DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 5, 2017

Zephyr Sleep Technologies
Sabina Bruehlmann
Director, Technology
610A 70 Ave SE
Calgary, Alberta T2H-2J6
Canada

Re: K163665
Trade/Device Name: Matrx Plus
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: April 5, 2017
Received: April 6, 2017

Dear Sabina Bruehlmann:

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,

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)*
K163665

Device Name
MATRx plus

Indications for Use *(Describe)*
The device is indicated for use by the Health Care Professional (HCP), where it may aid in the diagnosis and assessment of sleep disordered breathing for adult patients.

MATRx plus 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. The device is intended for home and hospital use under the direction of a HCP.

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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ZEPHYR Sleep Technologies
Unit A, 610 - 70th Avenue S.E. Calgary, AB, T2H 2J6, Canada

510k Summary – MATRx plus

Manufacturer Name:	Zephyr Sleep Technologies Inc.
Contact Name:	Sabina Bruehlmann, PhD
Postal Address:	610A, 70 Ave SE Calgary, Alberta T2H-2J6 Canada
Phone Number:	587-332-0285
Title:	Director, Technology
Date:	May 2, 2017
Device Proprietary Name:	MATRx plus
Device Common or Usual Name:	Ventilatory Effort Recorder
Classification Name:	Breathing Frequency Monitor
Classification Code:	Class II
Product Codes:	MNR (Ventilatory Effort Recorder)
Regulation Number:	MNR 21 CFR 868.2375

Predicate Devices:
The MATRx plus is a ventilatory effort recorder. Substantial equivalence is claimed to the Apnealink Air (K143272).

The Snore SAT Recorder (K002159), Nox T3 (K082113), and Masimo SET Rad-8 pulse oximeter (K053269) and Compumedics Somte System (K021176) are used as reference devices.

Device Description:
The MATRx plus is a new ventilatory effort recorder device. The MATRx plus recorder is a 5-channel battery-powered respiratory pressure sensor and oximetry system. MATRx plus provides recordings of respiratory pressure, respiratory effort, pulse rate, oxygen saturation, snoring and body position during sleep. The physician prescribed device is worn on the patient's abdomen attached to a reusable effort belt and all relevant respiratory information during sleep is collected via nasal cannula, pulse oximetry

module and respiratory effort sensor. The disposable plastic nasal cannula is connected to the MATRx plus recorder and fixed at the patient's nose. The cannula is dual lumen and functions to individually sample the pressure from each naris. The oximetry sensor is fixed at the patient's finger and connects directly to the device. The Recorder receives input from the sensors and wirelessly transmits the data to a bedside Tablet during the study.

The Tablet is set up through a connection to the web portal by the Health Care Professional (HCP) prior to deploying the device to the patient for use in the home. The Tablet runs the MATRx plus application according to the selected study type, records and stores the data. The MATRx plus application on the Tablet is also used to guide the user through the set up and conduct of the study through a stepwise user interface. At the end of a recording the Tablet advises the patient if sufficient data for analysis were recorded during the night.

After recording, the MATRx plus must be returned to the HCP. The data are automatically uploaded to the secure Portal where they can be accessed and downloaded to the Data Viewer. The Data Viewer can generate a report with the recorded and analyzed data (respiratory pressure, respiratory effort, pulse rate, oxygen saturation) to aid in diagnosis.

Subject Device Components	**Material**	**Use type**
Nasal Cannula	Polyvinyl Chloride (PVC)	Single patient
Oximeter Sensor	3rd party accessory (K051212, K090662, K101896) provided in finished form	Multiple patient
Recorder	Housing: ABS Soft grip edge: Thermoplastic Elastomer Key pad: Autotex (polyester film)	Multiple patient
Recorder Body Strap	Nylon	Multiple patient
Effort Belt	3rd party accessory (K042253) provided in finished form	Multiple patient

Indications for Use:

The device is indicated for use by the Health Care Professional (HCP), where it may aid in the diagnosis and assessment of sleep disordered breathing for adult patients.

