DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Respironics, Inc.
Alexander L. Friedman, Ph.D.
Senior Regulatory Engineer
1740 Golden Mile Highway
Monroeville, PA 15416

Re: K140424
Trade/Device Name: Philips Respironics Reusable Heated Tubing
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: II
Product Code: BZE
Dated: October 20, 2014
Received: October 21, 2014

Dear Dr. Friedman:

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

Section 4 Indications for Use

Indications for Use

510(k) Number (if known): K140424

Device Name: Philips Respironics Reusable Heated Tubing

The Philips Respironics Reusable Heated Tubing is a heated wire breathing tube intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. It is indicated for single-patient reuse in the home and multi-patient use in clinical settings, such as hospitals, institutions, sleep laboratories, and sub-acute care facilities. It may be used with non-invasive ventilation for patients weighing over 10 kg (22lbs). It is compatible with the Philips Respironics System One Heated Humidifier and Philips Respironics A-Series System One Heated Humidifier.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Date of Submission	18 February 2014
Date of Preparation	14 November 2014
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-5311 (724) 387-3999 (fax)
Official Contact	Alexander L. Friedman, Ph.D. Senior Regulatory Affairs Engineer Sleep & Diagnostics Business Unit
Proprietary Name	Philips Respironics Reusable Heated Tubing
Common/Usual Name	Heated Breathing Tube
Classification	Class II
Classification Name / Product Code	BZE – Breathing system, heater
Regulation Number	868.5270
Predicate Device(s)	Respironics Disposable Heated Wire Circuits (K110398)

Intended Use:

The Philips Respironics Reusable Heated Tubing is a heated wire breathing tube intended to provide warmed and/or humidified breathing gases before they enter a patient's airway. It is indicated for single-patient reuse in the home and multi-patient use in clinical settings, such as hospitals, institutions, sleep laboratories, and sub-acute care facilities. It may be used with non-invasive ventilation for patients weighing over 10 kg (22lbs). It is compatible with the Philips Respironics System One Heated Humidifier and Philips Respironics A-Series System One Heated Humidifier.

Device Description:

The Philips Respironics Reusable Heated Tubing warms air, or breathable gas, as it travels to and from the respiratory patient along the breathing circuit of a respiratory system. It reduces condensation that can form in breathing circuit. The Philips Respironics Reusable Heated

Tubing is disinfected between patients through one of the following chemical methods: Cidex, or Cidex OPA. It is alternatively disinfected through the following thermal method: 75 °C for 30 minutes.

The Philips Respironics Reusable Heated Tubing has a proprietary connector with two locking tabs (unchanged) that makes it compatible with the Philips Respironics System One Humidifier (K113068) and Philips Respironics A-Series System One Heated Humidifier (K121623).

Summary of Technological Characteristics of Device Compared to the Predicate Devices

The Philips Respironics Reusable Heated Tubing has the following similarities in the technological characteristics to the previously cleared predicate device, Respironics Disposable Heated Wire Circuits (K110398):

- Same operating principle
- Same scientific concepts that form the basis for the device
- Same technology
- Similar materials used
- Similar device design and physical properties

The Philips Respironics Reusable Heated Tubing has the following differences in the technological characteristics to the previously cleared device (K110398):

- The device may be used by multiple patients

Summary of Non-Clinical Performance Data

The Philips Respironics Reusable Heated Tubing was tested and meets all applicable requirements of the following standards:

- ISO 8185, edition 3, Humidifiers for Medical Use - General Requirements for Humidification Systems
- IEC 60601-1, edition 3, Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2, edition 2.1, Medical electrical equipment, Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility – Requirements and tests

All patient contacting and gas path materials used in the device have been previously cleared by the FDA. The modification of the present device was adding the ability to reuse the device between patients. Extensive performance testing was performed pre and post cleaning and disinfection treatments to demonstrate performance and functionality was unaffected as a result of these changes. The post disinfection performance testing included mechanical testing, electrical testing, and temperature accuracy under environmentally controlled conditions. These

include electrical continuity, visual inspection, microscopic inspection of connectors, temperature control and humidity control.

The device will be released for distribution after testing for the following, under worst case conditions, with passing results: cleaning efficacy, disinfection efficacy and removal of disinfectant residue. Cleaning efficacy and disinfection efficacy testing will be performed in accordance with AAMI TIR No.12-2010, AAMI TIR No. 30-2011, ASTM E1837-96 (2007), and the "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants" – FDA CDRH, January 3, 2000. Removal of disinfectant residue testing will be performed in accordance with ISO 10993 Part 5: Tests for in vitro cytotoxicity, or ISO 10993 Part 17: Establishment of allowable limits for leachable substances

Assessment of Non-Clinical Performance Data

The performance testing demonstrates that the subject device, Philips Respironics Reusable Heated Tubing is substantially equivalent to as the predicate device, Respironics Disposable Tubing.

Clinical Data

Use of heated tubing on respiratory systems is a proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the Philips Respironics Reusable Heated Tubing, as was the case with the predicate device.

Conclusions

Conclusions drawn from the passing nonclinical tests (discussed above) demonstrate that the device is as safe, as effective, and performs as safe and as effective as the predicate device, and is substantially equivalent to the predicate device.