July 12, 2021

Respironics, Inc.
Anna Danley
Senior Regulatory Affairs Engineer
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K210386
Trade/Device Name: Magneto Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: June 3, 2021
Received: June 3, 2021

Dear Anna Danley:

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)*
K210386

Device Name
Magneto Nasal Mask

Indications for Use *(Describe)*
This 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 and multi-patient use in the hospital/institutional environment. The mask is to be used on patients > 7 years old (>40 lbs) 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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Date 510(k) Summary Prepared	July 9, 2021
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Contact	Anna Danley Senior Regulatory Affairs Engineer P: (412)-542-3513 E: anna.danley@philips.com
Establishment Registration #	2518422
Proprietary Name	Magneto Nasal 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	Simple T Youth Nasal Mask (K140268)

Device Description

The Magneto Nasal Mask includes two cushion type options: a nasal, cradle cushion and nasal, pillows cushion. The nasal cradle cushion seals around the bottom of the patient's nose, and comes in five sizes (extra small, small, medium, medium wide, large). The nasal pillows cushion tips seal at the entrance to the nares. The pillows cushion base sits under the nares, and comes in five sizes (extra small, small, medium, medium wide, large). Both of the cushion design options contain enclosed magnets.

The mask frame also contains enclosed magnets, and connects to the mask cushion magnetically for easy and secure assembly/disassembly by the user. The mask frame comes in one size and connects to the tubing with a snap fit, which allows the user to keep the frame attached to the tubing.

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.

The mask includes 10 mm tubing. The 10 mm tubing contains built-in exhalation at the top of the tube where the tubing connects to the mask frame. The tubing also includes an ISO 5356-1 compliant, 22 mm male conical swivel. The tubing swivel connects directly to ISO 5356-1 compliant, 22 mm female connections used on therapy device tubing. The tubing swivel detaches from the mask tubing, via a quick disconnect feature. The tubing connects to 12 mm connections when the tubing swivel is detached.

The key benefits of this device to the patient are:

- Ease of use
- Secure magnetic cushion and frame fitting
- Comfort
- Choice through two nasal cushion options
- User appeal and non-intimidating design

Indications for Use Statement

This 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 and multi-patient use in the hospital/institutional environment. The mask is to be used on patients > 7 years old (> 40 lbs) for whom CPAP or bi-level therapy has been prescribed.

Similarities and Differences of the Indications for Use

Like the predicate device, Simple T Youth Nasal Mask (K140268), the subject device, the Magneto Nasal 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 > 7 years old (> 40 lbs) 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 Magneto Nasal Mask, has the following similarities to the previously cleared predicate device, Simple T Youth Nasal Mask (K140268):

- 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)

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

Comparison Table of Predicate and Subject Device

Feature/Function	**Predicate Device:** Simple T Youth Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140268	**Subject Device:** Magneto Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210386	**Similarities and/or Differences**
Product Code	BZD	BZD	Unchanged from K140268.
Intended Use	The Simple T Youth 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 by patients 7 years or older (>40lbs) for	This 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 and multi-patient use in the hospital/institutional environment. The mask is to be used on patients > 7	Unchanged from K140268.

Feature/Function	**Predicate Device:** Simple T Youth Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140268	**Subject Device:** Magneto Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210386	**Similarities and/or Differences**
	whom CPAP or bi-level therapy has been prescribed.	years old (> 40 lbs) for whom CPAP or bi-level therapy has been prescribed.	
Patient Population	Patients 7 years or older (>40 lbs)	Patients >7 years (>40 lbs)	Unchanged from K140268.
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 K140268.
Environment of Use	home or hospital/institutional environment	home or hospital/institutional environment	Unchanged from K140268.
Patient Usage Type	Single patient use or multi-patient use	Single patient use or multi-patient use	Unchanged from K140268.
Anatomical Sites	Nose	Nose	Unchanged from K140268.
Provided Sterile or Non-Sterile	Non-sterile	Non-sterile	Unchanged from K140268.
Pressure Range Specification	4 cm H_2O to 30 cm H_2O	4 cm H_2O to 30 cm H_2O	Unchanged from K140268.
Deadspace Volume	Small size – 37.4 ml Medium size – 48.7 ml Large size – 72.8 ml	*Nasal Cradle Cushion:* Extra small size – 13.6 ml Small size – 17.9 ml Medium size – 18.5 ml Medium wide size – 16.9 ml Large size – 23.7 ml *Nasal Pillows Cushion:* Extra small size – 11.4 ml	The deadspace values of the subject device are lower than the predicate device.

