K062943

510(k) Summary

September 26, 2006

Name and Address of Applicant

Neurotronics, Inc.
102 NE 10 Avenue Ste. 5
Gainesville, FL, 32601

MAY - 9 2007

Phone: 352.372.9955
Fax : 815.550.2871

Primary Contact

Jennifer Laine
Hardware Design Manager
352.372.9955 ext. 302

Proprietary Name of Device

Polysmith Sleep System

Common Names of the Device

Polysomnography Monitoring System

Device Classification

The device is classified as a Class II device by the Neurology Panel under 21 CFR Part 882.1400 "Electroencephalograph": OLZ, OLV, DQA

Establishment Registration Number of Manufacturer

1063925

Legally Marketed Predicate

Nihon Kohden PSG Input Box, Model JE-912AK, cleared under 510(k), K022121
Polysmith cleared under 510(k), K971803

Summary of Technological Characteristics of Device Compared to Predicates

The device has similar indications for use and intended use as the predicate devices. Both systems sample, filter, amplify, and transfer biologic potentials critical in Sleep Studies to a personal computer running dedicated PSG software. They are both non-ambulatory devices and applicable to patients of all ages.

The energy source for both the device and predicates is equivalent. They receive power and ground via the USB port of a PC. Neither device makes physical contact with the patient; the patient-side electronics of both are electrically isolated from the computer mains.

Description

The device is intended to amplify and record physiologic potentials used for Polysomnography (PSG) or Sleep Studies. The bio-potentials are transferred to Polysmith polysomnography software running on a personal computer. Qualified practitioners use the information to score Polysomnograms and diagnose Sleep Disorders. The device is intended for use on both adults and children only under the direction of a physician or qualified sleep technician.

Intended Use

The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a Sleep Study, such as EEG, EOG, EMG, Respiration Effort, and SpO_2. The data may be analyzed in real-time or offline on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of Sleep Disorders.

This device, or any accessory, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system.

This device, or any accessory, is not to be used alone as a life support device or as a critical component of a life support system.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Performance and Safety Testing

The accessories of the device comply with IEC 601-1 subclause 56.3(c) as determined by 21 CFR Part 898: Performance Standard for Electrode Lead Wires and Patient Cables.

The device complies voluntarily with the following industrial standards:

UL 60601-1
EN 60601-1
EN 60601-1-4
IEC 60601-2-26:2002
IEC 60601-1-2:2001
IEC 60601-1:1998

CAN/CSA 22.2 No 601.1 M90
CAN/CSA-ISO13485:2003
21 CFR Part 820
MDD: 93/42/EEC Annex II, IIa (per manufacturer)
CISPR11 Group 1, Class B

These standards guarantee that the device was designed by a company possessing a full quality system and meets the safety and performance criteria required for an Electrical Medical Device in markets within the European Union. The device was verified and validated according to the product specifications. The test criteria consist of standardized levels and internal product requirements. Tests performed on the device include environmental and mechanical stress testing, electromagnetic immunity and emissions testing, and medical device safety testing. Software on the device was verified and validated according to the functionality of the operations of the device. The test results confirm that the device is in accordance with its specifications.

Classification Criteria

- The device provides Class II protection against electric shock.
- The device does not contact the patient directly but plugs into medical grade electrodes and probes which are electrically floating and at times have conductive contact with the skin of the patient. These accessories are legally marketed and sold in the United States.
- The degree of protection against the ingress of water is IPX0.
- The device is not sterile.
- The use of the device is not suitable in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- During normal operating conditions, the device is in a continuous mode of operation.
- The device is externally supplied by a direct current source, and at times may supply non harmful energy to the patient to monitor physiological processes.
- The device is portable. It may be moved while worn by the patient or between uses.

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

Neurotronics, Inc.
c/o Ms. Dawn M. Lauryn
Quality Manager
102 NE 10th Avenue, Suite 5
Gainesville, FL, 32601

Re: K062943

APR - 9 2012

Trade/Device Name: Polysmith Sleep System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLZ, OLV, DQA
Dated (Date on orig SE ltr): February 8, 2007
Received (Date on orig SE ltr): February 8, 2007

Dear Ms. Lauryn:

This letter corrects our substantially equivalent letter of May 9, 2007.

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 (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 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,

Kesia Alexander

for

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

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Polysmith Sleep System

Indications for Use:

The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a Sleep Study. The physiological signals are recorded and conditioned for analysis and display. The data may be analyzed in real-time or offline on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of Sleep Disorders.

This device, or any accessory, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system.

This device, or any accessory, is not to be used alone as a life support device or as a critical component of a life support system.

This device is intended for use on both adults and children only under the direction of a physician or qualified sleep technician.

Prescription Use __x__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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

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