October 29, 2019

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

Re: K191925
Trade/Device Name: MATRx Plus
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, QCJ
Dated: August 2, 2019
Received: August 5, 2019

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,

for Srinivas Nandkumar, Ph.D.
Acting 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)*
K191925

Device Name
MATRx Plus

Indications for Use *(Describe)*
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.

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

Submission Date:	July 16, 2019
510(k):	K191925
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 (K181996)
Reference Device:	K190051 TD Clip; K182312 Zyppah

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 predicates cleared in DEN170090 and K181996. Minor changes have been made to device hardware to make the Recorder and mandibular positioner components slightly smaller and lighter, and to software to provide the healthcare professional with additional option for test set up and study workflow. The Titration Trays used during an auto-titration study can now be used for up to 6 nights and can be fit by a trained healthcare professional.

Comparison to Predicate Devices:

The MATRx plus subject device is substantially equivalent to the MATRx plus device (K181996 and DEN170090;), 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**	**Proposed MATRx plus**	**Discussion of Differences**
510k Number	**K181996/DEN170090**	**--**	
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	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	Identical

Trade Name	MATRx plus	Proposed MATRx plus	Discussion of Differences
510k Number	K181996/DEN170090	--	
Manufacturer	Zephyr Sleep Technologies, Inc.	Zephyr Sleep Technologies, Inc.	
	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. 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.	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. 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 (K181996); 2) Identifying patients with mild to moderate sleep apnea for whom an oral appliance is	1) Data to assist in the diagnosis of sleep disordered breathing; 2) Identifying patients with mild to moderate sleep apnea	Identical

Trade Name	MATRx plus	Proposed MATRx plus	Discussion of Differences
510k Number	**K181996/DEN170090**	--	
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	a suitable therapy (DEN170090).	for whom an oral appliance is a suitable therapy.	
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 loose teeth or advanced periodontal disease; have full dentures or dental implants.	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 loose teeth or advanced periodontal disease; have full dentures or dental implants.	Identical

Proprietary Name	MATRx plus	Proposed MATRx plus subject device	Discussion of Differences
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
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 2040D) attaches to patient worn recorder, measures degree of oxygen saturation of the blood and pulse rate. Sampling frequency of 1 Hz.	Functionally identical; oximeters have same technology and performance standards. Substantially equivalent.
Airflow	Dual channel nasal cannula attaches to patient worn recorder; records pressure and translates to airflow and snoring. Sampling frequency of 350 Hz. In auto-titration mode, an alert will notify the user	Dual channel nasal cannula attaches to patient worn recorder; records pressure and translates to airflow and snoring. Sampling frequency of 350 Hz. In auto-titration mode, an alert will notify the user	No changes to airflow collection or analysis. Change to airflow alert in auto-titration study mode has no effect on data collected or test outcome. Substantially equivalent.

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	if the airflow signal has been absent for 90 s.	if the airflow signal has been absent for 120 s.	
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
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 consists of one sealed rod with a double seal design. The mandibular positioner is made from acrylonitrile butadiene styrene (ABS). The actuator rod material is made from acetal resin or anodized stainless steel. Digital transfer of mandibular position, sound, and acceleration. Powered by 14 V (hardware configurable).	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 consists of one sealed rod with a double seal design. The mandibular positioner is made from acrylonitrile butadiene styrene (ABS). The actuator rod material is made from acetal resin, anodized stainless steel, or anodized aluminum. Digital transfer of mandibular position, sound, and acceleration. Powered by 14 V (hardware configurable).	Identical aside from addition of anodized aluminum actuator. Mandibular positioner function is not affected by change to actuator material. Substantially equivalent.

