November 27, 2019

NordicNeurolab AS
Chandana Bhandari
VP Quality
Mollendalsveien 1
5009 BERGEN,
NORWAY

Re: K191032
Trade/Device Name: fMRI Hardware System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: October 29, 2019
Received: October 31, 2019

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Thalia Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191032

Device Name
fMRI Hardware System (VisualSystem HD)

Indications for Use *(Describe)*

fMRI Hardware System

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.

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
NordicNeuroLab AS
fMRI Hardware System

510(k) Type: Traditional: Device Modification

Submission Date: 25 November 2019

Submitter: NordicNeuroLab AS
Møllendalsveien 1
N-5009 Bergen
Norway

Phone: +47 55 70 70 95
E-mail: chandana@nordicneurolab.com
Establishment Registration Number: 3006738448

Contact: Chandana Gurung Bhandari
Møllendalsveien 1
N-5009 Bergen
Norway

Direct: +47 41 76 62 39
Phone: +47 55 70 70 95
E-mail: chandana@nordicneurolab.com

Legally marketed Device name and 510(k) number: fMRI Hardware System. **K092253**

Modified Device Name	fMRI Hardware System
Device Common Name:	Accessory to MRI System, Nuclear Magnetic Resonance Imaging
Basis for Submission:	Device Modification
Classification Regulation:	21 CFR 892.1000
Class:	II
Panel:	Radiology
Product Code:	LNH
Trade/Proprietary Name:	fMRI Hardware System

Device Description

9.1 Intended Use

fMRI Hardware system

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.

Visual system

The visual system 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 (VisualSystemHD) or by an in-room LCD monitor.

9.2 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 useful when determining certain diseases, gaining more information about a patient's condition or investigating cognitive functions. The technique is also used for examining the area of the brain affected in patients suffering from a brain tumor in both the pre-operative and post-operative stages.

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 audio stimulation is critical to make sure that the correct MR image of the brains activity 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.

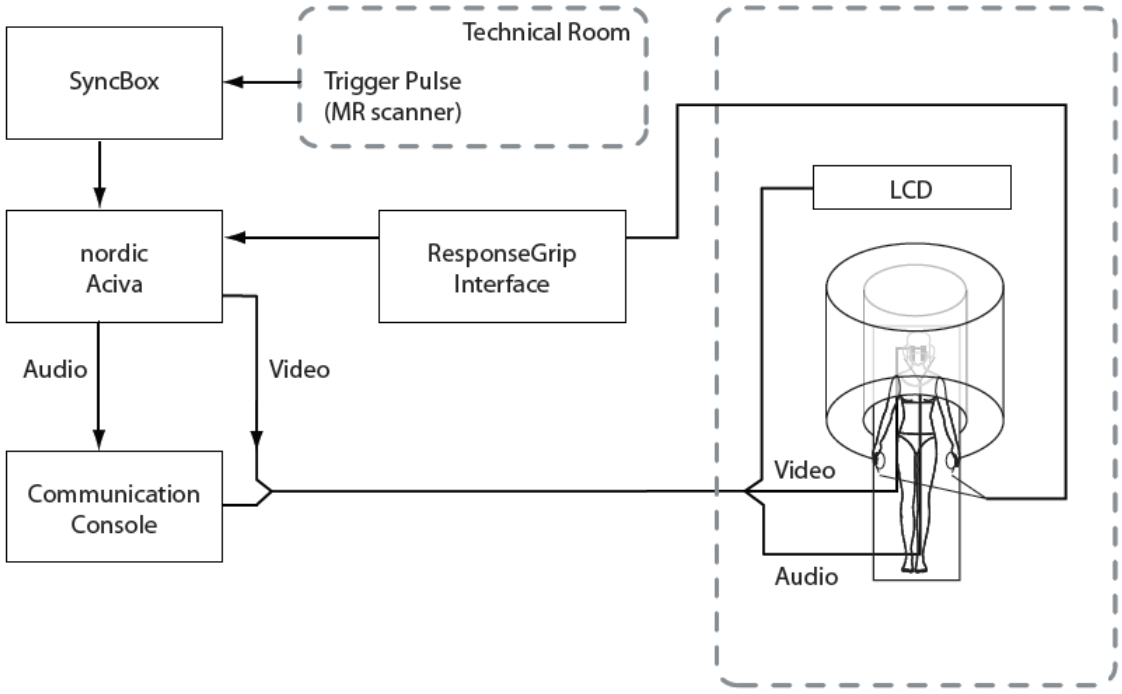

Figure 1 presents the complete configuration of the fMRI Hardware System. All signals entering or leaving the scanner room are received and transmitted by use of fiber optics. The system allows video and audio signals from the stimulus PC to enter the shielded scanner room and to be presented to the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

9.3 Sub-system components and description

9.3.1 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.

9.3.2 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. A communication console allows the operator to adjust the sound from the PC and to speak directly to the patient through a built-in microphone.

9.3.3 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. The ResponseGrip is connected to an optical-electrical adapter which converts

light to electrical signals. The electrical signal is fed to the Stimulus PC by using standard PC communication interfaces.

9.3.4 SyncBox

The SyncBox is connected directly to the MRI scanner where it receives timing pulses sent out with each image series and demodulates this signal before it's forwarded to the stimulus PC. In this way one can ensure that the stimulus presentation software is synchronized with the MRI image recordings.

9.3.5 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 the ResponseGrip, as well as the synchronization pulses from the SyncBox.

9.4 Identification of Change to Unmodified Device

The VisualSystem will be updated with a new version of the coil mounted displays [VisualSystem HD] for attachment to the MR head coil. The brand name for the new version is VisualSystem HD. The same video signal can be presented on the VisualSystem HD and the in-room LCD-monitor that was cleared in K092253. The operator has the choice to use either the VisualSystem HD or the in-room LCD monitor as before.

9.4.1 Technological Characteristics and Substantial Equivalence

To summarize, the modified fMRI Hardware System is found substantial equivalent to the previously cleared device. The modified system only has a new device added to display video. The indications for use for the modified fMRI Hardware System have remained unchanged.

Changes:	**fMRI Hardware System, K092253** [Coil Mounted Displays]	**Modified fMRI Hardware System** [VisualSystem HD]
Display Resolution	800x600 pixels	1920x1200 pixels
Video source	VGA - Standard PC video output	HDMI - Standard PC video output
EyeTracking	Separate unit	Integrated

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 and lab 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.

9.5 Summary of Testing

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

9.5.1 Functional test

All functional testing was carried out as per internal test protocols. Testing involved performance and bench testing.

9.5.2 Biocompatibility test results

The direct components of applied parts contacting with the users in the VisualSystem HD were tested for the following:

In Vitro cytotoxicity - Cytotoxicity testing was carried out in accordance to ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity. Under the conditions of the study, the test article (rubber eye guard) extract did not show potential toxicity.

Skin irritation - Skin irritation testing was carried out in accordance to ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10.Under the conditions of the study, the test article (rubber eye guard) extract did not show any significant evidence of causing skin irritations.

Skin Sensitization testing was carried out with accordance to ISO 10993-10:2010 Biological Evaluation of Medical Devices – Part 10: Under the conditions of the study, the test article (rubber eye guard) extract did not induce signs of general toxicity. In coherence with the negligible proliferation response of the Lymph Node Cells (LNCs), the test items (rubber eye guard) was identified as a non-sensitizing agent in the LocaL Lymph Node Assay.

9.5.3 Safety tests

Electrical safety and EMC safety testing was performed to, and passed, the following standards

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests