December 19, 2017

Consolidated Research of Richmond, Inc.
Richard Kaplan, PhD
President
26250 Euclid Avenue, Suite 709
Cleveland, Ohio 44132

Re: K172986
Trade/Device Name: Zmachine Synergy
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, OMC, MNR
Dated: October 25, 2017
Received: October 26, 2017

Dear Dr. Kaplan:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172986

Device Name
Zmachine Synergy

Indications for Use *(Describe)*
The Zmachine Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep 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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Leaders in Advanced EEG Technologies

510(k) Summary

Zmachine® Synergy 510(k) Notification
Consolidated Research of Richmond, Inc.

Date Prepared	December 14, 2017
510(k) Owner	Consolidated Research of Richmond, Inc.
Contact Person	Richard F. Kaplan, Ph.D., President Phone: (216) 289-2331 Extension 1001 E-mail: kaplan@generalsleep.com
Address	26250 Euclid Avenue, Suite 709 Euclid, Ohio 44132 Phone: (216) 289-2331 Fax: (216) 393-0079
Trade Name	Zmachine® Synergy
Common Name	Sleep monitoring system
Classification Name	Electroencephalograph
Product Codes	OLV, OMC, and MNR
Indications for Use	The Zmachine Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.
Predicate Devices	Zmachine DT-100 (K101830) – primary ApneaLink Air (K143272)

Device Description

The Zmachine Synergy system is a portable, battery operated, medical device housed within an ABS enclosure. The system combines the single-channel EEG recording capability of the Zmachine DT-100 (K101830) with the respiratory signal recording capability of the Resmed ApneaLink Air (K143272). The Zmachine Synergy is thereby capable of recording EEG, respiratory airflow, respiratory effort, blood oxygen saturation, pulse rate, and body position during sleep.

A healthcare provider will supply a Zmachine Synergy device to a patient. Prior to going to bed, the patient is instructed to clean each mastoid and the back of their neck with a supplied alcohol swab. After allowing a few seconds for the alcohol to dry, the patient then applies the supplied peel-and-stick, disposable, EEG sensor pads onto each mastoid (recording electrodes) and one onto the back of the neck (ground). The EEG cable, with three individual lead wires, is snapped onto the conductive studs of the three EEG sensor pads and the free end of the EEG cable is inserted into the corresponding socket of the Zmachine Synergy device. Respiratory effort is sensed using a thoracic belt which serves double duty in also holding the device onto the patient. The patient is instructed to click the belt onto each of the two tabs of the Zmachine Synergy device, position the device just under the armpits, adjust the tension for a snug but comfortable fit, and snap the belt cables onto the conductive studs of the belt. Respiratory nasal airflow is sensed using a nasal cannula. The patient is instructed to place the cannula in their nostrils, drape over their ears, remove slack with the slider, and screw the free end of the cannula onto the luer fitting of the Zmachine Synergy device. Blood oxygen saturation and pulse are sensed using a finger probe pulse oximeter. The patient is instructed to insert a finger from either hand into finger probe and clip the oximeter module to the effort belt. Body position is sensed by an accelerometer located within the body of the Zmachine Synergy device and no additional patient instructions are requires for this signal. The patient presses the center button of the Zmachine Synergy for approximately one second to start the test before going to sleep, and holding for approximately three seconds to end the test in the morning. LED indicators are used to indicate the status of all sensors.

Data from the overnight recording is streamed to a non-removable microSD memory card located inside the Zmachine Synergy device. When patient returns the Zmachine Synergy device to the healthcare provider, the healthcare provider can access the recorded data by connecting the Zmachine Synergy device to their PC using a supplied USB cable. The USB cable is also used to re-charge the Zmachine Synergy device when connected to a USB wall charger or PC. A fully charged Zmachine Synergy device can be used for approximately 30 hours of recording and can finish re-charging within approximately five hours.

Technology Overview

Electroencephalograph (EEG)

Both the Zmachine Synergy and Zmachine DT-100 use the same EEG hardware (both technology and design) to acquire a single EEG channel.

Respiratory nasal airflow

Both the Zmachine Synergy and ApneaLink Air use the same pressure transducer to acquire the respiratory nasal airflow signals.

Blood oxygen saturation and pulse

Both the Zmachine Synergy and ApneaLink Air use the same pulse oximeter module to acquire the blood oxygen saturation and pulse signals. However, the Zmachine Synergy and ApneaLink Air operate the module using slightly different data output modes.

Respiratory effort

Both the Zmachine Synergy and ApneaLink Air use a thoracic effort belt to sense chest expansion and contraction during inhalation and exhalation (i.e. respiratory effort). However, the Zmachine Synergy records changes in belt stretch using respiratory inductance plethysmography (RIP), whereas the ApneaLink Air measures changes in belt stretch using an in-line air cell and pressure transducer.

Body position

Both the Zmachine Synergy and ApneaLink Air use solid-state accelerometers to acquire the body position signal.

Substantial Equivalence

The table, starting on the next page, summarizes the technological characteristics of the Zmachine Synergy in comparison to the predicate devices.

	Zmachine Synergy (New Device)	Zmachine DT-100 (Primary Predicate)	ApneaLink Air (Predicate)
Manufacturer	Consolidated Research of Richmond, Inc.	Consolidated Research of Richmond, Inc.	ResMed Germany Inc.
510(k) number	K172986	K101830	K143272
Classification regulation	21 CFR 868.2375	21 CFR 882.1400	21 CFR 868.2375
Product code	MNR	OLV and OMC	MNR
Indications for use	The Zmachine Synergy is an EEG and respiratory signal recorder. The device is intended for use by adult patients in the home or clinical environment, under the direction of a qualified healthcare practitioner, to aid in the diagnosis of sleep disorders.	The CRI Zmachine is a single-channel, EEG acquisition and analysis system, designed for use in the home or clinical environments. This device is intended to be used by qualified healthcare practitioners to monitor the wake and sleep states of adult patients and as an adjunct to their diagnosis of sleep disorders.	The ApneaLink™ Air device is indicated for use by Health Care Professionals (HCP), where it may aid in the diagnosis of sleep disordered breathing for adult patients. ApneaLink Air records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position during sleep. The device uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing or for further clinical investigation. The device is intended for home and hospital use under the direction of a HCP.
Intended environment(s)	Home or clinical environment	Home or clinical environment	Home or hospital environment
Patient population	Adults	Adults	Adults
Acquired Channels	Airflow Pulse Oximeter Respiratory Effort Body Position EEG	n/a n/a n/a n/a EEG	Airflow Pulse Oximeter Respiratory Effort Body Position n/a

	Zmachine Synergy (New Device)	Zmachine DT-100 (Primary Predicate)	ApneaLink Air (Predicate)
Sensor technology	Airflow: Honeywell solid state pressure transducer (±6 mbar range) Pulse Oximetry: Nonin XPOD LP module Respiratory Effort: Thoracic effort belt based on respiratory inductance plethysmography (RIP) Body position: Solid state accelerometer Zmachine DT-100 EEG technology	n/a n/a n/a n/a Zmachine DT-100 EEG technology	Airflow: Honeywell solid state pressure transducer (±6 mbar range) Pulse Oximetry: Nonin XPOD LP module Respiratory Effort: Thoracic effort belt based on pneumatics Body position: Solid state accelerometer n/a
Display type	LED indicators. A full-color LED indicator is located beside each connector (airflow, effort, oximeter, and EEG) to indicate correct or incorrect hookup/operation. Another full-color LED is located under the main power button to indicate system status.	LCD display. A full color, 320x240 pixel, LCD display with an LED backlight is used to present all system information.	LED indicators. 3 LED indicators are located beside each connector (airflow, effort and oximeter) to indicate correct or incorrect function. Another LED is used to indicate the "test complete" status based on recording time.
Power source	Internally powered using li-ion rechargeable battery	Internally powered using li-ion rechargeable battery	Internally powered using 2xLR03 (AAA) primary or rechargeable
Internal memory / data storage	Fixed microSD card	Removable microSD card	Fixed microSD card
Communication interface	USB	USB card reader	USB
Access to recorded data	Recorded data is stored in the device. When the device is connected to PC via USB cable the device provides access to its internal memory.	Recorded data is stored in the device. The microSD card is removed and connected to PC via USB card reader to access internal memory.	Recorded data is stored in the device. When the device is connected to PC via USB cable the device provides access to its internal memory.
Recorded data format	Each channel of recorded data is stored in an individual file of the GSC2 data format.	Each channel of recorded data is stored in an individual file of the binary data format.	All channels of recorded data are stored in EDF+ data format.

	Zmachine Synergy (New Device)	Zmachine DT-100 (Primary Predicate)	ApneaLink Air (Predicate)
Device dimensions LxWxH (mm)	120 x 61 x 24	116 x 68 x 21	61 x 102 x 31

The table above shows that there are no significant differences between Zmachine Synergy and the predicate devices that adversely affect product safety and effectiveness.

Testing Summary

Design and verification activities have been performed on the Zmachine Synergy as a result of the risk analysis and product requirements. External tests have been completed for electrical safety (IEC 60601-1:2012), EMC (IEC 60601-1-2:2007), and mechanical and environmental requirements (IEC 60601-1-11:2010). In addition, side-by-side bench comparison testing, summarized in the table below, was performed in which a Zmachine Synergy was compared against a Zmachine DT-100 (K10183) and an ApneaLink Air (K143272).

