DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 17, 2017

TereoPneuma, Inc.
Warren Young
President and COO
13223 Black Mountain Rd., Suite 1-224
San Diego, California 92129

Re: K161953
Trade/Device Name: ReDe Mask
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: PRK
Dated: January 3, 2017
Received: January 9, 2017

Dear Mr. Young:

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
-S

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)*
K161953

Device Name
ReDe Mask

Indications for Use *(Describe)*
The ReDe Mask is indicated for use by healthcare professionals in healthcare facility procedural areas and recovery rooms as an adjunct to monitor breathing in adult patients who are sedated for a diagnostic or therapeutic procedure. The ReDe Mask measures the time period between the current and previous exhalation and illuminates a colored light during the exhalation that reflects the interval of time between breaths. If the interval is less than 7.5 seconds, the green light illuminates during exhalation; if the interval is greater than 7.5 seconds but up to 20 seconds, the yellow light illuminates during exhalation; and if the interval between breaths is 20 seconds or longer, the red light flashes continuously. The ReDe Mask is only to be used when supplemental oxygen is provided by the facemask. The ReDe Mask is not a standalone device and is only to be used as an adjunct to pulse oximetry.

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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TereoPneuma™

510(k) Summary

Date summary prepared Jan 3, 2017

510(k) Submitter/Holder

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Contact

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Name of Device

Trade Name	ReDe Mask
Common Name	Breathing Monitor
Classification Name	monitor, breathing frequency (21 CFR § 868.2375, class II, PRK)

Predicate Device

Trade Name:	Oral/Nasal Thermal Airflow Sensor
Device Common Name	Airflow Sensor
510(k) Number:	K080922 (cleared 7/2008)
Manufacturer:	Salter Labs

Reference Devices

Two reference devices are used in the clinical evaluations:

Trade Name:	MicroCap/NPB-75
Device Common Name	Combination Oximeter/ Carbon Dioxide Gas Analyzer
510(k) Number:	K964239
Manufacturer:	Spegas Industries Ltd.

Trade Name:	ExSpiron
Device Common Name	Respiratory Monitor
510(k) Number:	K120087
Manufacturer:	Respiratory Motion, Inc.

Indications for Use

The ReDe Mask is indicated for use by healthcare professionals in healthcare facility procedural areas and recovery rooms as an adjunct to monitor breathing in adult patients who are sedated for a diagnostic or therapeutic procedure. The ReDe Mask measures the time period between the current and previous exhalation and illuminates a colored light during the exhalation that reflects the interval of time between breaths. If the interval is less than 7.5 seconds, the green light illuminates during exhalation; if the interval is greater than 7.5 seconds but up to 20 seconds, the yellow light illuminates during exhalation; and if the interval between breaths is 20 seconds or longer, the red light flashes continuously. The ReDe Mask is only to be used when supplemental oxygen is provided by the facemask. The ReDe Mask is not a standalone device and is only to be used as an adjunct to pulse oximetry.

Intended Use

The ReDe Mask is to be used as a breathing frequency monitor by recording nasal and/or oral airflow while supplying oxygen. The ReDe Mask itself performs no diagnostic functions and only supports the recording of airflow for use as an adjunct with pulse oximetry. It is intended for adult prescription and single use only in healthcare facility procedural areas and recovery rooms.

Because sedation produces respiratory depression in every patient, healthcare providers must monitor ventilation by counting the respiratory rate during and after procedures in which sedatives are administered. Counting the respiratory rate may be inaccurate because it is difficult to gauge the rise and fall of a chest in a patient who is sedated, both because the size of the breaths are diminished by the sedatives and because the sedatives may cause airway obstruction. When the airway is obstructed, the chest continues to rise and fall as the diaphragm moves up and down, but no breath is going in and out of the patient due to the airway obstruction.

Device Description

The ReDe Mask is a breathing frequency monitor that provides a visual signal at each breath event (i.e., an inhalation followed by an exhalation). The proposed device consists of a temperature-sensing circuit attached externally to a standard face mask. This circuit continuously analyzes the temperature inside the face mask and determines when a breath event has occurred.

