January 7, 2026

RemSleep Holdings, Inc.
% Anne Dryden Siegal
QA / RA Director
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K253939
Trade/Device Name: DeltaWave Nasal Pillow System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 9, 2025
Received: December 9, 2025

Dear Anne Dryden Siegal:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.01.07 12:55:08 -05'00'

For

Rachana Visaria
Assistant Director
DHT1C: Division of Anesthesia, Respiratory, and Sleep 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K253939

Device Name
DeltaWave Nasal Pillow System

Indications for Use *(Describe)*
The DeltaWave Nasal Pillow System channels airflow noninvasively to a patient from a noninvasive positive airway pressure device (PAP) such as CPAP, bi-level.

It is intended for adult patients weighing ≥66lbs (30 Kg), and for whom positive airway pressure has been prescribed. It is intended for single patient reuse in the home and hospital/institutional/sleep center environment.

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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| | |
|---|---|
| **Date Prepared:** | January 7, 2026 |
| **Sponsor:** | RemSleep Holdings, Inc.<br>3222 Hwy 84<br>Suite 101<br>Blackshear, GA 31516 |
| **Sponsor:** | Tom Wood, CEO<br>T: 912-590-2001 |
| **Submission Correspondent:** | Anne Dryden Siegal<br>ProMedic, LLC |
| **Subject Device Trade Name:** | DeltaWave™ Nasal Pillow System |
| **Common/Usual Name:** | Nasal Mask, Mask, Cannula |
| **Classification Name:** | Ventilator, Non-Continuous (Respirator) |
| **Product Code:** | BZD |
| **Regulation Number:** | 21 CFR 868.5905 |
| **Predicate Device Trade Name:** | DeltaWave™ Nasal Pillow System |
| **Common/Usual Name:** | Nasal Mask, Mask, Cannula |
| **Classification Name:** | Ventilator, Non-Continuous (Respirator) |
| **Product Code:** | BZD |
| **Regulation Number:** | 21 CFR 868.5905 |
| **Clearance Number:** | K233415 |
| **Reference Device Trade Name:** | Respironics, Inc. DreamWear Silicone Pillows Mask |
| **Common/Usual Name:** | Nasal Mask, Mask, Cannula |
| **Classification Name:** | Ventilator, Non-Continuous (Respirator) |
| **Product Code:** | BZD |
| **Regulation Number:** | 21 CFR 868.5905 |
| **Clearance Number:** | K210844 |

**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.

**Principle of Operation**
The device provides non-invasive means of delivering positive airway pressure to the user by creating a sealed interface using nasal pillows that fit directly into the patients' nostrils.

**Indications for Use:**
The DeltaWave Nasal Pillow System channels airflow noninvasively to a patient from a noninvasive positive airway pressure device (PAP) such as CPAP, bi-level.

It is intended for adult patients weighing ≥66lbs (30 Kg), and for whom positive airway pressure has been prescribed. It is intended for single patient reuse in the home and hospital/institutional / sleep center environment.

| | |
|---|---|
| **Patient Population**: | Adult patients weighing ≥66lbs (30 Kg) |
| **Environments of use**: | Home and hospital/institutional/sleep center environment |

**Substantial Equivalence Discussion**

**Indications for Use** –
The indications for use for the subject and predicate device are similar.
**Discussion** – The indications for use was simplified and aligns with other CPAP masks.

**Technology and construction** –
The technology of the subject and predicate device are identical.
**Discussion** – There is no difference in the technology and construction between the subject and predicate device.

**Environment of Use** –
The environment of use is similar. We have expanded the patient population from single patient use in the home to single patient use in the home and hospital/institution/sleep center environment. Therefore, we have included a reference device with a similar environments of use to the subject device.
**Discussion** – The environments of use are identical to the reference device (home and hospital/institution/sleep center).

