August 24, 2021

Respironics, Inc.
Steve Lawrie
Senior Regulatory Affairs Engineer
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K210844
Trade/Device Name: DreamWear Silicone Pillows Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 23, 2021
Received: July 23, 2021

Dear Steve Lawrie:

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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of ENT, 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

Enclosure

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)*
K210844

Device Name
DreamWear Silicone Pillows Mask

Indications for Use *(Describe)*
The DreamWear Silicone Pillows Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

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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510(k) Summary

Date 510(k) Summary Prepared	August 24, 2021
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Contact	Steve Lawrie Senior Regulatory Affairs Engineer
Establishment Registration #	2518422
Proprietary Name	DreamWear Silicone Pillows Mask
Common/Usual Name	Nasal Mask
Classification	Class II device
Classification Panel	Anesthesiology
Classification Reference	21 CFR 868.5905
Classification Name/Product Code	Ventilator, non-continuous (respirator)/BZD
Predicate Device	TI Nasal Mask (K140980)

Device Description

The DreamWear Silicone Pillows Mask consists of a nasal pillows cushion, a silicone mask frame, an elbow with swivel and exhalation ports, headgear with arm extenders, and optional fabric sleeves. The nasal pillows cushion tips seal at the entrance to the nares. The pillows cushion base sits under the nares, and comes in four sizes (small, medium, medium wide, large).

Exhalation ports are incorporated into the mask. The built-in exhalation ports are molded into the front of the cushion as well as the top of the elbow. The mask exhalation ports for the DreamWear Silicone Pillows Mask were incorporated in both components, rather than only one of these components, to optimize diffusion, noise, comfort of breathing and CO_2 inside the mask. The exhalation openings are used to flush exhaled CO_2 out of the circuit. The fabric headgear is attached through the slots on the left and right headgear arms, which in turn are inserted into the slots on the sides of the frame to support the mask fit. The headgear can be adjusted with the hook and loop tabs. The elbow is inserted to the top of the frame.The fabric headgear goes over the top of the mask frame and around the patient's head. The headgear comes in one size and includes adjustment sliders to allow for a large or small fitting on the patient's head. Fabric sleeves (optional) are also provided to provide additional comfort if desired.

The mask design is intended to remove movement restrictions during sleep with the air inlet on the top of the head and air movement through both sides of the frame and cushion for therapy delivery to the patient's nose. The tubing frame is intentionally designed such that one side can collapse when the patient is lying on their side, while therapy is delivered to the cushion through the open side of the frame. The frame is available in three sizes (small, medium, and large) The mask was tested and verified to ensure performance is maintained according to its specifications.

The mask elbow can rotate freely through 360 degrees and has a 22mm quick disconnect swivel that is used to connect the conventional air delivery hose between the mask and pressure source. The 22mm quick disconnect swivel can also rotate freely through 360 degrees and be easily removed from the elbow.

The mask is designed in such a way that they can be easily disassembled for cleaning or replacement purposes. The mask components may be cleaned by the patient in the home (single patient use) or disinfected by the professional in the hospital/institutional environment (multi-patient use).

The key benefits of this device to the patient are:

- Ease of use
- Comfort
- Fewer movement restrictions
- Easy disassembly

Indications for Use Statement

The DreamWear Silicone Pillows Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Similarities and Differences of the Indications for Use

Like the predicate device, the TI Nasal Mask (K140980), the subject device, the DreamWear Silicone Pillows Mask, is intended to provide an interface for application of CPAP or bi-level therapy. Both masks provide a connection between the noninvasive positive pressure ventilation device and the patient wearing the mask.

Both the predicate and the subject device are to be used on patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed. CPAP or bi-level therapy treats Sleep Disordered Breathing and Respiratory Insufficiency caused by central and/or mixed apneas, periodic breathing, and intermittent ventilatory support for individuals who require mechanical ventilation.

Additionally, both the predicate and the subject device are for single patient use in the home or multi-patient use in the hospital/institutional environment.

Subject Device Compared to the Predicate Device

The subject device, the DreamWear Silicone Pillows Mask, has the following similarities to the previously cleared predicate device, Simple T Youth Nasal Mask (K140980):

- Same operating principle
- Same nasal mask design type
- Same patient population
- Same environment of use
- Same patient usage type (single patient use/multi-patient use)
- Similar performance specifications and materials

Respironics, Inc. has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the DreamWear Silicone Pillows Mask device in this submission is substantially equivalent to the predicate device.

Comparison Table of Predicate and Subject Device

Feature/Function	**Predicate Device:** TI Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140980	**Subject Device:** DreamWear Silicone Pillows Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210844	**Similarities and/or Differences**
Product Code	BZD	BZD	Unchanged from K140980.
Intended Use	The TI Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66 lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.	The Dreamwear Silicone Pillows Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66 lbs/30 kg) for whom CPAP or bi-level therapy has been prescribed.	Unchanged from K140980.
Patient Population	Patients (>66 lbs/30kg)	Patients (>66 lbs/30kg)	Unchanged from K140980.
Functional Indication	Interface for application of CPAP or bi-level therapy to patients	Interface for application of CPAP or bi-level therapy to patients	Unchanged from K140980.
Environment of Use	home or hospital/institutional environment	home or hospital/institutional environment	Unchanged from K140980.
Patient Usage Type	Single patient use or multi-patient use	Single patient use or multi-patient use	Unchanged from K140980.
Anatomical Sites	Nose	Nose	Unchanged from K140980.