The ReDe Mask is designed to detect breathing events (cycles of inhalation followed by exhalation) by measuring temperature changes in the immediate vicinity of a patient's nose and/or mouth. Exhalations produce a temperature warming as expired air exits the mouth and nose, while inhalations result in a temperature cooling as ambient air and supplied oxygen enter the mask. The overall pattern is thus one of repeating periods of a warming and a cooling phase with every breath. The rate of warming and cooling, that is, the slope of the temperature change (degrees C per unit time) depends on the vigor with which the patient is breathing, which can range from very shallow breathing (small slope values) to vigorous breaths (large slope values). The ReDe Mask's breath detection algorithms are based on continuously measuring the warming and cooling slopes coupled with real-time analysis to determine the changeover point from negative slope (inhalation phase) to

positive slope (exhalation phase). It is the detection of inflection points in the slope (negative to positive) that yield the elapsed time period between successive breaths. With each new breath the elapsed time between inflection points is used to determine which LED to illuminate.

Predicate Device Comparison

Similarities in the intended use and indications for use between the ReDe Mask and predicate are:

- Both are to be used to record nasal and/or oral airflow while supplying oxygen.
- Both do not perform diagnostic functions and only support the recording of airflow for use as an adjunct with other clinical devices.
- Both are to be used as a breathing frequency monitor, with the proposed device conveying this information with colored indicator lights and the proposed predicate with a waveform display on a computer monitor.
- Both are non-invasive medical devices.

Differences in the intended use and indications for use between the ReDe Mask and predicate are:

- The ReDe Mask is intended to be used to measure the time period between the current and previous exhalation. The predicate averages the breathing rate over a period of time.
- The ReDe Mask uses colored light indicators to reflect the interval of time between breaths. The predicate uses waveforms on a computer monitor and digital readouts to reflect the averaged breathing rate.
- The ReDe Mask is indicated for use by healthcare professionals in healthcare facility procedural areas and recovery rooms as an adjunct to monitor breathing in adult patients who are sedated for a diagnostic or therapeutic procedure. The predicate is used in sleep laboratory settings to monitor a patient's breathing rate while sleeping.

These differences do not change the intended use for the ReDe Mask and do not raise different questions of safety and effectiveness per 807.92(a)(5).

Location of Use

The ReDe Mask is used in healthcare facility procedural areas and recovery rooms as an adjunct to monitor breathing in adult patients while the ThermiSense predicate is used in sleep laboratory settings. In both cases, the patients are not awake. The bench and clinical performance testing show that the device performs as specified within its operating ranges and effectively detects breathing in the patients in the healthcare facility procedural areas and recovery rooms. Both the ThermiSense and the ReDe Mask are designed to detect breathing rate by measuring breathing pattern waveforms. The waveforms in both devices are the electrical signals produced by each devices' thermistor circuitry in response to breathing-caused temperature changes. These waveform patterns are analyzed to determine a breathing rate. The ThermiSense transfers its waveform data to external

equipment for analysis. The ReDe Mask retains its waveform data and performs the waveform analysis internal to the device itself. However, regardless of where the analyses take place, both devices are measuring and analyzing the same phenomenon: breathing pattern temperature waveforms. These waveforms are necessarily fundamental to the operation of both devices. Both devices measure temperature changes using thermistors, produce breathing waveforms corresponding to measured temperature patterns, and analyze those waveform patterns.

Based on these fundamental characteristics, which we view as equally inherent in both devices, we believe a claim of substantial equivalence is supported

Technological and Performance Characteristics

Technology Similarities

The ReDe Mask and the predicate were compared in the following areas and found to have similar technological characteristics and to be equivalent:

Characteristic	ReDe Mask	ThermiSense (K080922)
Similar power source using a battery	Yes	Yes
Similar permanent, non-replaceable battery	Yes	Yes
Similar technology using a thermistor	Yes	Yes
Similar electronic components	Yes	Yes
Similar device function	Yes	Yes
Similar oxygen supply system	Yes	Yes
Similar sampling position	Yes	Yes

A. Both devices measure respiratory rate with the same technology:
   - Both devices use a thermistor sensor to detect changes in temperature in the nasal and/or oral airflow pathways reflecting exhalation and inhalation (i.e., a breath).
   - Both devices use a low-power 3V coin battery (CR2032) as the electrical power source.
   - Both devices use a battery that is permanent and non-replaceable.

