



Food and Drug Administration
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Silver Spring, MD 20993-0002

January 27, 2016

Blackrock Neuromed
% John Ziobro
Principal
Spectramedex
117 West South Street
Oconomowoc, Wisconsin 53066

Re: K151354
Trade/Device Name: Cervello Stim
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: December 22, 2015
Received: December 29, 2015

Dear Mr. Ziobro:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

William J. Heetderks -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151354

Device Name

Cervello® STIM

Indications for Use (Describe)

The Cervello® STIM cortical stimulator is a low power, constant current, bi-phasic stimulator intended for cortical stimulation during electroencephalography examinations (i.e. stereoEEG).

The stimulation is applied to the brain using third-party stimulation probes (including cortical or intracranial electrodes) and the resulting cortical or deep brain potentials themselves are recorded using third-party cortical or intracranial electrodes.

The Cervello® STIM itself is an accessory to the Cervello® Basic Biopotential Signal Acquisition System. The stimulation parameters, the electrodes selection and the activation of the stimulation current are all set-up and controlled from it. The Cervello® STIM can operate only when so connected and with the Cervello software; it cannot serve as a stand-alone cortical stimulator.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary

1. Applicant Name: Blackrock NeuroMed, LLC
630 Komas DR, Suite 200
Salt Lake City, UT 84108
USA
Establishment Registration Number: 3009161142
2. Submission Correspondent: On behalf of Blackrock NeuroMed, the following consultant is assigned the responsibility of submission correspondence:
John F. Ziobro
Principal Consultant
SpectraMedEx, LLC
117 W. South Street
Oconomowoc, WI 53066
262.719.8922
3. Trade Name: CERVELLO[®] STIM
4. Common Name: Cortical stimulator
5. Description: Cortical Electrode (Per FDA Classification)
6. Manufacturing Site: MICROMED S.P.A.
(Hardware & Software) Via giotto 2
Mogliano veneto
Treviso, ITALY 31021
Establishment Registration Number: 3005994236
7. Sterilization Site: N/A, The device is not provided sterile, nor does it need to be sterilized for its intended use
8. Suggested Classification Regulation, Class & Product Code & Panel:
21 CFR 882.1310 Neurology
Class II
Product Code: GYC
Panel: Neurology
9. Reason for Traditional 510(k):
New submission
10. Predicate Device(s): 510(k) Number: **K072964**
Manufacturer: Cardinal Health (Natus)
Trade Name: Nicolet Cortical Stimulator
Product Code: GYC (cortical electrodes)
Classification: 21 CFR 882.1310

Predicate Device(s): 510(k) Number: **K924226**
Manufacturer: Integra Life Sciences
Trade Name: Ojemann Cortical Stimulator OCS2
Product Code: GYC (cortical electrodes)
Classification: 21 CFR 882.1310

Predicate Device(s): 510(k) Number: **K110410**
Manufacturer: Nihon Khoden

Trade Name: MS-120-BK
 Product Code: GYC (cortical electrodes), GWF (evoked response, electrical)
 Classification: 21 CFR 882.1310

Predicate Device(s): 510(k) Number: **K082629**
 Manufacture: Grass Telefactor (Astromed)
 Trade Name: S12X
 Product Code: GYC (cortical electrodes)
 Classification: 21 CFR 882.1310

11. Compliance to Special Controls / Performance Standards: Compliance to the following recognized consensus standards is declared:

Harmonized standard	Title :
IEC 60601—1:2005 + /A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601—1—1:2000	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601—1—4:1996 +A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
IEC 60601—2—26:2012	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601—2—40:1998	Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
IEC 60601—1—2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 62304:2006	Medical device software - Software life-cycle processes

12. Summary Date: May 15, 2015

13. Indication for Use

The Cervello® STIM cortical stimulator is a low power, constant current, bi-phasic stimulator intended for cortical stimulation during electroencephalography examinations (i.e. stereoEEG).

The stimulation is applied to the brain using third-party stimulation probes (including cortical or intracranial electrodes) and the resulting cortical or deep brain potentials themselves are recorded using third-party cortical or intracranial electrodes.

