K140190

MAY 2 9 2014

510(k) Summary

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

DATE: May 29, 2014

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:

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

DEVICE:

TRADE NAME: Night Shift – Sleep Positioner

COMMON/USUAL NAME: Night Shift

CLASSIFICATION NAMES: 872.5570 Intraoral Devices for Snoring and Intraoral Devices for Snoring and Sleep Apnea

PRODUCT CODE: MYB

PREDICATE DEVICE(S):

K100160 ZZOMA Positional Sleeper

K112514 Apnea Risk Evaluation System (ARES), Model 610

DEVICE DESCRIPTION:

The Night Shift is worn around the neck to reduce the amount of time the user sleeps in the supine position as a treatment for positional obstructive sleep apnea. Night Shift combines hardware and firmware to detect when the user attempts to sleep in the supine position and can initiate vibro-tactile feedback with increasing intensity until the user shifts to a non-supine position. The initiation of positional feedback from the time the Night Shift is turned on is programmable to allow the user to fall asleep (if they must) on their back. Each night the Night Shift is worn, it monitors sleep position (% time supine), behavioral sleep efficiency, and snoring levels (% time snoring > 40 and 50 dB) as well as the frequency, duration and intensity of the feedback (when applied). These data can be optionally transferred via the USB port to the Night Shift Web Portal where the user can generate a report to assess how well the positional feedback is working. A "trial" protocol can include one night with no feedback to establish a baseline and two nights with feedback to assess compliance/efficacy. Utilization information is saved on the device that allows reports to be generated that compares daily use by month and monthly averages for one year. The portal also allows the device to be reformatted (to eliminate all previously recorded data) for a new user, adjust the feedback settings to a new user's personal preferences, and/or upgrade the firmware. For large healthcare organizations that limit internet access, desktop software is provided as an alternative to the portal.

INTENDED USE:

The Night Shift is indicated for prescription use for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index < 20, and to reduce or alleviate snoring. It records position, movement, and sound so that positional changes in sleep quality and snoring can be assessed.

TECHNOLOGY:

The Night Shift uses the same fundamental technology as a therapeutic massager (i.e., regulation number 890.5975) to deliver vibro-tactile feedback with haptic motors when the user attempts to sleep on their back. The Night Shift is functionally equivalent to the ZZOMA positional sleeper as both devices prevent users from sleeping on his or her back. The Night Shift provides information used to assess user benefit by recording position, movement, snoring and feedback frequency and duration using the actigraphy and acoustic microphone signals equivalent to Apnea Risk Evaluation System. The technologies used in the Night Shift are used in the same manner as the predicate products and do not raise new questions of safety and effectiveness.

Table 5.1 summarizes the similarities and differences of the Night Shift to the legally marketed predicate devices to which substantial equivalency is claimed. The Night Shift is equivalent to the ZZOMA Sleep Positioner (K100160) for treatment of positional OSA and equivalent to the

Apnea Risk Evaluation System (ARES), Model 610 (K112514) for recording position, movement, and sound so that positional changes in sleep quality and snoring can be assessed.

Table 5.1 Comparison of Night Shift to Predicate Device

Specification	Night Shift	ZZOMA Positional Sleeper (K100160)	ARES Model 610 (K112514)
Indications for Use	The Night Shift is indicated for prescription use for the treatment of patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index < 20, and to reduce or alleviate snoring. It records position, movement, and sound so that positional changes in sleep quality and snoring can be assessed.	The ZZOMA Positional Sleeper is indicated for use and intended for professional use for the treatment of mild to moderate obstructive sleep apnea (OSA) and to reduce or alleviate snoring.	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.
Patient Population	Adults	Adults	Adults
Anatomical Sites	Positions on the back of the neck	Positions on the back	Positions on the forehead
Therapeutic Methodology	Vibro-tactile feedback with increasing intensity when user is detected to be sleeping supine	Backpack style pillow that prevents user from sleeping supine.	Not applicable.
Environment of Use	Home during sleep every night	Home during sleep every night	Home during sleep for up to three nights

Specification	Night Shift	ZZOMA Positional Sleeper (K100160)	ARES Model 610 (K112514)
User Interface	User control, visual and vibro-tactile indicators	N/A	User control, visual and audio indicators
Accessories	Silicone enclosure strap	Velcro elastic belt	Elastic enclosure strap. EEG and ECG electrodes and nasal cannula
Signals Acquired	• 3-D actigraphy • Microphone	None	• 3-D actigraphy • Microphone • Nasal Pressure & cannula • Respiratory Effort • Forehead EEG • Red and infra-red (IR) optical signals
Acquisition modes	Records sleep data.	None	Records sleep data.
Cleaning	Enclosure is disinfected using alcohol wipes; the strap is cleaned with dish detergent	None	Cleaned and disinfected by rubbing with alcohol-based hand sanitizer and isopropyl alcohol.
Data transfer from SD card	Data transfer from flash storage via native USB on microcontroller	None	Data transfer from SD Card via Native USB
Software	Software provides device management, data analysis and report presentation on a web-portal	None	Software provides device management, data analysis and report presentation on a web-portal

