August 24, 2020

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

Re: K200695
Trade/Device Name: MATRx plus
Regulation Number: 21 CFR 872.5571
Regulation Name: Auto Titration Device For Oral Appliances
Regulatory Class: Class II
Product Code: QCJ, MNR
Dated: July 21, 2020
Received: July 31, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K200695

Device Name
MATRx plus

Indications for Use *(Describe)*
The MATRx plus is indicated for use by a lay person in a home and hospital use under the direction of a Health Care Professional (HCP).

MATRx plus records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position during sleep.

MATRx plus uses these recordings to produce a report for the HCP that may aid in the diagnosis and assessment of sleep disordered breathing for adult patients.

The MATRx plus device may also be used with an automated mandibular positioner that uses feedback control to record changes in the patient's respiratory status related to repositioning of the mandible during an overnight study.

MATRx plus uses these recordings to produce a report for the HCP that can be used to prospectively identify patients with mild to moderate obstructive sleep apnea who may be suitable for oral appliance therapy and to recommend a target mandibular position.

The use of the device does not replace the need for follow-up testing to determine the initial and ongoing effectiveness of the therapy as recommended by clinical practice guidelines.

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

K200695 – 510k Summary – MATRx plus

Date:	**August 24, 2020**
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:	587-317-1976
Establishment Registration Number:	3008960597
Device Proprietary Name:	MATRx plus
Classification Name:	CFR 872.5571 Closed Loop Auto Titration Device for Oral Appliances; CFR 868.2375 Ventilatory Effort Recorder
Classification Code:	Class II
Product Code:	QCJ, MNR
Primary Predicate:	MATRx plus (K191925)

Device Description:

MATRx plus is a ventilatory effort recorder and closed loop auto-titration device for oral appliances. MATRx plus is a 5-channel battery-powered respiratory pressure sensor and oximetry system. MATRx plus provides recordings of respiratory pressure, snoring, respiratory effort, pulse rate, oxygen saturation, and body position during sleep.

The 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 healthcare professional (HCP) prior to deploying the device to the patient for home use. The Tablet runs the MATRx plus application and 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.

During an auto-titration study, the patient wears temporary Titration Trays connected to a mandibular positioner. During the study, the device moves the mandible in response to respiratory events in order to determine if the patient is a suitable candidate for oral appliance therapy.

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 (when used as a ventilatory effort recorder) or to assist the HCP in the clinical management of oral appliance therapy for patients with obstructive sleep apnea.

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

The device is not to be used as an apnea monitor or in a life supporting or life sustaining situation and must not be used in the vicinity of an MRI device.

Indications for Use:

The MATRx plus is indicated for use by a lay person in the home and hospital use under the direction of a Health Care Professional (HCP).

MATRx plus records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position during sleep.

MATRx plus uses these recordings to produce a report for the HCP that may aid in the diagnosis and assessment of sleep disordered breathing for adult patients.

The MATRx plus device may also be used with an automated mandibular positioner that uses feedback control to record changes in the patient’s respiratory status related to repositioning of the mandible during an overnight study.

MATRx plus uses these recordings to produce a report for the HCP that can be used to prospectively identify patients with mild to moderate obstructive sleep apnea who may be suitable for therapy with an oral appliance and to recommend a target mandibular position.

The use of the device does not replace the need for follow-up testing to determine the initial and ongoing effectiveness of the therapy as recommended by clinical practice guidelines.

Technology:

The MATRx plus subject device is an updated version of the predicate cleared in K191925. The auto-titration study has been revised to rely only on the oxygen saturation signal to guide the positioning of the mandible during sleep and to establish the prediction of therapeutic response to an oral appliance. There is no change to the information provided to the user, no change to the hardware and no change that impacts the use of the device as a ventilatory effort recorder.

Comparison to Predicate Devices:

The MATRx plus subject device is substantially equivalent to the MATRx plus device (K191925), 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 predicates.

Trade Name	**MATRx plus - Predicate**	**MATRx plus - Subject**	**Discussion of Differences**
510k Number	**K191925**	**K200695-**	
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
Indications for Use	The MATRx plus is indicated for use by a lay person in the home and hospital use under the direction of a Health Care Professional (HCP). MATRx plus records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position during sleep. MATRx plus uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing for adult patients. The MATRx plus device may also be used with an automated mandibular positioner that uses feedback control to record changes in the patient's respiratory status related to repositioning of the mandible during an overnight study.	The MATRx plus is indicated for use by a lay person in the home and hospital use under the direction of a Health Care Professional (HCP). MATRx plus records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort and body position during sleep. MATRx plus uses these recordings to produce a report for the HCP that may aid in the diagnosis of sleep disordered breathing for adult patients. The MATRx plus device may also be used with an automated mandibular positioner that uses feedback control to record changes in the patient's respiratory status related to repositioning of the mandible during an overnight study.	Identical

