K092699

MAR 18 2010

510(K) SUMMARY

Name and Address of Applicant

Nomad is designed and distributed by:
Neurotronics®, Inc.
912 NE 2nd Street
Gainesville, FL, 32601
Phone.: 352.372.9955

Fax: 815.550.2871

Contact Information:

James Schubert
Vice President
Tel: 352.372.9955
Ext. 309
Email: James.schubert@neurotronics.com

Indications for Use:

The Nomad device is a digital amplifier capable of measuring bio-potential signals that may be incorporated into a Polysomnogram.

The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a Sleep Study, such as Limb Movement, Respiration Effort, and SpO2. The data may be analyzed 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 associated accessories, is not to be used alone as an apnea monitor or as a component in an apnea monitoring system.

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

The device is not sterile.

The device does not directly contact patients. Accessories that contact patients, such as oximeter finger probe, are the same accessories used with other legally marketed products. Therefore, good laboratory practice studies were not required per 21 CFR Part 58.

The device was subjected to electromagnetic, environmental, safety and performance testing. The results of validation and verification confirmed that the device performed within expected specifications. The risk evaluation also confirmed all the risks have been properly mitigated.

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

****** The device is substantially equivalent to the predicate as stated. **********

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 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 Limb Movement, Body Position, 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.

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Performance and Safety Testing

The accessories of the device comply with IEC 60601-1 Subclause 56.3(c) as determined by 21 CFR Part 898: Performance Standard for Electrode Lead Wires and Patient Cables.

The device was verified and validated according to the product specifications. The test criteria consists 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.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Based on the statements made above, the device and the predicates have the same intended use, the same principles of operation, similar physical/functional descriptions, and equivalent voluntary standards.

Therefore, Neurotronics, Inc. believes that the Nomad is substantially equivalent to the predicate device, the Neurotronics Sphinx.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR 18 2010

Neurotronics®, Inc.
c/o Mr. James Schubert
Vice President
912 NE 2nd Street
Gainesville, FL 32601

Re: K092699
Trade/Device Name: NOMAD, Polysmith Sleep System
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological Signal Amplifier
Regulatory Class: Class II
Product Code: GWL, MNR, and DQA
Dated: February 12, 2010
Received: February 12, 2010

Dear Mr. Schubert:

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

G. Indications for Use Statement

510(k) Number (if known): K092699

Device Name: NOMAD, Polysmith Sleep System

Indications for Use:

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The device is intended to measure, amplify, and record physiological signals acquired from a patient for archival in a Sleep Study, such as Limb Movement, Respiration Effort, and SpO2. The data may be analyzed on dedicated polysomnography software running on a personal computer by a qualified sleep clinician to aid in the diagnosis of Sleep Disorders.

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

This device is intended for use on both adults and children on the order of physician.

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.

The device is not sterile.

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

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

JOE HUTTER

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices