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

April 24, 2017

Watermark Medical
% Michael Leigh
Consultant
Michael Leigh
19019 W. Coffee Road
New Berlin, Wisconsin 53146

Re: K160499
Trade/Device Name: Apnea Risk Evaluation System (ARES), Model 620
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: March 20, 2017
Received: March 24, 2017

Dear Michael Leigh:

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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160499

Device Name
Apnea Risk Evaluation System (ARES), Model 620

Indications for Use *(Describe)*
The Apnea Risk Evaluation System (ARES), Model 620 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 the patient's home to aid a physician in diagnosing adults with possible sleep-related breathing disorders.

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 for Watermark Apnea Risk Evaluation System

Submitter: Watermark Medical

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Corporate Contact: Frank Katarow, VP Product Development
Watermark Medical

Telephone: 877-710-6999

Establishment Registration #: 3008208119

Submission Contact: Michael Leigh
consultant

Trade Name: Apnea Risk Evaluation System (ARES™), Model 620

Common/Usual name: ARES

Classification Names: 868.2375 Ventilatory Effort Recorder. Class II

Product Code: MNR

Predicate Device: K111194 Apnea Risk Evaluation System (ARES), Model 610

Device Description:

The Apnea Risk Evaluation System (ARES™) includes a battery powered patient worn device called a Unicorder (Model 620). The Unicorder is worn by a patient for one to three nights, each night recording up to 7 hours of data. Data recorded includes oxygen saturation, snoring level, head movement, head position, and airflow. Additionally, the Unicorder 620 allows collection of data from ARES compatible peripheral devices. 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, residing on a local PC or a physical or virtual server 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), head movement, head position, snoring sounds, airflow, and EEG or respiratory effort. The red and IR signals are used to calculate the SpO_2. 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™ data can also assist the physician to identify patients who will likely have a successful OSA treatment outcome, including CPAP and oral appliance therapies. ARES™ can help identify patients who would benefit from a laboratory PAP titration.

Intended Use:

The Apnea Risk Evaluation System (ARES™), Model 620 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 the patient's home to aid a physician in diagnosing adults with possible sleep-related breathing disorders

Technology:

The ARES™ Model 620 being submitted is an update to the predicate ARES™ Model 610 (K111194) and includes the following changes:

- Enhanced physical design
  - Reduced size
  - Physical enhancements (rubber sensor block as opposed to exposed silicone forehead sensor)
  - Integrated sensor technology
- Integrated SPO2 technology (currently derived via Insight)
  - Dual SPO2 integrated sensors
- Integrated video display
- Integrated Bluetooth

COMPARISON TO PREDICATE DEVICES

The modified ARES™ Model 620 has the same intended use and fundamental scientific technology as the cleared ARES™ Model 610. Technological characteristics are described in the table below.

Specification	**Predicate Device ARES Model 610, K111194 as cleared on 07/07/2011**	**Proposed ARES Model 620**	**Discussion of Differences**
Classification	MNR, Ventilatory Effort Recorder	MNR, Ventilatory Effort Recorder	Identical
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.	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.	Identical
Patient Population	Adults	Adults	Identical
Anatomical Sites	Forehead	Forehead	Identical
Environment of Use	Home (data acquisition) Physician office (data analysis and reporting)	Home (data acquisition) Physician office (data analysis and reporting)	Identical
Unicorder User Interface			
User Control	Single button Control • On/Off	Multi-button control • On/Off • Volume Up/Down Menu navigation	Equivalent - Same On/Off, with addition of • Volume controls • Clinical menu with special key sequence
Visual Indicator	Green LED	Visual Display	Equivalent – added device specific updates and visual queues
Audio Indicator	Speaker – voice message alert user to problems during recording	Speaker – voice message alert user to problems during recording	Identical
Specifications of			

