K130007

Advanced Brain Monitoring, Inc. Sleep Profiler

## 510(k) Summary

APR 17 2013

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: January 31, 2012

SUBMITTER:
Advanced Brain Monitoring
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Carlsbad, CA 92008
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PRIMARY CONTACT PERSON:
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Founder
Pathway Regulatory Consulting, LLC
T 262-290-0023

SECONDARY CONTACT PERSON:
Dan Levendowski President and
Co-founder Advanced Brain
Monitoring, Inc.

DEVICE:

TRADE NAME: Sleep Profiler

COMMON/USUAL NAME: automatic event detection software for polysomnograph with electroencephalograph

CLASSIFICATION NAMES: 882.1400 Electroencephalograph

PRODUCT CODE: OLZ

PREDICATE DEVICE(S):
K120450 Sleep Profiler
K112514 Apnea Risk Evaluation System (ARES), Model 610

DEVICE DESCRIPTION:
The Sleep Profiler is a software application that analyzes previously recorded physiological signals obtained during sleep. The Sleep Profiler software can analyze any EDF files meeting defined specifications, including signals acquired with the Advanced Brain Monitoring X4 System.

Automated algorithms are applied to the raw signals in order to derive additional signals and interpret the raw and derived signal information. The software automates recognition of: a) sleep stage, b) snoring frequency and severity, c) pulse rate, d) cortical (EEG), sympathetic (pulse) and behavioral (actigraphy and snoring) arousals. A single channel of electrocardiography, electrooculargraphy, electromyography, or electroencephalography can be optionally presented for visual inspection and interpretation. The software identifies and rejects periods with poor electroencephalography signal quality. The full disclosure recording of derived signals and automated analyses can be visually inspected and edited prior to the

results being integrated into a sleep study report.

Medical and history information can be input from a questionnaire. Responses are analyzed to provide a pre-test probability of Obstructive Sleep Apnea (OSA) (a condition that cannot be diagnosed with Sleep Profiler) so an appropriate referral to a sleep physician is made. The automated analyses of physiological data are integrated with the questionnaire data, medical and history information to provide a comprehensive report. Several report formats are available depending on whether the user has acquired more than one night of data, wishes to obtain a narrative summary report or provide patient reports.

The capability to enter or edit patient information, call the application to generate a study report, and/or download a report is provided using either the desktop PC application or in a web-based module which emulates the desktop functionality. The same analysis and report generation software is used for both the desktop and web-portal applications.

INTENDED USE:
Sleep Profiler is intended for the diagnostic evaluation by a physician to assess sleep quality in adults only. The Sleep Profiler is a software-only device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals and snoring.

TECHNOLOGY:
The Sleep Profiler software is identical to the previously cleared Sleep Profiler (K120450). A web-based module was developed to provide the user with an interface to enter and edit patient information and generate or download reports from a portal thus delivering the same functions provided by the PC software. The web-interface module runs on a cloud server and uses the same fundamental technology as the ARES Model 610 portal (K112514). No changes were made to the software used to analyzed the signals or generate study reports. The technologies used in the Sleep Profiler are used in the same manner as the predicate products and do not raise new questions of safety and effectiveness.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:
SUMMARY OF NON-CLINICAL TESTS:
Support for the substantial equivalence of the Sleep Profiler was provided as a result of risk management and software testing.

The Sleep Profiler software has been thoroughly tested through verification of specifications and validation. The key metric for software verification/validation was confirmation of identical performance using either the desktop or portal for the key functions associated with the web-based software:

- Enter questionnaire responses,
- Edit study data
- Initiate generation of a study report
- Download a study report

The results of the verification and validation activities that have been performed demonstrate that the software meets requirements for safety, function, and intended use.

SUMMARY OF CLINICAL TESTS:
The modifications to the Sleep Profiler that are the subject of this premarket submission did not require clinical studies to support substantial equivalence. The functionality of the modified device was completely evaluated by performing nonclinical verification and validation.

CONCLUSION:
Advanced Brain Monitoring considers the Sleep Profiler software to be as safe, as effective, and substantially equivalent to the predicate device.

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

April 17, 2013

Advanced Brain Monitoring Inc.
c/o Ms. Adrienne Lenz
Pathway Regulatory Consulting, LLC
W324 S3649 County Road E
Dousman, WI 53118

Re: K130007
Trade/Device Name: Sleep Profiler
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Lenz:

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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting 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): K130007

Device Name: Sleep Profiler

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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