

510(k) Summary

K120447

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

DATE: May 25, 2012

SUBMITTER:

Advanced Brain Monitoring
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Carlsbad, CA 92008
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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):

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 photoplethysmographic (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) that is intended to be analyzed with third party software, including Advanced Brain Monitoring's Sleep Profile Software (K120450).

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), accelerometer, acoustical and photoplethysmographic 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 uses the same fundamental technology as the ARES Model 610 for most features including the electrophysiological (EEG), photoplethysmographic (PPG) and actigraphy signals. Acquisition of the electrocardiograph signal requires minor modification to the band pass filters and is equivalent to the Compumedics Somte. Wireless acquisition of the physiological signals is equivalent to the Infinite Biomedical Technologies I200 two-channel EEG system. 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 testing which included electrical and biological safety, performance and software tests. This testing includes conformity to FDA recognized consensus standards and voluntary standards as follows:

Standard Number	Standard Title
IEC 60601-1-1:1988+A1: 1991+A2: 1995	Medical Electrical Equipment – Part 1: General requirements for safety
IEC 60601-1-2: 2007	Medical Electrical Equipment Part 1-2: Collateral standard: Electromagnetic compatibility – requirements and tests
ISO 10993-1: 2009	Biological evaluation of medical devices Part 1
IEC 60601-1-11: 2010	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-2-26:2002	Particular requirements for the safety of electroencephalographs

Additional verification and validation testing confirmed:

- All features of the X4 System were compliant with the system level requirements.
- Signals acquired with the X4 System provide similar information as compared to the predicate device that would allow a physician to interpret the signals.

SUMMARY OF CLINICAL TESTS:

The X4 has been the subject of clinical testing to demonstrate it can be used by patients in the home. The results support that over 90% of studies recorded overnight with the X4 are interpretable and behave as expected. The X4 instructions were applied without difficulty, allowing all subjects to properly apply the device so that it remained in the proper position and allowing any problems that triggered an audio alarm to be properly resolved.

CONCLUSION:

Advanced Brain Monitoring considers the X4 System to be as safe, as effective, and substantially equivalent to the predicate devices.



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

Advanced Brain Monitoring, Inc.
C/O Ms. Adrienne Lenz
Pathway Regulatory Consulting, LLC
Regulatory Affairs Consulting
W324 S3649 County Road E
Dousman, Wisconsin 53118

JUN 20 2012

Re: K120447
Trade/Device Name: X4 System
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OMC
Dated: May 25, 2012
Received: May 30, 2012

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.

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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,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Advanced Brain Monitoring, Inc. X4 System

510(k) Number (if known): K120447

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 photoplethysmographic 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)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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