Data Acquisition Unit			
Data acquisition	Via forehead sensor: • Red/IR LEDs • Photodetector Microphone • Nasal Cannula • Nasal pressure transducer • 3D accelerometers • EEG sensor • Respiratory Effort Belt • Chain of Custody	Via forehead sensor: • Red/IR LEDs • Photodetector Microphone • Nasal Cannula • Nasal pressure transducer • 3D accelerometers • EEG sensor • Respiratory Effort Belt • Chain of Custody	Identical
SpO2 measurement	Derived via Insight	Integrated on-board algorithm	Equivalent
File size per 7 hr. recording	31.2 MB	25 MB	Equivalent – no impact on use
Dimensions	4.5” long x 2” wide x 1” deep	4” long x 2” wide x .8” deep	Equivalent – no impact on use
Weight	4 oz with batteries	3.4 oz with batteries	Equivalent – no impact on use
Data Acquisition Unit Materials			
Case	ABS blend	ABS blend	Identical
Enclosure Strap	• Single piece strap. • Non-latex elastic, • polyethylene, • metal rivets, plastic sizing strap	• Single piece strap. • Non-latex elastic, • polypropylene shield, Velcro Velstretch brand tape (sizing)	Equivalent – Eliminated unnecessary pieces
Stabilizing straps	Santoprene	Not used in this model	Equivalent – Eliminated in design
Forehead sensor pad	Silicone – combined with enclosure pad	Not used in this model	Equivalent – Eliminated in design
Cannula	Salter SO-1314	Salter SO-1314	Identical
Cleaning	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.	Identical
Cable			
Dimensions	Standard USB “A” to mini “B”	Standard USB “A” to mini “B”	Identical
Recharging Indicator	LED – Green, pattern – blinking	Graphic display	Similar
Communication			
Data Transfer	Native USB	Native USB	Identical
Data Transfer Rate	>256 MB per minute	>240 MB per Minute	Equivalent – no impact on use
Performance			

Software Code base	Assembler code	C	Equivalent - new code base for improved maintenance and processing efficiency
Estimated file Size per Minute	~ 67 KB/min	~52 KB/min	Equivalent – no impact on use
Saturation Accuracy	Sp02 Range Error (± 1 SD) Saturation Accuracy 70-100%	70 to 100% SpO2 ± 2%	Equivalent
Airflow	Via Nasal Pressure Range ± 0.55 cm H20 Accuracy ± 2%	Via Nasal Pressure Range ± 0.55 cm H20 Accuracy ± 2%	Identical
Head Position	Via accelerometers Position accuracy 3° @ 30°C	Via accelerometers Position accuracy 3° @ 30°C	Identical
Snoring Level	From microphone 40 dB (min) 70 dB (max)	From microphone 20 dB (min) 70 dB (max)	Equivalent - Additional low frequency range available
Sleep/awake Signal	Optional EEG Sensor: ±1000 µV @ 256 samples/sec	Optional EEG Sensor: ±1000 µV @ 240 samples/sec	Equivalent – No impact on use
Enhanced physical design			
Reduced size	4.5” long x 2” wide x 1” deep	4” long x 2” wide x 0.8” deep	Similar
Forehead sensor	Silicone – combined with enclosure pad	rubber sensor block	Similar
Enhancements addressing ease of use		Incorporate user feedback	Equivalent - Improved design for user comfort
hardware			
memory capacity	2 GB	8 GB	Equivalent - additional memory capacity
processor	Three secondary processors for interfacing to external PC and SD card	Single secondary processor for interfacing to external PC and SD card	Equivalent - Improved technology eliminating need for additional secondary processors
battery			
Battery type	two 250 mAh lithium ion connected in parallel	single 1500 mAh lithium ion	Equivalent – • Improved battery efficiency • eliminates potential performance or safety issues from running batteries in parallel
battery protection	internal overcharge/discharge protective circuit	internal overcharge/discharge protective circuit, with additional overcurrent/short circuit protection	Equivalent - Additional protective circuits

battery charge indicator	None	battery charge gauge - visible to user	Similar
charge control	controller including pre-charge and fast-charge safety timers	• controller including pre-charge and fast-charge safety timers • battery temperature sensing • over-temperature safety cutoff • storage disconnect	Similar
oximeter			
control	timing, optical hardware, and data collection on main processor	timing, optical hardware, and data collection on separate processor	Equivalent
optical components	single LED/Photo diode	two LED/Photo diodes	Equivalent - redundant sensors
sensor construction	optical components encapsulated in silicone gel that is attached to rubber pad	optical components mounted directly to rubber pad and sealed with silicone gel	Equivalent – new design for ease of cleaning and serviceability
EEG			
design	no lead drive, no current limiters	cross couple pair of amplifiers current limiting resistors	Equivalent - simultaneous use of peripheral respiratory belt(s) and EEG
processing	processor with internal 12 bit A/D converter	processor with internal 12 bit A/D converter	Identical
signal chain	data captured by ADC and transferred directly to SD card with no filtering or transformation	data captured by ADC and transferred directly to SD card with no filtering or transformation	Identical
airflow			
pressure transducer	miniature pressure sensor package with Integrated temperature compensation and calibration	miniature pressure sensor package with Integrated temperature compensation and calibration	Equivalent
offset handling	no DC rejection circuit, so offset must be calibrated during manufacturing	high pass filter to eliminate all transducer offsets and maximize usable range of A/D converter	Equivalent