510(k) Summary

Feature/Function	**Predicate Device:** TI Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140980	**Subject Device:** DreamWear Silicone Pillows Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210844	**Similarities and/or Differences**
Provided Sterile or Non-Sterile	Non-sterile	Non-sterile	Unchanged from K140980.
Pressure Range Specification	4 cm H_2O to 30 cm H_2O	4 cm H_2O to 30 cm H_2O	Unchanged from K140980.
Deadspace Volume	*Largest Cushion:* 20 ml	*S Frame* S Cushion – 72.8 ml M Cushion – 74.0 ml MW Cushion – 75.3 ml L Cushion – 77.8 ml *Medium Frame* S Cushion – 75.8 ml M Cushion – 77.0 ml MW Cushion – 78.3 ml L Cushion – 80.8 ml *Large Frame* S Cushion – 78.7 ml M Cushion – 79.9 ml MW Cushion – 81.2 ml L Cushion – 83.7 ml	There are no performance requirements for dead space volume. Measured dead space is disclosed in labelling.
Pressure Drop	*50 SPLM* 1.1 cm H_2O *100 SPLM* 3.6 cm H_2O *50 SPLM (one tube occluded* 2.1 cm H_2O	*50 SPLM* S Cushion – 1.3 cm H_2O M Cushion – 1.19 cm H_2O MW Cushion – 1.02 cm H_2O L Cushion – 1.11 cm H_2O *100 SPLM* S Cushion – 4.71 cm H_2O M Cushion – 4.29 cm H_2O MW Cushion – 3.7 cm H_2O	There are no performance requirements for pressure drop. The pressure drop for a device is disclosed in labeling consistent with the ISO

510(k) Summary

Feature/Function	**Predicate Device:** TI Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140980	**Subject Device:** DreamWear Silicone Pillows Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210844	**Similarities and/or Differences**
	100 SPLM (one tube occluded) 6.7 cm H_2O	L Cushion – 4.13 cm H_2O *50 SPLM (one tube occluded)* S Cushion – 2.2 cm H_2O M Cushion – 2.1 cm H_2O MW Cushion – 1.94 cm H_2O L Cushion – 2.1 cm H_2O *100 SPLM (one tube occluded)* S Cushion – 7.7 cm H_2O M Cushion – 7.41 cm H_2O MW Cushion – 6.66 cm H_2O L Cushion – 7.21 cm H_2O	17510:2015 requirements.
Sound Power and Pressure Level	Measured Sound Pressure Level: 25dBA Measured Sound Power Level: 18dBA	Measured Sound Pressure Level: 27dBA Measured Sound Power Level: 19dBA	There is no specification for this parameter, but values are comparable to the predicate.
Intentional Mask Leak Specification	Specification: > 13.5 SLPM @ 5 cm H_2O > 20 SLPM @ 10 cm H_2O > 25 SLPM @ 20 cm H_2O Results: Not provided in K140980	Specification: > 13.5 SLPM @ 5 cm H_2O > 20 SLPM @ 10 cm H_2O > 25 SLPM @ 20 cm H_2O Results: *5 cm H_2O* S Cushion – 18.2 SPLM M Cushion – 17.9 SPLM MW Cushion – 17 SPLM L Cushion – 17.3 SPLM	Specification unchanged from K140980. Results from the subject device have been provided.

Feature/Function	**Predicate Device:** TI Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140980	**Subject Device:** DreamWear Silicone Pillows Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210844	**Similarities and/or Differences**
		10 cm H_2O S Cushion – 27.1 SPLM M Cushion – 26.6 SPLM MW Cushion – 25.6 SPLM L Cushion – 26.3 SPLM *20 cm H_2O* S Cushion – 41 SPLM M Cushion – 40.9 SPLM MW Cushion – 39.3 SPLM L Cushion – 40.6 SPLM	
Total Mask Leak	*5 cm H_2O* 18.7 SPLM *10 cm H_2O* 27.8 SPLM *20 cm H_2O* 41.3 SPLM	*4 cm H_2O* S Cushion – 18.4 SPLM M Cushion – 18.9 SPLM MW Cushion – 19.3 SPLM L Cushion – 19.6 SPLM *5 cm H_2O* S Cushion – 21 SPLM M Cushion – 21.4 SPLM MW Cushion – 21.9 SPLM L Cushion – 22.3 SPLM *10 cm H_2O* S Cushion – 31.7 SPLM M Cushion – 32.3 SPLM MW Cushion – 33.2 SPLM L Cushion – 32.9 SPLM *20 cm H_2O* S Cushion – 48.9 SPLM M Cushion – 50.1 SPLM MW Cushion – 51.2 SPLM	There are no performance requirements for total mask leak. The measured leak rates are similar

