July 2, 2024

RemSleep Holdings
℅ Judy Strzepek
Regulatory Consultant
Strzepek Consulting
18111 Littleton Place
Lakewood Ranch, Florida 34202

Re: K233415
Trade/Device Name: DELTAWAVE Nasal Pillows System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: October 4, 2023
Received: October 10, 2023

Dear Judy Strzepek:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2024.07.02 14:35:07 -04'00'

For

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233415

Device Name
DELTAWAVE Nasal Pillows System

Indications for Use *(Describe)*
The DELTAWAVE Nasal Pillows System is intended to noninvasively channel pressurized airflow to a patient from a Continuous Positive Airway Pressure (CPAP) or Bi-Level medical device.

This medical device is intended for adult patients weighing 66 lbs (30kg), and for whom noninvasive Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy has been prescribed by a physician or other authorized healthcare professional. It is intended for single-patient reuse in the home.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K233415

510(k) SUMMARY

July 2, 2024

1 SUBMITTER

REMSLEEP Holdings Inc.,

14175 ICOT Blvd, Suite 300

Clearwater FL 33760

2 SUBMITTER CONTACT

Tom Wood

Chief Executive Officer

REMSLEEP Holdings Inc.

3 SUBMISSION CORESPONDENT

Judy Strzepek,

Regulatory Consultant

4 DEVICE

Subject Device	DELTAWAVE™ Nasal Pillows System
Common Name:	Nasal Mask, Mask, Cannula
Classification Name	Ventilator, Non-Continuous (Respirator)
Regulation Number	§21 CFR 868.5905
Medical Device Class	II
Product Code	BZD
Classification Panel	Anesthesiology

5 PREDICATE DEVICE

K200089, Fisher & Paykel EVORA™ Nasal Mask, Model A. This product is marketed in the US. No reference devices have been used for this submission.

6 DEVICE DESCRIPTION

The DELTAWAVE™ Nasal Pillow System is the subject device for this submission. It is a non-invasive medical device that directs pressurized air from a Continuous Positive Airway Pressure (CPAP) or Bi-level medical device to the patient. The

subject device is a type of medical device prescribed by a physician or authorized professional for patients who have been diagnosed with Sleep Apnea.

The subject device is designed to prevent pressure drop from the CPAP machine to the patient's nasal passages. That is accomplished by maintaining the same, or greater flow space from the machine output to the patient's nostrils. To further ensure the least amount of pressure drop the nasal pillows are designed to gently dilate the patient's nostrils to avoid restrictions to incoming air entering the nostrils. This allows air to enter the patient's nostrils at a lower driving pressure. **Table 1** provides a list of the subject device components with the number of each provided to the patient in a system.

Table 1: Contents of DELTAWAVE™ Nasal Pillow System

Part	Quantity
Retainer Bar	2
Head Strap	1
Cannula/Mask	3
Tubing	1
Swivel Adapter	1
Swivel Angle Adapter	1

7 INTENDED USE

The DeltaWave Nasal Pillow System is intended to noninvasively channel pressurized airflow to a patient from a Continuous Positive Airway Pressure (CPAP) or Bi-Level medical device.

This medical device is intended for adult patients weighing 66lbs (30kg), and for whom noninvasive Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy has been prescribed by a physician or other authorized healthcare professional. It is intended for single-patient reuse in the home.

7.1 TECHNOLOGY CHARACTERISTICS

The subject device and predicate devices have similar appearance characteristics, both the subject and Predicate have the same mode of action, which is to function as the interface for CPAP pressurized air coming to the patient.

- The Subject Device Cannula connects to the (CPAP) device through standard conical connector, tubing, and a swivel adapter.

The predicate device has the same method of supplying pressurized air to the patient's nose.

8 COMPARATIVE CHARACTERISTIC OF DELTAWAVE™ TO THE PREDICATE

The following is a comparison of the DELTAWAVE™ Nasal Pillow System to the chosen predicate, F&P EVORA™ A Model. The content of this comparison is based upon several FDA guidance including "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"* and "*Format for Traditional and Abbreviated 510(k)s".* .