MATRx plus 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. The device is intended for home and hospital use under the direction of a HCP.

Contraindications:

- This device is not to be used as an apnea monitor or in a life supporting or life sustaining situation.
- This device is not to be used by persons under the age of 18.
- The MATRx plus is MR Unsafe.

Patient Population:

The device is intended to be used on adult patients, upon referral from their healthcare provider.

Technological Characteristics:

The MATRx plus is substantially equivalent to the ApneaLink Air [510(k) # K143272, Summary Exhibit 12-01], manufactured by Resmed Germany Inc. The following tables provide a detailed comparison of the MATRx plus technological characteristics in comparison of the intended use for the predicate.

Trade Name	APNEALINK AIR	MATRx plus
510k Number	K143272	K163665
Manufacturer	Resmed Germany Inc.	Zephyr Sleep Technologies, Inc.
Intended Use	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.	The MATRx plus™ is indicated for use by the Health Care Professional (HCP), where it may aid in the diagnosis and assessment of sleep disordered breathing for adult patients. MATRx plus 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. The device is intended for home and hospital use under the direction of a HCP.

Trade Name	APNEALINK AIR	MATRx plus
510k Number	K143272	K163665
Manufacturer	Resmed Germany Inc.	Zephyr Sleep Technologies, Inc.
Environment of Use	Deployed from Clinics, Hospitals Used unsupervised in the Home or Clinic Analyzed from physician's office	Deployed from Clinics, Hospitals Used unsupervised in the Home or Clinic Analyzed from physician's office
Outcome	Data to aid in the diagnosis of sleep disordered breathing	Data to aid in the diagnosis of sleep disordered breathing
Contra-indications	The ApneaLink Air system must not be used in the vicinity of an MRI device.	The MATRx plus system must not be used in the vicinity of an MRI device. This device is not to be used as an apnea monitor or in a life supporting or life sustaining situation.

Proprietary Name	**APNEALINK AIR**	**MATRx plus**	**Comments Predicate vs MATRx plus**
510k Number	**K143272**	**K163665**	
Manufacturer	**Resmed Germany Inc.**	**Zephyr Sleep Technologies, Inc.**	
Sensors			
Finger Pulse Oximeter	Third party oximeter sensor (Nonin Xpod 3012 LP) attaches to patient worn recorder, measure degree of oxygen saturation of the blood and pulse rate. Sampling frequency of 1 Hz	Third party oximeter sensor (Masimo SET 2040) attaches to patient worn recorder, measure degree of oxygen saturation of the blood and pulse rate. Sampling frequency of 1 Hz	Substantially Equivalent
Airflow	Single channel nasal cannula attaches to patient worn recorder; records pressure and translates to airflow and snoring. Sampling frequency of 100 Hz	Dual channel nasal cannula attaches to patient worn recorder; records pressure and translates to airflow and snoring. Sampling frequency of 350 Hz.	Substantially Equivalent – Sampling airflow separately from each naris can reduce artefact with temporary blockages.
Respiratory Effort	Respiratory effort channel to measure the respiratory effort using a pneumatic principle. Sampling frequency of 10 Hz.	Respiratory effort channel to measure the respiratory effort using an inductance principle. Third-party belt (Sleep Sense, K042253) Sampling frequency of 25 Hz.	Substantially Equivalent – Both are commonly used and are sufficiently sensitive to detect breathing effort
Position	Channel to determine body position of the patient during sleep by 3D axis accelerometer	Channel to determine body position of the patient during sleep by 3D axis accelerometer	Substantially Equivalent –
Snoring	Nasal airflow fluctuation envelope signal (between 10 and 60 Hz). User adjustable threshold.	Nasal airflow fluctuation envelope signal (between 10 and 70 Hz). Set threshold.	Substantially Equivalent –
Other channels	none	none	Equivalent
Method of connection to the patient	Plastic tubing and cannula for pressure sensing; belts for respiratory effort; probes or Flexi Wrap for oximetry; touch proof electrode cables; belts for attaching of device and clip straps to secure position of device. The device is worn on the patient's chest.		Equivalent

