TAB 3

510(K) SUMMARY

Date of Submission	November 17, 2010
510(k) Owner	Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 (724) 387-4146 (724) 387-3999 (fax)
Official Contact	Michelle Brinker Regulatory Affairs Manager, Patient Interface
Proprietary Name	PerforMax Total Face Mask
Common/Usual Name	Face Mask
Classification Name / Product Code	BZD – Ventilator, non-continuous (respirator)
Predicate Device(s)	Respironics PerforMax Total Face Mask (K072592) Respironics PerforMax Total Face Mask/BiPAP Synchrony 2 (K092043)

Device Description

The PerforMax Total Face Mask is intended to be used with positive airway pressure devices such as CPAP or bi-level systems. The small size mask is intended for use on patients 7 years or older (>40 lbs/20kg) and the large size mask is intended for use on patients (>66 lbs/30 kg) for whom CPAP or bi-level therapy has been prescribed.

The PerforMax Total Face Mask consists of a polycarbonate faceplate and a silicone cushion seal for the face. The PerforMax Total Face Mask can utilize a bronchoscopy elbow. This elbow will allow physicians to perform bronchoscopy procedures on a patient while the patient is receiving non-invasive ventilation. A pressure-pick off port is located on the elbow. A separate exhalation device is required when using the Respironics PerforMax Total Face Mask with bronchoscopy elbow because exhalation is not built into the mask. 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 therapy device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen 22mm tubing and a method of venting exhaled gases.

Intended Use

The PerforMax Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. For multi-patient, multi-use in the hospital/institutional environment or single patient reuse in the home. The mask is to be used on patients 7 years or older (>40 lbs/18.2 kg) for whom CPAP or bi-level therapy has been prescribed.

Summary of Technological Characteristics of Device Compared to the Predicate Device

The modified mask has the following similarities in the technological characteristics to the previously cleared device Respironics PerforMax Total Face Mask (K072592/K092043):

- Same intended use
- Same operating principle
- Same technology
- Similar device design
- Similar physical properties
- Similar material used
- Same scientific concepts that form the basis for the device

The modified mask has the following differences in the technological characteristics to the previously cleared device Respironics PerforMax Total Face Mask (K072592/K092043):

- The bronchoscopy elbow is being utilized instead of the entrainment elbow.
- The bronchoscopy elbow will be for single use only in the hospital/institutional environment.
- The bronchoscopy elbow material is being tinted green to differentiate between elbows.

Summary of the Non-Clinical Test Submitted, Referenced or Relied on in the 510(k)

To demonstrate performance and functionality was unaffected as a result of this modification, extensive performance testing, including unintentional leak, pressure drop, CO2 rebreathing, mask deadspace and therapy device compatibility tests were completed on the modified PerforMax Total Face Mask. These tests are consistent with the tests that were completed on the predicate device, PerforMax Total Face Mask (K072592/K092043). A biocompatibility assessment in accordance with ISO 10993-1 was completed for all new skin-contacting and air path-contacting materials. As required by the standard, the test suite included irritation and sensitization (ISO 10993-10) and cytotoxicity (ISO 10993-5) biocompatibility tests.

Results from this verification testing concluded that the modified PerforMax Total Face Mask meets its performance specifications, raises no new issues of safety or effectiveness, and is substantially equivalent to the identified device predicates.

Clinical Data

Use of full face masks with CPAP or bi-level therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the modified PerforMax Total Face Mask, as was the case with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Michelle Brinker
Regulatory Affairs Manager, Patient Interface
Respironics, Incorporated
365 Plum Industrial Court
Pittsburgh, Pennsylvania 15239

MAR 24 2011

Re: K103395
Trade/Device Name: Respironics PerforMax Total Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 18, 2011
Received: February 22, 2011

Dear Ms. Brinker:

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 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/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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): 103395

Device Name: Respironics PerforMax Total Face Mask

The PerforMax Total Face Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. For multi-patient, multi-use in the hospital/institutional environment or single patient reuse in the home. The mask is to be used on patients 7 years or older (>40 lbs/18.2 kg) 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 801 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: K103395