DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 16, 2015

Respironics, Inc.
Colleen Witt
Manager, Regulatory Affairs, Patient Interface
1001 Murry Ridge Lane
Murrysville, PA 15668

Re: K140580
Trade/Device Name: Revolution Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 18, 2014
Received: December 19, 2014

Dear Mrs. Witt:

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K140580

Device Name
Revolution Full Face Mask

Indications for Use *(Describe)*
The Revolution Full Face Mask is intended to provide an interface for continuous positive airway pressure (CPAP) or bi-level therapy. The mask is intended for single-patient reuse in the home or hospital/institutional environment. The mask is to be used by patients greater than 66lbs/30kg.

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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Section 6: 510(k) Summary

Date of Submission	3/3/14
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4870 (724) 387-3999 (fax)
Official Contact	Colleen Witt Regulatory Affairs Manager, Patient Interface
Establishment Registration #	2518422
Proprietary Name	Respironics Revolution 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) Respironics Comfort Gel Full Face Mask (K073600)

Device Description

The Respironics Revolution Full Face Mask consists of a frame (faceplate) with a silicone cushion and an elbow with an integral entrainment valve. The faceplate holds multiple sizes in order to exchange mask cushion sizes on one (frame) faceplate. The Revolution Full Face Mask cushion has eight exhalation vents, with four vents located on either side of the mask cushion. As a result, a separate exhalation device is not required for use of this mask. The mask has an integrated entrainment valve elbow with a two-piece polycarbonate valve body with a silicone flapper and exhalation vents located on the valve body. This feature was modified from Revolution Full Face (K082866) from a “stream-line” design however this elbow design was cleared under K073600. The design of the Revolution Full Face Mask headgear has two slide-through top strap adjustments, side and back straps, a Lower

Headgear Band and a Chin Support Band. The mask is available in four sizes – small, medium, and large.

Indications for Use

The Revolution Full Face Mask is intended to provide an interface for continuous positive airway pressure (CPAP) or bi-level therapy. The mask is intended for single-patient reuse in the home or hospital/institutional environment. The mask is to be used by patients greater than 66lbs/30kg.

Similarities and Differences of the Subject Device Compared to the Predicate Devices

The Revolution Full Face Mask (subject device) has the following similarities in the technological characteristics to the previously cleared devices (Revolution Full Face Mask K082866 and Comfort Gel Full K073600):

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

The Revolution Full Face Mask (subject device) has the following differences in the technological characteristics to the previously cleared device (Revolution Full Face Mask K082866 and ComfortGel Full K073600):

- Additional material that has been added to the current cushion material that comes into contact with the face.

These differences do not raise new questions of safety and effectiveness.

Clinical Tests

Clinical tests were not required to demonstrate the safety and effectiveness of the Revolution Full Face Mask. Product functionality has been adequately assessed by non-clinical tests.

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:

- Intentional Leak
- Total Mask Leak
- Deadspace Volume
- Pressure Drop
- Anti- Asphyxia Feature Open to Atmosphere Pressure
- Anti- Asphyxia Feature Closed to Atmosphere Pressure
- CO2 Rebreathing
- Cleaning and Disinfection Efficacy
- Storage

The Revolution Full Face 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

Conclusion

The performance and technological characteristics of the modified Revolution Full Face Mask are substantially equivalent to those of the Revolution Full Face Mask (K082866). The differences described above do not raise new questions of safety and effectiveness.