The Cervello® STIM itself is an accessory to the Cervello® Basic Biopotential Signal Acquisition System. The stimulation parameters, the electrodes selection and the activation of the stimulation current are all set-up and controlled from it. The Cervello® STIM can operate only when so connected and with the Cervello software; it cannot serve as a stand-alone cortical stimulator.

14. Technological Characteristics

The hardware and software is very similar to other products on the market and does not differ significantly in any respect. This system is combines the hardware and software platforms of the predicates and as such has it has identical technological characteristics.

15. Comparison to Predicates

The main differences between the CERVELLO® STIM device under review and the predicate(s) (Namely the Nicolet Cortical Stimulator as the primary predicate) are as follows:

- Physical size (the proposed device is smaller)

- Stand-alone versus component (The primary predicate is equivalent to the proposed device in terms that both are “accessories” to their parent systems)
- Required components (The proposed device **MUST** be used in concert with the CERVELLO[®] amplifier. The predicates may be used as stand-alone devices).
- User interface (The proposed device does not have any display – it’s information is conveyed to the user via the software interface that is part of the EEG amplifier system. The predicate devices may include displayed information on the physical devices themselves).
- Stimulation parameters. Some of the parameters of the proposed device are at the low end of the predicates (e.g. the train length of the proposed device = 1-15 seconds while predicates extend to 20 or 30 seconds), while some of the stimulation parameters exceed the range of the predicate (e.g. the pulse width duration of the proposed device is 3 msec, while the predicate(s) do not exceed 2 msec). However, these differences do not impact the overall design intent of the device (it is still intended for the same intended use, intended user and intended use environment).

A comparison of their stimulators and their parameters are shown in the following table:

CERVELLO® STIM Traditional 510(k) Summary	VOLUME 2 SECTION 3
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Feature	Nicolet Cortical Stimulator (K072964)	Integra Life Sciences Ojemann Cortical Stimulator OCS2 (K924226)	Nihon Kohden MS-120 BK (K110410)	Grass-Telefactor S12X (K082629)	CERVELLO® STIM SD LTM STIM (New – Under Review)	Substantial Equivalence Comments
STIMULATOR COMPARISONS & PERFORMANCE SPECIFICATIONS						
Stimulation Output Method	Constant Current	Constant Current	Constant Current	Constant Current	Constant Current	Identical specification. Therefore, Substantially Equivalent
Maximum Stimulation Charge	15µC	20µC	4.5µC	20µC	20µC	Within the range of the predicates. Therefore, Substantially Equivalent
Current Stimulation Range	0.1 to 15mA (peak)	0 to 10 mA (peak)	0 to 15 mA (peak)	0.2 to 15 mA, except at 2ms when current is limited to 10 mA	0 to 15 mA (peak; up to 2KΩ load) in steps of 0.1 mA	Within the range of the predicates. Therefore, Substantially Equivalent
Stimulation Frequency	1 to 100Hz Single pulse or continuous	5,10,20,50,75,100Hz	0.1 to 50Hz	2 to 100Hz except at pulse widths of 1 or 2 ms when the frequency is limited to 50Hz	Single pulse; continuous: from 0.1 Hz to 100 Hz in steps of 0.1 Hz	Within the boundaries of the predicates. Therefore, Substantially Equivalent
Stimulation Pulse Width Duration	0.1 to 1.0 msec per phase	0.1 to 2.0 ms per phase	0.05 to 0.3 msec per phase	0.1 to 2.0 ms	50 µs to 1000 µs in steps of 1 µs (Equivalent to 0.1 to 1.0 msec)	Within the boundaries of the predicates. Therefore, Substantially Equivalent
Stimulation Train Length	User specified 0.1-30 seconds	Unknown	Unknown	0.2 to 20 sec in 7 steps	User specified 1-15 seconds	Within the range of the predicates. Therefore, Substantially Equivalent
Output Trigger	Trigger Out permits synchronizing external equipment	Unknown	Trigger input and output on the connected acquisition system ME1000-A	Unknown	Trigger on single pulse for stimulation rate up to 20 Hz, trigger on train start for higher	Trigger capability similar to

