28 July 2023

Respironics Inc.
Shipra Gulati
Principal Regulatory Affairs Engineer
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K231313
Trade/Device Name: Therapy Mask 3100 NC/SP
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: June 30, 2023
Received: June 30, 2023

Dear Shipra Gulati:

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 -S

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

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)*
K231313

Device Name
Therapy Mask 3100 NC/SP

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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510(k) Summary

Date 510(k) Summary Prepared	July 27, 2023
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Contact	Shipra Gulati Principal Regulatory Affairs Engineer P: 617.650.7502 E: SRC.RA.Dept@philips.com
Establishment Registration #	2518422
Proprietary Name	Therapy Mask 3100 NC/SP
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	Therapy Mask 3100 NC/SP (K210386)

510(k) Summary

Device Description

The Therapy Mask 3100 NC/SP consists of a minimal contact nasal mask cushion (NC: nasal cushion/SP: silicone pillows cushion), a two-point headgear, and a mask frame with exhalation port. The mask frame contains enclosed magnets and connects to the nasal mask cushion (NC/SP) magnetically for easy and secure assembly/disassembly by the user. The nasal mask cushion enclosed magnets and the mask frame enclosed magnets are of opposite polarity to prevent incorrect assembly of the mask. The Therapy Mask 3100 NC/SP has a pig tail tube in front mask.

The nasal cushion seals around the bottom of the patient's nose. Nasal cushion (NC) has five sizes: extra small (XS), small (S), medium (M), medium wide (MW), and large (L). The silicone pillows cushion tips seal at the entrance to the nares and the pillows cushion base sits under the nares. The silicone pillows cushion (SP) has five sizes: extra small (XS), small (S), medium (M), medium wide (MW), large (L). The headgear has one size and includes adjustment sliders to allow for a large or small fitting on the patient's head. The mask frame is one size and connects to the pig tail tubing. The mask frame connects to the mask cushion magnetically for easy and secure assembly/disassembly by the user.

The Therapy Mask 3100 NC/SP has a 10 mm pig tail tube in front mask. The 10 mm pig tail tubing contains built-in exhalation at the top of the tube where the pig tail tubing connects to the mask frame. The pig tail tubing will also include an ISO 5356-1 compliant, 22 mm male conical swivel connector. The male conical swivel connector will connect directly to ISO 5356-1 compliant, 22 mm female connector used on therapy device tubing. The male conical swivel connector is detachable from the pig tail tubing, via a quick disconnect feature. When the male conical swivel connector is detached, the pig tail tubing connects to 12 mm therapy device tubing directly.

The Therapy Mask 3100 NC/SP is designed to be easily disassembled for cleaning or replacement purposes. The components may be cleaned by the patient in the home (single patient – multiple use) or cleaned and disinfected by the professional in the hospital/institutional environment (multiple patient – multiple use).

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.

Subject Device Compared to the Predicate Device

The subject device, the Therapy Mask 3100 NC/SP, has the following similarities to the previously cleared predicate device, Therapy Mask 3100 NC/SP (K210386):

- 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 Therapy Mask 3100 NC/SP device in this submission is substantially equivalent to the predicate device.

510(k) Summary

Comparison Table of Predicate and Subject Device

Feature / Function	Predicate Device: Magneto Nasal Mask(K210386)	Subject Device: Therapy Mask 3100 NC/SP (K231313)	Similarities and/or Differences
Product Code	BZD	BZD	Same
Intended Use	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.	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.	Same
Indications for use	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.	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.	Same

510(k) Summary

Feature / Function	**Predicate Device:** Magneto Nasal Mask(K210386)	**Subject Device:** Therapy Mask 3100 NC/SP (K231313)	**Similarities and/or Differences**
Contraindications	Use of this mask is contraindicated in patients with the following metallic implants: brain shunts, aneurysm clips, splinters in the eyes, and certain neurostimulators used in and around the head and neck.	Use of the mask is contraindicated for patients and their household members, caregivers, and bed partners that may be in close vicinity to patients using the masks, that have implanted devices that may be affected by magnets, including but not limited to: • Pacemakers • Implantable cardioverter defibrillators (ICD) • Neurostimulators • Magnetic metallic implants/electrodes/valves placed in upper limbs, torso, or higher (i.e., neck and head) • Cerebral spinal fluid (CSF) shunts (e.g., ventriculo peritoneal (VP) shunt) • Aneurysm clips • Embolic coils • Intracranial aneurysm intravascular flow disruption devices • Metallic cranial plates, screws, burr hole covers, and bone substitute devices • Metallic splinters in the eye • Ocular implants (e.g., glaucoma implants, retinal implants) • Certain contact lenses with metal • Implants to restore hearing or balance that have an implanted magnet (such as cochlear implants, implanted bone conduction hearing devices, and auditory brainstem implants) • Magnetic denture attachments • Metallic gastrointestinal clips • Metallic stents (e.g., aneurysm, coronary, tracheobronchial, biliary) • Implantable ports and pumps (e.g., insulin pumps)	The updated contraindications provide a more detailed list of covered user groups and now includes other possible impacted populations (e.g., household members, caregivers, and bed partners) that may be in close vicinity to patients that use the masks.

