



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

October 30, 2015

Advanced Brain Monitoring, Inc.
% Adrienne Lenz
Member
Pathway Regulatory Consulting, LLC
W324S3649 County Road E
Dousman, Wisconsin 53118

Re: K152040

Trade/Device Name: X8 System - Sleep Profiler (SP40), X8 System - Sleep Profiler PSG2
(SP29), X8 System - Stat X8 (XS29)

Regulation Number: 21 CFR 882.1400

Regulation Name: Electroencephalograph

Regulatory Class: Class II

Product Code: OMC, OLV

Dated: July 17, 2015

Received: July 22, 2015

Dear Adrienne 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
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)

K152040

Device Name

X8 System - Sleep Profiler (SP40), X8 System - Sleep Profiler PSG2 (SP29), X8 System - Stat X8 (XS29)

Indications for Use (Describe)

The X8 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. All X8 models (SP40, SP29, and XS29) acquire, record, transmit, and/or display electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals, with optional accelerometer, acoustical, and photoplethysmographic signals. Model SP29 additionally includes a nasal pressure transducer and cannula (for airflow), thoracic and abdomen respiratory effort, and pulse rate and oxyhemoglobin saturation from the finger. The X8 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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

DATE: September 24, 2015

SUBMITTER:

Advanced Brain Monitoring
2237 Faraday Avenue, Suite 100
Carlsbad, CA 92008
T 760.720.0099
F 760.720.3337

PRIMARY CONTACT PERSON:

Adrienne Lenz, RAC
Member
Pathway Regulatory Consulting, LLC
T 262-290-0023

SECONDARY CONTACT PERSON:

Dan Levendowski
President and Co-founder
Advanced Brain Monitoring, Inc.

DEVICE:

TRADE NAME: X8 System (Sleep Profiler, Sleep Profiler PSG2, X8 Stat)

COMMON/USUAL NAME: X8

CLASSIFICATION NAMES: 882.1400 Electroencephalograph

REVIEW PANEL: Neurology

PRODUCT CODE: OMC

PREDICATE DEVICE(S):

K130013 X4 System

DEVICE DESCRIPTION:

The X8 System is indicated for acquiring, recording/storing, transmitting, and displaying physiological data in patients. It can be used by patients in the home, healthcare facility, or clinical research environment. Patients can move within their home or healthcare environment without having to remove the device (e.g. walk to the restroom).

The X8 System is comprised of the X8 device which is worn on the patient's head and body, accessories, the Device Manager software, and the X-Series Basic-Utility Software. The study records are saved to the PC in EDF format and are available for analysis by third party software applications, such as Persyst Reveal (K011397).

The X8 System combines hardware, firmware, and software to acquire physiological signals. It acquires physiological data through a battery powered headset worn by the patient and provides a flexible platform for applying sensors and acquiring signals from multiple locations on the head or body, transmitting and recording the signals, and providing visual and auditory indications to ensure high quality data are obtained.

Model SP40 Sleep Profiler is applied by the patient to acquire and record electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals, with optional accelerometer, acoustical, and photoplethysmographic signals during sleep. This model utilizes the X8 Sleep Profiler Strip.

Model SP29 Sleep Profiler PSG2 is applied by the patient to acquire and record electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals, with optional accelerometer, acoustical, and photoplethysmographic signals during sleep. This model additionally includes a nasal pressure transducer and cannula (for airflow), thoracic and abdomen respiratory effort, and pulse rate and oxyhemoglobin saturation from the finger. This model utilizes the X8 Sleep Profiler Strip.

Model XS29 X8 Stat is applied by a technician to acquire, record, transmit, and/or display electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals, with optional accelerometer, acoustical, and photoplethysmographic signals acquired during non-sleep conditions. This model utilizes either the X8 Midline or the X8 Referential strip.

The Device Manager software application provides a means to communicate with the X8 Device, transfer study data, and format a device. The software transfers data saved in the memory of the X8 device using either a PC application or a web-based data entry application operating in a cloud server environment.

The X-Series Basic-Utility Software acquires, presents, and stores physiological signals from the X8 Device. The software has a modular architecture that allows the users to interact using either the Graphical User Interface (GUI) provided with the installation, or programmatically via a Software Development Kit. Additional functionalities provided by X-Series Basic-Utility Software include impedance measurements, custom markers, and interface with the Bluetooth Receiving Dongle.