Feature/Function	**Predicate Device:** Simple T Youth Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140268	**Subject Device:** Magneto Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210386	**Similarities and/or Differences**
		Small size – 11.6 ml Medium size – 12.0 ml Medium wide size – 13.0 ml Large size – 12.4 ml	
Pressure Drop	0.8 cm H_2O @ 50 SLPM * 3.1 cm H_2O @ 100 SLPM	*Nasal Cradle Cushion:* Extra small size – 1.7 cm H_2O @ 50 SLPM 6.3 cm H_2O @ 100 SLPM Small size – 1.5 cm H_2O @ 50 SLPM 6.5 cm H_2O @ 100 SLPM Medium size – 1.4 cm H_2O @ 50 SLPM 6.1 cm H_2O @ 100 SLPM Medium wide size – 1.6 cm H_2O @ 50 SLPM 6.1 cm H_2O @ 100 SLPM Large size – 1.5 cm H_2O @ 50 SLPM 5.3 cm H_2O @ 100 SLPM *Nasal Pillows Cushion:* Extra small size – 1.9 cm H_2O @ 50 SLPM 7.5 cm H_2O @ 100 SLPM Small size – 2.0 cm H_2O @ 50 SLPM 7.2 cm H_2O @ 100 SLPM	The pressure drop values of the subject device are different to the predicate device. There are no performance requirements for pressure drop. The pressure drop for a device is disclosed in labeling consistent with ISO 17510:2015 requirements.

Feature/Function	**Predicate Device:** Simple T Youth Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140268	**Subject Device:** Magneto Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210386	**Similarities and/or Differences**
		Medium size – 1.5 cm H_2O @ 50 SLPM 6.1 cm H_2O @ 100 SLPM Medium wide size – 1.6 cm H_2O @ 50 SLPM 6.3 cm H_2O @ 100 SLPM Large size – 1.8 cm H_2O @ 50 SLPM 6.8 cm H_2O @ 100 SLPM	
Sound Power and Pressure Level	A-weighted Sound Power Level – 26.5 dBA A-weighted Sound Pressure Level – 18.5 dBA	A-weighted Sound Power Level – 28 dBA A-weighted Sound Pressure Level – 20 dBA	The sound levels of the subject device are different from the predicate device but do not raise different questions of safety and effectiveness. The sound levels are disclosed in labeling consistent with ISO 17510:2015 requirements.
Total Mask Leak	19.8 SLPM @ 5 cm H_2O 29.5 SLPM @ 10 cm H_2O 43.6 SLPM @ 20 cm H_2O	9.2 SLPM @ 4 cm H_2O 10.8 SLPM @ 5 cm H_2O 17.2 SLPM @ 10 cm H_2O 26.7 SLPM @ 20 cm H_2O 34.6 SLPM @ 30 cm H_2O	The total mask leak values are lower than the predicate device.

Feature/Function	**Predicate Device:** Simple T Youth Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140268	**Subject Device:** Magneto Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K210386	**Similarities and/or Differences**
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 – Low level chemical and thermal disinfection	Additional disinfection options were added for the subject device. These methods were validated.
Mask Weight	No mask weight stated	XS Pillow Mask 37.3 g S Pillow Mask 37.4 g M Pillow Mask 37.6 g MW Pillow Mask 37.7 g L Pillow Mask 37.8 g XS Cradle Mask 39.3 g S Cradle Mask 40.8 g M Cradle Mask 41.6 g MW Cradle Mask 40.9 g L Cradle Mask 43.1 g	No mask weight was provided for the predicate device.
Exhalation/Exhaust	Built-in exhalation through the mask elbow	Built-in exhalation through the mask tubing	The subject device includes exhalation in the mask tubing instead of a separate elbow with built-in exhalation.
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 K140268.

**SLPM is Standard Liters Per Minute. SLPM is a unit of volumetric flow rate of a gas at standard conditions for temperature and pressure (STP)*

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)
- CO_2 rebreathing
- A-weighted sound power and pressure levels
- Deadspace
- Magnetic strength
- Cleaning validation
- Cleaning residuals
- Disinfection validation
- Disinfection residuals

Standards

The Magneto Nasal 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 14971: 2019 Medical devices – Application of risk management to medical devices
- 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 Magneto Nasal 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 Magneto Nasal Mask are substantially equivalent to those of the Simple T Youth Nasal Mask (K140268). The differences described above do not raise new questions of safety and effectiveness.