K102502

# TAB 3

DEC 2 2 2010

## 510(K) SUMMARY

| | |
|---|---|
| Date of Submission | 30 August 2010 |
| 510(k) Owner | Respironics, Inc.<br>1001 Murry Ridge Lane<br>Murrysville, PA 15668<br><br>(724) 387-4146<br>(724) 387-7490 (fax) |
| Official Contact | Michelle Brinker<br>Regulatory Affairs Manager, Patient Interface |
| Proprietary Name | GoLife Nasal Mask |
| Common/Usual Name | Nasal Mask |
| Classification Name / Product Code | BZD – Ventilator, non-continuous (respirator) |
| Predicate Device(s) | Respironics ComfortLite Nasal Mask (K082558)<br><br>Respironics Monarch Mini Mask (K945938) |

## Device Description

The GoLife 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 (multi-patient use).

The design consists of a silicone nasal pillows cushion designed to fit in the patients' nostrils. The cushion is designed in such a way that it minimizes leaks and is comfortable for the patient. The cushion is connected to a nasal cushion support (frame) that rests along the patient's cheeks and supports the cushion. Areas of the frame that contact the patient's cheeks are covered in a fabric material for comfort purposes. A polycarbonate elbow is connected at the frame. The elbow is capable of rotating freely through 360 degrees. The fabric headgear is connected to the mask through slots in the frame. The nasal

pillows cushion is designed in such a way that it can be easily removed, from the frame for cleaning or replacement purposes.

The elbow connects to 15mm EVA tubing that is fitted at the end with a 22mm polycarbonate swivel connector. This fitting is used to connect 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.

The built-in vent openings are molded into the front side of the elbow. The vent openings are used to flush exhaled CO2 out of the circuit and may be visually inspected for obstruction prior to use.

## Intended Use

The GoLife 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.

## Summary of Technological Characteristics of Device Compared to the Predicate Device

The GoLife Nasal Mask has the following similarities in the technological characteristics to the previously cleared device (ComfortLite, K082558):

- 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 GoLife Nasal Mask has the following differences in the technological characteristics to the previously cleared device (ComfortLite, K082558):

- The nasal pillows cushion on the predicate is offered in one size, but will be offered in multiple sizes for the modified mask to increase options available for fit.
- The nasal cushion supports, nasal cushion support padding, tubing swivel, and headgear materials are changed. The predicate and modified mask are molded of similar plastic component and fabric headgear materials.
- The multi-vent hole exhalation device is changed to a design that consists of fewer vent holes that are larger in size.
- The nasal pillows cushion is supported on the patient's nose through the nasal cushion support (frame) that attaches to the cushion and rests along the patient's cheeks. This nasal cushion support feature is the similar to the predicate Monarch Mini.
- The tubing length has been extended and the size reduced. The predicate mask tubing consists of a combination of 22mm and 15mm tubing which is being replaced by 15mm tubing only. This tubing size is the same as the predicate Monarch Mini.
- Added the option to position the tubing over or below the patient's head. The tubing on the predicates could only be directed either above or below the patient's head (no option to change directions).
- The hospital/institutional cleaning and disinfection treatment options for the modified mask includes a thermal disinfection process, whereas the predicate may be disinfected through both thermal and chemical methods.

## 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, unintentional leak, pressure drop, CO2 rebreathing, deadspace, and flow triggering testing was completed. Testing was performed pre and post home/clinical cleaning and disinfection treatments. Additionally, cleaning 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. A biocompatibility assessment in accordance with ISO 10993-1 was completed for all 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 testing concluded that the verification testing performed verified that the GoLife 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 GoLife 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

Respironics, Incorporated
Ms. Michelle Brinker
Manager, Regulatory Affairs
Sleep and Home Respiratory Group
365 Plum Industrial Court
Pittsburgh, Pennsylvania 15239

DEC 2 2 2010

Re: K102502
Trade/Device Name: GoLife Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 10, 2010
Received: December 14, 2010

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): K102502

DEC 2 2 2010

Device Name: GoLife Nasal Mask

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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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schutter

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

510(k) Number: K102502