**Patient Population** –
The patient population of the subject device and predicate are identical.
**Discussion** – The patient population for both are adults weighing ≥66lbs (30 kg) who have been prescribed PAP therapy.

| | **Subject Device**<br>**RemSleep Holdings, Inc.**<br>**DeltaWave Nasal Pillow System** | **Predicate Device**<br>**RemSleep Holdings, Inc.**<br>**DeltaWave Nasal Pillow System** | **Reference Device**<br>**Respironics, Inc.**<br>**DreamWear Silicone Pillows Mask** | **Comparison** |
|---|---|---|---|---|
| **K#** | K253939 | K233415 | K210844 | |
| **Product Code** | BZD | BZD | BZD | |
| **CFR** | 21 CFR 868.5905 | 21 CFR 868.5905 | 21 CFR 868.5905 | |
| **Indications for Use** | The DeltaWave™ Nasal Pillow System channels airflow noninvasively to a patient from a noninvasive positive airway pressure device (PAP) such as CPAP, bi-level.<br><br>It is intended for adult patients weighing ≥66lbs (30 Kg), and for whom positive airway pressure has been prescribed. It is intended for single patient reuse in the home and hospital/institutional / sleep center environment. | 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.<br><br>DELTAWAVE™ Nasal Pillow System is intended for single patient reuse in the home. | The DreamWear Silicone Pillows Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients.<br><br>The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment.<br><br>The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed. | We have updated the Indications for Use statement to be clearer.<br><br>The only difference between the Subject and Predicate devices are the expanded environment of use for the Subject device.<br><br>Unlike the reference device, the Subject device is not intended for multi-patient use. |
| **Patient Population** | Adults weigh ≥66 lbs. (30kg) | Adults weigh ≥66 lbs. (30kg) | Patients weigh >66lbs (30kg) | Identical |
| **Environment of Use** | Home, Hospital/Institution / Sleep Centers | Home | Home and Hospital/Institutional environmental | Similar<br><br>We have expanded the environment use, which is similar to the reference device |
| **Availability to Patient** | Rx | Rx | Rx | Identical |
| **Mask Type** | Nasal Pillow with 2 ports fitting into the entrance of the patient's nostrils | Nasal Pillow with 2 ports fitting into the entrance of the patient's nostrils | Silicone nasal pillows cushion with tips that seal at the entrance to the nares. | Identical |
| **Exhalation Vent** | Many tiny air vents in the Cannula of the nasal pillow | Many tiny air vents in the Cannula of the nasal pillow | Exhalation ports incorporated into the front of the cushion and elbow | Identical |
| **Tubing to connect to CPAP Device** | 22mm | 22mm | 22mm | Identical |

| | **Subject Device**<br>**RemSleep Holdings, Inc.**<br>**DeltaWave Nasal Pillow System** | **Predicate Device**<br>**RemSleep Holdings, Inc.**<br>**DeltaWave Nasal Pillow System** | **Reference Device**<br>**Respironics, Inc.**<br>**DreamWear Silicone Pillows Mask** | **Comparison** |
|---|---|---|---|---|
| **Dead Space volume for nasal pillows** | 1.19 cu inch | 1.19 cu inch | S Frame<br>S Cushion – 72.8 ml<br>M Cushion – 74.0 ml<br>MW Cushion – 75.3 ml<br>L Cushion – 77.8 ml<br><br>Medium Frame<br>S Cushion – 75.8 ml<br>M Cushion – 77.0 ml<br>MW Cushion – 78.3 ml<br>L Cushion – 80.8 ml<br><br>Large Frame<br>S Cushion – 78.7 ml<br>M Cushion – 79.9 ml<br>MW Cushion – 81.2 ml<br>L Cushion – 83.7 ml | Identical |
| **Pressure Range** | 4 to 20 cm$H_2O$ | 4 to 20 cm$H_2O$ | 4 cm $H_2O$ to 30 cm $H_2O$ | Identical |
| **Exhaust Flow Rates** | 4 cm $H_2O$ – 24.5 LPM<br>8 cm $H_2O$ – 36.1 LPM<br>12cm $H_2O$ – 45.8 LPM<br>16cm $H_2O$ – 53.7 LPM<br>20 cm $H_2O$ – 61.2 LPM | 4 cm $H_2O$ – 24.5 LPM<br>8 cm $H_2O$ – 36.1 LPM<br>12cm $H_2O$ – 45.8 LPM<br>16cm $H_2O$ – 53.7 LPM<br>20 cm $H_2O$ – 61.2 LPM | Unknown | Identical |
| **Resistance – Pressure Drop** | 0.3cm H2O at 50 L/min<br>1.2 cm H2O at 100 L/min | 0.3cm H2O at 50 L/min<br>1.2 cm H2O at 100 L/min | 50 SPLM<br>S Cushion – 1.3 cm H2O<br>M Cushion – 1.19 cm H2O<br>MW Cushion – 1.02 cm H2O<br>L Cushion – 1.11 cm H2O<br><br>100 SPLM<br>S Cushion – 4.71 cm H2O<br>M Cushion – 4.29 cm H2O<br>MW Cushion – 3.7 cm H2O<br>L Cushion – 4.13 cm H2O<br><br>50 SPLM (one tube occluded)<br>S Cushion – 2.2 cm H2O<br>M Cushion – 2.1 cm H2O<br>MW Cushion – 1.94 cm H2O<br>L Cushion – 2.1 cm H2O | Identical |