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF NON-CLINICAL TESTS:

Support for the substantial equivalence of the Night Shift 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 voluntary standards as follows:

Standard Number	Standard Title
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)	Part 1: General requirements for basic safety and essential performance.
Comments	Complied with use and labeling with respect to environmental conditions of transport and storage, after removal from protective package and subsequent use, and indicated instructions for use. Maintained basic safety and essential performance in the presence of condensation and thermal shock. Met accessibility requirements of 60601-1 Part 1-11. Passed usability assessment of the design, identification, markings and accompanying documents met requirements for a lay operator with 8 years of education. Tested against excessive temperatures and other hazards. Confirmed a lay operator can perform cleaning and sterilization. Passed IEC 60529:1989 for IP22, and mechanical strength, shock, vibration, free fall tests. Confirmed design protects against strangulation or asphyxiation
IEC 60601-1-2: 2007	Medical Electrical Equipment Part 1-2: Collateral standard: Electromagnetic compatibility – requirements and tests.
Comments	Passed conducted emissions, radiated emissions, harmonics and Flicker, electrostatic discharge, radio frequency immunity, EFT immunity, power lines surge immunity, RF common mode immunity, power frequency magnetic field immunity test and voltage dips/short interruptions test.
ISO 10993-1: 2009	Biological evaluation of medical devices Part 1
Comments	Passed irritation, sensitization, and cytotoxicity 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.
Comments	Met standards for: Temperature and Humidity, Operating Environmental/Atmospheric Pressure, Operating Environment/ Temperature and Relative Humidity, Operating Environment/Shock, Operating Environment/Random Vibration, and Push Test.

Additional verification and validation testing confirmed:

- All features of the Night Shift were compliant with the system, software and firmware level requirements.
- Night Shift provides information useful in assessing user benefit equivalent to the predicate device.

SUMMARY OF CLINICAL TESTS:

A clinical study was conducted to evaluate safety and efficacy of the Night Shift. For this evaluation, patients who had completed a baseline PSG with a minimum of four hours of sleep time were to wear the Night Shift for two nights without feedback to confirm their willingness to continue with the study, followed by 28 nights of vibro-tactile position therapy. A follow-up PSG was conducted as soon as possible to the completion of the 28-nights of treatment.

With respect to effectiveness of Night Shift therapy, the following primary endpoint was evaluated: 65% of positional therapy (PT) compliant participants with baseline overall AHI > 10 will demonstrate a clinically important reduction in sleep apnea severity based on a minimum 50% reduction. The indication for use for Night Shift was further refined to include only those patients with a non-supine AHI <20. Results from 27 patients with pre-treatment positional obstructive sleep apnea with a non-supine AHI < 20 were included in the analysis. They are stratified by outcome and the post-treatment overall AHI in the table below. This analysis confirms that the primary endpoint was met and that Night Shift is efficacious in the treatment of patients with positional obstructive sleep apnea (POSA) with a non-supine AHI <20.

	Pre-treatment				95% Confidence Interval
	≥5 AHI <15	≥15 AHI < 30	AHI ≥ 30	Total	
Treatment outcome	n = 11	n = 10	n = 6	n =27	
AHI >50% decrease, % (n)	81.8 (9)	80.0 (8)	100.0 (6)	85.2 (23)	71.8 – 98.6
AHI >35% decrease, % (n)	9.1 (1)	0.0 (0)	0.0 (0)	3.7 (1)	-3.4 – 10.8
Non-responder, % (n)	9.1 (1)	20.0 (2)	0.0 (0)	11.1 (3)	-0.8 – 23.0

In addition to the primary endpoint discussed above, the study evaluated the following additional primary, secondary and exploratory endpoints. For these endpoints, the analysis includes an additional 3 subjects that were part of the full study but had a pre-study non-supine AHI >20 and were therefore outside of the indication evaluated for effectiveness.