Proprietary Name	**APNEALINK AIR**	**MATRx plus**	**Comments Predicate vs MATRx plus**
510k Number	**K143272**	**K163665**	
Manufacturer	**Resmed Germany Inc.**	**Zephyr Sleep Technologies, Inc.**	
Device Design			
Sensor Connection	Sensors (airflow, oximeter, effort belt) are attached to a body worn recorder unit.		Equivalent
Recorder Dimensions	Recorder: 2.4” x 4” x 1.2” Oximeter: 2.1” x 0.8” x 0.6”	Recorder: 2.48” x 3.11” x 0.83” Oximeter: 1.9”x 0.6”x 1.3”	Substantially Equivalent Same as reference device (K021176) which measures 2.5”x4.5”x1.2”
Recorder Weight	66 g	230 g	Substantially Equivalent Same as reference device (K021176) which is body worn and weighs 234g
Data collection	All sensors connect direct to recorder. Study data is stored on the Recorder until study conclusion and then uploaded via USB cable upon return of the unit.	All sensors connect direct to recorder. Study data is wirelessly transferred (Bluetooth) from recorder to tablet and stored on the tablet until study conclusion. Data is wirelessly collected via device to web portal at the end of the study.	Substantially Equivalent – If desired, the MATRx plus user can have reviewed the data prior to the return of the device and contact the patient if the study was not successfully completed. Bluetooth connectivity substantially equivalent to Nox T3 (K082113).
Processor	The microprocessor system (ARM Cortex M3 based LPC1853) processes the recorder patient’s data (1MB)	Recorder microprocessor system (ARM Cortex M4 based, STM32 F4, 168 MHz) processes the patient’s data (1MB). Tablet minimum requirements: 1.33 GHz processor, 1 GB RAM.	Substantially Equivalent – The MATRx plus includes a Tablet to store the data and guide user interactions.
Indicators	Via LED: Test Complete Respiratory Flow	Via Tablet User interface: Test Started Test Paused	Substantially Equivalent –

Proprietary Name	**APNEALINK AIR**	**MATRx plus**	**Comments Predicate vs MATRx plus**
510k Number	**K143272**	**K163665**	
Manufacturer	**Resmed Germany Inc.**	**Zephyr Sleep Technologies, Inc.**	
	Oximetry Connection Effort Sensor Connection	Test Complete Respiratory Flow Oximetry Connection Effort Sensor Connection Battery Charge	Additional feedback provided to the MATRx plus user to help facilitate the test.
Recording Time	4 x 12 hours	6 x 8 hours	The total number of study hours in the MATRx plus is set by the software. Internal memory is > 100hours.
Internal memory	48 hours	48 hours	
Battery Cover	User accessible	Tamper-proof and locked	MATRx plus battery is recharged and is not replaceable by the user.
Study Set up and Management			
Patient Set up	Set up on device software and transferred to Device via USB	Set up on device software and transferred to Device via internet	Substantially Equivalent – Removal of USB port to increase cybersecurity features of the device.
Data Storage and Access	Data is stored and accessible via local database. Copies are downloaded locally for analysis.	Data is stored and accessible via database. Database is located on manufacturer's secure internet accessible server. Copies are downloaded locally for analysis.	Substantially Equivalent –
Design - Data Viewer (PC Application)			
Data Display	Real time waveforms displayed for all channels; Autoscored oxygen desaturation events are temporally displayed in relation to the airflow, oxygen, pulse rate and other signals. Summary data is calculated.		Equivalent
Data Reporting	Data related to patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position can be analyzed/displayed by Software and a report can be generated automatically.		Equivalent –
Proprietary Name	**APNEALINK AIR**	**MATRx plus**	**Comments Predicate vs MATRx plus**
510k Number	**K143272**	**K163665**	
Manufacturer	**Resmed Germany Inc.**	**Zephyr Sleep Technologies, Inc.**	