Test	Test Method Summary	Results
EEG	EEG is sensed by the Zmachine Synergy and the Zmachine DT-100 using the identical EEG amplifier and analog-to-digital conversion hardware. As such, the acquired signals from both systems are expected to be substantially equivalent. To test, a multi-channel EEG analog playback system was connected to the EEG input of a Zmachine Synergy and Zmachine DT-100 device. Broad spectrum shaped white noise and a zero-level output signal were generated and acquired by each system.	The acquired data from each system was analyzed in order to determine the EEG amplifier gain, highpass filter cutoff frequency, lowpass filter cutoff frequency, DC offset, and noise floor levels at various points across the frequency spectrum. The EEG amplifier characteristics were found to be in high agreement with both the design limits and each other for all points of comparison. As such, the EEG recording capabilities were found to be substantially equivalent.
Respiratory Airflow	Respiratory Airflow is sensed by the Zmachine Synergy and the ApneaLink Air using the identical pressure transducer hardware. As such, the acquired signals from both systems are expected to be substantially equivalent. To test, a variable pressure air pump was connected to the Respiratory Airflow input of a Zmachine Synergy and ApneaLink Air device. A stepped variable air pressure signal was generated, split, and delivered to both systems.	The acquired data from each system was analyzed in order to compare the Respiratory Airflow readings. Because the two systems record airflow using different units of measure, Pearson's correlation coefficient was used to compare the recorded signals. The correlation coefficient between the Zmachine Synergy and ApneaLink Air reveals a strong linear relationship in the Respiratory Airflow signal between the two systems. As such, the Respiratory Airflow characteristics were found to be substantially equivalent.

Test	Test Method Summary	Results
Respiratory Effort	Respiratory Effort is sensed by the Zmachine Synergy and the ApneaLink Air using a thoracic effort belt to qualitatively record chest expansion and contraction during inhalation and exhalation (i.e. respiratory effort). The Zmachine Synergy senses this expansion and contraction by monitoring changes in belt inductance (RIP), whereas the ApneaLink Air monitors changes in air pressure within an in-line air cell. Although the two systems utilize different techniques for measuring respiratory effort, they are both responsive to belt expansion and contraction and are expected to produce substantially equivalent output. To test, the Zmachine Synergy and ApneaLink Air were subjected to simulated inhalation and exhalation by controlled belt stretching and partial relaxing against a linear scale.	The acquired data from each system was analyzed in order to compare the Respiratory Effort readings. Because the two systems record airflow using different units of measure, Pearson's correlation coefficient was used to compare the recorded signals. The correlation coefficient between the Zmachine Synergy and ApneaLink Air reveals a strong linear relationship in the Respiratory Effort signal between the two systems. As such, the Respiratory Effort characteristics were found to be substantially equivalent.
Pulse Oximetry	Pulse Oximetry is sensed by the Zmachine Synergy and the ApneaLink Air using the identical pulse oximeter hardware and similar data output modes. As such, the acquired signals from both systems are expected to be substantially equivalent. To test, a patient simulator was connected in place of the finger probe of a Zmachine Synergy and ApneaLink Air device, one-at-a-time, under the same conditions.	The acquired data from each system was analyzed in order to compare the Pulse Oximeter readings. The heart rate and oxygen saturation readings were found to be in high agreement with the specified calibrator output levels and having a low mean squared error when comparing the two systems together. As such, the Pulse Oximeter recording capabilities were found to be substantially equivalent.

Test	Test Method Summary	Results
Body Position	Body Position is sensed by the Zmachine Synergy and the ApneaLink Air using an accelerometer module. Because each system is measuring the angle of the system with regard to gravity, and both systems are worn by the patient in the same configuration, the acquired signals from both systems are expected to be substantially equivalent if it can be demonstrated that the Zmachine Synergy reports angle with regard to gravity appropriately against an angular reference. To test, the Zmachine Synergy is rotated through 360 degrees against an angular reference.	The acquired data from the Zmachine Synergy was analyzed in order to compare the Body Position angular readings against the angular reference. The angular readings and angular reference positions were found to be in very high agreement throughout 360 degrees of rotation. As such, the Body Position recording capabilities were found to be substantially equivalent.

All tests confirmed that the Zmachine Synergy device meets the predetermined acceptance criteria for both the external tests and side-by-side comparisons. General Sleep has determined that the Zmachine Synergy is Substantially Equivalent to the predicate devices.

Conclusion

Based on the results of the performance testing for the Zmachine Synergy and the substantial equivalence comparison with the predicate devices, no new concerns about safety and effectiveness were raised. We believe that the presented information is sufficient to determine that the Zmachine Synergy is substantially equivalent to the predicate Zmachine DT-100, K101830, and ApneaLink Air, K143272, devices.