K130570

DEC 26 2013

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5. 510K Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.92, the following summary of information is provided:

Applicant Information

Christine Vergely
Regulatory Affairs Manager
Neurovision Medical Products, Inc.
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Date of Summary: 11/4/13

Device Identification:

Trade or Proprietary Name:	Neurovision Medical Motion Sensor
Common or Usual Name:	Medical Motion Sensor
Classification Name:	Breathing Frequency Monitor
Device Class:	Class II
Classification:	§868.2375
Product Code:	BZQ

Predicate Devices

The Neurovision Medical Motion Sensor is substantially equivalent to the following predicate devices currently distributed commercially in the U.S.:

- K062883; Gereonics Ultra-Piezo Limb Movement Sensor

Device Description

The Neurovision Medical Motion Sensor is a disposable, multipurpose piezo accelerometer sensor configured to be self-powered (by "watch" type battery), disposable, and capable of being read by a small signal electrophysiologic monitor.

Indication for Use

The Neurovision Medical Motion Sensor is intended to detect, monitor and/or record limb movements on a physiological recorder, in adult patient sleep disorder studies, in a clinical setting.

Technological Characteristics of Device in Relation to Predicate Devices

The Neurovision Medical Motion Sensor is similar to the Gereonics Ultra-Piezo Limb Movement Sensor in terms of materials, design, performance and indications for use, differing only in being battery powered whereas the predicate is powered by a dedicated monitor.

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Table 1 Device Comparison Table

	K062883	Subject Device
Brand Name	Gereonics Ultra-Piezo Limb Motion Sensor	Medical Motion Sensor
Description	Piezo Sensor, attachable	Piezo Sensor, attachable
Indications for Use	For adult use. The Gereonics Ultra-Piezo Limb Movement Sensor (LMS) is used to detect periodic limb movements for recording or monitoring on a physiological amplifier. The LMS is intended for use in sleep disorders studies.	The Neurovision Medical Motion Sensor is intended to detect, monitor and/or record limb movements on a physiological recorder, in adult patient sleep disorder studies, in a clinical setting.
Product Code	BZQ	BZQ
Materials and Design	Nonsterile attachment electrode with **unpowered** Piezo Sensor	Nonsterile attachment device with **battery powered** Piezo Accelerometer
Bio-compatibility	N/A	N/A
Compatible devices	Dedicator Monitor (Gereonics)	Electrophysiologic Monitors
Sterility	Non-sterile	Non-sterile
Attachment to Monitor	DIN connector	DIN connector

Performance Testing

Compatibility with representative testing equipment was demonstrated.

Bench testing included in the submission includes:

- Demonstrated ability of the Neurovision Medical Motion Sensor to signal gross motor movement with 2 different model EMG units.
- Demonstrated ability of the Neurovision Medical Motion Sensor to signal gross motor movement with a standard ECG unit.
- Compliance with IEC 60601-1:1988 + A1:1991 + A2:1995; EN 60601-1:1990+A1+A2+A13, UL 60601-1:2003 R4.06, CAN/CSA-C22.2
- Comparable sensitivity of the Neurovision Medical Products Motion Sensor to typical patient movements expected under the conditions of intended use to the sensitivity of the Predicate Devices, Gereonics Ultra-Piezo Limb Movement Sensor, to similar movements, based on the testing submitted by the predicate for 510k review.

Conclusion

The Neurovision Medical Motion Sensor is substantially equivalent to the Gereonics Ultra-Piezo Limb Movement Sensor in terms of materials, design, performance and indications for use, differing only in being battery powered whereas the predicate is powered by a dedicated monitor. There are no additional safety or effectiveness risks associated with this design difference.

(End of 510(k) Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 26, 2013

Neurovision Medical Products Inc.
Christine Vergely
Regulatory Affairs Manager
2225 Sperry Ave, Suite 1000
VENTURA, CA 93003

Re: K130570
Trade/Device Name: Neurovision Medical Motion Sensor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: November 25, 2013
Received: November 26, 2013

Dear Ms. Vergely:

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 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. 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,

Kwame O. Ulmer -S for

Erin I. Keith
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130570

Device Name
Neurovision Medical Motion Sensor

Indications for Use *(Describe)*
The Neurovision Medical Motion Sensor is intended to detect, monitor and/or record limb movements on a physiological recorder, in adult patient sleep disorder studies in a clinical setting.

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)*

FDA

Digitally signed by
Richard C.
Chapman
Date: 2013.12.26
12:26:15 -05'00'