DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 10, 2015

Respironics, Inc.
Shaylee Masilunas
Regulatory Affairs Engineer
1001 Murray Ridge Lane
Murrysville, PA 15668

Re: K140980
Trade/Device Name: TI Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB).
Regulatory Class: II
Product Code: BZD
Dated: February 6, 2015
Received: February 9, 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" (21CFR 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.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140980

Device Name
Respironics TI Nasal Mask

Indications for Use *(Describe)*
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 (>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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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TAB 5

510(K) SUMMARY

Date of Submission	10 February 2015
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Official Contact	Shaylee Masilunas Regulatory Affairs Engineer, Patient Interface
Proprietary Name	TI 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 Kangaroo Nasal Mask (K122847) Respironics Simple T Nasal Mask (K121631) Innomed Technologies Nasal Aire II (K022465)

Indications for 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 (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Device Description

The Respironics TI Nasal Mask is intended to be used with positive airway pressure devices such as CPAP or bi-level systems. 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 an adjustable headgear. It may be

cleaned by the patient in the home (single-patient use) or cleaned by the professional in the hospital/institutional environment through high-level disinfection processes (multi-patient use).

The TI mask's cushion consists of a silicone nasal cushion designed to seal around the patient's nostrils. The silicone mask frame supports the cushion by connecting to the lateral ends of the cushion and resting along the sides of the patient's face up to the crown of the head. The fabric headgear is attached through the slots on the side of the frame to support the mask fit. The elbow is inserted into the opening in the frame.

The 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 is designed in such a way that it can also rotate freely through 360 degrees and be easily removed from the elbow.

Substantial Equivalence

The Respironics TI Nasal Mask has the following similarities to the previously cleared predicate devices Respironics Kangaroo Nasal Mask (K122847), Respironics Simple T Nasal Mask (K121631), and Innomed Technologies Nasal Aire II (K022465):

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

Table 1 – Material comparison for the Respironics TI Nasal Mask and its predicate devices

Component	**Primary Predicate:** **Device:** Kangaroo Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K122847	**Secondary Predicate:** **Device:** Simple T Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K121631	**Additional Predicate:** **Device:** Nasal Aire II **Manufacturer:** Innomed Technologies, Inc. **510(k) Number:** K022465	**Subject Device:** **Device:** TI Nasal Mask **Manufacturer:** Respironics, Inc. **510(k) Number:** K140980
Cushion	Silicone	Silicone	Information not available	Silicone and Polycarbonate
Frame	Nylon/Spandex	Nylon/Spandex		Silicone and Polycarbonate
Elbow and Elbow Swivel	Polycarbonate	Polycarbonate		Polycarbonate
Quick-Disconnect Swivel	N/A	N/A		Polycarbonate
Headgear	Polyurethane Foam, Nylon/Spandex	Nylon/Spandex		Polyurethane Foam, Nylon/Spandex

The TI Nasal Mask has the following differences in the technological characteristics to the previously cleared predicate devices Respironics Kangaroo Nasal Mask (K122847), Respironics Simple T Nasal Mask (K121631), and Nasal Aire II (K022465):

- Cushion design modified
- Frame and headgear design modified
- Built-in exhalation modified
- Patient circuit connection modified

Design verification tests were performed on the Respironics TI Nasal Mask as a result of the risk analysis and product requirements. 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

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

- Intentional Leak
- Total Leak
- Deadspace Volume
- Pressure Drop
- CO_2 Rebreathing
- Cleaning and Disinfection Efficacy
- Storage

The TI 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 Respironics TI Nasal Mask. Product functionality has been adequately assessed by non-clinical tests.

Conclusion

The Respironics TI Nasal Mask has passed all of the aforementioned non-clinical tests and required no clinical tests in order to demonstrate safety or effectiveness. The Respironics TI Nasal Mask is substantially equivalent to the predicate devices.