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Table 2: Characteristic comparison of subject device to the predicate

DEVICE CHARACTERISTICS	DELTAWAVE™ Nasal Pillow System K233415	Predicate F&P EVORA™ A Model K200089	COMMENTS
Trade Name	DELTAWAVE™ Nasal Pillow System	F&P EVORA™ Nasal Mask (A model)	None
CLASSIFICATION CHARACTERISTICS			
Intended Use/Indications For Use	DELTAWAVE™ Nasal Pillow System is intended for adult patients weighing ≥66lbs (30kg), and for whom non-invasive Continuous Positive Airway Pressure (CPAP) or Bi-Level therapy has been prescribed by a physician or other authorized healthcare professional. DELTAWAVE™ Nasal Pillow System is intended for single patient reuse in the home.	The F&P EVORA Nasal Mask is intended to be used by adults weighing ≥66lbs (30kgs) who have been prescribed non- invasive positive airway pressure therapy such as CPAP or bilevel by a physician. The F&P Evora Nasal Mask (A model) is intended for single patients' use in the home.	SAME
Product Code	BZD	BZD	SAME
Regulation #	868.5905	868.5905	SAME
Patient Population	Adults weigh ≥66 lbs. (30kg). Home use only	A Model - Adults weighing ≥66 lbs. (30kg). Home use.	SAME

DEVICE CHARACTERISTICS	DELTAWAVE™ Nasal Pillow System K233415	Predicate F&P EVORA™ A Model K200089	COMMENTS
Availability to Patient	By Prescription	By Prescription	SAME
Sterile or Non-sterile	Non-Sterile	Non-Sterile	SAME
PHYSICAL CHARACTERISTICS-			
Operating Environment	Home	Home	SAME
Mask Type	Nasal Pillow	Nasal	Both device masks are confined to the patients nose area. Design differences do not raise new/different questions of safety and effectiveness
Exhalation Vent	Small vents in the nasal cannula/mask serve as exhaust ports.	Small vents in the Frame which attaches to the Seal serve as the exhaust ports.	SAME
Tubing to connect Nasal Pillow to CPAP Device	22 mm	22 mm	SAME
OPERATING CHARACTERISTICS			
Dead Space volume for nasal pillows	Small = 19.50 cc Medium = 19.50 cc Large = 19.50 cc	Small = 28 cc Medium = 26 cc Large = 28 cc Wide = 34 cc	All subject device cannula/masks have the same Dead Space volume and Internal Measurements regardless of size. Dead Space is disclosed per ISO 17510. Design differences do not raise new/different questions of safety and effectiveness.

DEVICE CHARACTERISTICS	DELTAWAVE™ Nasal Pillow System K233415	Predicate F&P EVORA™ A Model K200089	COMMENTS
Pressure Range	4 to 20 cmH_2O	4 to 25 cmH_2O	Subject device has a narrower pressure range. Design differences do not raise new/different questions of safety and effectiveness.
Exhaust Flow Rates	SMALL 4 cm H_2O – 18.4 LPM 8 cm H_2O – 28.0 LPM 12 cm H_2O – 36.2 LPM 16 cm H_2O – 43.1 LPM 20 cm H_2O – 49.6 LPM MEDIUM 4 cm H_2O – 22.0 LPM 8 cm H_2O – 33.8 LPM 12 cm H_2O – 43.5 LPM 16 cm H_2O – 51.8 LPM 20 cm H_2O – 59.6 LPM LARGE 4 cm H_2O – 26.2 LPM 8 cm H_2O – 39.4 LPM 12 cm H_2O – 50.4 LPM 16 cm H_2O – 59.7 LPM 20 cm H_2O – 68.6 LPM	Unavailable	Pressure – Flow curves of Exhaust flow are disclosed to the user per Clause 4 of ISO 17510. Design differences do not raise new/different questions of safety and effectiveness.
Resistance – Pressure Drop** **(cmH_2O)**	• Pressure drop through Small @50L/min = 0.4 • Pressure drop through Medium @50L/min = 0.2 • Pressure drop through Large @50L/min = 0.2 • Pressure drop through Small @ 100L/min = 1.5 • Pressure drop through Medium @100L/min = 1.0 • Pressure drop through Large @100L/min = 0.8	• Pressure drop through small 50l/min: 1.0 ± 0.1cmH2O • Pressure drop through medium 50l/min: 1.0 ± 0.1cmH2O • Pressure drop through large 50l/min: 1.0 ± 0.1cmH2O • Pressure drop through wide 50l/min: 1.0 ± 0.1cmH2O • Pressure drop through small	SIMILAR Resistance at 50 L/min and 100 L/min are disclosed to user per Clause 4 of ISO 17510. The subject device does not have a cannula/mask in a size Wide. Design differences do not raise new/different questions of safety and effectiveness.