CERVELLO® STIM Traditional 510(k) Summary	VOLUME 2
	SECTION 3

Feature	Nicolet Cortical Stimulator (K072964)	Integra Life Sciences Ojemann Cortical Stimulator OCS2 (K924226)	Nihon Kohden MS-120 BK (K110410)	Grass-Telefactor S12X (K082629)	CERVELLO® STIM SD LTM STIM (New – Under Review)	Substantial Equivalence Comments
					stimulation rates	predicates. Therefore, Substantially Equivalent
Pulse shape	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Identical specification. Therefore, Substantially Equivalent
Stimulation Mode	Biphasic	Biphasic	Biphasic (high output mode; not specified for the low output mode)	Selectable positive, negative, or alternating on successive pulses Biphasic	Biphasic (with independently controllable main & reverse phases)	All devices are biphasic Therefore, Substantially Equivalent
Stimulator features As per advertising materials	The Nicolet Cortical Stimulator interfaces with the NicOne • Stand alone unit or seamlessly integrates with NicOne EEG application software	The Model OCS2 Ojemann Cortical Stimulator is a portable, battery-operated, bipolar stimulator designed according to the specifications of Dr. George Ojemann of the University of Washington, Seattle. It is especially useful for cortical stimulation prior to epilepsy surgery and for intraoperative cortical mapping before cortical incision or placement of depth electrodes in patients with seizure disorders.	The high and low setting, stimulation current and frequency of stimulation is selected by the user. The Nihon Kohden MS-120BK is connected to the MEE 1000A through the JB-116BK or JB-132BK amplifier. In the Low output setting the Nihon Kohden MS-120BK applies cortical stimulation energy through the Nihon Kohden stimulation pod (JS-102B) which is connected to commercially available cortical electrodes (strip and grid electrodes). In the High output setting, the MS-120BK outputs electrostimulation pulse through the Nihon Kohden extension cord (BM-121B) which is connected to commercially available stimulation electrode(s)	Stimulation can be via a traditional hand-held electrode probe for intraoperative stimulation, or via intracranial electrodes using the Grass ESAX Electrode Switching Array option in conjunction with Grass Technologies' Beehive Video/EEG monitoring systems.	<ul style="list-style-type: none"> • It works in conjunction with Micromed amplifier models SD LTM 64 EXPRESS (i.e. Cervello 64) • Direct connection to the amplifier inputs, connection to the patient through the standard amplifier jackbox and commercially available electrodes (strip, grid or depth electrodes). 	Equivalent Features. Differences are for marketing purposes and do not impact the design intent / Intended use. Therefore, Substantially Equivalent

CERVELLO® STIM Traditional 510(k) Summary	VOLUME 2
	SECTION 3

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Number of Channels Capable of Being Selected	<ul style="list-style-type: none"> • Two Stimulus Switching Units may be used to electronically select 128 electrodes, 64 electrode pairs • Stimulates “user selectable” electrode pairs or bipolar probe 			<ul style="list-style-type: none"> • Direct Connect up to 128 channels for electrode selection and EEG recording • Two ESAX switching units can be daisy chained for up to 128 channels • ESAX connects any combination of 64 electrodes to the plus and minus stimulus output of the S12X 	<ul style="list-style-type: none"> • Number of Stimulators: 1 electrical stimulators, positive and negative electrode can be switched to any of the 64 available output channels 	Within the range of the predicates. Therefore, Substantially Equivalent

16. Conclusions

Blackrock Neuromed, believes the proposed CERVELLO[®] STIM (Model SD LTM STIM) and its predicates, the Nicolet Cortical Stimulator, the Integra Ojemann Cortical Stimulator, The Nihon Kohden Model MS-120 BK Cortical Stimulator and the Grass-Telefactor Model S12X System, are substantially equivalent in their intended use, intended users, intended use environment and indications for use. Furthermore, both systems have the same/equivalent technological characteristics, physical characteristics and safety standards. The differences that exist between the devices, relating to their physical size, the interconnectiveness with the other common components, their user interface, and minor differences in the stimulation parameters do not affect the relative safety and/or effectiveness.