INTENDED USE:

The X8 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. All X8 models (SP40, SP29, and XS29) acquire, record, transmit, and/or display electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), and/or electromyogram (EMG) signals, with optional accelerometer, acoustical, and photoplethysmographic signals. Model SP29 additionally includes a nasal pressure transducer and cannula (for airflow), thoracic and abdomen respiratory effort, and pulse rate and oxyhemoglobin saturation from the finger. The X8 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 X8 System has similar indications for use and uses the same fundamental technology as the X4 System for most features including the electrophysiological (EEG, EOG, ECG, EMG), wireless acquisition, and actigraphy. Like the X4 System, the X8 system acquires, records and transmits EEG, EOG, ECG, EMG, accelerometer, acoustical and photoplethysmographic signals. Additional respiratory signals acquired by the X8 system use similar technology as reference device ARES Model 610. The technologies used in the X8 System are used in the same manner as the predicate and reference products and do not raise new questions of safety and effectiveness. A comparison of key specifications is presented in the following table:

Specification	X8 System (New)	Predicate Device X4 System (K130013)	Reference Device ARES Model 610 (K112514)
<i>Patient Population</i>	Adults	Adults	Adults
<i>Anatomical Sites</i>	Forehead, Head, Chest, Abdomen, Chin and Finger	Forehead, Chest, Chin	Forehead, Chest
<i>Environment of Use</i>	Home (data acquisition) Healthcare facility (data acquisition, analysis and reporting) Clinical Research Environment	Home (data acquisition) Healthcare facility (data acquisition, analysis and reporting) Clinical Research Environment	Home (data acquisition) Healthcare facility (data acquisition, analysis and reporting)
<i>User Control</i>	ON/OFF	ON/OFF	ON/OFF

Advanced Brain Monitoring, Inc. X8 System

Specification	X8 System (New)	Predicate Device X4 System (K130013)	Reference Device ARES Model 610 (K112514)
<i>Visual Indicator</i>	Green and yellow LED	Green and yellow LED	Green LED
<i>Audio Indicator</i>	Speaker. Voice messages alert user to problems during recording.	Speaker. Voice messages alert user to problems during recording.	Speaker. Voice messages alert user to problems during recording.
<i>EEG Electrodes</i>	Vermed VersaTrobe Sensor 40-4305 (K781430)	Kendall Meditrace Mini 230 (K960968) Kendall Meditrace Mini 533 (K945479)	Kendall Meditrace Mini 130 (K864722)
<i>EOG Electrodes</i>	Vermed VersaTrobe Sensor 40-4305 (K781430)	Kendall Meditrace Mini 130 (K864722)	Kendall Meditrace Mini 130 (K864722)
<i>ECG Electrodes</i>	Vermed VersaTrobe Sensor 40-4305 (K781430)	Kendall Meditrace Mini 533 (K945479)	None
<i>EMG Electrodes</i>	Vermed NeuroPlus Sensors A10041-60 (K010638)	Kendall Meditrace Mini 130 (K864722)	None
<i>Linked Mastoid Sensors</i>	MBS (3BF3) Disposable Ag/Cl sensors with adhesive (K842514)	MBS (3BF3) Disposable Ag/Cl sensors with adhesive (K842514)	None
<i>2-pin Leadwire</i>	2-pin leadwire with touch-proof connector	2-pin leadwire with touch-proof connector	2-pin leadwire with touch-proof connector
<i>3-pin Leadwire</i>	3-pin leadwire with touch-proof connector	3-pin leadwire with touch-proof connector	None
<i>Respiratory Accessory</i>	Nasal Cannula and nasal pressure sensor Chest and abdomen effort belts	None	Nasal Cannula and nasal pressure sensor Chest effort belt
<i>Signals Acquired</i>	<ul style="list-style-type: none"> • Forehead/head EEG • Infra-red (IR) optical signal • Microphone • 3-D actigraphy • Optional channel (ECG/EEG/EOG/EMG) • Nasal Pressure & cannula • Respiratory Effort 	<ul style="list-style-type: none"> • Forehead/head EEG • Infra-red (IR) optical signal • Microphone • 3-D actigraphy • Optional channel (ECG/EEG/EOG/EMG) 	<ul style="list-style-type: none"> • Forehead EEG • Red and infra-red (IR) optical signals • Microphone • 3-D actigraphy • Derived EOG and EMG • Nasal Pressure & cannula • Respiratory Effort
<i>Power Supply</i>	1 x 600 mA 3.7V Li-ION battery	1 x 600 mA 3.7V Li-ION battery	2 x 250 mA 3.7V Li-ION batteries

