K083322

510(k) Summary
for
NeuroMetrix Bioamplifier

MAY 27 2009

1. SPONSOR

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451

Contact Person: Rainer Maas
Telephone: (781) 314-2781
Date Prepared: May 11, 2009

2. DEVICE NAME

Proprietary Name: Bioamplifier
Common/Usual Name: One channel wireless electromyography amplifier
Classification Name: 890.1375 Electromyograph, Diagnostic

3. PREDICATE DEVICES

- EB Neuro S.p.A. NeMus PC Peripheral (K073415)

4. INTENDED USE

The NeuroMetrix Bioamplifier is intended for amplification and transmission of the electrical activity of peripheral nerves and muscles recorded through surface electrodes.

5. DEVICE DESCRIPTION

The NeuroMetrix Bioamplifier ("Bioamplifier") is a one channel wireless electromyography amplifier. This device is intended to differentially measure, amplify, digitize, and wirelessly transmit bioelectrical signals from peripheral nerves and muscles transduced by surface electrodes, which are provided separately.

The Bioamplifier consists of the following components:

5.1 Amplifier/Digitization Unit. The electronic circuitry and software required to measure, amplify and digitize bioelectrical signals generated by nerves and muscles.

5.2 Battery. The Bioamplifier is powered from a high capacity re-chargeable Li-polymer battery.

5.3 RF Trigger. The Bioamplifier includes an RF receiver that allows a host device to precisely trigger data acquisition in order to synchronize to events such as stimuli.

5.4 Bluetooth. The Bioamplifier is equipped with Bluetooth wireless technology that provides communication between it and a host device.

The Bioamplifier is typically used with a host device that controls the operation of the Bioamplifier and may provide other functionality such as a user interface, electrical or other stimuli, data analysis, data storage, and document generation.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Bioamplifier, which is the subject of this 510(k) Premarket Notification, is substantially equivalent to the predicate EB Neuro S.p.A. NeMus PC Peripheral as previously cleared for marketing. The two devices have similar indications for use, which is the recording of bioelectrical activity from peripheral nerves and muscles using surface electrodes, converting these signals into digital form, and transmitting this data to a host device. The two devices have comparable system components. They both have amplifier and digitization circuits. They both have a DC power source which in the Bioamplifier is provided by an embedded rechargeable battery and in the NeMus PC Peripheral by an AC/DC adapter. They both have a wired connector to surface electrodes. Finally, they both have a digital link to an external device. In the Bioamplifier this is accomplished through a Bluetooth wireless link while in the NeMus PC Peripheral it is provided via a wired Ethernet cable. Although the technology used in some system components is different (e.g., battery vs. AC/DC adapter; wireless vs. wired link), the functionality is comparable. Furthermore, the performance of all Bioamplifier system components has been validated. Therefore any differences in system component technologies do not raise new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NeuroMetrix, Inc.
% Rainer Maas
62 Fourth Avenue
Waltham, Massachusetts 02451

Re: K083322
Trade/Device Name: Bioamplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological signal amplifier
Regulatory Class: II
Product Code: GWL
Dated: April 1, 2009
Received: April 3, 2009

Dear Rainer Mass:

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 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) 276-0120. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K083322

Device Name: **Bioamplifier**

Intended Use:

The NeuroMetrix Bioamplifier us intended for amplification and transmission of the electrical activity of peripheral nerves and muscles recorded through surface electrodes.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083322