Data Analysis	The following indices are generated from the ApneaLink Software: AHI, RI, Apnea Index (unclassified, central, mixed, obstructive), Hypopnea Index, Number of flow limited breaths without snoring, Number of flow limited breaths with snoring, Cheyne-Stokes Breathing, ODI, Average saturation, Minimum saturation, Maximum saturation, Basal saturation, Minimum Pulse Rate, Maximum Pulse Rate, Average Pulse Rate	The following indices are generated from the MATRx plus Software: ODI, Average Saturation, minimum saturation, maximum saturation, min pulse rate, max pulse rate, average pulse rate.	Substantially Equivalent – The MATRx plus does not calculate or report: AHI, RI, Apnea Index (unclassified, central, mixed, obstructive), Hypopnea Index, Number of flow limited breaths without snoring, Number of flow limited breaths with snoring, Cheyne-Stokes Breathing. The raw data necessary for manual calculation of these parameters and to review ODI, saturation, and pulse rate are available for display.
Components in Patient contact	Recorder and Sensors (Nasal cannula, finger oximeter, effort belt)	Recorder and Sensors (Nasal cannula, finger oximeter, effort belt)	Substantially Equivalent –
Biocompatibility	Cleared under K131932	All body contacting components previously cleared	Substantially Equivalent –
Reprocessing	Patient contacting and indirectly contacting components are reprocessed	Patient contacting and indirectly contacting components are reprocessed	Substantially Equivalent –
Safety Testing	Tested to IEC 60601-1-11: 2010; Tested to IEC 60601-1-2:2007; Tested to IEC 60601-1:2005		Equivalent
Patient isolation	Device has no galvanic connections to mains as it is a battery-operated device. Not possible to connect auxiliary devices to the device		Equivalent -
Battery Powered	Internally powered: 2 x batteries: LR03 / Micro / AAA / 1.5V / at least 1.0 Ah or 2 x NiMh accumulators: HR03 / Micro / AAA / 1.2 V / at least 1.0 Ah	Internally powered: single cell rechargeable Li-Ion battery (3.7V). The battery is not replaceable by the user. The battery is charged by a 5V - 2A medical grade (double insulated) wall power supply connected with a standard barrel power jack.	Substantially Equivalent – The battery was safety tested for compliance to IEC 62133:2012.

ZEPHYR Sleep Technologies
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Bench Testing Summary:
Design and system verification testing included, among others, mechanical and environmental testing according to IEC 60601-1-11:2010, electrical safety testing according to IEC 60601-1:2005+1 and EMC testing according to IEC 60601-1-2:2007 has been performed. Reprocessing validation testing was completed. A comparison of all performance characteristics for the oximeter and other sensor inputs was completed using bench testing to substantiate equivalence. Autoscoring algorithm for ODI was compared with the Snore SAT monitor output (K002159) on data from 179 patients. Software on the device was verified and validated according to the functionality in conformity to IEC 62304:2006 for software life cycle processes. Test results confirm that the device is in accordance with its specifications.

Biocompatibility:
All body contacting components have been cleared in previous 510K devices.

Patient contacting Components	Contact Type	Contact Duration	510K Clearance
Nasal Cannula	Externally Communicating – Tissue/Bone/Dentin	≤24 hr, cumulative exposure	K151506
Oximeter sensor	Skin contact	≤24 hr, cumulative exposure	K051212 K090662 K101896

Conclusion:
Based on the results of the performance testing for MATRx plus and the substantial equivalence comparison with the predicate devices, MATRx plus is substantially equivalent to the predicate device, the Apnealink Air (K143272).