DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 15, 2016

Respironics, Inc.
Shaylee Masilunas
Regulatory Affairs Engineer
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K151120
Trade/Device Name: Simple T Pediatric Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: March 2, 2015
Received: March 4, 2015

Dear Ms. Masilunas:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Division of Anesthesiology,
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Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Simple T Pediatric Nasal Mask

Indications for Use *(Describe)*
This mask is intended to provide an interface for application of non-invasive ventilation 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 greater than 10 kg/22 lbs (>10 kg/22 lbs) for whom non-invasive ventilation has been prescribed. Use of this mask is limited by the indications for use of the compatible therapy device with respect to patient weight.

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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TAB 6

510(K) SUMMARY

510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Contact	Shaylee Masilunas Regulatory Affairs Engineer, Patient Interface
Establishment Registration #	2518422
Proprietary Name	Simple T Pediatric Nasal Mask
Common/Usual Name	Nasal Mask
Classification Name / Product Code	21 CFR 868.5905, Product Code BZD – Ventilator, non-continuous (respirator)
Predicate Device(s)	Respironics Simple T Youth Nasal Mask (K140268) Respironics Profile Lite Small Child (K093416)
Reference Device	Respironics Trilogy 200 (K093416)

Indications for Use

This mask is intended to provide an interface for application of non-invasive ventilation 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 greater than 10 kg/22 lbs (>10 kg/22 lbs) for whom non-invasive ventilation has been prescribed. Use of this mask is limited by the indications for use of the compatible therapy device with respect to patient weight.

Device Description

The Simple T Pediatric Nasal Mask is intended to be used with positive airway pressure devices. For use of this mask with a CPAP therapy device, the patient population is limited by the intended use of the device (e.g. > 30 kg). In other words, this mask can be used with a variety of therapy devices which may have their own limitations on patient population. If the therapy device itself is limited to patients

greater than 10 kg (e.g. 30 kg), then the use of this mask does not expand the intended use of that therapy device.

The mask provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose. It is held in place with a fabric frame and an adjustable headgear. The cushion contains an adjustment dial that can be engaged to reduce minor leaks around the nose. The mask may be cleaned in the home (single-patient use) or reprocessed by the professional in the hospital/institutional environment through high-level disinfection processes (multi-patient use).

Substantial Equivalence

The Simple T Pediatric Nasal Mask has the following similarities to the previously cleared predicate devices Respironics Simple T Youth Nasal Mask (K140268) and Respironics Profile Lite Small Child mask (K093416):

- Same operating principle
- Similar intended use
- Similar materials
- Similar design
- Similar manufacturing process

The following modifications have been made to the previously cleared predicate devices Respironics Simple T Youth Nasal Mask (K140268) and Respironics Profile Lite Small Child mask (K093416) for the Simple T Pediatric Nasal Mask:

- The intended use population was modified to include patients greater than 10kg/22lbs
- An existing warning was converted to a contraindication to align with the definition of a contraindication. The language of that statement was revised to reflect standardized terminology.
- The mask components were modified for sizing. The cushion was modified to include a leak adjustment dial.

Table 1 – Technological characteristics comparison of the Simple T Pediatric Nasal Mask and its predicate devices