Advanced Brain Monitoring, Inc. X8 System

Specification	X8 System (New)	Predicate Device X4 System (K130013)	Reference Device ARES Model 610 (K112514)
<i>Battery Charging</i>	Patients - external battery pack Technicians - Via USB cable connected to USB port or USB wall charger	Via USB cable connected to USB port or USB wall charger	Via USB cable connected to USB port or USB wall charger
<i>Typical Charging Time</i>	0.5 – 3.0 hours	0.5 – 3.0 hours	0.5 – 2.5 hours
<i>Acquisition modes</i>	Record or Monitor	Record or Monitor	Record only
<i>Operating Time</i>	Hours of Use: 0-4 days after charging: Model SP40 Record: 16.0 - 18.5 Model XS29 Monitor: 10.5 - 12.5 Model SP29 Record: 11.5 -13.5 5-10 days after charging: Model SP40 Record: 14.0 - 16.5 Model XS29 Monitor: 9.5 - 12.0 Model SP29 Record: 10.0 - 13.0	Hours of Use: 0-4 days after charging: Record: 13.0 - 15.5 Monitor: 6.5 - 7.8 5-10 days after charging: Record: 11.5 - 14.8 Monitor: 6.0 - 7.3	Hours of Use: 0-4 days after charging: Record: 19.0 hours 5-10 days after charging: Record: 17.0 hours
<i>Data Storage</i>	8 GB Micro-SDHC memory card or greater capacity	2 GB Micro-SD memory card	2 GB Micro-SD memory card
<i>File size per 8 hr recording</i>	Standard mode – 72 MB PSG2 Mode – 134 MB	72 MB	31.2 MB
<i>Dimensions</i>	2.1” long, 1.5”wide, 0.75” deep	2.1” long, 1.5”wide, 0.75” deep	2.5” long x 2” wide x 1” deep
<i>Weight</i>	2.5 ounces with battery	2.5 ounces with battery	4 ounces with batteries
<i>Cleaning enclosures and EEG Strip</i>	Cleaned and disinfected by rubbing with alcohol-based hand sanitizer and isopropyl alcohol.	Cleaned and disinfected by rubbing with alcohol-based hand sanitizer and isopropyl alcohol.	Cleaned and disinfected by rubbing with alcohol-based hand sanitizer and isopropyl alcohol.
<i>Cleaning enclosure strap</i>	Cleaned and disinfected by washing with dish soap.	Cleaned and disinfected by washing with dish soap.	Single patient use.

Advanced Brain Monitoring, Inc. X8 System

Specification	X8 System (New)	Predicate Device X4 System (K130013)	Reference Device ARES Model 610 (K112514)
<i>Nasal Pressure Transducer</i>	Pressure transducer incorporated into airflow adapter, Affixes to USB connector Size: 3.5 (l) x 2.5 (w) x 1.5 (d) cm Weight - 5.5 grams	Not available	Pressure transducer incorporated into main enclosure
<i>Oximeter</i>	Bluetooth (BT) used to obtain pulse and SpO2 acquired with wrist oximeter. Nonin WristOx2 Wireless Pulse Oximeter (K102350)	Not available	Pulse and oximeter incorporated into main enclosure
<i>Respiratory effort belts</i>	Uses 3 rd party respiratory induced plethysmography (RIP) thorax and abdomen effort belts Philips/Pro-Tech ezRIP Respiratory Effort Sensors (K913395), and Ambu SleepMate RIPmate Respiratory Effort Sensor (K903300)	Not available	Single piezzo chest belt
<i>Data transfer from SD card</i>	Native USB	Native USB	Native USB
<i>USB data transfer rate</i>	> 250 MB per minute	> 250 MB per minute	> 250 MB per minute
<i>Wireless data transfer</i>	Bluetooth	Bluetooth	N/A
<i>Maximum Bluetooth wireless transfer distance and rate</i>	Transfer distance 10 meters line of sight, maximum transfer rate 3 Mbaud	Transfer distance 10 meters line of sight, maximum transfer rate 3 Mbaud	N/A
<i>Compatibility</i>	Personal computer with 2.4GHz (Pentium 4) Processor or better, 2 GB RAM or higher (or equivalent) with Windows 7, 8, or Mac iOS Operating System	Personal computer with Pentium 4, 2 GB RAM or higher processor (or equivalent) with Windows 7 Operating System	Personal computer with Pentium 4, 1 GB RAM or higher processor (or equivalent) with Windows XP Operating System
<i>Estimated file size per minute</i>	Standard Mode: 150 KB/Min PSG2 Mode: 280 KB/Min	150 KB/Min	67 KB/Min
<i>File format type</i>	European Data Format (EDF)	European Data Format (EDF)	Proprietary

