



JAN 28 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Hrishikesh Gadagkar, Ph.D.  
Director of Product Development  
and Manufacturing  
Neurognostics, Inc.  
10437 Innovation Drive, Suite 309  
MILWAUKEE WI 53226

Re: K043290  
Trade/Device Name: MindState Functional Data  
Acquisition Device (fDAD)  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance  
diagnostic device  
Regulatory Class: II  
Product Code: 90 LNH  
Dated: November 26, 2004  
Received: December 10, 2004

Dear Dr. Gadagkar:

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 (Premarket Approval), 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.

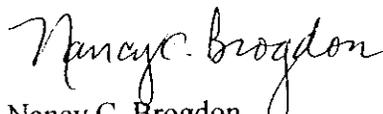
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the 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" (21 CFR 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

## SECTION D – STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): NA K043290

Device Name: MindState Functional Data Acquisition Device (fDAD)

### Indications for Use:

The MindState Functional Data Acquisition Device (fDAD) is used as a data acquisition tool in the MRI environment to perform functional MRI (fMRI) procedures based on Blood Oxygen Level Dependent (BOLD) contrast.

fDAD presents a stimulus to the patient and collects the patient's responses from a button (response) device. Execution of specific cognitive or motor activation tasks by the patient in response to a set of stimuli creates the necessary behavioral data. The fMRI data comprised of the MR images (in DICOM format) sent from the MR scanner control station, and the behavioral response (binary) data are archived to a removable media by fDAD.

The fDAD-PT (fDAD Personal Trainer) is used to train the patient in the use of the four button response device and to ensure their understanding and ability to perform the specific task. A short activation task is presented on the fDAD-PT control station and the patient is allowed to become familiar with the nature of the activation task and the nature of the response to be provided.

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 IF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maneje Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K043290