K110010

510(k) Summary
NeuroPort™ Electrode (SIROF)

FEB 9 2011

1. Sponsor/Applicant

Blackrock Microsystems, LLC
391 Chipeta Way, Suite G
Salt Lake City, UT 84108

Telephone: 801-582-5533
Facsimile: 801-582-1509

Primary Contact: Jerry Alperin

2. Consultant/Contact

3. Device Name

Proprietary Name:	NeuroPort™ Electrode (SIROF) (1.0mm) and NeuroPort™ Electrode (SIROF) (1.5mm)
Common/Usual Name:	Depth Electrode
Classification Name:	Depth Electrode

4. Device Classification

A Depth Electrode has been classified by the Neurological Devices Panel as a Class II device per 21 CFR 882.1330, Product Code GZL. A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

5: PREDICATE DEVICES

The predicate device NeuroPort™ Electrode previously cleared August 3, 2007 under K070272.

6: DEVICE DESCRIPTION

The NeuroPort™ Electrode (SIROF) detects the electrical activity of cortical neurons during sub-chronic-monitoring procedures for less than thirty consecutive days. All of the components in the NeuroPort™ Electrode (SIROF) are passive and are intended exclusively for recording applications: monitoring brain electrical activity, defining the location of the epileptogenic foci and brain mapping.

The NeuroPort™ Electrode (SIROF) consists of high impedance electrodes. The NeuroPort™ Electrode (SIROF) has 100 electrode contacts on a silicon substrate of 4mm by 4mm.

The electrodes provide the patient contact device. The electrodes connect the users recording and monitoring equipment. The electrodes are used under the supervision of a physician. Physicians in the areas of biopotential recording and monitoring understand the use of depth electrodes.

7. INTENDED USE/INDICATIONS FOR USE

The NeuroPort™ Electrode (SIROF) 1.0 mm and 1.5 mm are indicated for temporary (<30 days) recording and monitoring of brain electrical activity.

8. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject of this Special 510(k) is a modification of the NeuroPort™ Electrode previously cleared August 3, 2007 under K070272. These devices are identical and only differ in the length of the Array and the length of the respective inserter wands. Copy of the premarket clearance letter for K070272 is provided. The subject of this Special 510(k) is a modification of the NeuroPort™ Electrode. The modifications are:

- A change in the component material of the tip of the electrodes in the array from platinum to sputtered iridium oxide film (SIROF) which is currently used in cardiac pacemaker implants.
- A minor manufacturing change of an addition of an epoxy potting material composed of Loctite M-31CL™ Hysol to the back of the Micro-electrode array.

No modification is being made to the other components. The change is being made to the component material in the electrode to lower the impedence. The change to the epoxy potting is being made to reinforce the wire bonds on the array.

9. PERFORMANCE TESTING

Validation activities to support the use of the modified NeuroPort™ electrode consisted of three main elements:

- Biocompatibility testing

  Biocompatibilty testing was conducted in conformance with ISO 10993 guidelines

- Sterility Validation

  Sterility Validation was conducted in conformance with EN ISO 11737-1

  sterilization process demonstrated a spore (BI) kill to achieve a sterility assurance level (SAL) of $1x10^{-6}$

- Performance testing of the NeuroPort™Electrode (SIROF)

  Impedance measurement was used as a performance metric which allows a quantitative measurement of the quality of the electrode solution interface.

Testing of the modified NeuroPort™ Electrode has demonstrated that the NeuroPort™ Electrode (SIROF) fulfills prospectively defined performance criteria and that the modified system meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Blackrock Microsystems, LLC
c/o Mr. Jerry Alperin, M.Sc., RAC
Manager Regulatory Affairs
391 Chipeta Way, Suite G
Salt Lake City, UT 84108

FEB 9 2011

Re: K110010
Trade/Device Name: NeuroPort™ Electrode (SIROF)
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: December 20, 2010
Received: January 10, 2011

Dear Mr. Alperin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110010

Indications for Use

510(k) Number (if known): K110010

Device Name: NeuroPort™ Electrode (SIROF) (1.0mm), NeuroPort™ Electrode (SIROF) (1.5mm)

Indications for Use:

The intended use of the Blackrock Neurosystems LLC, 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110010