



Date of Submission 17 September 2012

510(k) Owner Respironics, Inc.
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Official Contact Michelle Brinker
Regulatory Affairs Manager, Patient Interface

Proprietary Name Kangaroo Nasal Mask

Common/Usual Name Nasal Mask

Classification Class II

Classification Name /
Product Code BZD – Ventilator, non-continuous (respirator)

Predicate Device(s) Respironics GoLife Nasal Mask (K110008)

Respironics TrueBlue Nasal Mask (K110405)

Intended Use

The Kangaroo Nasal Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. This mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital/institutional environment. This mask is to be used on patients greater than 66 lbs /30 kg.

Device Description

The Kangaroo 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 (single patient use) or cleaned by the professional in the hospital/institutional environment through high-level disinfection processes (multi-patient use).

The Kangaroo Nasal Mask consists of a frame with a gel cushion. The cushion is designed in such a way that it minimizes leaks and is comfortable for the patient. An elbow is connected to the cushion and includes integrated exhalation features. The elbow can rotate freely through 360 degrees and is connected to 15 mm tubing that includes an integrated 22 mm swivel connector. 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 22 mm swivel connector on the 15 mm tubing is used to connect the mask to a conventional 22 mm air delivery hose that is in turn connected to the positive airway pressure source. The swivel connector can rotate freely through 360 degrees.

Summary of Technological Characteristics of Device Compared to the Predicate Devices

The Kangaroo Nasal Mask has the following similarities in the technological characteristics to the previously cleared device (Respironics GoLife Nasal Mask, K110008 and Respironics TrueBlue Nasal Mask, K110405):

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

The Kangaroo Nasal Mask has the following differences in the technological characteristics to the previously cleared primary predicate device (Respironics GoLife Nasal Mask, K110008):

- The nasal cushion design has been modified to include gel.
- The frame, exhalation elbow and headgear designs have been modified
- The mask materials and selected disinfection methods have been modified.

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

Extensive performance testing was performed pre and post cleaning and disinfection treatments to demonstrate performance and functionality was unaffected as a result of these changes. Additionally, disinfection efficacy testing was performed in accordance with AAMI TIR No.12-2010, AAMI TIR No. 30-2011 and 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 biocompatibility tested in accordance with the guidance provided by ISO 10993-1.

Results from this testing demonstrate that the Kangaroo 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 Kangaroo Nasal Mask, as was the case with the predicate devices.



March 6, 2013

Ms. Michelle Brinker
Regulatory Affairs Manager
Respironics, Incorporated
1001 Murry Ridge Lane
MURRYSVILLE PA 15668

Re: K122847
Trade/Device Name: Kangaroo Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: January 31, 2013
Received: February 4, 2013

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/ucml15809.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,

Kwame O. Ulmer

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122847

Device Name: Kangaroo Nasal Mask

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Prescription Use 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)

Lester W. Schultheis Jr

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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122847

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