NordicNeuroLab
Bergen, Norway

510(k) Summary

Submitter: NordicNeuroLab AS

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Submission Date: 09.18.2007

Device Name and Classification: fMRI Hardware System,
Nuclear Magnetic Resonance Imaging,
Class II
Product Code: LNH

Equivalent Device Identification: MindState Functional Data Acquisition Device (fDAD)

Device Description:

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.

System Overview

The system presents audio and video stimuli to the patient and the patient gives feedback through a pair of handheld grips. A synchronization module synchronizes the Stimuli PC (not a part of the system) to the MR scanner. The System consists of four subsystems: AudioSystem, VisualSystem, ResponseGrip and a SyncBox.

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The System is intended 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 stimuli necessary to provoke physiological processes in the brain.
Visual and auditory stimuli and manual responses from the patient are of primary interest. As the timing of the data is critical to make sure that the correct MR image of the brain activity is linked to the stimuli presented, it is included in the System a synchronization unit connected between the MR-scanner and the PC running the stimuli software to make sure that the synchronization is correct. The stimuli presenting PC is not a part of the system.
Figure 1 presents the complete configuration of the 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 stimuli PC to enter the shielded scanner room and to be presented to the subject lying inside the MR. The subject responds to the stimuli by using the handheld grips.

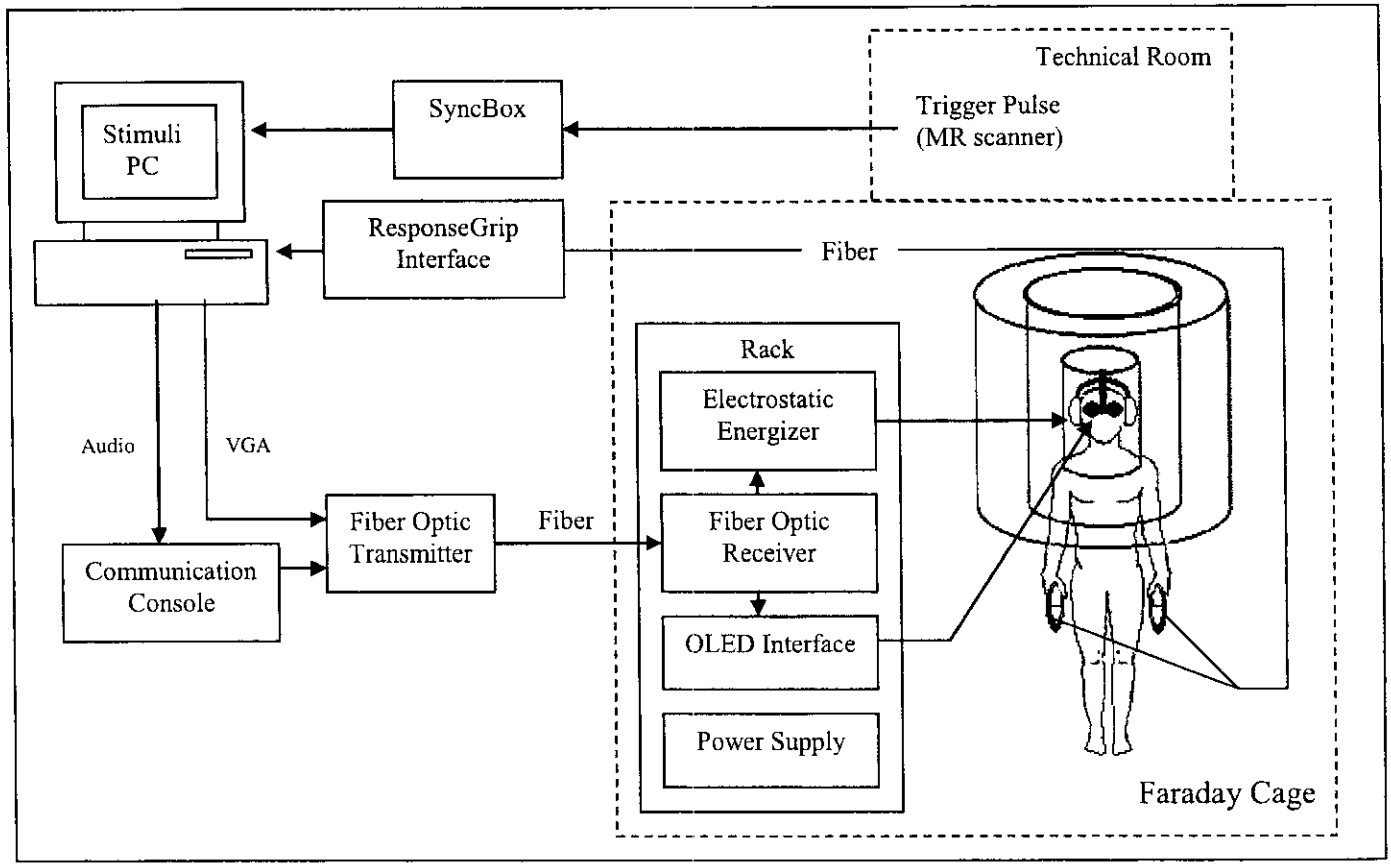

Figure 1: Complete configuration

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Sub-system components and description

1. Visual system
The VisualSystem allows video signals from the stimulus presentation PC to enter the shielded scanner room and to be presented to the patient.

2. AudioSystem
The AudioSystem allows auditory signals from the stimulus presentation PC to enter the scanner room and to be presented to the patient. A communication console allows the operator to adjust the sounds from the PC and to speak to the patient through a built-in microphone.

3. ReponseGrip
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. The patient holds a grip in each hand. By pressing the two buttons, one for the index finger and one for the thumb, the patient can respond to the presented stimuli. The ResponseGrip is connected to an optical-electrical adapter which converts light to electrical signals. The electrical signal is fed to the stimuli PC by using standard PC signals. The ResponseGrip is based on fiber-optics and contains no electronics. All parts are plastic.

4. SyncBox
The SyncBox synchronizes stimulus presentation with the acquisition sequence.

Statement of Substantial Equivalence: The NordicNeuroLab fMRI System is substantially equivalent to the MindState Functional Data Acquisition Device (fDAD), K043290. The two devices have the same intended use and use similar components to achieve the intended use.

Summary of Testing: The NordicNeuroLab fMRI 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
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2007

Nordic NeuroLab AS
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K073099
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: October 31, 2007
Received: November 2, 2007

Dear Mr. Lehtonen:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073099

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 __ of ___

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
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