K110405

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JUN - 6 2011

510(K) SUMMARY

Date of Submission	11 February 2011
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	TrueBlue Nasal Mask
Common/Usual Name	Nasal Mask
Classification Name / Product Code	BZD – Ventilator, non-continuous (respirator)
Predicate Device(s)	Respironics ComfortGel Blue Nasal Mask (K092835) Respironics ComfortTwin Nasal Mask (K091843)

Device Description

The TrueBlue Nasal Mask is intended to be used with positive airway pressure devices such as CPAP or bi-level systems. It provides a seal such that positive pressure from the positive pressure source is directed into the patient's nose. It is held in place with an adjustable headgear. It may be cleaned by the patient in the home using warm water and a mild liquid dish washing detergent (single patient use) or cleaned by the professional in the hospital/institutional environment through a thermal high-level disinfection process or a chemical high-level disinfection process (multi-patient use).

The TrueBlue Nasal Mask consists of a polycarbonate faceplate, with a gel cushion encapsulated in a polyester seal for the face. The gel cushion is attached to the face plate via a silicone spring which allows for a self-adjustment of the gel cushion to achieve proper mask fitting. A polycarbonate elbow is connected to the faceplate. The elbow includes integrated exhalation features and is capable of rotating freely through 360 degrees. The fabric 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 cleaning or to replace several of the mask components.

The elbow includes an integrated 22mm Lubriloy swivel connector. The fitting is used to connect a conventional air delivery hose between the mask and the positive airway pressure source. The 22mm swivel connector is designed in such a way that it can rotate freely through 360 degrees.

Intended Use

The TrueBlue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

Summary of Technological Characteristics of Device Compared to the Predicate Device

The TrueBlue Nasal Mask has the following similarities in the technological characteristics to the previously cleared devices (Respironics ComfortGel Blue Nasal Mask, K092835 and Respironics Comfort Twin Nasal Mask K091843):

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 TrueBlue Nasal Mask has the following differences in the technological characteristics to the previously cleared devices (Respironics ComfortGel Blue Nasal Mask, K092835 and Respironics Comfort Twin Nasal Mask K091843):

1. The faceplate is no longer part of the gas pathway and now serves as a mechanical support.

2. The forehead pad position selector, previously used to fit the mask, has been replaced by a self-adjusting silicone spring that is part of the gas pathway.
3. The forehead pad has changed from a single silicone cushion to a three cushion gel pad.
4. The headgear clips have changed from a ball and socket design to a talon design.
5. The sealing cushion flap design was changed.
6. The shape of the sealing cushion has changed.
7. The large size was removed.
8. Several mask materials have changed color, durometer or other properties
9. A thermal disinfection treatment has been added

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, including intentional leak, total leak, pressure drop, CO2 rebreathing, and deadspace was completed. Testing was performed pre and post hospital/institutional cleaning and disinfection treatments. Additionally, disinfection efficacy testing was performed to ensure that the mask could be high level disinfected to assure a minimum of 6 log reductions for this mask as tested 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 tested in accordance with the guidance provided by ISO 10993-1. 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 testing demonstrate that the TrueBlue Nasal 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 nasal 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 TrueBlue Nasal 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
Respironics, Incorporated
Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

JUN - 6 2011

Re: K110405
Trade/Device Name: TrueBlue Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 12, 2011
Received: May 13, 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): _____

Device Name: TrueBlue Nasal Mask

The TrueBlue Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy to patients. The mask is for single patient use in the home or multi-patient use in the hospital/institutional environment. The mask is to be used by patients (>66lbs/30kg) for whom CPAP or bi-level therapy has been prescribed.

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)

L Schultheiss

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

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