	Primary Predicate: **Device:** Simple T Youth K140268 **Manufacturer:** Respironics, Inc.	**Secondary Predicate:** **Device:** Profile Lite Small Child K093416 **Manufacturer:** Respironics, Inc.	**Subject Device:** **Device:** Simple T Pediatric Nasal Mask **Manufacturer:** Respironics, Inc.
Intended Use	The Simple T Youth Nasal Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy.	The Small Child Profile Lite Nasal Mask and Softcap are intended to provide an interface when used with CPAP or bi-level therapy.	This mask is intended to provide an interface for application of non-invasive ventilation to patients.
Patient Population	Patients 7 years or older (>40 lbs/18kg)	Profile Lite Small Child Mask: Patients 1 year or older (>7 kg) Trilogy 200 Ventilator: Patients at least 5kg/11lbs	Patients greater than 10kg/22lbs (>10kg/22lbs)
Environment of Use	Home or Hospital/ Institutional Environment	Home or Hospital/ Institutional Environment	Unchanged from K140268, K093416
Patient Usage Type	Single patient reuse or multi-patient use	Single Patient Use	Unchanged from K140268
Provided Sterile or Non-Sterile	Non-Sterile	Non-Sterile	Unchanged from K140268, K093416
Anatomical Sites	Nose	Nose	Unchanged from K140268, K093416
Device Design	1. Nasal cushion 2. Frame 3. Elbow with built-in exhalation device 4. Tubing with 15mm to 22mm swivel connector 5. Headgear	1. Nasal cushion 2. Faceplate 3. Elbow with built-in exhalation device 4. Tubing with 15mm to 22mm swivel connector. 5. Headgear	Unchanged from K140268 1. Nasal Cushion with Dial 2. Frame 3. Elbow with built-in exhalation device 4. Tubing with 15 mm to 22 mm swivel connector. 5. Headgear
Cushion	Silicone sealing cushion that fits around the nose.	Encapsulated gel cushion that fits around the nose.	Similar to K140268 The cushion contains an adjustment dial.
Cushion Sizes	3 sizes	1 size	2 sizes
Frame Design	The frame stabilizes the cushion on the nose and allows clearance of facial features. Four slots exist for insertion of headgear tabs.	The faceplate and forehead arm secure the cushion to the face. Four slots exist for insertion of headgear tabs.	Unchanged from K140268
Exhalation device design	No separate exhalation device is required. 18 exhalation ports are integrated.	No separate exhalation device is required. Two exhalation ports are integrated.	Unchanged from K140268
Tubing	15 mm tubing	15 to 22 mm tubing	Unchanged from K140268

	Primary Predicate: **Device:** Simple T Youth K140268 **Manufacturer:** Respironics, Inc.	**Secondary Predicate:** **Device:** Profile Lite Small Child K093416 **Manufacturer:** Respironics, Inc.	**Subject Device:** **Device:** Simple T Pediatric Nasal Mask **Manufacturer:** Respironics, Inc.
General headgear design	Four point headgear with hook and loop tabs for attaching to frame.	Four point bonnet with hook and loop tabs for attaching to frame.	Unchanged from K140268
Patient Circuit Connection	22 mm swivel connector	22 mm swivel connector	Unchanged from K140268 and K093416

Table 2 – Material comparison for the Simple T Pediatric Nasal Mask and its predicate devices

Component	**Primary Predicate:** **Device:** Simple T Youth K140268 **Manufacturer:** Respironics, Inc.	**Secondary Predicate:** **Device:** Profile Lite Small Child K093416 **Manufacturer:** Respironics, Inc.	**Subject Device:** **Device:** Simple T Pediatric Nasal Mask **Manufacturer:** Respironics, Inc.
Cushion	Silicone	Gel encapsulated in urethane	Silicone
Frame	Polyurethane Foam, Nylon	Polycarbonate	Polyurethane Foam, Nylon
Elbow and Swivel	Polycarbonate	Polycarbonate	Polycarbonate
Tubing	Thermoplastic Elastomer	Ethylene Vinyl Acetate	Thermoplastic Elastomer
Headgear	Polyurethane Foam, Nylon/Spandex	Nylon and Lycra	Polyurethane Foam, Nylon/Spandex

Design verification tests were performed on the Simple T Pediatric Nasal Mask. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

Non-Clinical Tests

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

- Intentional Leak
- Total Mask Leak
- Mask Deadspace
- Pressure Drop
- CO_2 Rebreathing
- Performance Post Cleaning, Disinfection and Sterilization
- Cleaning and Disinfection Validation Testing
- Storage

The Simple T Pediatric Nasal Mask has been designed to meet the requirements of the following standards:

- ISO 17510-2 Sleep Apnoea Devices Part 2: Masks and Application Accessories
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 14971 Medical devices – Application of risk management to medical devices

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of the Simple T Pediatric Nasal Mask. Product functionality has been adequately assessed by non-clinical tests.

Conclusion

The performance and technological characteristics of the Simple T Pediatric Nasal Mask are substantially equivalent to those of the Simple T Youth Nasal Mask (K140268) and the Profile Lite Small Child (K093416). The differences described above do not raise new questions of safety and effectiveness.