K130013

510(k) Summary

JAN 31 2013

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

DATE: December 28, 2012

SUBMITTER:

Advanced Brain Monitoring
2237 Faraday Avenue, Suite 100
Carlsbad, CA 92008
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F 760.720.3337

PRIMARY CONTACT PERSON:

Adrienne Lenz, RAC
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: X4 System

COMMON/USUAL NAME: X4

CLASSIFICATION NAMES: 882.1400 Electroencephalograph

PRODUCT CODE: OMC

PREDICATE DEVICE(S):

K120447 X4 System

K112514 Apnea Risk Evaluation System (ARES), Model 610

DEVICE DESCRIPTION:

The X4 system is used for configurable acquisition of physiological signals. Model X4-E provides for acquisition of three channels of electroencephalography (EEG) and one photoplethesmographic (PPG) signal from a head strip, with an optional channel connected to two sensors via a dual-lead connector with twice the gain. Model X4-M provides four channels of EEG with the dual-lead connector providing the input for reference sensors. Both models measure sound via an acoustic microphone, and movement and position measured via a 3-D accelerometer. The device is designed so it can be affixed by the patient and to record data. Alternatively, a technician can affix the device and display the signals via a wireless connection during acquisition. The X4 system firmware monitors signal quality to ensure that the sensors are properly applied and that high quality signals are being acquired.

The X4 software provides a means to: a) initiate a study and track patient information, b) acquire and save signals to the memory of the device, c) acquire and wirelessly transmit signals from the device, d) upload data saved in the memory of the device to a PC, and e) visually inspect the signal quality.

The acquired signals are saved in a universal data format (European Data Format – EDF). The study record, once saved on the PC, is available for analysis by Advanced Brain Monitoring's Sleep Profiler software application. The X4's downloaded study will reside on either or local PC or a cloud server, which can be a physical or virtual server. Software on the cloud server is accessed via web portal software.

INTENDED USE:

The X4 System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, transmit and display physiological signals from adult patients. The X4 System acquires, records, transmits, and displays electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG); and accelerometer, acoustical, and photoplethesmographic signals. The X4 system only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.

TECHNOLOGY:

The X4 System is identical to the previously cleared X4 System (K120447). A Device Manager Module was developed to run via a web portal as an alternative to the identical functions provided in the PC software. The Device Manager module running on the cloud server uses the same fundamental technology as the ARES Model 610 portal (K112514). The technologies used in the X4 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 X4 System was provided as a result of risk management and software testing.

The X4 software has been thoroughly tested through verification of specifications and validation, including software 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 Device Manager software:

- format the device for a new patient,
- enter and upload study identification information to the device,
- download study information to data storage, and
- upload new firmware.

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 X4 System 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 X4 System to be as safe, as effective, and substantially equivalent to the predicate devices.

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

January 31 2013

Advanced Brain Monitoring, Incorporated
C/O Ms. Adrienne Lenz, RAC
Pathway Regulatory Consulting, Limited Liability Company
W324 S3649 County Road East
DOUSMAN, WI 53118

Re: K130013
Trade/Device Name: X4 System
Regulation Number: 21 CFR 882.1400
Regulation Name: Neurological Diagnostic Devices
Regulatory Class: II
Product Code: OMC
Dated: December 31, 2012
Received: January 29, 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.

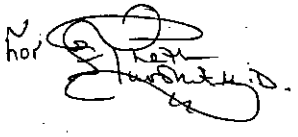
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130013

Device Name: X4 System

Indications for Use:

The X4 System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, record, transmit and display physiological signals from adult patients. The X4 System acquires, records, transmits and displays electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), accelerometer, acoustical and photoplethesmographic signals. The X4 system only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.

Prescription Use_X___ AND/OR Over-The-Counter Use__

(Part 21 CFR 801 Subpart D) (Part 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)

Lester W. Schultheis Jr
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Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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