Advanced Brain Monitoring, Inc. X8 System

Specification	X8 System (New)	Predicate Device X4 System (K130013)	Reference Device ARES Model 610 (K112514)
<i>Presents raw signals during acquisition in monitoring mode</i>	Yes	Yes	Yes
<i>Presents previously acquired signals</i>	No	Yes	Yes

Advanced Brain Monitoring, Inc. X8 System

Specification	X8 System (New)	Predicate Device X4 System (K130013)	Reference Device ARES Model 610 (K112514)
<i>Desktop interface minimum computer requirements</i>	<ol style="list-style-type: none"> Processor : 2.4 GHz Operating System: Windows 7 or 8 RAM: 2GB USB port: 1 	<ol style="list-style-type: none"> Processor : 2.4 GHz Operating System: Windows 7 RAM: 2GB USB port: 1 	<ol style="list-style-type: none"> Processor : 2.4 GHz Operating System: Windows XP RAM: 1GB USB port: 1
<i>Web interface minimum computer requirements</i>	<ol style="list-style-type: none"> Processor : Minimum 2.4 GHz Operating System: Windows 7 or 8, Mac iOS Java version 6 or greater RAM: 1GB USB port: 1 Internet connection: constant Web browser: Internet Explorer, Firefox, Opera, Chrome, or Safari 	<ol style="list-style-type: none"> Processor : Minimum 2.4 GHz Operating System: Windows XP or 7 Java version 6 or greater RAM: 1GB USB port: 1 Internet connection: constant Web browser: Internet Explorer, Firefox, Opera, or Chrome 	<ol style="list-style-type: none"> Processor : Minimum 2.4 GHz Operating System: Windows XP or 7 JAVA version 6 or greater RAM: 1GB USB port: 1 Internet connection: constant Web browser: Internet Explorer, Firefox, or Chrome
<i>Web interface server requirements.</i>	<p>Virtual Server:</p> <ol style="list-style-type: none"> Processor: > 2 GHz Operating system: Win Server 2008. RAM: > 2GB Certificates: Signed SSL .NET framework: version 2.0 – web server version 3.5 – processing server or Win Server 2008 Database: SQL server 2005 <p>Physical Server:</p> <ol style="list-style-type: none"> Processor: > 2 GHz Operating system: Win Server 2008 Enterprise edition (for virtual servers). RAM: > 2GB 	<p>Virtual Server:</p> <ol style="list-style-type: none"> Processor: > 2 GHz Operating system: Win Server 2008. RAM: > 2GB Certificates: Signed SSL .NET framework: version 2.0 – web server version 3.5 – processing server or Win Server 2008 Database: SQL server 2005 <p>Physical Server:</p> <ol style="list-style-type: none"> Processor: > 2 GHz Operating system: Win Server 2008 Enterprise edition (for virtual servers) RAM: > 2GB 	<p>Virtual server:</p> <ol style="list-style-type: none"> Processor: > 2 GHz Operating system: Win Server 2008. RAM: > 2GB Certificates: Signed SSL .NET framework: version 2.0 – web server version 3.5 – processing server or Win Server 2008 Database: SQL server 2005 <p>Physical server:</p> <ol style="list-style-type: none"> Processor: > 2 GHz Operating system: Win Server 2008 Enterprise edition (for virtual servers). RAM: > 2GB