510(k) Summary

Feature / Function	Predicate Device: Magneto Nasal Mask(K210386)	Subject Device: Therapy Mask 3100 NC/SP (K231313)	Similarities and/or Differences
		• Hypoglossal nerve stimulators • Devices labeled as MR (Magnetic Resonance) unsafe • Magnetic metallic implants not labeled for MR or not evaluated for safety in a magnetic field	
Additional Labeling update	Current warning Magnets are used in the mask. The magnetic field strength is 400 mT. Ensure the mask is kept at least 2 inches (5 cm) away from any active medical implant or medical device that can be impacted by the magnetic field (e.g., pacemaker, defibrillators, neurostimulators, cochlear implants, hearing aids) to avoid possible effects from localized magnetic fields.	Updated Warning Magnets with a magnetic field strength of 400 mT are used in the mask. With the exception of the devices identified in the contraindication, ensure the mask is kept at least 6 inches (approx. 15.24 cm) away from any other medical implants or medical devices that can be impacted by the magnetic fields to avoid possible effects from localized magnetic fields. This includes household members, caregivers, and bed partners that may be in close vicinity to patients that use the masks.	The updated warning extended the mask use distance to avoid possible effects from localized magnetic fields. This extended mask use distance will enhance the patient safety when using the masks that contain magnets. The updated warning includes possible impacted populations (e.g., household members, caregivers, and bed partners) that may be in close vicinity to patients that use the masks.
Patient Population	Patients >7 years (>40 lbs)	Patients >7 years (>40 lbs)	Same
Functional Indication	Interface for application of CPAP or bi-level therapy to patients	Interface for application of CPAP or bi-level therapy to patients	Same
Environment of Use	home or hospital/institutional environment	home or hospital/institutional environment	Same
Patient Usage Type	Single patient use or multi-patient use	Single patient use or multi-patient use	Same
Anatomical Sites	Nose	Nose	Same
Provided Sterile or Non-Sterile	Non-sterile	Non-sterile	Same
Pressure Range Specification	4 cm H_2O to 30 cm H_2O	4 cm H_2O to 30 cm H_2O	Same

510(k) Summary

Feature / Function	**Predicate Device:** Magneto Nasal Mask(K210386)	**Subject Device:** Therapy Mask 3100 NC/SP (K231313)	**Similarities and/or Differences**
Deadspace Volume	*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 Small size – 11.6 ml Medium size – 12.0 ml Medium wide size – 13.0 ml Large size – 12.4 ml	*Under the nose nasal cushion size:* 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 Silicone Pillows Cushion: Extra small size – 11.4 ml Small size – 11.6 ml Medium size – 12.0 ml Medium wide size – 13.0 ml Large size – 12.4 ml	Same **Note**: Nasal Pillows Cushion has been re-named as Silicone Pillows Cushion to better differentiate between product lines. There is no change in design, materials, or use.
Pressure Drop	*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 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	*Under the nose nasal cushion size:* 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 *Silicone 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 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	Same **Note**: Nasal Pillows Cushion has been re-named as Silicone Pillows Cushion to differentiate between product lines. There is no change in design, materials, or use.
Sound Power and Pressure Level	A-weighted Sound Power Level – 28 dBA A-weighted Sound Pressure Level @1m: – 20 dBA	A-weighted Sound Power Level – 28 dBA A-weighted Sound Pressure Level @1m: – 20 dBA	Same

510(k) Summary

Feature / Function	**Predicate Device:** Magneto Nasal Mask(K210386)	**Subject Device:** Therapy Mask 3100 NC/SP (K231313)	**Similarities and/or Differences**
Total Mask Leak	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	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	Same
Reprocessing Methods	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	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	Same
Mask Weight	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	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	Same
Exhalation/Exhaust	Built-in exhalation through the mask tubing	Built-in exhalation through the mask tubing	Same
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%	Same

Note: 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 and/ or Clinical tests

No non-clinical and/or clinical tests summaries are submitted with this CBE submission. These labeling changes do not affect the product performance related to design outputs or specifications; therefore, additional design validation of product performance requirements was not required to implement this change.

Standards

The Therapy Mask 3100 NC/SP 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: 2021 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements

Conclusion

The performance and technological characteristics of the Therapy Mask 3100 NC/SP (K231313) are substantially equivalent to those of the Therapy Mask 3100 NC/SP (K210386). The differences described above do not raise new questions of safety and effectiveness.