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	Digital signal is converted from analogue on the MP board. Mandibular positioning is constrained to the anterior/posterior direction and uses a protrusive step size of 0.2 to 0.3 mm. A 5 s delay is imposed by the software. The maximum force that the mandibular positioner can apply is 70 N. The position is held by the linear actuator and measured by the software. The mandibular positioner requires reprocessing between patients.	Digital signal is converted from analogue on the MP board. Mandibular positioning is constrained to the anterior/posterior direction and uses a protrusive step size of 0.2 to 0.3 mm. A 5 s delay is imposed by the software. The maximum force that the mandibular positioner can apply is 70 N. The position is held by the linear actuator and measured by the software. The mandibular positioner requires reprocessing between patients.	
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 trays have slits in the tray base to promote flexibility. The trays are available in 2 sizes to accommodate the incisor region, medium and large. The relative displacement is visible on a scale on the mounting bracket. The scale ranges from -6 to	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 trays have slits in the tray base to promote flexibility. The trays are available in 2 sizes to accommodate the incisor region, medium and large. The relative displacement is visible on a scale on the mounting bracket. The scale ranges from -6 to	The Titration Trays used in the subject device are unchanged from those used in the predicate device. Additional biocompatibility and performance testing were demonstrated for the identical Titration Trays in a reference device (K190051). Therefore, the allowed test duration has been increased to that allowed by the device software (6 nights). As the trays themselves are unchanged, the devices are substantially equivalent.

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	14 mm (20 mm range). Incisor edge-to-edge is marked by the zero position on the tray scale. The mounting bracket is integral with the trays, manufactured from a single mold design. The trays are vertically constrained by interconnection between the two mounting brackets. The Titration Trays are single patient, multi-use and are not reprocessed. Titration Trays can be used for 24 hours. The Titration Trays are fit by a qualified dentist or dental professional.	14 mm (20 mm range). Incisor edge-to-edge is marked by the zero position on the tray scale. The mounting bracket is integral with the trays, manufactured from a single mold design. The trays are vertically constrained by interconnection between the two mounting brackets. 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.	The change to the fitting of the Titration Trays is supported by reference devices such as the Zyppah (K182312), which is an over-the-counter oral appliance (LRK) that is fitted by the patient – an untrained individual. Since the creation and use of a custom oral appliance by a patient without direction from an HCP has been cleared as safe and effective for applying a protrusive repositioning during sleep, the subject device's Titration Trays can similarly be fitted by a non-healthcare professional. The subject device is substantially equivalent in this manner to the reference device.
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			
Sensor Connection	Sensors (airflow, oximeter, effort belt, mandibular positioner	Sensors (airflow, oximeter, effort belt, mandibular positioner	Identical

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	during auto-titration study) are attached to a body worn recorder unit.	during auto-titration study) are attached to a body worn recorder unit.	
Recorder Dimensions/Weight	6.30 x 7.90 x 6.60 cm 230 g	11.0 x 8.0 x 3.5 cm 166 g	Subject device is smaller and lighter than predicate. Substantially equivalent.
Mandibular Positioner Dimensions/Weight	5.2 x 5.7 x 2.8 cm 80 g	5.2 x 5.5 x 2.6 cm 80 g	Subject device is slightly smaller than predicate and the same weight. New design has been tested to ensure it meets the same performance criteria as predicate device. Substantially equivalent.
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, STM32F407, 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, STM32F407, 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

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
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
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. 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).	HCP may continue to set up the study in the web Portal and load on Tablet or can alternatively start the study directly on the Tablet. No new functionality introduced (just change of function location). Addition of option for HCP to set up multiple studies for one patient removes the need for the device to be returned to the HCP between studies. Study types remain the same. Addition of risk that is mitigated by Tablet software. Substantially equivalent.
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 function:** Real time waveforms displayed for all channels; autoscored 4% or 3% oxygen	**MNR function:** Real time waveforms displayed for all channels; autoscored 4% or 3% oxygen	Identical

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	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. **QCJ function:** Real time data displayed for all channels: mandibular protrusion, autoscored 4% oxygen desaturation events, airflow, oxygen, pulse rate, respiratory effort.	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. **QCJ function:** Real time data displayed for all channels: mandibular protrusion, autoscored 4% oxygen desaturation events, airflow, oxygen, pulse rate, respiratory effort.	
Data Reporting/Analysis	**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. **QCJ function:** A report is generated that provides: 1) raw data of oxygen saturation, airflow, body position, respiratory effort, and mandibular position collected over the multi-	**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. **QCJ function:** A report is generated that provides: 1) raw data of oxygen saturation, airflow, body position, respiratory effort, and mandibular position collected over the multi-	Identical

