K060523

MAR 2 8 2006

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Cyberkinetics
Neurotechnology Systems, Inc.
100 Foxborough Blvd. Suite 240 Foxborough, MA 02035 508.549.9981 F. 508.549.9985
www.cyberkineticsinc.com

510(k) Summary

Company Name:	Cyberkinetics Neurotechnology Systems, Inc.
Device Name:	NeuroPort System
510(k) Sponsor:	Cyberkinetics, Inc. A/k/a Cyberkinetics Neurotechnology Systems, Inc. F/k/a Trafalgar Ventures, Inc. 100 Foxborough Blvd., Suite 240 Foxborough, MA 02035
510(k) Contact:	Jon Joseph Vice President R+D and Applications Development Cyberkinetics Neurotechnology Systems, Inc. 391 Chipeta Way, Suite G Salt Lake City, UT 84108 Phone: (801) 582-5533 Fax: (801) 582-1509
Summary Date:	March 23, 2006
Trade Name:	NeuroPort System
Common Name:	Electroencephalograph
Classification Name:	Electroencephalograph, CFR 882.1400, Product Code: GWQ, Class II
Predicate Device:	NeuroPort System, 510(k) K042626

1.0 Description of Device

The NeuroPort System, when connected to the NeuroPort Array Electrode, supports recording and display of local field potentials and extra cellular spikes from the brain. The NeuroPort Array is not modified by this 510(k) submission.

The NeuroPort Electrode Array has 100 electrode contacts on a substrate of 4mm by 4mm. The NeuroPort Electrode array is implanted in the cortex of the brain for less than 30 days. The NeuroPort Electrode Array passes neural activity of the brain cortex to the NeuroPort System through a Patient Cable assembly.

The modification described within this 510(k) submission is summarized as:

a) the addition of an impedance test switch to the Patient Cable,
b) a hardware change to support automated impedance testing of the NeuroPort Electrode Array, and
c) a software change to support automated impedance testing of the NeuroPort Electrode Array.

1.2 Clinical Application

The NeuroPort System is used in clinical, operating room and epilepsy monitoring unit environments. This 510(k) does not affect the environment of use of the NeuroPort System.

By the automated impedance test option, the user is provided the feature of an impedance test of the NeuroPort Electrode Array.

2.0 Intended use of Device

The intended use of the modified NeuroPort System is the same as the unmodified NeuroPort System:

> The intended use of the Cyberkinetics Neurotechnology Systems, Inc. NeuroPort System is for temporary (< 30 days) recording and monitoring of brain electrical activity.

3.0 Technological Characteristics

The technical characteristics of the modified NeuroPort System are the same as those of the unmodified NeuroPort System.

4.0 Data Summary

Testing of the automated impedance test of the NeuroPort Electrode Array modification was performed in compliance with the Cyberkinetics, Inc. design control process. Testing included:

1. Software verification and validation,
2. Hardware verification of design output meeting design input requirements,

Testing is completed. No safety or effectiveness concerns remain.

5.0 Conclusions

The safety and effectiveness of the modified NeuroPort System was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the modified NeuroPort System is the same as the unmodified NeuroPort System. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2006

Cyberkinetics Inc.
c/o Quality & Regulatory Associates, LLC
Mr. Gary Syring
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K060523
Trade/Device Name: Modified NeuroPort System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: February 17, 2006
Received: February 27, 2006

Dear Mr. Syring:

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.

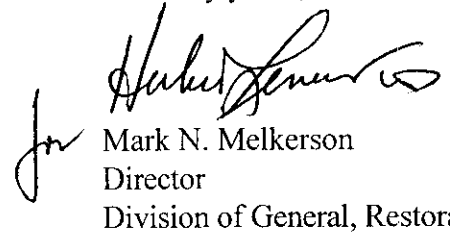
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060523

Device Name: Modified NeuroPort System

Indications for Use:

The intended use of the Cyberkinetics Neurotechnology Systems, Inc. NeuroPort System is for temporary (< 30 days) recording and monitoring of brain electrical activity.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060523