TAB 5

JUL 17 2012

510(K) SUMMARY K120562

Date of Submission	21 February 2012
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 Pediatric EE Total Face Mask
Common/Usual Name	Face Mask
Classification Name / Product Code	BZD – Ventilator, Non-Continuous (Respirator)
Predicate Device(s)	Respironics PerforMax Youth EE Total Face Mask (K092043) Respironics Small Child Profile Lite Nasal Mask (K093416)

Device Description

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. It provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose and mouth. It is held in place with an adjustable bonnet headgear. It may be cleaned by the professional in the hospital/institutional environment through a thermal high-level disinfection process or a chemical high-level disinfection process for multi-patient use.

The PerforMax Pediatric EE Total Face Mask consists of a faceplate with a bonded silicone seal for the face and an elbow with an integral entrainment valve. The mask features an interchangeable elbow hub which accepts an EE Leak 1 and EE Leak 2 elbow. The EE Leak 2 elbow includes built-in exhalation, an entrainment valve, a flexible tube, and a 22 mm connection. The EE Leak 1 elbow includes an entrainment valve and a 22 mm connection. The 22 mm elbow is used to connect a conventional air delivery hose between the mask and the positive airway pressure source. The bonnet headgear is

connected to the mask through slots in the upper part of the frame and clips that attach to the lower part of the frame. The mask is designed in such a way that it can be easily disassembled for disinfection or to replace several of the mask components, such as the headgear and elbow.

Intended Use

PerforMax Pediatric EE Total Face Mask is intended to provide an interface for application of non-invasive positive airway pressure delivered to patients by a device such as a CPAP or bi-level system. The mask is for multi-patient use in the hospital / institutional environment only. The mask is to be used on patients 1 year or older (> 7 kg) for whom positive airway pressure therapy has been prescribed.

Summary of Technological Characteristics of Device Compared to the Predicate Devices

The PerforMax Pediatric EE Total Face Mask has the following similarities in the technological characteristics to the previously cleared devices (Respironics PerforMax Youth EE Total Face Mask, K092043, and Respironics Small Child Profile Lite Nasal Mask, K093416):

1. Same intended use
2. Same operating principle
3. Same technology
4. Similar device design
5. Similar physical properties
6. Similar materials used
7. Same scientific concepts that form the basis for the device

The PerforMax Pediatric EE Total Face Mask has the following differences in the technological characteristics to the previously cleared devices (Respironics PerforMax Youth EE Total Face Mask, K092043, and Respironics Small Child Profile Lite Nasal Mask, K093416):

1. Faceplate and cushion have been reduced in size.
2. Elbow modified
3. Operating pressure range has been modified.
4. Addition of inspiratory and expiratory resistance performance specification.
5. Mask leak specifications has been modified.
6. The elbow body, elbow hub, and headgear materials have been modified.

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 these changes, extensive performance testing was completed. Testing was performed pre and post hospital/institutional cleaning and disinfection treatments. Additionally, the mask was tested for high level disinfection in accordance with AAMI TIR No. 12-2004, AAMI TIR 30-2003, ASTM E1837-96 (2007), and the "Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants" – FDA CDRH, January 3, 2000. All patient contacting or gas path materials used in the mask have been previously cleared by the FDA or evaluated in accordance with the guidance provided by ISO 10993-1.

Results from this testing demonstrate that the PerforMax Pediatric EE 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 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 PerforMax Pediatric EE 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
Sleep and Home Respiratory Group
365 Plum Industrial Court
Pittsburg, Pennsylvania 15239

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Re: K120562
Trade/Device Name: PerforMax Pediatric EE Total Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 9, 2012
Received: July 10, 2012

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): K120562

Device Name: PerforMax Pediatric EE Total Face Mask

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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: K120562