November 21, 2018

Zephyr Sleep Technologies
Sabina Bruehlmann
Director, Technology
#102, 701 64th Ave SE
Calgary, Alberta, Canada
T2H-2C3

Re: K181996
Trade/Device Name: MATRx Plus
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: July 18, 2018
Received: July 26, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Amy K. Levelle -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181996

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 an 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
#102, 701 - 64th Avenue SE, Calgary, AB, T2H 2C3, Canada

Section 5 – 510k Summary – MATRx plus

Date:	July 18, 2018
Manufacturer Name:	Zephyr Sleep Technologies, Inc.
Contact Name:	Sabina Bruehlmann, PhD
Title:	Director, Technology
Postal Address:	#102, 701 64th Ave SE Calgary, Alberta, Canada T2H-2C3
Phone Number:	587-332-0285
Establishment Registration Number:	3008960597
Device Proprietary Name:	MATRx plus
Classification Name:	CFR 868.2375 Ventilatory Effort Recorder
Classification Code:	Class II
Product Code:	MNR
Predicate Device:	K163665 MATRx plus
Reference Device:	K122516 Embletta MPR Sleep Data Recording System

Device Description:

The MATRx plus device is a ventilatory effort recorder. 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 oximeter, and respiratory effort sensor. The disposable plastic nasal cannula is connected to the MATRx plus recorder and positioned 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. The Tablet 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.

Intended Use:
The device is indicated for use by the 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 an HCP.

Technology:
The MATRx plus subject device is an update to the predicate MATRx plus (K163665) and includes the following changes:

- Expansion of the oxygen desaturation index to include 3% desaturation
- Addition of an apnea-hypopnea index for both 3 and 4% desaturation
- Addition of option to toggle between a moving average baseline (previously cleared) and a preceding peak baseline (new)
- Modifications to the event scoring algorithms

Comparison to Predicate Device:
The MATRx plus subject device is substantially equivalent to the MATRx plus device [K163665 Summary, Exhibit 12-01], manufactured by Zephyr Sleep Technologies, Inc. The following tables provide a detailed comparison of the MATRx plus technological characteristics in comparison of the intended use for the predicate.

	MATRx plus (K163665)	Proposed MATRx plus (subject device)	Discussion of Differences
Classification	MNR, Ventilatory Effort Recorder	MNR, Ventilatory Effort Recorder	Identical
Indications for Use	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 an 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 an HCP.	Identical
Patient Population	Adults	Adults	Identical
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.	Identical
Outcome	1) Data to assist in the diagnosis of sleep disordered breathing	1) Data to assist in the diagnosis of sleep disordered breathing	Identical
Contraindications	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.	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.	Identical

	MATRx plus (K163665)	Changes from the predicate (K163665; MATRx plus)	Discussion of Differences
Sensors			
Pulse Oximeter	Third party oximeter sensor (Masimo SET 2040) attaches to patient worn recorder, measures 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, measures degree of oxygen saturation of the blood and pulse rate. Sampling frequency of 1 Hz.	Identical
Airflow	Dual channel nasal cannula attaches to patient worn recorder; records pressure and translates to airflow and snoring. Sampling frequency of 350 Hz.	Dual channel nasal cannula attaches to patient worn recorder; records pressure and translates to airflow and snoring. Sampling frequency of 350 Hz.	Identical
Respiratory Effort	Respiratory effort channel to measure the respiratory effort using an inductance principle. Third-party belt (Sleep Sense, K042253). Sampling frequency of 25 Hz.	Respiratory effort channel to measure the respiratory effort using an inductance principle. Third-party belt (Sleep Sense, K042253). Sampling frequency of 25 Hz.	Identical
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.	Identical
Snoring	Nasal airflow fluctuation envelope signal (between 10 and 70 Hz). Set threshold.	Nasal airflow fluctuation envelope signal (between 10 and 70 Hz). Set threshold.	Identical
Other channels	None	None	Identical
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.	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.	Identical
Device Design			

	MATRx plus (K163665)	Changes from the predicate (K163665; MATRx plus)	Discussion of Differences
Sensor Connection	Sensors (airflow, oximeter, effort belt) are attached to a body worn recorder unit.	Sensors (airflow, oximeter, effort belt) are attached to a body worn recorder unit.	Identical
Recorder Dimensions	Recorder: 2.48" x 3.11" x 0.83" Oximeter: 1.9"x 0.6"x 1.3"	Recorder: 2.48" x 3.11" x 0.83" Oximeter: 1.9"x 0.6"x 1.3"	Identical
Recorder Weight	230 g	230 g	Identical
Data collection	All sensors connect direct to recorder. Study data are wirelessly transferred (Bluetooth) from recorder to tablet and stored on the tablet until study conclusion. Data are wirelessly collected via device to web portal at the end of the study.	All sensors connect direct to recorder. Study data are wirelessly transferred (Bluetooth) from recorder to tablet and stored on the tablet until study conclusion. Data are wirelessly collected via device to web portal at the end of the study.	Identical
Processor	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. The MATRx plus includes a Tablet to store the data and guide user interactions.	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. The MATRx plus includes a Tablet to store the data and guide user interactions.	Identical
Indicators	Via Tablet User interface: Test Started Test Paused	Via Tablet User interface: Test Started Test Paused	Identical
Oximetry Connection Effort Sensor Connection	Additional feedback provided to the MATRx plus user to help facilitate the test.	Additional feedback provided to the MATRx plus user to help facilitate the test.	Identical
Recording Time	6 x 8 hours. The total number of study hours in the MATRx plus is set by the software. Internal memory is > 100 hours.	6 x 8 hours. The total number of study hours in the MATRx plus is set by the software. Internal memory is > 100 hours.	Identical