Feature/Function	**Predicate Device:** TI Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140980	**Subject Device:** DreamWear Silicone Pillows Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210844	**Similarities and/or Differences**
		L Cushion – 49.5 SPLM *30 cm H_2O* S Cushion – 64.8 SPLM M Cushion – 66.5 SPLM MW Cushion – 67.6 SPLM L Cushion – 64.4 SPLM	
CO_2 Rebreathing ($ETCO_2$%)	Results: *Largest Cushion* 5 cm H_2O – 4.8% 10 cm H_2O – 4.7%	Results: *MW Cushion with Large Frame* 4 cm H_2O – 5.0% 5 cm H_2O – 5.0% 10 cm H_2O – 5.0%	The CO_2 Rebreathing is consistent with ISO 17510:2015 requirements.
Reprocessing Methods	Air path and non-air path components – Cleaning with liquid dish detergent Air path components – High level chemical and thermal disinfection	Air path and non-air path components – Cleaning with liquid dish detergent Air path components – High level chemical and thermal disinfection Non-air path components – thermal disinfection	Additional disinfection options were added for the subject device. These methods were validated.
Cushion Design	A silicone nasal cradle cushion that seals around the bottom of the nose. The cushion contains an exhalation port.	A silicone nasal pillows cushion with tips that seal at the entrance to the nares. The cushion contains exhalation ports	The subject device includes a different nasal cushion design that seals at the entrance to the nares.
Frame Design	The tubing frame connects to nasal cushion; Two slots	The tubing frame connects to nasal cushion; Two slots	Identical to K140980

Feature/Function	**Predicate Device:** TI Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140980	**Subject Device:** DreamWear Silicone Pillows Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210844	**Similarities and/or Differences**
	exist for insertion of headgear straps	exist for insertion of headgear straps, or headgear stabilizer arms	
Exhalation/Exhaust	No separate exhalation device is required. Exhalation is built into the elbow and nasal cushions	No separate exhalation device is required. Exhalation is built into the elbow and nasal cushions	Identical to K140980
Headgear Design	Headgear with slots to accept velcro pads on frame.	Headgear includes stabilizer arms that connect to the headgear strap and the slots on the mask frame.	The subject device includes an additional headgear option, which includes stabilizer arms that connect the headgear strap and the slots on the mask frame.
Patient Circuit Connection	22 mm swivel connector	22 mm swivel connector	Identical to K140980
Sizes	One size headgear 3 nasal cradle cushion sizes: Small, Medium, Large 1 frame size	One size headgear 4 nasal pillows cushion sizes: Small, Medium, Medium Wide, Large Three frame sizes (small, medium, large	The subject device includes an additional cushion size and frame sizes
Storage Conditions	Temperature: -4º to 140º F (-20º to +60º C) Relative Humidity: 15% to 95%	Temperature: -4º to 140º F (-20º to +60º C) Relative Humidity: 15% to 95%	Unchanged from K140980.

Non-Clinical Tests

Performance testing was performed to verify that the device modifications did not affect the safety and effectiveness of the subject device. Performance testing included:

- Resistance, derived from pressure drop (pre & post cleaning and disinfection)
- Total Mask Leak (pre & post cleaning and disinfection)
- Intentional Mask Leak
- CO_2 rebreathing
- A-weighted sound power and pressure levels
- Deadspace
- Cleaning validation
- Cleaning residuals
- Disinfection validation
- Disinfection residuals

Standards

The DreamWear Silicone Pillows Mask has been designed per the following standards:

- ISO 17510: 2015 Medical Device - Sleep Apnoea Breathing Therapy: Masks and Application Accessories
- ISO 5356-1: 2015 Anaesthetic and Respiratory Equipment – Conical Connectors: Part 1: Cones and Sockets
- ISO 10993-1: 2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing 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 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- ISO 10993-17:2002 Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
- ISO 18562-1: 2017 Biocompatibility Evaluation of Breathing Gas Pathways In Healthcare Applications – Part 1: Evaluation and Testing Within A Risk Management Process
- ISO 18562-2:2017 Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications-Part 2: Tests for Emissions of Particulate Matter
- ISO 18562-3:2017 Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications-Part 3: Tests for Emissions of Volatile Organic Compounds
- ISO 18562-4:2017 Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications-Part 4: Tests for leachables in Condensate

- ISO 17664: 2017 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 15223-1: 2016 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of the DreamWear Silicone Pillows Mask. All risks have been sufficiently mitigated and product functionality has been adequately assessed by non-clinical tests.

Conclusion

The performance and technological characteristics of the DreamWear Silicone Pillows Mask are substantially equivalent to those of the TI Nasal Mask (K140980). The differences described above do not raise new questions of safety and effectiveness.