B. Both devices have components that perform data analysis:
   - The ReDe Mask uses a thermistor connected to a microcontroller and other electronic components on a printed circuit board that is sealed in a small plastic housing mounted on the face mask.

- The predicate uses a thermistor housed in a nasal cannula that is connected to other electronic components housed in a separate box that is located next to the patient,
- Both devices use firmware that performs algorithm analysis of temperature changes during exhalation and inhalation and correlates it to a breath.

C. Both devices include an oxygen supply system.
   - Uses a standard oxygen supply tube.

D. Both have similar sampling position under the nares and in the airflow path of the mouth.
   - The ReDe Mask uses a face mask and elastic strap to hold in place on the face.
   - The predicate uses a molded plastic nasal cannula.

Technology Differences

The ReDe Mask and the predicate were compared in the following areas and found to have different technological characteristics but do not impact safety or performance:

Characteristic	ReDe Mask	ThermiSense (K080922)
Requires additional connections	No	Yes
Data Reported	Breathing rate by way of colored indicator lights	Airflow and breathing rate by readout of waveform on computer monitor
Stored Data	Accumulated data stored internal to the device.	Dependent upon recording device selected
Mounting Design	Face mask and electronics housing is placed on patient's face.	Nasal cannula and is placed on patient's face and connected to external box of electronics.
Ambient Operating Temperature	16^0 to 31^0 C	5^0 to 32^0 C
Weight	40 grams	30 grams
Dimensions (control unit)	43.43 mm H 30.48 mm W 14.99 mm D	17.2 mm H 34.8 mm W 57.5 mm D

A. Different methods are used to report the breathing rate:
   - The ReDe Mask reports the breathing rate by way of colored indicator lights.
   - The predicate reports the breathing rate by way of a readout of a waveform on a computer monitor.

The use of green, yellow and red lights to convey breathing rate information is simpler and easier than looking a waveform and counting the number of peaks on a moving signal on the computer monitor. This method of signaling the breathing rate does not impact safety and effectiveness of the ReDe Mask.

B. Different methods are used for the applied parts:
   - The ReDe Mask uses a face mask, a housing and a thermistor as applied parts to attach to the face of the patient.
   - The predicate uses nasal cannula as applied parts to attach to the face of the patient.

   The use of a standard face mask is as safe and accepted as the use of a nasal cannula. The face mask applied part does not impact the safety and effectiveness of the ReDe Mask.

C. The ambient operating temperature of the ReDe Mask is specified in a range within the ambient operating temperature range of the predicate device.

   Because the ambient operating temperature range of the ReDe Mask falls within the ambient operating temperature range of the predicate device, there is no impact on its safety and effectiveness.

D. The weight of the ReDe Mask is on 10 grams heavier than the proposed predicate.

   The 10 grams heavier weight of the ReDe Mask does not impose any extra burden on the patient that would impact safety and effectiveness of the ReDe Mask.

E. The overall dimensions of the ReDe Mask is smaller than the predicate when comparing the volumes. The ReDe Mask is 19.843 cm^3 while the predicate is 34.417 cm^3.

   The ReDe Mask is smaller and does not increase its impact on the safety and effectiveness.

Performance Data

The design of the ReDe Mask features the same operating principle, technology and manufacturing processes as the predicate device. The following performance tests were conducted to confirm the safety and effectiveness of the ReDe Mask.

Electromagnetic Compatibility Testing

The tests were performed according to following standard:

- IEC 60601-1-2: 2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

Remark: This device is ranged to the Group 1 Class B apparatus according to the standard of CISPR 11: 2010 clause 5.2.

