Cyberkinetics
Neurotechnology Systems, Inc.

K070272

AUG - 3 2007

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## 510(k) Summary

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|---|---|
| Company Name: | Cyberkinetics Neurotechnology Systems, Inc. |
| Device Name: | NeuroPort™ Microelectrode Array System (NeuroPort Array) |
| 510(k) Sponsor: | Cyberkinetics Neurotechnology Systems, Inc.<br>A/k/a Cyberkinetics, Inc.<br>F/k/a Trafalgar Ventures, Inc.<br>100 Foxborough Blvd., Suite 240<br>Foxborough, MA 02035 |
| 510(k) Contact: | Timothy Surgenor, President and Chief Executive Officer<br>Cyberkinetics Neurotechnology Systems, Inc.<br>391 Chipeta Way, Suite G<br>Salt Lake City, UT 84108<br>Phone: (801) 582-5533<br>Fax: (801) 582-1509 |
| Summary Date: | January 22, 2007 |
| Trade Name: | NeuroPort Array |
| Common Name: | Depth Electrode |
| Classification Name: | Depth Electrode, CFR 882.1330, Product Code: GZL, Class II |
| Predicate Device: | NeuroPort™ Microelectrode Array System (NeuroPort Array)<br>K042384 |

### 1.0 Description of Device

The NeuroPort Array connects to the NeuroPort System (510(k) K042626 and K060523). This combination of devices supports recording and display of local field potentials and extra cellular spikes from the brain. The NeuroPort System is not modified by this 510(k) submission.

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

The NeuroPort Array consists of high impedance electrodes. The NeuroPort Array impedance is in the range of 0.1 to 1.0 Meg ohms per electrode.

The modification described within this 510(k) submission is summarized as providing a 1.5 mm length NeuroPort Array option in addition to the cleared to market 1.0 mm NeuroPort Array option. The 1.5 mm length variation has the following features and properties in common with the1.0 mm NeuroPort Array:

1. Same materials,
2. Same manufacturing processes,
3. Same insertion technique,
4. Same package and terminal sterilization process.

Along with the longer NeuroPort Array, the Inserter Wand applied to place the NeuroPort Array is modified to support a variation with the 0.5 mm additional insertion depth.

## 1.2 Clinical Application

The NeuroPort Array, with 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 Array and NeuroPort System.

The NeuroPort Array is placed in brain tissue to support recording of cell potentials. Placement of the NeuroPort Array is accomplished by an Inserter Wand. The Inserter Wand is a pneumatic device that supports placement of the NeuroPort Array to the desired depth. The Inserter Wand is modified to two variations, a 1.0 mm and a 1.5 mm variation. The 1.0 mm Inserter Wand is cleared to market with the 1.0 mm NeuroPort Array, 510(k) K042384.

The 1.0 mm Inserter Wand variation is modified to allow the inserter to travel an additional 0.5 mm to support insertion of the 1.5 mm NeuroPort Array. Section 7.0 explains the Inserter Wand changes and evaluation of conformance.

With the 1.5 mm electrode length option, the user is given the opportunity to acquire signals from a deeper level of the brain than the 1.0 mm NeuroPort Array. The selection of NeuroPort Array variation is at the discretion of the user.

## 2.0 Intended use of Device

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

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

## 3.0 Technological Characteristics

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

## 4.0 Data Summary

Testing of the NeuroPort Array modification was performed in compliance with the Cyberkinetics Neurotechnology Systems, Inc. design control process. Testing included:

1. Confirmation of NeuroPort Array impedance characteristics,
2. Confirmation of Inserter Wand dimensional changes.

Testing is completed. No safety or effectiveness concerns remain.

## 5.0 Conclusions

The safety and effectiveness of the modified NeuroPort Array was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the modified NeuroPort Array is the same as the unmodified NeuroPort Array. 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

AUG - 3 2007

Cyberkinetics Neurotechnology Systems, Inc.
% Gary Syring
Principal Consultant
Quality & Regulatory Associates
800 Levanger Lane
Stoughton, Wisconsin 53589

Re: K070272
Trade/Device Name: NeuroPort™ Electrode
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: Class II
Product Code: GZL
Dated: March 22, 2007
Received: March 23, 2007

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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,

Mark N. Melkerson, M.S.
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): _____

Device Name: Modified NeuroPort™ Microelectrode Array System (NeuroPort Array)

Indications for Use:

The intended use of the Cyberkinetics Neurotechnology Systems, Inc. NeuroPort Microelectrode Array 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070272