Trade Name	**MATRx plus - Predicate**	**MATRx plus - Subject**	**Discussion of Differences**
510k Number	**K191925**	**K200695-**	
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	MATRx plus uses these recordings to produce a report for the HCP that can be used to prospectively identify patients with mild to moderate obstructive sleep apnea who may be suitable for therapy with an oral appliance and to recommend a target mandibular position. The use of the device does not replace the need for follow-up testing to determine the initial and ongoing effectiveness of the therapy as recommended by clinical practice guidelines.	MATRx plus uses these recordings to produce a report for the HCP that can be used to prospectively identify patients with mild to moderate obstructive sleep apnea who may be suitable for therapy with an oral appliance and to recommend a target mandibular position. The use of the device does not replace the need for follow-up testing to determine the initial and ongoing effectiveness of the therapy as recommended by clinical practice guidelines.	
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; 2) Identifying patients with mild to moderate sleep apnea for whom an oral appliance is a suitable therapy.	1) Data to assist in the diagnosis of sleep disordered breathing; 2) Identifying patients with mild to moderate sleep apnea for whom an oral appliance is a suitable therapy.	Identical
Contra-indications	The device is not to be used as an apnea monitor or in a life supporting or life sustaining situation. The device is not to be used by persons under the age of 18. The MATRx plus is MR unsafe. In auto-titration study mode, the device is not recommended for use in patients who: have	The device is not to be used as an apnea monitor or in a life supporting or life sustaining situation. The device is not to be used by persons under the age of 18. The MATRx plus is MR unsafe. In auto-titration study mode, the device is not recommended for use in patients who: have	Identical

Trade Name	MATRx plus - Predicate	MATRx plus - Subject	Discussion of Differences
510k Number	K191925	K200695	
Manufacturer	Zephyr Sleep Technologies, Inc.	Zephyr Sleep Technologies, Inc.	
	loose teeth or advanced periodontal disease; have full dentures or dental implants.	loose teeth or advanced periodontal disease; have full dentures or dental implants.	

Proprietary Name	MATRx plus	Proposed MATRx plus subject device	Discussion of Differences
510(k) Number	K191925	K200695	
Manufacturer	Zephyr Sleep Technologies, Inc.	Zephyr Sleep Technologies, Inc.	
Sensors			
Pulse Oximeter	Third party oximeter sensor (Masimo SET 2040D) 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 2040D) 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.	Dual channel nasal cannula attaches to patient worn recorder; records pressure and translates to airflow and snoring Not required for use in the auto-titration device.	No changes to nasal cannula or collection of airflow data for basic study type. Removal of airflow from auto-titration study does not affect device efficacy. Substantially equivalent.
Respiratory Effort	Respiratory effort channel to measure the respiratory effort using an inductance principle.	Respiratory effort channel to measure the respiratory effort using an inductance principle.	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	Nasal airflow fluctuation envelope signal	No changes to snoring data for basic study type.

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**K191925**	**K200695**	
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
		Tracing is no longer visible in auto-titration study.	Removal of airflow-based snoring from auto-titration study does not affect device efficacy. Substantially equivalent.
Mandibular Positioner	Small, lightweight, motorized positioner attached to temporary Titration Trays. Mandibular positioner is held in place by the Titration Trays, which fit firmly to the dentition. The mandibular positioner requires reprocessing between patients.	Small, lightweight, motorized positioner attached to temporary Titration Trays. Mandibular positioner is held in place by the Titration Trays, which fit firmly to the dentition. The mandibular positioner requires reprocessing between patients.	Identical
Titration Trays	Maxillary and mandibular U-shaped trays with two walls to receive impression material. Full arch that encapsulates the incisors and canines, narrower at the front and lower wall height on inner surface. The Titration Trays are single patient, multi-use and are not reprocessed. Titration Trays can be used for 6 nights, i.e., the maximum duration allowed by the Tablet software. The Titration Trays are fit by a trained healthcare professional.	Maxillary and mandibular U-shaped trays with two walls to receive impression material. Full arch that encapsulates the incisors and canines, narrower at the front and lower wall height on inner surface. The Titration Trays are single patient, multi-use and are not reprocessed. Titration Trays can be used for 6 nights, i.e., the maximum duration allowed by the Tablet software. The Titration Trays are fit by a trained healthcare professional.	Identical
Other channels	None	None	Identical
Device Design			
Recording Time	6 x 8 hours. The total number of study hours in	6 x 8 hours. The total number of study hours in	Identical

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**K191925**	**K200695**	
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	the MATRx plus is set by the software. Internal memory is > 100 hours.	the MATRx plus is set by the software. Internal memory is > 100 hours.	
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. HCP may start a new study for a patient previously created in the web Portal. HCP may opt to set up a study containing both study types (i.e., basic sleep study preceding or following auto-titration study).	Set up on device software and transferred to Device via internet. HCP may start a new study for a patient previously created in the web Portal. HCP may opt to set up a study containing both study types (i.e., basic sleep study preceding or following auto-titration study).	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 – (MNR) Ventilatory effort function	**MNR function:** 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.	**MNR function**: 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.	Identical

