TAB 5

MAR 2 5 2009

510(K) SUMMARY

Date of Submission	August 28, 2008
Official Contact / Address of Manufacturing facility	Andrew P. Zeltwanger Manager, Regulatory Affairs Respironics Inc. 1740 Golden Mile Highway Monroeville, PA 15146 Phone: 724-387-7442 Fax: 724-387-7490 Andrew.zeltwanger@Respironics.com
Proprietary Name	ComfortLite™ Nasal Mask
Common/Usual Name	Nasal Mask
Device Classification Name	Mask, Ventilator, Non-Continuous, Reprocessed
Classification Reference	21 CFR 868.5905
Classification	Class II
Appropriate Classification Panel	Anesthesiology
Product Code	BZD
Predicate Devices	Respironics ComfortLite Nasal Mask (K053352)
Reason for submission	Include a multi-patient re-use claim

Substantial Equivalence

The modified device has the following similarities to the previously cleared device:

- ❑ Same design
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the ComfortLite™ Nasal Mask as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate device.

Intended Use

The ComfortLite 2 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 ComfortLite™ Nasal Mask is unchanged from the device design submitted and cleared in K053352. The Comfortlite Nasal Mask designed for patients (> 66 lbs / 30 kg) as a nasal interface for application of non-invasive CPAP or bi-level therapy. It consists of a nasal interface with a built-in exhalation device, interface adjustment mechanisms, and 6" of standard 22 mm tubing connected to a crown swivel (elbow) for connection to the CPAP or Bi-level device. The mask is supported by a baseball-cap type headgear to allow a seal with the patient's nostrils via the nasal interface. Three types of nasal cushions are compatible with the base frame structure that comes in one frame size. These include a simple cushion, a direct seal cushion, and nasal pillows. All nasal interfaces are available in multiple sizes to meet the needs of the user.

Performance Data:

Performance testing has been carried out to verify the safety and effectiveness of the ComfortLite Nasal Mask with all cushion types. The results of the testing confirm that exposure to the specified

cleaning, and disinfection agents do not degrade the performance of the ComfortLite Nasal Mask as it was originally cleared in K053352. Test data is provided in Tab 18A of this submission.

Mask Efficacy Testing

All mask materials that come in contact with the specified cleaning and disinfection agents have been tested by an independent laboratory to confirm efficacy of the cleaning methods specified in the ComfortLite Nasal Mask Cleaning and Disinfection guide. The details are specified in Tab 14 of his submission.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2009

Respironics, Incorporated
Mr. Andrew P. Zeltwanger
Manager, Regulatory Affairs
Sleep & Home Respiratory Group
1740 Golden Mile Highway
Monroeville, Pennsylvania 15146

Re: K082558
Trade/Device Name: ComfortLite™ Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 27, 2009
Received: March 2, 2009

Dear Mr. Zeltwanger:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting 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): K082558

Device Name: ComfortLite™ Nasal Mask

Indications for Use:

The ComfortLite 2 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K082558