| | **Subject Device**<br>**RemSleep Holdings, Inc.**<br>**DeltaWave Nasal Pillow System** | **Predicate Device**<br>**RemSleep Holdings, Inc.**<br>**DeltaWave Nasal Pillow System** | **Reference Device**<br>**Respironics, Inc.**<br>**DreamWear Silicone Pillows Mask** | **Comparison** |
|---|---|---|---|---|
| | | | 100 SPLM (one tube occluded)<br>S Cushion – 7.7 cm H2O<br>M Cushion – 7.41 cm H2O<br>MW Cushion – 6.66 cm H2O<br>L Cushion – 7.21 cm H2O | |
| **Sound Pressure & Power Level** | A-weighted Sound Pressure is 29.7 dBA (at 10 cm H2O)<br>A-weighted Sound Power Level 37.7 (at 10 cm H2O) | A-weighted Sound Pressure is 29.7 dBA (at 10 cm H2O)<br>A-weighted Sound Power Level 37.7 (at 10 cm H2O) | Measured Sound Pressure Level: 27dBA<br>Measured Sound Power Level: 19dBA | Identical |
| **Reprocessing methods** | Mild soap and water | Mild soap and water | Air path and non-air path components – Cleaning with liquid dish detergent<br><br>Air path components – High level chemical and thermal disinfection<br><br>Non-air path components thermal disinfection | Identical |
| **CO2 Rebreathing** | Results:<br>4 cm H2O -2.0%<br>5 cm H2O -2.0%<br>10 cm H2O -4.0% | Results:<br>4 cm H2O -2.0%<br>5 cm H2O -2.0%<br>10 cm H2O -4.0% | Results:<br>MW Cushion with Large Frame<br>4 cm H2O – 5.0%<br>5 cm H2O – 5.0%<br>10 cm H2O – 5.0% | The CO2 Rebreathing is consistent with ISO 17510:2015 requirements. |

**Non-Clinical Testing Summary –**

**Bench testing –**
Performance testing demonstrated that the subject device met its acceptance criteria, though no new testing was performed on the subject device. Testing on the predicate device included biocompatibility, performance and cleaning validation testing. The following is a summary of the tests performed and standards conformance:

Bench Testing

- Cleaning Validation Testing
- Shelf-life, Storage and Transportation
- CO2 Rebreathing
- Dead Space
- Pressure – Flow Curve/Leakage
- Resistance to Flow/Pressure Drop
- Vibration and Noise

Standards/Guidance Conformation

- ISO 17510:2015 Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
- ISO 10993-1: 2025 Biological evaluation of medical devices Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
- ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993−11:2017 Biological Evaluation of Medical Devices − Part 11: Tests for Systemic
- Toxicity -Acute Systemic Toxicity
- ISO 10993-17:2023 Biological evaluation of medical devices Part 17: Toxicological risk assessment of medical device constituents
- ISO 10993-18:2020 Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 18562-1: 2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
- FDA Biocompatibility Guidance - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" : Guidance for Industry and Food and Drug Administration Staff (09/08/2023)
- FDA Reprocessing Guidance - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling : Guidance for Industry and Food and Drug Administration Staff (03/17/2015)

**Discussion of Differences**

The predicate device – DeltaWave™ Nasal Pillow System - K233415 was cleared for home use only. In this new submission, the environment of use is being expanded to Home, Hospital/Institution, and Sleep Centers. There are no other changes to the subject device.

We have included a reference device –Respironics, Inc. DreamWear Silicone Pillows Mask (K210844), which has clearance for Home and Hospital/Institution environments

**Substantial Equivalence Conclusion**

The subject device is substantially equivalent to the predicate device. No new questions of safety or efficacy have been raised compared to the predicate.