Electrical Safety Testing

Electrical Safety Testing was conducted in accordance with the following standards:

- IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007 + A1:2012

Bench Testing:

Test	ReDe Mask proposed device	ThermiSense predicate device	Comment
Battery Discharge Sufficiency	Self contained coin battery (CR2032) with an 8 hour life to enforce single use.	Uses the same CR2032 coin battery	Proposed device is as safe and effective as the predicate.
Ambient Temperature Sensor	Operates properly in range from 16^{o} - 31^{o} C as specified.	Specified operating range is 5^{0} to 32^{0} C.	Proposed device is as safe and effective as the predicate by operating well within the range specified by the predicate.
Operational Time Limits	Properly indicates that device is about to expire to enforce single use.	Device has no enforceable single use method.	Proposed device is as safe and effective as the predicate.
Single Use Enforcement	Properly expires to enforce single use.	Device has no enforceable single use method.	Proposed device is as safe and effective as the predicate.
Worst-Case Scenario	Operates as specified with breathing rate, tidal volume and oxygen flow parameters.	Parameters unknown.	Proposed device is as safe and effective as the predicate given that the predicate can perform at least the same parameters that are the minimum physiological/medical requirements.
Aging	Ambient aging up to 1 year does not produce loss of performance or physical integrity.	Thermistor unit is warranted for 3 months and an outboard interface box is warranted for 1 year.	Proposed device is as safe and effective as the predicate and will not expire for at least the maximum warranty time period offered by the predicate.

Transit	Transit conditions do not produce loss of performance or physical integrity.	Unknown, but presumably operates after transit to distributors and end-users.	Proposed device is as safe and effective as the predicate by continuing to perform after transit conditions, as does the predicate.
Breath Detection	Operates as specified with breathing rate, tidal volume and oxygen flow parameters and beyond the specifications.	Parameters unknown.	Proposed device is as safe and effective as the predicate given that the predicate can perform at least the same parameters that are the minimum physiological/medical requirements.
Breath Detection at BPM, TV and O^2 Limits	Operates as specified with breathing rate, tidal volume and oxygen flow parameters at the limits of the specifications.	Parameters unknown.	Proposed device is as safe and effective as the proposed predicate given that the proposed predicate can perform at least the same parameters that are the minimum physiological/medical requirements.
Light Indicator Accuracy	Operates as specified with breathing rate, tidal volume and oxygen flow parameters and beyond the specifications and light indicators perform as designed.	Parameters unknown.	Proposed device is as safe and effective as the predicate given that the predicate can perform at least the same parameters that are the minimum physiological/medical requirements.
Lifetime Consistency and Robustness	Operates as specified over the entire lifetime of 8 hours of operation detecting all breaths (consistency) and shows that large changes in breathing rate do not affect its accuracy (robustness).	Parameters unknown.	Proposed device is as safe and effective as the predicate given that the predicate can perform at least the same parameters that are the minimum physiological/medical requirements.

Temperature Swings at Upper Operating Temperature	Operates as specified at the upper limits of the operating temperature of 31^0 C where all the correct lights illuminate as expected in their breathing rate ranges. Temperature swings from a low of 0.17^0 C to 1.40^0 C over a tidal volume of 100 and 500 ml and breathing rates from 2 to 45 BPM. The very low swings reflect the precision and accuracy of the device in detecting breaths.	Parameters unknown.	Proposed device is as safe and effective as the predicate given that the predicate can perform at least the same parameters that are the minimum physiological/medical requirements.

Conclusion from Bench Performance Tests

Overall, the bench performance tests shows that the ReDe Mask passes all expectations and requirements. The conclusions from bench performance test data after performing non-clinical performance and safety studies is that the data shows that the ReDe Mask is as safe, as effective, and performs as well as the predicate device.

Biocompatibility Testing:

Four biocompatibility tests were conducted by NAMSA:

- Cytotoxicity Study Using the ISO Elution Method (skin contact and external communication)
- ISO Guinea Pig Maximization Sensitization Test (skin contact and external communication)
- ISO Intracutaneous Study in Rabbits (skin contact and external communication)
- ISO Systemic Toxicity Study in Mice (external communication)

Conclusion from Biocompatibility Tests

No effects of the applied parts were noted for cytotoxicity, skin irritation or skin sensitization and is as safe

Clinical Testing:

The Human Factors and Usability testing of the proposed device is established by the evaluation of the user interface, user interactions and instructions accompanying the device in accordance with FDA guidance documents and established standards: Human Factors and Usability Testing per FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices" and ISO 14971:2012. See "Section 6 - Risk Analysis" for more information on risk and usability factor identification.

