MAY 2 8 2009

K090957

510(k) Summary

Device Name: Blackrock NeuroPort Biopotential Signal Processing System

510(k) Sponsor: I2S Micro Implantable Systems, LLC,
d/b/a Blackrock Microsystems
391 Chipeta Way, Suite G
Salt Lake City, UT 84108

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Director of Product Development
Blackrock Microsystems
391 Chipeta Way, Suite G
Salt Lake City, UT 84108

Summary Date: May 15, 2009

Trade Name: Blackrock NeuroPort Biopotential Signal Processing System

Common Name: Bio-potential Signal Acquisition System

Classification Name: CFR 882.1835 Physiologic Signal Amplifier, Product Code: GWL
CFR 882.1845 Physiological Signal Conditioners, Product Code: GWK

Predicate Devices:

510(k) Number: K042626
Trade Name: NeuroPort™ Neural Signal Processing (NSP) System

510(k) Number: K060803
Trade Name: g.USBamp

510(k) Number: K040113
Trade Name: Sandman SD20 Amplifier

1.0 Description of Device

The Blackrock NeuroPort Biopotential Signal Processing System (System), when connected to customer supplier bio-potential electrodes or the NeuroPort Electrode Array (K042384), supports recording and display of bio-potential signals. Bio-potential signals that can be recorded by the System include:

1. Electrooculography (EOG),
2. Electrocorticography (ECoG),

3. electroencephalography (EEG),
4. electromyography (EMG),
5. electroencephalography (ECG) and
6. evoked potential (EP).

The System is not a monitoring system. No physiologic alarms are provided. The acquisition and display of bio-potential signals is for the interpretation and use of the clinician.

1.2 Clinical Application

The System is used in research institution, clinic, hospital, operating room and epilepsy evaluation environments to acquire (record) bio-potential signals from user supplied electrodes or the NeuroPort Array. All of these electrodes require a high input impedance amplifier to acquire and display the bio-potential signal from the human body the electrodes contact.

2.0 Intended use of Device

The Blackrock NeuroPort Biopotential Signal Processing System supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential signals include: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP).

3.0 Technological Characteristics

The only hardware modifications to the predicated NeuroPort System are:

1. The addition of interface cables to support connection of user supplied electrodes to the amplifier. These interface cables are verified by the continuity of the single pathway, commercial electrode input connector to the amplifier output connector.
2. A passive signal splitter box allows the user supplied electrodes to connect to the System Amplifier and the user's own equipment. This passive box will be verified by continuity of the signal pathways between the user supplied electrode input connector and the two signal connector outputs (System Amplifier output connector and User defined equipment connector).
3. Sync to an external EEG instrument, such as the X-CEL TEK device is addressed in the software testing, see Section 6.0.

4. The syncing of two Systems to be capable of recording up to 256 input channels is supported in the software testing, see Section 6.

3.1 Comparison to Predicates

Feature	System Under Review	Predicate NeuroPort Instrument (K060523)	Predicate g.USBamp (K060803)	Predicate Sandman SD20 Amplifier (K0040113)	Comments
Intended Use, Indications for Use	The Blackrock NeuroPort Biopotential Signal Processing System supports recording, processing and display of biopotential signals from user supplied electrodes. Biopotential signals include, but are not limited to: Electrocorticography (ECoG), electroencephalography (EEG), electromyography (EMG), electrocardiography (ECG), electrooculography (EOG) and Evoked Potential (EP).	The intended use of the Cyberkinetics Neurotechnology Systems, Inc. NeuroPort Neural Signal Processor System is for temporary (< 30 days) recording and monitoring of brain electrical activity.	Measuring, recording and analysis of electrical activity of the brain and/or through the attachment of multiple electrodes at various locations to aid in morning and diagnosis as routinely found in clinical settings of EEG.	The SD20 Amplifier is intended to be use by or under the directions of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.	Equivalent The Blackrock NeuroPort Biopotential Signal Processing System under review acquires, conditions and supports analysis of the same types of biopotential signals as the predicate devices. Polygraphy and polysmnography includes EEG, EMG, ECG, EOG, biopotential signals.
Typical Biopotential Signals Recorded	Electroencephalography (EEG) Electrocorticography (ECoG) Electrocardiography (ECG) Electromyography (EMG) Electrooculography (EOG) Evoked potential (EP)	EEG	EEG ECoG ECG EMG EOG	EEG ECG EMG EOG EP	Equivalent
Number of Signal Recording Channels	Up to 128 with one device; Up to 256 by cascading two devices	96	Up to 128	Up to 128	Equivalent
Amplifier Input Impedance	1000 Megohm	1000 Megohm	> 100 Megohm	Unknown	Same as predicate NeuroPort Instrument.
A/D Conversion	16 Bit	16 Bit	24 Bit	16 Bit	Equivalent
Sampling Rate	Up to 30,000 Hz	Up to 30,000 Hz	Up to 38,400 Hz	Up to 32,000 Hz	Equivalent
CMRR	> 90 dB	> 90 dB	> 100 dB	> 100 dB	Equivalent

Feature	System Under Review	Predicate NeuroPort Instrument (K060523)	Predicate g.USBamp (K060803)	Predicate Sandman SD20 Amplifier (K0040113)	Comments
Analysis Software	Embedded, commercially available and user defined. Examples: Persyst Insight™ NeuroPlex™ Matlab™ Spike 2™ and others.	Embedded, commercially available and user defined. Examples: Persyst Insight™ NeuroPlex™ Matlab™ Spike 2™ and others.	Embedded and commercially available. Examples: Matlab™ and others.	Embedded and commercially available	Equivalent The physician/clinician may apply their own analysis software as a research tool or other commercially available software supporting analysis.
Power	110 VAC	110 VAC	USB Port	Unknown	Safety of the power source is verified by standards compliance.
Alarms	No	No	No	Unknown	Same
Safety Standards Compliance	IEC 60601-1:1998 IEC 60601-1-2:2001 IEC 60601-2-26	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26	IEC 60601-1 IEC 60601-1-2	Same

4.0 Data Summary

Software documentation, system testing and standards compliance were provided to support the substantial equivalence, safety and effectiveness of the System.

5.0 Conclusions

The modifications to the Predicate NeuroPort System to create the Blackrock NeuroPort Biopotential Signal Processing System were evaluated and raise no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

I2S Micro Implantable Systems, LLC
c/o Gary Syring, Principal Consultant
Quality & Regulatory Associates, Inc.
800 Levanger Lane
Stoughton, WI 53589

MAY 2 8 2009

Re: K090957
Trade/Device Name: Blackrock NeuroPort Biopotential Signal Processing System
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiologic Signal Amplifier
Regulatory Class: II
Product code: GWL (and GWK)
Dated: April 2, 2009
Received: April 6, 2009

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Malvina B. Eydelman, M.D.

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

Enclosure

K090957

Indications for Use

510(k) Number (if known): K090957

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Indications for Use:

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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 and Ear, Nose and Throat Devices
510(k) Number K090957