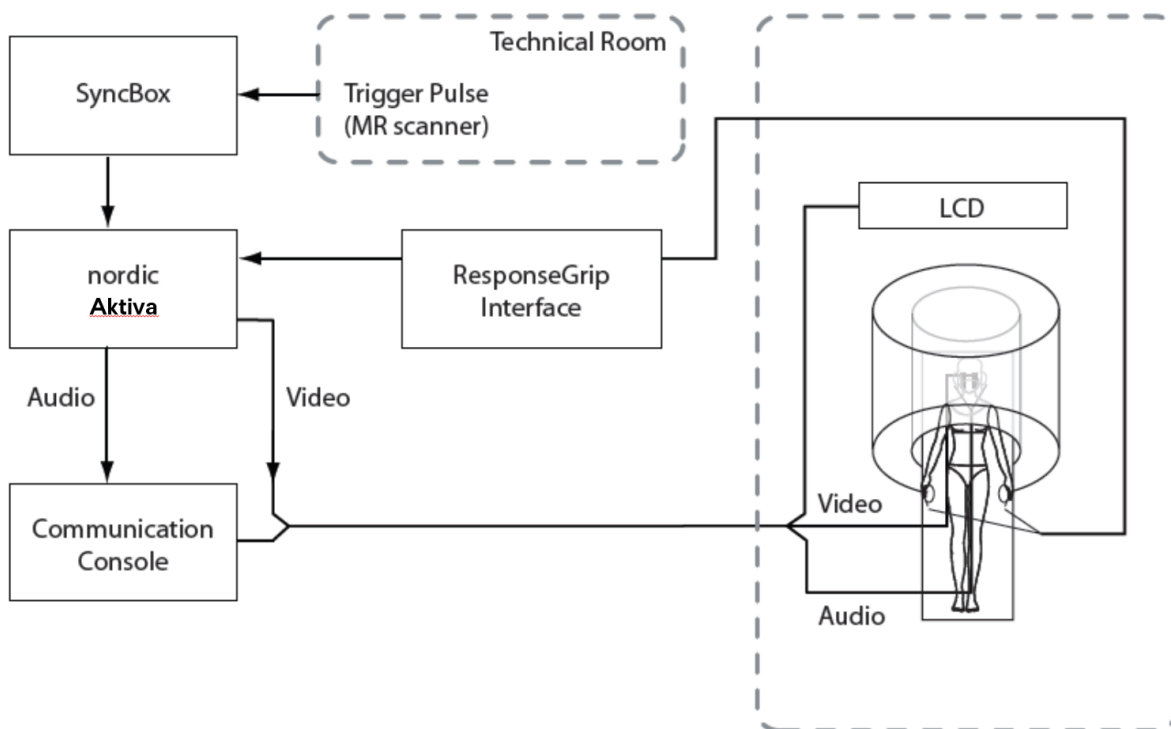


Figure 1 presents the complete configuration of the fMRI Hardware System. All signals entering or leaving the scanner room are received and transmitted by use of fiber optics. The system allows video and audio signals from the stimulus PC to enter the shielded scanner room and to be presented to the subject lying inside the MR. The subject may be asked to respond to the stimulus by using handheld grips.

1.3 Sub-system components and description

1.3.1 VisualSystem

The VisualSystem allows video signals from the stimulus presentation PC to enter the shielded scanner room and to be presented to the patient through a set of coil-mounted displays [VisualSystem HD] or by an in-room LCD monitor, which they can see through a mirror mounted above their eyes.

1.3.2 AudioSystem

The AudioSystem allows auditory signals from the stimulus presentation PC to enter the scanner room and to be presented to the patient wearing a set of headphones. Connection via a communication console provided by the MR vendor allows the operator to adjust the sound from the PC and to speak directly to the patient through an intercom system.