Advanced Brain Monitoring, Inc. X8 System

Specification	X8 System (New)	Predicate Device X4 System (K130013)	Reference Device ARES Model 610 (K112514)
<i>Computer/portal Security</i>	<ol style="list-style-type: none"> 1. The person installing the Java applet must have administrator privileges. 2. User must have rights to the account and group to access data via the portal. 3. The firewall is not configured to prevent input or output communication with access to the server via ports 22 and 30-39. 	<ol style="list-style-type: none"> 1. The person installing the Java applet must have administrator privileges. 2. User must have rights to the account and group to access data via the portal. 3. The firewall is not configured to prevent input or output communication with access to the server via ports 22 and 30-39. 	<ol style="list-style-type: none"> 1. The person installing the Java applet must have administrator privileges. 2. User must have rights to the account and group to access data via the portal. 3. The firewall is not configured to prevent input or output communication with access to the server via ports 22 and 30-39.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF NON-CLINICAL TESTS:

Support for the substantial equivalence of the X8 System was provided as a result of risk management and testing which included comparison of signals to the predicate device, electrical safety, electromagnetic compatibility and software tests. This testing includes conformity to FDA recognized consensus standards and voluntary standards as follows:

Standard Number	Standard Title
IEC 60601-1:2005 (3rd Edition)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
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 60601-2-26:2012	Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 62133: 2012	Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications
ISO 14971:2007	Medical devices - Application of risk management to medical devices

Additional analysis, verification and validation testing confirmed:

- Instructions for disinfecting the reusable parts of the X8 System and the materials used in the reusable portions of the X8 System (i.e. Sensor strip forehead, sensor strip head, and enclosure strap) are identical to those used in the previously cleared X4 System (K120047) and X-Series System (K131383). The remaining reusable portions (i.e. Respiratory Effort Belts and Wireless finger pulse oximeter) of the X8 System are cleared on their own by the supplier. The size and shape of the device enclosure of the X8 System is identical to that of the previously cleared X4 System and the material used is the same Black ABS. The Airflow Adapter enclosure is made of the same Black ABS as the device enclosure. Advanced Brain Monitoring evaluated the differences between the X8 System and the X-Series and X4 Systems and concluded that previously performed cleaning validation was also applicable to the X8 System.
- All materials of the X8 System are identical to materials tested for biocompatibility in the predicate X4 System and reference device X-Series System (K131383).
- All features of the X8 System were compliant with the system and software level requirements.
- Signals acquired with the X8 System provide equivalent information as compared to the predicate device that would allow a physician to interpret the signals.

SUMMARY OF CLINICAL TESTS:

Advanced Brain Monitoring has conducted prospective studies to: A) compare equivalence of signals obtained with X8 System airflow and respiratory effort signals with an FDA cleared device, Compumedics Somte (K072201), and B) demonstrate that high quality signals can be obtained when the X8 System is self-applied with the user instructions. X8 System Model SP29 was used for both portions of the study.

The following endpoints were successfully achieved:

- No more than 10% of the breathing events recorded with the X8-PSG2 airflow signal were inferior to predicate signal. No events recorded with the X8-PSG2 airflow signal (0%) were found inferior to the predicate signal.
- No more than 20% of the breathing events recorded with the X8-PSG2 respiratory effort will be inferior to the predicate signal. The X8 thorax and abdomen belts were inferior to the predicate in only 4.0% (9/225) and 1.3% (3/232) of the events, respectively.
- At least 80% of subjects will be able to acquire at least one night of data (i.e., the entire period they were in bed). The results demonstrated that 91% (10 of 11 subjects) were able to acquire at least one night of data for the entire night.
- At least 70% of each night of recording time will be valid across the oximetry, nasal pressure, and effort belt signals. The percentage of good data obtained for oximetry, nasal pressure (airflow) and respiratory effort (thorax and abdomen) exceeded 90% on each night. While not identified as a primary endpoint for the assessment of cardio-

respiratory signal quality, high EEG quality was also obtained in over 90% of the recording time on each night.

- At least 70% of subjects did not report X8-PSG2 audio alerts (for signal quality) substantially affected (i.e., strongly agreed) their ability to stay asleep. The results demonstrated that 90% (9 of 10 subjects) did not “strongly agree” that the PSG2 made it difficult for them to stay asleep.

CONCLUSION:

Advanced Brain Monitoring considers the X8 System to be substantially equivalent to the predicate devices.