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K042384

MAR 2 9 2005

510(K) SUMMARY
NeuroPort™ Cortical Microelectrode Array System (Neuroport Electrode)

Submitter Name:	Cyberkinetics, Inc.
Submitter Address:	100 Foxborough Boulevard, Suite 240 Foxboro, MA 02035
Contact Person:	Nandini Murthy, V.P. Regulatory Affairs and Quality Systems
Phone Number:	(508) 549-9981, Extn 103
Fax Number:	(508) 549-9985
Date Prepared:	Aug 30, 2004
Device Trade Name:	NeuroPort™ Cortical Microelectrode Array System (Neuroport Electrode)
Device Common Name:	Depth electrode
Predicate Devices:	Ad-Tech Spencer® Depth Electrode
Device Description:	The NeuroPort™ Array System (Neuroport Electrode) is comprised of a base approximately 4 mm x 4 mm dimensionally with 100 microelectrodes. Each microelectrode is approximately 1 mm long. The lead connects the microelectrode array to the percutaneous pedestal connector.
Intended Use:	The NeuroPort™ Array System (Neuroport Electrode) is intended for temporary (<30 days) recording and monitoring of brain electrical activity.
Performance Data:	Results of non-clinical testing indicate that the NeuroPort™ Array System is deemed biocompatible for its proposed intended use and that the NeuroPort™ Array System records brain electrical activity.
Conclusion:	The NeuroPort™ Array System has the same intended use as compared to the predicate device. Based on the supporting performance data, the NeuroPort™ Array System is capable of recording brain electrical activity and is therefore substantially equivalent to the predicate device technologically.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2005

Ms. Nandini Murthy
Vice President, Vice President Regulatory Affairs
and Quality Systems
Cyberkinetics, Inc.
100 Foxborough Boulevard, Suite 240
Foxborough, Massachusetts 02035

Re: K042384
Trade/Device Name: Neuroport™ Cortical Microelectrode Array System
(Neuroport™ Electrode)
Regulation Number: 21 CFR 882.1330, 21 CFR 882.1835
Regulation Name: Depth electrode; Physiological signal amplifier
Regulatory Class: II
Product Code: GZL and GWL
Dated: February 8, 2005
Received: February 9, 2005

Dear Ms. Murthy:

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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): K042384

Device Name: Neuroport™ Microelectrode Array System (Neuroport Electrode)

Indications For Use:

The intended use of the Cyberkinetics, 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 801 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 K042384