1.3.3 ResponseGrip

The purpose of this component is to collect patient responses during an fMRI study. The ResponseGrip consists of two hand-held grips with two buttons each. By pressing the buttons the patient can respond to the presented stimulus. These responses could be used to monitor the level of engagement and

understanding during a task, or they could be used subsequently in the analysis of the BOLD imaging data. The ResponseGrip is connected to an optical-electrical adapter which converts light to electrical signals. The electrical signal is fed back to the Stimulus PC via the SyncBox, using standard PC communication interfaces.

1.3.4 SyncBox

The SyncBox receives a signal input (e.g. optical or TTL) from the MRI scanner at various times during a BOLD fMRI scan. It demodulates this signal before it is forwarded to the stimulus PC in order to start the presentation of stimuli. In this way one can ensure that the stimulus presentation software is synchronized with the MRI image recordings.

1.3.5 nordicAktiva

nordicAktiva is a software that generates visual and auditory stimulus to the patient. The stimulus presentation is synchronized with the scanner through the SyncBox, and presented to the patient through the VisualSystem and AudioSystem. nordicAktiva records the responses fed to the Stimulus PC from ResponseGrip, as well as the synchronization pulses from the SyncBox. It also allows for the creation and modification of stimulus experiments, or ‘paradigms’, according to the user’s needs.

1.4 Identification of Change to Unmodified Device

nordicAktiva will be updated with a new version.

1.4.1 Technological Characteristics and Substantial Equivalence

To summarize, the modified fMRI Hardware System is found substantially equivalent to the previously cleared device. The indications for use for the modified fMRI Hardware System have remained unchanged.

Changes:	fMRI Hardware System, K191032 [nordicAktiva]	Modified fMRI Hardware System [nordicAktiva]
Development framework	Embarcadero C++ Builder 2010	Electron (back-end), Aurora (front end)
Programming language	C++	JavaScript
Operating environment	Windows 7, 8, 10	Windows 10, 11
Input data	Pulses from SyncBox Paradigms coded in XML format including media files for stimuli (pictures, videos audio)	Pulses from SyncBox Paradigms coded in XML format for conversion to JSON Media files for stimuli (pictures, videos audio)
General software functionality	Register patient Select and run paradigm containing stimuli (open source, editable)	Select and run paradigm containing stimuli Test connections to system hardware components (visual

	Test connections to system hardware components (visual system, audio, ResponseGrip, SyncBox) Log responses from ResponseGrip Send design files to external workstation	system, audio, ResponseGrip, SyncBox) Log responses from ResponseGrip Create paradigms within the user interface
Output	Log files Design files	Log files Design files Exported paradigms

The rationale for determining the substantial equivalence between the previously cleared device and the modified fMRI Hardware System is based on the defined intended use, indications for use, and the technical and operational characteristics. To verify that the modified device fulfils the defined characteristics and requirements, it has been subject to extensive in-house testing. The successful completion of said tests verifies the claimed characteristics of the modified fMRI Hardware System, and thus supports the determination of substantial equivalence.

1.5 Summary of Testing

The fMRI Hardware System has been tested for function and safety and fulfills all requirement specifications.

1.5.1 Performance Testing

Prospectively defined verification and validation activities for the nordicAktiva assure that the product meets design and performance specifications as well as user needs when operated according to the operating instructions.

Brief discussion of the nonclinical tests submitted, referenced, or relied on

Non-clinical performance testing has been performed on the nordicAktiva and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices

The nordicAktiva was tested in accordance with verification and validation processes. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

The test results in this 510(k) premarket notification demonstrates that nordicAktiva:

- Complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, and
- Meets the acceptance criteria and is adequate for its intended use and specifications.

Overall conclusion

The nordicAktiva is substantially equivalent to the identified predicate device, fMRI Hardware System nordicAktiva Software (K191032) in terms of core features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, verification and validation testing demonstrate the safety and efficacy of the device to meet its intended use and specifications.

NordicNeuroLab AS believes that the proposed device, nordicAktiva, is substantially equivalent to its identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.