510(k) Summary

K092253

510(k) Type: Special: Device Modification
Submission Date: July 20th, 2009

OCT - 8 2009

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Legally marketed Device name and 510(k) number: fMRI Hardware System. K080515

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

3.1. Intended 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.

This is the same intended use as previously cleared for the fMRI Hardware System, K080515.

3.2. 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 nordicAktiva stimulus presentation software with the MR scanner. The System consists of five subsystems: AudioSystem, VisualSystem, ResponseGrip, SyncBox and nordicAktiva.

The intended use of the system is to support 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 to patients suffering from a brain tumor in both the pre-operative and post-operative stage by examining the area of the brain affected.

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.

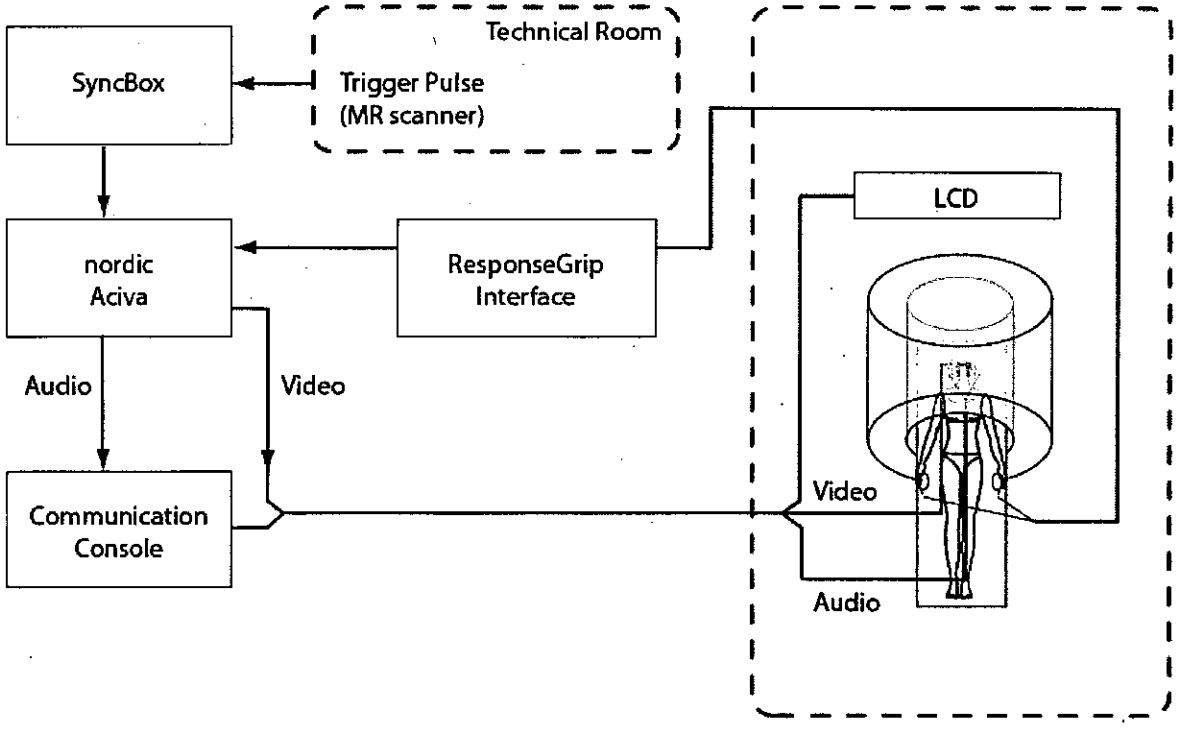

Figure 1 presents the complete configuration of the fMRI Hardware System. All signals entering or leaving the scanner room are received and transmitted by use of fiber optics. The system allows video and audio signals from the stimulus PC to enter the shielded scanner room and to be presented to the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

3.3. Sub-system components and description

3.3.1. VisualSystem

The VisualSystem allows video signals from the stimulus presentation PC to enter the shielded scanner room and to be presented to the patient trough a set of coil-mounted displays or an in-room LCD monitor.

3.3.2. 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.

3.3.3. 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.

3.3.4. 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.

3.3.5. 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.

3.4. Identification of Change to Unmodified Device

The VisualSystem will be expanded with the option of using an in-room LCD monitor instead of the coil-mounted display. The LCD monitor is placed outside magnets bore behind the MR scanner and is in no physical contact with the patient. The same video signal can be presented on the coil-mounted display and the in-room LCD-monitor. The operator has the choice to use either the coil mounted display or the in-room LCD monitor.

3.5. Statement of 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.

3.6. Summary of Testing

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mrs. Chandana Gurung Bhandari
Quality Manager
NordicNeuroLab
Møllendalsveien, Bergen, Hordaland, N-5009
NORWAY

OCT – 8 2009

Re: K092253
Trade/Device Name: fMRI Hardware System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: September 9, 2009
Received: September 14, 2009

Dear Mrs. 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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NordicNeuroLab AS
Bergen, Norway

Indications for Use

510(k) Number (if known): K092253

Device Name: fMRI Hardware System

Indications 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.

Prescription Use ___X___
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092253