DEVICE CHARACTERISTICS	DELTAWAVE™ Nasal Pillow System K233415	Predicate F&P EVORA™ A Model K200089	COMMENTS
		100l/min: 1.4 ± 0.25cmH2O • Pressure drop through medium 100l/min: 1.2 ± 0.25cmH2O • Pressure drop through large 100l/min: 1.2 ± 0.25cmH2O • Pressure drop through wide 100l/min: 1.3 ± 0.25cmH2O	
CO2 Rebreathing cm H2O	SIZE / Pre / Post / Difference SMALL: 2% 4% 2%; 1% 3% 2%; 0% 1% 1% MEDIUM: 0% 3% 3%; 1% 2% 1%; 0% 0% 0% LARGE: 1% -1% 0%; 0% -1% -1%; 0% -1% -1%	Unavailable	PRE values were measured with subject device prior to aging study. POST values were measured with subject devices after aging study. Relative Increase % is the difference between the Baseline measurement (ETCO2%) and the Cannula/Mask measurement (ETCO2%). Adheres to Clause 5.3.1 of ISO 17510
Sound Pressure & Power Level	A-weighted Sound Pressure 29.7 dBA (at 10 cm H20) A-weighted Sound Power Level 37.7 dBA (at 10 cm H20)	A-weighted sound pressure level of the mask is 18.8 dBA, with uncertainty of 2.5 dBA. A-weighted sound power level of the mask is 26.8 dBA, with uncertainty of 2.5 dBA.	Values disclosed to user per Clause 6 of ISO 17510 These differences do not raise different risk concerns.
Cleaning	Single patient, reusable. Hand wash in lukewarm water with mild detergent. Rinse with clear fresh water and allow to air dry out of direct sunlight. Visually	Unavailable	Cleaning method supported through validation.

DEVICE CHARACTERISTICS	DELTAWAVE™ Nasal Pillow System K233415	Predicate F&P EVORA™ A Model K200089	COMMENTS
	inspect the device for residue and rewash if necessary. Inspect for damage and replace with a new device if damage is observed.		Any differences do not raise different questions of safety or effectiveness.

9 NON-CLINICAL PERFORMANCE TESTING

Testing for DELTAWAVE™ was conducted to demonstrate the Subject Device's compliance with its pre-determined specifications and regulatory requirements. Performance and Biocompatibility testing and Validation of reprocessing claims were conducted to verify compliance with FDA Consensus Standards and Guidance documents to ensure the Subject Device is safe and substantially equivalent for its Intended Use. The DELTAWAVE Nasal Pillow System is compared to the Fisher & Paykel EVORA Model A, demonstrating Substantial Equivalence to the predicate device.

Summary of Non-Clinical Testing Performed:

1. Cleaning Validation Testing
2. Shelf-life, Storage and Transportation
3. CO2 Rebreathing
4. Dead Space
5. Pressure – Flow Curve/Leakage
6. Resistance to Flow/Pressure Drop
7. Vibration and Noise

Standards Conformance	DELTAWAVE™ Nasal Pillow System K233415	Predicate F&P EVORA™ A Model K200089
ISO 17510:2015 Sleep Apnea Breathing Therapy- Masks and Application Accessories	YES	YES
ISO 5356-1:2015 Anesthetic and respiratory equipment- Conical connectors: Part 1: Cones and sockets	YES	YES

ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	YES	YES
ISO 10993-3:2014, Biological evaluation of medical devices – Part 3: Tests for Genotoxicity Carcinogenicity and reproductive toxicity	YES	YES
ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	YES	YES
ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	YES	YES
ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic Toxicity	YES	YES
ISO 10993-17:2002, Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances	YES	YES
ISO 10993-18:2005, Biological evaluation of medical devices – Part 18: chemical characterization of materials	YES	YES
ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, Part 1: Evaluation and testing within a risk management process	YES	YES
ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, Part 2: Tests for emissions of particulate matter	YES	YES
ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications, Part 3: Tests for emissions of volatile organic compounds (VOCs)	YES	YES

10. CONCLUSION

The differences between the subject device and predicate do not raise new/different questions of safety and effectiveness. The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the device is as safe and as effective as the predicate device. The Deltawave Nasal Pillow System is substantially equivalent to the F&P EVORA Nasal Mask Model A.