K071230

510(k) Summary

Date of submission	May 2, 2007

OCT 3 ˇ 2007

Official contact/address of manufacturing facility	Daniel J. Levendowski President Advanced Brain Monitoring, Inc. 2237 Faraday Avenue, Suite 100 Carlsbad, CA 92008 Tel: 760.720.0099 x 6040 Fax: 760.720.3337
Proprietary name	Apnea Risk Evaluation System - Model 600
Common/Usual name	ARES™
Device classification name	Ventilatory Effort Recorder
Classification reference	21 CFR 868.2375
Classification	Class II
Appropriate classification panel	Anesthesiology
Product code	MNR
Predicate Devices	Advanced Brain Monitoring ARES (Model 500)(K041662) Sandman Digital (K003154), Watch_Pat 100S (K042916)
Reason for submission	Modified design

Substantial Equivalence

Design verification and validation tests were performed on the ARES Unicorder Model 600 to ensure it meets the specified product requirements. As a result of its risk analysis, Advanced Brain Monitoring has determined that the modifications have no impact on safety and effectiveness of the device. In summary, the device described in the submission is substantially equivalent to the predicate devices.

Indications for Use

The Apnea Risk Evaluation System (ARES™) is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting

events). The device is designed for prescription use in home diagnosis of adults with possible sleep-related breathing disorders.

Device Description

The Apnea Risk Evaluation System (ARES) includes a device called a Unicorder which records oxygen saturation, pulse rate, snoring level, head movement and head position, airflow, respiratory effort, and a physiological signal from the forehead used to stage sleep. The battery-powered Unicorder provides sufficient capacity to record for 18-hours of continuous use. The device monitors signal quality during acquisition and notifies the user via voice messages when adjustments are required.

A standard USB cable connects the Unicorder to a USB port on a host computer when patient data is to be uploaded or downloaded. The USB cable provides power to the Unicorder during recharging from the host computer or from a USB wall charger. The Unicorder cannot record nor can it be worn by the patient when connected to the host computer or the wall charger.

Software controls the uploading and downloading of data to the Unicorder, processes the sleep study data and generates a sleep study report. Algorithms are applied to the physiological data to automatically detect apneas and hypopneas, distinguish sleep from awake and rapid eye movement sleep from non-rapid eye movement sleep. A full disclosure recording is provided, allowing a clinician to edit any of the events detected by the detection algorithms. The software includes the capability to assign a pre-test probability of a patient having OSA based on questionnaire responses. Six disposable components must be replaced and the forehead sensor must be cleaned before reuse.

Comparison to Predicate Devices

Characteristic	ARES Model 500 K041662	Sandman Digital 32 K003154	ARES Model 600 K071230	Watch_Pat 100S K042916
Intended Use	The Apnea Risk Evaluation System (ARES™) is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES can record and score respiratory events (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home screening of adults with possible sleep disorders.	The Sandman digital system is a Polysomnographic System intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.	The Apnea Risk Evaluation System (ARES™) is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home screening of adults with possible sleep disorders.	The Watch_PAT is a diagnostic aid for the detection of sleep related breathing disorders and rapid eye movement (REM) sleep staging. The WP100S generates a peripheral arterial tonometry, respiratory disturbance and PAT REM sleep stage identification.

Portable Design	Yes	Yes	Yes	Yes
Battery powered	Yes	No	Yes	Yes
Data collection	Yes	Yes	Yes	Yes
Present collected data	Yes	Yes	Yes	Yes
Automated data analysis	Optional (always present, but a clinician may choose to use it or not)	Same	Same	Same
Capable of data transfer for analysis and report generation	Yes	Yes	Yes	Yes
Data input types	Respiratory	Respiratory, neurological, ECG	Respiratory, neurological, actigraphy	Peripheral arterial tonometry, oximetry, pulse rate, actigraphy
Channels	7	51	10	4
Raw data storage	Yes, flash	Yes, hard disk	Yes, flash	Yes, flash
Study modes	Over-night recordings at home, retrieval and replay	Polysomnography recordings, long term monitoring, retrieval and replay	Over-night recordings at home, retrieval and replay	Over-night recordings at home, retrieval and replay

Materials

All materials used in the manufacture of the device are suitable for this use and have been used in numerous previously cleared products.

Performance Testing

Support for the safety and efficacy of the ARES Unicorder (Model 600) was provided as a result of extensive testing which included safety, performance and comparative tests. This testing includes conformity to the FDA recognized list of consensus standards and voluntary standards. The list of performance testing conducted prior to this submission is as follows:

- IEC 60601-1: 1988+A1: 19991 + A2: 1995 + CAN/CSA-C22.2+ UL60601-1:2003, Medical Electrical Equipment – Part 1" General requirements for Safety
- IEC 60601-1-2: 2001 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic compatibility – requirements and tests
- FDA Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices – May 2005
- ARES 600 System Requirements Test Procedure/Report; assesses the features of the ARES 600 to ensure compliance with the System level requirements
- ARES 600 and ARES 500 bench comparison report for the measurement of head position and head movement
- ARES 600 and ARES 500 airflow, respiratory effort, pulse rate and SpO2 channel/signal comparisons to determine the equivalence in the data collection and the waveform presentation between the ARES 500 and ARES 600.
- ARES 600 and Sandman Digital EEG, EOG and EMG channel/signal comparisons to determine the equivalence in the data collection and waveform presentation between the ARES 600 and Sandman Digital.

- The accuracy of the automated detection of awake and sleep and REM vs. non-REM compared to technician scoring of laboratory PSG was assessed and compared to the predicate device. The technician scoring was considered the gold—standard for purposes of assessing accuracy.

Summary of Substantial Equivalence

It is the conclusion of Advanced Brain Monitoring, Inc. that the ARES – Model 600 is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Daniel J. Levendowski
President
Advanced Brain Monitoring, Incorporated
2237 Faraday Avenue, Suite 100
Carlsbad, California 92008

OCT 3 2007

Re: K071230
Trade/Device Name: Apnea Risk Evaluation System (ARES™)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: September 6, 2007
Received: September 7, 2007

Dear Mr. Levendowski:

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.

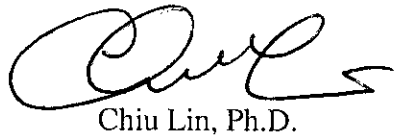
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): This application

Device Name: Apnea Risk Evaluation System (ARES™)

Indications for Use:

The Apnea Risk Evaluation System (ARES) is indicated for use in the diagnostic evaluation by a physician of adult patients with possible sleep apnea. The ARES can record and score respiratory events during sleep (e.g., apneas, hypopneas, mixed apneas and flow limiting events). The device is designed for prescription use in home diagnosis of adults with possible sleep-related breathing disorders.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K071230