	MATRx plus (K163665)	Changes from the predicate (K163665; MATRx plus)	Discussion of Differences
Internal memory	48 hours	48 hours	Identical
Battery Cover	Tamper-proof and locked. MATRx plus battery is recharged and is not replaceable by the user.	Tamper-proof and locked. MATRx plus battery is recharged and is not replaceable by the user.	Identical
Study Set up and Management			
Patient Set up	Set up on device software and transferred to Device via internet.	Set up on device software and transferred to Device via internet.	Identical
Data Storage and Access	Data are stored and accessible via database. Database is located on manufacturer's secure internet accessible server. Copies are downloaded locally for analysis.	Data are stored and accessible via database. Database is located on manufacturer's secure internet accessible server. Copies are downloaded locally for analysis.	Identical
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.	Real time waveforms displayed for all channels; Autoscored 4% or 3% oxygen desaturation and 4% or 3% apnea-hypopnea events are temporally displayed in relation to the airflow, oxygen, pulse rate and other signals. Summary data are calculated.	Addition of 3% oxygen desaturation index, 4% and 3% apnea-hypopnea index. Option for HCP to select moving average baseline (used in predicate) or preceding peak baseline.
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.	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.	Addition of ODI 3% and AHI parameters automatically generated on report.
Data Analysis	The following indices are generated from the MATRx plus software: ODI, average saturation,	The following indices are generated from the MATRx plus software: ODI (4% and 3%), AHI	Addition of calculation of: ODI 3%, AHI (3% and 4%),

	MATRx plus (K163665)	Changes from the predicate (K163665; MATRx plus)	Discussion of Differences
	minimum saturation, maximum saturation, min pulse rate, max pulse rate, average pulse rate.	(4% and 3%), AI (4% and 3%), average saturation, minimum saturation, maximum saturation, minimum pulse rate, maximum pulse rate, average pulse rate.	AI (3% and 4%).
Components in Patient contact	Recorder and Sensors (Nasal cannula, finger oximeter, effort belt).	Recorder and Sensors (Nasal cannula, finger oximeter, effort belt).	Identical
Biocompatibility	All body contacting components previously cleared.	All body contacting components previously cleared.	Identical
Reprocessing	Patient contacting and indirectly contacting components are reprocessed.	Patient contacting and indirectly contacting components are reprocessed.	Identical
Safety Testing	Tested to IEC 60601-1-11: 2010; Tested to IEC 60601-1-2:2007; Tested to IEC 60601-1:2005.	Tested to the new IEC 60601-1-2:2014 standard.	Testing updated to new standard (60601-1-2:2014)
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.	Device has no galvanic connections to mains as it is a battery-operated device. Not possible to connect auxiliary devices to the device.	Identical
Battery Powered	Internally powered: single cell rechargeable Li-Ion battery (3.7 V). 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. The battery was safety tested for compliance to IEC 62133:2012.	Internally powered: single cell rechargeable Li-Ion battery (3.7 V). 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. The battery was safety tested for compliance to IEC 62133:2012.	Identical

Testing Summary:
Non-clinical:

Mechanical and environmental verification testing were conducted according to IEC 60601-1-11:2010, electrical safety testing according to IEC 60601-1:2005+1, and EMC testing according to IEC 60601-1-2:2014 for the predicate device. As no changes have been made to the subject device that would affect such testing, this testing was not repeated. Similarly, reprocessing validation was not repeated for the subject device as no relevant changes have been made to the subject device that could affect reprocessing.

All features that were changed from the predicate devices are covered by additional verification testing to ensure the intended performance and was found to produce adequate results. Performance bench testing was performed to validate the addition of the ODI3% autoscoring method, the preceding peak baseline, event rounding, and the improvements to reduce erroneous scoring.

Clinical:
Clinical validation testing was performed with 27 individuals with confirmed or suspected sleep apnea in accordance with the requirements outlined in 21 CFR 812.28 to demonstrate that the autoscoring algorithm for the detection of apneas and hypopneas was accurate. This was performed by comparing the output of the MATRx plus autoscoring to that of the gold standard, polysomnography. The results of this testing demonstrate that the MATRx plus subject's apnea and hyponea detection algorithms have comparable sensitivity and accuracy with previously FDA cleared ventilatory effort recorder devices such as the Embletta MPR Sleep Data Recording System (K122516).

Conclusion:
The conclusions drawn from the non-clinical and clinical tests demonstrate that the device is as safe and effective and performs as well as or better than the legally marketed MATRx plus predicate device cleared under K163665.