DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 9, 2015

Respironics, Inc.
Ms. Amy Macevoy
Senior Regulatory Affairs Engineer, PI
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K142554
Trade/Device Name: Shimmer Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 8, 2014
Received: December 8, 2014

Dear Ms. Macevoy:

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 5: Indications for Use Statement

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)*

K142554

Device Name

Shimmer Full Face 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 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-5306 (724) 387-3999 (fax)
Official Contact	Amy Macevoy Sr. Regulatory Affairs Engineer
Establishment Registration #	2518422
Proprietary Name	Shimmer Full Face Mask
Common/Usual Name	Mask Accessory to a Non-Continuous Ventilator
Classification Panel	Anesthesiology Devices
Classification Reference	21 CFR 868.5905
Classification Name / Product Code	BZD – Ventilator, non-continuous (respirator)
Predicate Device(s)	Respironics Revolution Full Face Mask (K082866)

Indication 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 or multi-patient use in the hospital/institutional environment. The mask is to be used on patients (>66lbs/30kg) for whom CPAP and bi-level therapy has been prescribed.

Device Description

The Shimmer Full Face 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.

The Shimmer Full Face Mask is intended to be used with positive airway pressure devices such as CPAP or bi-level systems. Like the predicate device, Revolution Full

Face Mask (K082866), this mask covers the patients' nose and mouth, and is secured using a 4-point headgear. The mask seal directs positive pressure into the patient's nose and mouth.

The Shimmer Full Face Mask incorporated the anti-asphyxia feature into the cushion design, as opposed to the traditional full face mask anti-asphyxia feature typically located in the mask elbow component. Refer to Figure 3.

The anti-asphyxia feature incorporated into the Shimmer full face cushion is called a fresh air inlet valve (FAIV), and it is designed to work differently than other anti-asphyxia valves. A traditional anti-asphyxia valve opens to atmosphere during a single fault condition, which routes inspiratory and expiratory airflow through the same open to atmosphere hole, while occluding the patient connection port. The FAIV, in a single fault condition, opens to atmosphere during inspiratory airflow and it closes to atmosphere during expiratory airflow. Since the patient connection port is no longer occluded during single fault condition, air will exhaust through the patient connection port and mask exhalation features.

Substantial Equivalence

The Respironics Shimmer Full Face Mask has the following similarities to the previously cleared predicate devices Respironics Revolution Full Face Mask (K082866):

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

The Shimmer Full Face Mask has the following differences in the technological characteristics to the previously cleared predicate devices Revolution Full Face Mask (K082866):

- Cushion design
- Number of sizes
- Anti-asphyxia feature
- Patient circuit connection

Design verification tests were performed on the Respironics Shimmer Full Face 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 device.

General Safety and Effectiveness

The performance and technological characteristics of the Shimmer Full Face Mask are equivalent to those of the Revolution Full Face Mask (K082866) and raise no new types of safety or effectiveness questions.

Non-Clinical Tests

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:

Section 6: 510(k) Summary

- Pressure Drop
- Total Mask Leak
- Intentional Leak
- Anti-Asphyxia Feature Resistance
- Anti- Asphyxia Feature Activation Pressure
- Anti- Asphyxia Feature Deactivation Pressure
- Deadspace Volume
- CO2 Rebreathing
- Cleaning and Disinfection Efficacy
- Storage

The Shimmer Full Face Mask has been designed per the following standards:

- ISO 17510-2 Sleep Apnoea Devices Part 2: Masks and Application Accessories
    - Deviations
        - Clause 5.3 Protection against rebreathing
        - Clause 5.5 Breathing during single fault condition
- 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