K111194

JUL - 7 2011

510(K) SUMMARY

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

April 25, 2011

SUBMITTER:

Advanced Brain Monitoring
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PRIMARY CONTACT PERSON:

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SECONDARY CONTACT PERSON:

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

DEVICE:

TRADE NAME: Apnea Risk Evaluation System (ARES™), Model 610

COMMON/USUAL NAME: ARES

CLASSIFICATION NAMES: 868.2375 Breathing frequency monitor

PRODUCT CODE: MNR

PREDICATE DEVICE(S):

K110705 Apnea Risk Evaluation System (ARES), Model 610

K090484 Respironics Alice PDX

K072201 Compumedics Somté

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, and airflow. Additionally, a physiological signal from the forehead used to stage sleep or respiratory effort signal obtained from an optional piezo respiratory effort belt can be acquired. The battery powered Unicorder provides sufficient capacity to record two nights of data. 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. The ARES™ can auto-detect positional and non-positional obstructive and mixed apneas and hypopneas similarly to polysomnography. It can detect sleep/wake and REM and non-REM.

After the sleep study has been completed, data is transferred off the Unicorder and the Unicorder is prepared for the next study. The downloaded sleep study record is then processed with the ARES™ Insight software to transform the raw signals and derive and assess changes in oxygen saturation (SpO_2), pulse rate, head movement, head position, snoring sounds, airflow, and EEG or respiratory effort. The red and IR signals are used to calculate the SpO_2 and pulse rate. The actigraphy signals are transformed to obtain head movement and head position. A clinician can convert an auto-detected obstructive apnea to a central apnea based on visual inspection of the waveforms.

ARES™ Screener can predict pre-test probability of obstructive sleep apnea (OSA). The ARES™ can assist the physician to identify patients who will likely have a successful OSA treatment outcome, including CPAP and oral appliance therapies. ARES™ can also help identify patients who would benefit from a laboratory PAP titration.

INTENDED USE:

The Apnea Risk Evaluation System (ARES™), Model 610 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.

TECHNOLOGY:

The Apnea Risk Evaluation System (ARES™), Model 610 with the chest belt has the same indications for use and uses the same fundamental technology as the ARES™ Model 610 cleared via K110705. The ARES™ Model 610 with Respiratory Effort Belt is identical to the predicate ARES™ Model 610 without chest belt with the following modifications:

1. Modification of the flex circuit to allow amplifier input from either two EEG sensors (previously cleared, K071230) or two connectors for input from a commercially available piezo respiratory effort belt.

2. Updated firmware and software to allow acquisition and presentation of either the EEG signal or the effort belt signal.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

COMPARISON TO PREDICATE DEVICES

The ARES™ Model 610 with respiratory effort belt has the same intended use as the cleared ARES™ Model 610. All features are identical except those described in the table below.

Characteristic	ARES™ Model 610 (K110705)	ARES™ Model 610 (New)	Equivalence Discussion
Data acquisition	Via forehead sensor: • Red/IR LEDs • Photodetector • Microphone • Nasal Cannula • Nasal pressure transducer • 3D accelerometers • EEG sensor	Via forehead sensor: • Red/IR LEDs • Photodetector Microphone • Nasal Cannula • Nasal pressure transducer • 3D accelerometers • EEG sensor (optional – not available when Effort Belt is used) • Respiratory Effort Belt (optional – not available when EEG is used)	The ARES has been modified to acquire data from cleared piezo respiratory effort belts, similarly to Respironics Alice PDX (K090484) and Compumedics Somté (K072201).
Respiratory Effort	Not available	256 samples/sec hardware acquisition, displayed at 25 samples/sec	

SUMMARY OF NON-CLINICAL TESTS:

Support for the substantial equivalence of the ARES™ Model 610 was provided as a result of risk management and testing which included electrical 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

Additional verification and validation testing confirmed:

- All features of the ARES™ Model 610 were compliant with the system level requirements.
- The ARES Unicorder correctly acquires and stores the signal from a cleared respiratory effort belt.
- Signals acquired with the ARES™ Model 610 provide similar information as compared to the predicate device that would allow a physician, trained in sleep medicine to interpret the signals.

SUMMARY OF CLINICAL TESTS:

Two clinical studies were conducted to validate the ARES™ with chest belt. One study compared signals acquired from subjects with the ARES™ chest belt to those simultaneously acquired using the Compumedics Somté System (K021176) and confirmed the ARES™ chest signal and Somté chest signal were equivalent in their response to three types of breathing events. Snapshots acquired from the new and predicate device provide similar information that would allow a physician, trained in sleep medicine, to interpret the signals. The acceptance criteria of at least 95% waveforms being equivalent was met and the study result is Pass.

The second study evaluated the ability for users of the ARES™ with chest belt to properly apply the device such that signals acquired were useful for interpretation. The results support that at least 95% of signals from the ARES effort belt recorded during overnight studies are interpretable and behave consistently based on the airflow signal. Based on subject feedback from a Usability survey, the Unicorder with effort belt can be easily used by patients.

CONCLUSION:

The conclusions drawn from the nonclinical and clinical tests demonstrate equivalent performance of the Apnea Risk Evaluation System (ARES™), Model 610 and the legally marketed devices. The Apnea Risk Evaluation System (ARES™), Model 610 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Advanced Brain Monitoring, Incorporated
C/O Ms. Adrienne Lenz, RAC
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Re: K111194
Trade/Device Name: Apnea Risk Evaluation Systems (ARES)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: June 9, 2011
Received: June 10, 2011

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

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

510(k) Number (if known):

Device Name: Apnea Risk Evaluation System (ARES)

Indications for Use:

The Apnea Risk Evaluation System (ARES™), Model 610 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.

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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