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**K191925**	**K200695**	
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
Data Display – (QCJ) Auto-titration function	**QCJ function:** Real time data displayed for:: mandibular protrusion, autoscored 4% oxygen desaturation events, airflow, oxygen, pulse rate, respiratory effort.	**QCJ function:** Real time data displayed for: mandibular protrusion, autoscored 4% oxygen desaturation events, oxygen, pulse rate.	Raw airflow tracings no longer visible in Data Viewer display. Change to data display reflects the change to the operational algorithms by which the device commands movement of the mandible throughout the study (i.e., using oxygen saturation only). No changes to displayed events (only oxygen events displayed). No changes to device efficacy. Substantially equivalent.
Data Reporting – (MNR) Ventilatory effort function	**MNR function:** 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. The following indices are generated from the MATRx plus software: ODI (4% and 3%), AHI (4% and 3%), AI (4% and 3%), average saturation, minimum saturation, maximum saturation, minimum pulse rate, maximum pulse rate, average pulse rate.	**MNR function:** 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. The following indices are generated from the MATRx plus software: ODI (4% and 3%), AHI (4% and 3%), AI (4% and 3%), average saturation, minimum saturation, maximum saturation, minimum pulse rate, maximum pulse rate, average pulse rate.	Identical
Data Reporting – (QCJ) Auto-titration function	**QCJ function:** A report is generated that provides: 1) raw data of oxygen saturation, airflow, body position, respiratory effort, and mandibular position	**QCJ function:** A report is generated that provides: 1) raw data of oxygen saturation, body position, and mandibular position collected over the multi-night test; 2) a	Substantially Equivalent – Raw data tracing of airflow not visible on report. No change to any of the reported events or indices.

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**K191925**	**K200695**	
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	collected over the multi-night test; 2) a display of the oxygen desaturation events detected by the device, as calculated by the previously-cleared sleep recorder; an assessment of whether the patient is predicted to achieve an oxygen desaturation index (ODI) of less than 10 per hour with a third-party custom oral appliance; 4) a protrusive position that is predicted to be efficacious to achieve the desired therapeutic success criterion (ODI < 10 h^{-1})	display of the oxygen desaturation events detected by the device, as calculated by the previously-cleared sleep recorder; an assessment of whether the patient is predicted to achieve an oxygen desaturation index (ODI) of less than 10 per hour with a third-party custom oral appliance; 4) a protrusive position that is predicted to be efficacious to achieve the desired therapeutic success criterion (ODI < 10 h^{-1})	
Components in Patient contact	Recorder and Sensors (nasal cannula, pulse oximeter, effort belt, mandibular positioner, Titration Trays (QCJ only)	Recorder and Sensors (nasal cannula (MNR only), pulse oximeter, effort belt, mandibular positioner, Titration Trays (QCJ only))	Nasal cannula use decreased in duration – not used in auto-titration study. Substantially equivalent.
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, IEC 80601-2	Tested to: IEC 60601-1, IEC 80601-2	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 - 1A medical grade (double insulated) wall power supply connected with a standard barrel	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 - 1A medical grade (double insulated) wall power supply connected with a standard barrel	Identical

Proprietary Name	MATRx plus	Proposed MATRx plus subject device	Discussion of Differences
510(k) Number	K191925	K200695	
Manufacturer	Zephyr Sleep Technologies, Inc.	Zephyr Sleep Technologies, Inc.	
	power jack. The battery was safety tested for compliance to IEC 62133:2012.	power jack. The battery was safety tested for compliance to IEC 62133:2012.	

Testing Summary - Non-clinical:

The subject device was also retested to the following standards:

- IEC 60601-1-10:2007, AMD1:2013 for use in conjunction with IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012

Performance bench testing was completed to demonstrate the substantial equivalence of the control and prediction algorithms.

Testing Summary Clinical:
The device was tested using both a prospective, blinded single arm design and a non-inferiority cross over design to directly compare the device performance of the subject and predicate device for both the prediction of outcome (responder/non-responder) and the target protrusive position.

In the single arm study, the device performance was shown to exceed the previously established clinical endpoints used to clear the original MATRx plus device (LCL $\geq$ 0.60). Specifically, the device was found to have a sensitivity of 97.1% (LCL=84.7%) in the mild/moderate patient population with a target accuracy of 90.9% (LCL = 75.7%).

In the cross over study, the predictive accuracy of the subject device was demonstrated to be not inferior to the predicate device by the clinically relevant margin of 0.125, with a negligible mean target accuracy difference of 0.17 mm.

Conclusion:
The conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to the legally marketed MATRx plus predicate devices cleared under K191925.