K091271

ATTACHMENT 4

510(K) SUMMARY

MAY 29 2009

Date of Submission	29 April 2009
Official Contact	Andrew P. 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
Classification Reference	21 CFR 868.5905
Product Code	BZD – Ventilator, Non-Continuous (respirator)
Common/Usual Name	Ventilator, continuous, non-life supporting
Proprietary Name	Respironics Performax Total Face Mask
Predicate Device(s)	Respironics Performax Total Face Mask (K072592) - BZD
Reason for submission	Modification to add autoclaving

Substantial Equivalence

The Respironics Performax Total 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 Performax Total Face Mask is substantially equivalent to the design of the Respironics Performax Total Face Mask (K072592). The Performax Total Face Mask has been modified to add a new method of disinfection for multi-patient use in the hospital or institution. These modifications are described herein. Based on the testing performed, the additional cleaning and disinfection method has no effect on the safety or effectiveness of the device.

The following changes have been made:

- The addition of autoclaving as an approved method of disinfection
- The modification to the Swivel torque specification

Intended Use

The Performax Total Face Mask is intended to provide an interface for application of CPAP or BiPAP therapy to patients. The mask is for multi-patient reuse on adult patients in the home or hospital/institutional environment.

Device Description

The Respironics Performax Total Face Mask has the exact same design as the previously cleared Performax Total Face Mask (K072592). The Performax Mask consists of a polycarbonate faceplate with silicon cushion seal for the face. An integrated entrainment valve is provided for exhalation. The integrated entrainment valve elbow is polycarbonate with a silicone flapper. The function of the entrainment valve is unchanged from K992969. The mask when used with the integrated entrainment valve has two integrated exhalation features, which includes the one port on the faceplate and an exhalation site on the elbow. A separate exhalation device is not required for the integrated entrainment valve design. The mask faceplate contains headgear hooks upon which the premium headgear is attached. The mask is available in two sizes – small and large.

The Respironics Performax Total Face Mask is intended for use with a patient circuit that is used to connect the 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

MAY 29 2009

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

Re: K091271
Trade/Device Name: Respironics Performax Total Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: April 29, 2009
Received: April 30, 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 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/cdrh/comp/ 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,

Susan Runner

Susan Runner, D.D.S., MA
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): K091271

Device Name: Respironics Performax Total Face Mask

The Performax Total Face Mask is intended to provide an interface for application of CPAP or BiPAP therapy to patients. The mask is for multi-patient reuse on adult patients in the home or 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)

L Schultz

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

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