TAB 5

510(K) SUMMARY

Date of Submission	18 June 2009
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 724-387-7490 f
Classification Reference	21 CFR 868.5895
Product Code	BZD - Non-Continuous ventilator (IPPB)
Common/Usual Name	Nasal Mask
Proprietary Name	Respironics Comfort Twin Nasal Mask
Predicate Device(s)	Respironics Reusable II Contour Nasal Mask (K991648) Resmed Mirage Activa (K032916)
Reason for submission	**New device.** Includes multi-patient, multi-use claim

Substantial Equivalence

The Comfort Twin Nasal Mask has the following similarities to the previously cleared predicate device:

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

The Respironics Reusable II Contour Nasal Mask was cleared in K991648. The Resmed Mirage Activa was cleared in K032916. To update the design of the Reusable II, an inter sealing cushion was added to this device design. This cushion within a cushion design has been reviewed and cleared by the agency in K032916. The new device was validated using bench data. All performance characteristics performed within specification and comparable to the cited device predicates. This testing has confirmed that the Comfort Twin Nasal Mask performs equivalently to the cited device predicates.

Intended Use

The Comfort Twin Nasal Mask is an accessory to a non-continuous ventilator (respirator), intended for use by adult patients prescribed continuous positive airway pressure (CPAP) or bi-level therapy. The mask is intended for single-patient reuse in the home environment or multi-patient, multi-use in the hospital/institutional environment.

Device Description

The Comfort Twin Nasal mask is a respiratory nasal mask using a dual cushion design with built-in bellows and an inner sealing flap for improving unintentional leak. It is a multi-patient, multi- use accessory for use with CPAP or bi-level devices.

The Comfort Twin mask is strapped to the patient's face covering the nose, and connected to tubing to a CPAP or bi-level flow generator. Positive pressure ventilation is then able to be applied to the lungs in a non-invasive way.

Performance Data

. Performance testing has been carried out to verify the safety & effectiveness of the ComfortTwin Nasal Mask with all cushion sizes. The results of this testing confirm that exposure to the specified cleaning and disinfection agent (Cidex) does not degrade the performance of the ComfortTwin Nasal Mask. Test data is provided in Tab 18 of this submission.

Mask Efficacy Testing

All mask materials that come in contact with the specified cleaning and disinfection agent (Cidex) have been tested by an independent laboratory to confirm efficacy of the cleaning method specified in the ComfortTwin Nasal Mask Cleaning & Disinfection guide. The details are specified in Tab 14 of this submission.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 10 2009

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

Re: K091843
Trade/Device Name: Comfort Twin Nasal Mask – Multi-Patient, Multi-Use
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: June 18, 2009
Received: June 22, 2009

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 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,

for

Susan Runner, D.D.S., M.A.
Acting Division 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): K091843

Device Name: Comfort Twin Nasal Mask – Multi-patient, multi-use

The Comfort Twin Nasal Mask is an accessory to a non-continuous ventilator (respirator), intended for use by adult patients prescribed continuous positive airway pressure (CPAP) or bi-level therapy. The mask is intended for single-patient reuse in the home environment or multi-patient, multi-use in the hospital/institutional environment.

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: K091843