TAB 5

510(K) SUMMARY

Date of Submission 25 September 2008

Official Contact

Andrew Zeltwanger
Manager, Regulatory Affairs
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668
andrew.zeltwanger@respironics.com

724-387-7442 t
724-448-0543 c
724-387-7490 f

JAN 30 2009

Classification Reference 21 CFR 868.5905

Product Code BZD – Ventilator, Non-Continuous (respirator)

Common/Usual Name Ventilator, continuous, non-life supporting

Proprietary Name Respironics RevolutionFull Face Mask

Predicate Device(s) Respironics ComfortGel Full Face Mask (K073600) – BZD

MAP Medizintechnik Fur ARZT UND Papillon Mask Set (K023068) – BZD

Reason for submission New device

Substantial Equivalence

The Respironics RevolutionFull Face Mask has the following similarities to the previously cleared predicate device:

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

This premarket notification submission demonstrates that the Respironics RevolutionFull Face Mask is substantially equivalent to the design of the Respironics ComfortGel Full Face Mask (K073600) and the MAP Medizintechnik Fur ARZT UND Papillon Mask Set (K023068). Design modifications have been made to the predicate masks for this submission. These modifications are described herein. Based on the testing performed, none of the design modification affects the safety or effectiveness of the device.

The following changes have been made:

1. The exhalation vent location was changed from the entrainment valve to the mask cushion.
2. The number of exhalation vents was changed from two to eight.
3. The traditional polycarbonate mask faceplate was changed to a Hytrel frame.
4. The pressure pick-off port was removed.
5. The tubing quick release design that allows the accessory swivel to be released along with the mask tubing was changed to a swivel design, without release tabs, which can be directly pulled from the end of the entrainment valve.
6. The traditional four-point headgear design was changed to top, back and side headgear straps with a lower headgear band and a chin support band.
7. Change from a ball & socket "quick release" clip.
8. Change in dead space volume, due to mask design.
9. Change to the Occluded End Tidal CO2 due to larger dead space resulting from mask design.
10. Change to the dimensional specifications of the faceplate and cushion including the change to the size and shape of the mask frame (faceplate) and cushion and to the weight of the mask.
11. Elimination of the forehead arm, stability selector and forehead pad to open the users field of vision.
12. The change to the mask materials.

Intended Use

The RevolutionFull Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for multi-patient reuse in the home or 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 RevolutionFull Face Mask consists of a Hytrel faceplate that holds multiple sizes of a removable and replaceable silicone cushion seal for the face. The mask cushion has eight integrated exhalation vents, four on either side of the cushion. The location of the exhalation vents on the silicone mask cushion is unchanged from K023068. A separate exhalation device is not required for the integrated exhalation vent design. The integrated entrainment valve elbow is polycarbonate with a silicone flapper. The functionality and performance of the entrainment valve with fresh air inlets is unchanged from K073600, based on performance test data. The mask frame contains slots for attachment of the headgear straps, lower headgear band and chin support band. The mask is available in three sizes – small, medium and large.

The Respironics RevolutionFull Face Mask is intended for use with a patient circuit that is used to connect a therapy device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen 22mm tubing, a method of venting exhaled gases.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2009

Mr. Andrew P. Zeltwanger
Manager, Regulatory Affairs
Respironics Incorporated, Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K082866
Trade/Device Name: Revolution Full Face Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: January 12, 2009
Received: January 14, 2009

Dear Mr. Zeltwanger:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082866

Device Name: Revolution Full Face Mask

The Revolution Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is intended for single patient reuse in the home and multi-patient, multi-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.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082866