Endpoint	Study Result	Conclusion
Primary Endpoints		
80% of participants will complete the study with no adverse events resulting in him/her voluntarily dropping from the Study (primary)	100% of the subjects who were provided an intention to treat and were compliant with the protocol successfully completed the study. No adverse events were reported.	The primary endpoint is met.
Secondary Endpoints		
Night Shift will accurately measure the supine position such that the computation of percent time supine by Night Shift is within+/- 5% of the percent time supine by video recordings plus chest sensor in 73% of subjects.	Night Shift was within 5% of chest/video supine time in 92% of the studies.	The secondary endpoint is met.
At least 80% of participants will be compliant i.e., use Night Shift for a minimum of 5.5 hours/night or the length of their time in bed, five nights/week (e.g., 20 of 28 nights).	100% of the participants wore the Night Shift for a minimum of 20 nights across the 28 nights of intended use.	The secondary endpoint is met.
At least 70% of participants will average less than 15% time supine across the four weeks of home use.	97% of the participants averaged less than 15% of time in bed in the supine position when therapy was delivery.	The secondary endpoint is met.
50% of PT compliant participants will show an improved Epworth Sleepiness Score (ESS) of $\geq$ 2.	50% of participants exhibited an improvement of 2 or more, and 50% showed no change. None of the ESS scores worsened by 2 or more.	The secondary endpoint is met.
The Functional Outcomes of Sleep (FOSQ) total will improve by $\geq$2 points in at least 50% of subjects.	57% exhibited an improvement of 2 or more, 23% showed no change, and 20% showed a worsening of 2 or more.	The secondary endpoint is met.
The mean sensitivity (sleep) and specificity (wake) for Night Shift will be 0.85 and 0.50, respectively.	The endpoint was met based on the sensitivity and specificity of 90% and 58% across 65 studies.	The secondary endpoint is met.

Endpoint	Study Result	Conclusion
73% of subjects will be within the range of the predicate when subtracting PSG Total Sleep Time (TST) from Night Shift TST (i.e., range 151 and -129 minutes, respectively).	99% of the studies had TST derived from Night Shift within the maximum error (based on two standard deviations of the TST error for the predicate device) vs. PSG TST.	The secondary endpoint is met.
73% of subjects will be within the range of the predicate when subtracting PSG Sleep Efficiency (SE) from Night Shift SE (i.e., range 19.1 and -17.2%, respectively).	92% of studies had SE values derived from Night Shift within the maximum error (based on two standard deviations of the SE error for the predicate device) vs. PSG SE. 80% of subjects had sleep onset values <15-minutes. 82% of subjects had wake after sleep onset (WASO) values <45 minutes	The secondary endpoint is met.
Exploratory Endpoints		
There are no consistent patterns of increased N1 and cortical arousals or decreased N3 and REM.	87% showed in decrease in N1, 80% a decrease in cortical arousals, 17% an increase in N3, and 33% an increase in REM sleep. Only 3% of subjects showed increase in N1, 7% an increase in cortical arousals, 13% a decrease in N3, and 17% a decrease in REM sleep.	The exploratory endpoint is met.
The percent time snoring > 50 dB can be used to identify patients with an AHI $\geq$ 10 with a sensitivity > 0.80 and a specificity > 0.65 so that these Night Shift users will recognize the need to be evaluated for undiagnosed obstructive sleep apnea.	When the percentage of time snoring above 50 dB exceeds 10% of sleep time, the sensitivity was 0.85 and the specificity exceeded 0.58.	The exploratory endpoint was not met.
Supplemental analysis	Statistically significant improvements in loud snoring was observed. Loud snoring decreased in 59% of subjects, and only increased in 10% of the cases.	

Endpoint	Study Result	Conclusion
Those successfully or unsuccessfully treated with Night Shift can be identified via combination of changes in the AHI, daytime drowsiness (ESS), depression (PHQ9), Insomnia (ISI), anxiety (GAD7) and quality of life (FOSQ).	Evaluating trends across these measures, 50% of subjects showed a substantial improvement as a result of Night Shift therapy and an additional 10% showed improvement, and 33% showed no change. None showed a worsening and two cases (7%) showed substantial overall worsening of subjective measures. There was no consistent patterns which can be used to identify those who would likely benefit from therapy, in part, because most subjects benefited either physiologically, symptomatically or both. There was some evidence to suggest that limited time in-home untreated in the supine position was associated with no change in subjective measures.	This exploratory endpoint was suggested by the FDA under the assumption that there would be treatment failures and it would be beneficial to a clinician to identify patterns which define treatment success/ failure. In this study, the numbers of failures were too few to characterize.

CONCLUSION:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 29, 2014

Advanced Brain Monitoring, Inc.
c/o Mr. Daniel J. Levendowski
President and Co-Founder
2237 Faraday Ave., Suite 100
Carlsbad, CA 92008

Re: K140190
Trade/Device Name: Night Shift
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: MYB, MNR
Dated: April 23, 2014
Received: April 24, 2014

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. 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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat 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 on last page.

510(k) Number *(if known)*
K140190

Device Name
Night Shift

Indications for Use *(Describe)*
The Night Shift is indicated for prescription use for the treatment of adult patients with positional obstructive sleep apnea with a non-supine apnea-hypopnea index < 20, and to reduce or alleviate snoring. It records position, movement, and sound so that positional changes in sleep quality and snoring can be assessed.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Malshet -S

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