signal chain	signal is captured by 12-bit ADC in main processor and transferred directly to SD card with no filtering or transformation	signal is captured by 12-bit ADC in main processor and transferred directly to SD card with no filtering or transformation	Identical
microphone			
circuitry		smaller, equivalent first stage amplifier, modified reference circuit	Equivalent
microphone	6mm omnidirectional back electret condensor microphones	6mm omnidirectional back electret condensor microphones	Equivalent
gain	-44 dB +/-3DB	-42dB +/-3dB	Equivalent - Gain compensates for difference in acoustics due to mounting
signal chain	signal is captured by 12-bit ADC in main processor and transferred directly to SD card with no filtering or transformation	signal is captured by 12-bit ADC in main processor and transferred directly to SD card with no filtering or transformation	Identical
position sensor			
accelerometer	solid state accelerometer	solid state accelerometer	Similar
type	+/-2B 12 bit digital accelerometer with 1mg resolution	+/-2B 12 bit digital accelerometer with 1mg resolution	Identical
signal chain	signal is captured by SPI port of main processor and transferred directly to SD card with no filtering or transformation	signal is captured by I2C port of main processor and transferred directly to SD card with no filtering or transformation	Equivalent - design enhancement
user interface			
input type	single button, single LED, and a speaker for voice prompts and alerts to fault conditions	three buttons, small graphics display, and a speaker for voice prompts and alerts to fault conditions	Similar
UI circuit	button directly connected to processor	three buttons directly connected to processor	Identical
Bluetooth			

circuitry	none	Self-contained module connected to serial port of MSP430 main processor	Equivalent – Additional connectivity options
use	n/a	Watermark Respiration Adapter	Equivalent – Additional connectivity options
limit	n/a	Bluetooth modules supports one device at a time	Equivalent – Additional connectivity options
Bluetooth interface	none	open source Bluetooth stack, BTStack	Equivalent – Additional connectivity options
respiration			
data collection	uses EEG amplifier to measure belt resistance	uses Bluetooth module to collect data from chest belt	Improved - allows use of both EEG and respiration measurements, if desired
firmware			
function	collect data from EEG, SpO2, Position, Microphone, Nasal Cannula and pressure transducer, accelerometers, EEG sensor, Respiratory Effort Belt and store to SD card	collect data from EEG, SpO2, Position, Microphone, Nasal Cannula and pressure transducer, accelerometers, EEG sensor, Respiratory Effort Belt and store to SD card	Identical
language	assembly	structured C	Equivalent - 620 firmware partitioned into logical tasks for maintenance
operating system	no formal system; single super loop with interrupts for collecting data	real time FreeRTOS	Equivalent - 620 code organized into separate logical tasks for maintenance
file system	DOS compatible FAT16 - single file for all nights	FatFS - starts new study file at the beginning of each recording, able to store separate log and service files.	Equivalent - time periods more explicit during data analysis

Support for the substantial equivalence of the ARES^{TM} 620 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:

Name	Version
ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	3rd edition
60601-1-2:2007/(R)2012, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)	3rd edition
60601-1-6 Edition 3.0 2010-01, Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collaterial Standard: Usability	3rd edition
ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. • Cytotoxicity • Sensitization • Irritation	2009

Non-Clinical Testing:

Additional verification and validation testing confirmed:

- The ARES™ 620 hardware and firmware met the system requirements.
- All features of the Model 620 were compliance with the system level requirements.

Comparative testing between the Predicate Device ARES Model 610, K111194 as cleared on 07/07/2011 and the proposed ARES Model 610 demonstrates substantial equivalence. .

Specification	Discussion of Differences
SpO2	Identical
EEG	Identical
Airflow	Identical
Sound	Identical
Position	Identical
Respiration	Identical

CONCLUSION:

The conclusions drawn from the nonclinical and clinical tests demonstrate equivalent performance of the Apnea Risk Evaluation System (ARES™), Model 620 and the legally marketed device, Apnea Risk Evaluation System (ARES™), Model 610. The Apnea Risk Evaluation System (ARES™), Model 620 is substantially equivalent to the predicate device.