K073600

TAB 5

510(K) SUMMARY

Date of Submission	20 December 2007

APR 25 2008

Official Contact	Zita A. Yurko Director, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Zita.yurko@respironics.com 724-387-4120 t 724-882-4120 c 724-387-4216 f
Classification Reference	21 CFR 868.5905
Product Code	BZD – Ventilator, Non-Continuous (respirator)
Common/Usual Name	Ventilator, continuous, non-life supporting
Proprietary Name	Respironics ComfortGel Full Face Mask
Predicate Device(s)	Respironics Spectrum 2 Full Face Mask (K002465) - BZD Respironics Gel Mask (K954207) – BZD
Reason for submission	new device

Substantial Equivalence

The Respironics ComfortGel Full 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 ComfortGel Full Face Mask is substantially equivalent to the design of the Respironics Spectrum 2 Full Face Mask (K002465) and the Respironics Gel Mask (K954207 for the gel cushion feature only). Design modifications have been made to the ComfortGel Full Face Mask for this submission. These modifications are described here in. Based on the testing performed, none of the design modification affect the safety or effectiveness of the device.

The following changes have been made:

1. The addition of gel to the mask cushion design of the full face mask
2. The change in the dimensional specifications of the mask, including the change to the size and shape of the mask faceplate and cushion
3. The addition of available mask sizes
4. The addition of the claim for multi-patient use to be added
5. Change to the headgear clip design
6. The change to add a removable cushion
7. The change to the forehead support mechanism
8. The addition of a pressure pick-off port to the faceplate of the mask
9. The increased weight of the mask cushion due to use of gel
10. The change to the mask materials
11. Change to the dead space of the mask
12. Change to the intentional leak of the mask

Intended Use

The ComfortGel Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for multi-patient use in the home or hospital/institutional environment. The mask is to be used on patients (>66 lbs./30 kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.

Device Description

The Respironics ComfortGel Full Face Mask consists of a polycarbonate faceplate with a gel cushion encapsulated in a urethane seal for the face. The mask includes exhalation ports and an entrainment

valve that allows the patient to breath room air if positive pressure is discontinued. The integrated entrainment valve elbow is polycarbonate with a silicone flapper. The function of the entrainment valve is unchanged from K002465 and K954207, based on performance data. The mask when used with the integrated entrainment valve has integrated exhalation features that are located on the top of the valve. A separate exhalation device is not required for the integrated entrainment valve design. The mask faceplate contains a socket for attachment of the headgear via use of a mushroom-shaped "quick clip" mechanism. The mask is available in three sizes – small, medium and large.

The Respironics ComfortGel Full 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

APR 25 2008

Ms. Zita A. Yurko
Director, Regulatory Affairs
Respironics Incorporated, Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K073600
Trade/Device Name: Respironics ComfortGel Full Face Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 18, 2008
Received: April 21, 2008

Dear Ms. Yurko:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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): _____

Device Name: ___Respironics ComfortGel Full Face Mask_____

The ComfortGel Full Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for multi-patient use in the home or hospital/institutional environment. The mask is to be used on patients (>66 lbs/30 kg) for whom CPAP or bi-level therapy has been prescribed using a CPAP or bi-level system.

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: K073600