Human Factors and Usability Validation: The purpose of the HF/U validation was to determine if the instructions for use and overall device design facilitate safe and effective use for the intended users, uses and use environment. The test designs were comprised of participants running through the order of operations when operating the device, including unpacking the device, reading the IFU, using the device and disposing of the device, while a study monitor observed and recorded any instances of subject difficulty, mishandling and/or misuse. The first study utilized 30 anesthesia care providers. The participants reported that the instructions for use were easy to follow and the device was easy to use. The second study utilized the complete spectrum of health care providers who may use the device and was conducted inside the intended environment of use. In both studies, all participants were able to correctly interpret the green, yellow and red illuminations, and all were able to see the flashing LEDs from 20 feet away. The study monitor observed no observed participant use errors, close calls or use problems, and received overwhelming positive feedback that the device is easy to understand and use. These results and participant feedback support the conclusion that the ReDe mask is as safe and as effective for use as the predicate.

Comparison of Accuracy With Capnograph: The purpose of the study was to compare the detection of exhalation and low respiratory rates in non-patient volunteers using the ReDe mask device with simultaneous end-tidal CO_2 (capnograph) measurements of exhalation. A total of 38 individuals participated in this study. The data show conclusively that the proposed device is equivalent in all respects to a capnograph, considered the gold standard in monitor the breathing rate of a patient. No false positives or false negatives occurred with the use of the proposed device, ensuring that it can be used safely and without confusion in the detection of breath events.

Comparison of Accuracy With ExSpiron and Capnograph: The purpose of the study was to compare the detection of exhalation and low respiratory rate in non-patient volunteers using the ReDe mask device with simultaneous bioimpedance (ExSpiron) and end-tidal CO_2 (capnograph) measurements of exhalation. A total of 50 individuals participated in this study. The study looked at normal patient breathing, reduced patient breathing and cessation of patient breathing. The study also looked at the occurrence of false negatives and false positives. The data show conclusively that the ReDe Mask is equivalent in performance to an ExSpiron and a capnograph,

Animal Testing:

Animal testing was not required to demonstrate that the proposed device met its design requirements and therefore there are no animal data associated with this device.

Conclusions from clinical performance data

Human factor and usability studies showed that the device use and interpretation of instructions were easy to follow. Clinical performance data shows that the proposed device performs similarly to the capnograph, and to the ExSpiron, another reference device used for monitoring breathing.

Conclusion

In establishing substantial equivalence of the ReDe Mask to the predicate device, TereoPneuma evaluated the intended use, indications for use, technological characteristics, reported adverse events and instrument risk profiles. The use of the ReDe Mask in patient monitoring environments does not raise any new types of questions of safety and effectiveness compared with the predicate device currently in use.

We believe that the ReDe Mask and the ThermiSense are substantially equivalent. Both the ThermiSense and the ReDe mask are designed to detect breathing by measuring breathing pattern waveforms. The waveforms in both devices are the electrical signals produced by each devices' thermistor circuitry in response to breathing-caused temperature changes. These waveform patterns are analyzed to determine a breathing event. The ThermiSense transfers its waveform data to external equipment for analysis. The ReDe mask retains its waveform data and performs the waveform analysis internal to the device itself. However, regardless of where the analyses take place, both devices are measuring and analyzing the same phenomenon: breathing pattern temperature waveforms. These waveforms are necessarily fundamental to the operation of both devices. Both devices measure temperature changes using thermistors, produce breathing waveforms corresponding to measured temperature patterns, and analyze those waveform patterns to arrive at a final output showing that the patient is breathing. Both devices use the same underlying technology, both devices measure and analyze waveform patterns to determine breathing, and both devices present their outputs, a display of breathing events, to clinicians in real time.

The design intent of both devices is the same; the underlying technology of both devices is the same; and the output information content of both devices is the same: breathing by the patient. Based on these fundamental characteristics, a claim of substantial equivalence is supported.

Based on the clinical and non-clinical testing performed, we believe that the ReDe mask is as safe and as effective as the predicate.