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
	night test; 2) a display of the oxygen desaturation events detected by the device, as calculated by the previously-cleared sleep recorder (K181996); 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})	night test; 2) a display of the oxygen desaturation events detected by the device, as calculated by the previously-cleared sleep recorder (K181996); 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)	Recorder and Sensors (nasal cannula, pulse oximeter, effort belt, mandibular positioner, Titration Trays)	Identical
Biocompatibility	All body contacting components previously cleared	All body contacting components previously cleared. Titration Trays are now cleared for use for up to 29 nights (cleared in K190051) – change to allowable test duration from 3 to 6 nights.	Change to auto-titration test duration supported by biocompatibility testing on file for reference device (K190051). Substantially equivalent.
Reprocessing	Patient contacting and indirectly contacting components are reprocessed	Patient contacting and indirectly contacting components are reprocessed. Simplified instructions for reprocessing have been revalidated.	No changes to reprocessing requirements. New instructions have been validated for cleaning and low-level disinfection. Substantially equivalent.
Safety Testing	Tested to: IEC 60601-1, IEC 80601-2	Tested to: IEC 60601-1, IEC 80601-2	Testing performed as necessary for subject device to demonstrate conformance to same or

Proprietary Name	**MATRx plus**	**Proposed MATRx plus subject device**	**Discussion of Differences**
510(k) Number	**DEN170090/K181996**		
Manufacturer	**Zephyr Sleep Technologies, Inc.**	**Zephyr Sleep Technologies, Inc.**	
			updated standards as predicate devices. Substantially 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	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 - 1A 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.	Decrease in amperage of battery. Subject device battery has a slightly increased charging time from that of predicate devices (5 h for full charge instead of 4 h). The device remains usable upon reaching 85% charge. Change is deemed negligible. Substantially equivalent.

Testing Summary:
Non-clinical:

The subject device was tested to the following standards:

IEC 60601-1: 2005 3rd ed. + A1:2012. General Requirements for Basic Safety and Essential Performance.

IEC 60601-1-2: 2014. Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

IEC 60601-1-6: 2010. AMDI:2003. Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.

IEC 62366: 2007. Medical Devices – Part 1: Application of usability engineering to medical devices.

IEC 60601-1-10: 2007.Medical Electrical Equipment – Part 1-10: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers.
IEC 60601-1-11: 2015.Medical Electrical Equipment – Part 1-10: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements of Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
IEC 62304: 2006 1st Ed. + A1:2015. Medical Device Software - Software life cycle processes.
IEC 80601-2-61:2011 Medical electrical equipment -- Medical Electrical Equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEC 62133 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
EN 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
EN 300 328/l 1.8.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
EN 301 489-1 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-17 ElectroMagnetic Compatibility (EMC)
standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems
FCC Part 15B Equipment authorization of unintentional radiators
FCC Part 2.1091, 15.247 Radiofrequency radiation exposure evaluation: mobile devices, Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz.

Reprocessing validation was completed on the new device hardware and new, simpler reprocessing instructions.

Performance bench testing was completed to demonstrate that the subject device's mandibular positioner and oximeter meet the same performance criteria as those cleared in the predicate (cleared in DEN170090).

All materials in contact with the mucosal membrane were assessed and tested in accordance with ISO 10993-1 and the associated FDA guidance, *Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1 Evaluation*

and Testing within a Risk Management Process"" issued June 16, 2016. Specifically, the following tests were performed:

ISO 10993-5: 2009 Biological Evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.

IOS 10993-10: 2010 Biological Evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

Clinical:

Clinical performance testing was not required for the changes made to the subject device.

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 DEN170090 and K181996.