TAB 5

510(K) SUMMARY

Date of Submission	1 December 2005
Official Contact / Address of Manufacturing facility	Zita A. Yurko Manager, Regulatory Affairs Respironics Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: 724-387-4120 Fax: 724-387-4216 Zita.Yurko@Respironics.com
Proprietary Name	ComfortLite Nasal Mask
Common/Usual Name	Nasal Mask
Device Classification Name	Ventilator, Non-Continuous (Respirator)
Classification Reference	21 CFR 868.5905
Classification	Class II
Appropriate Classification Panel	Anesthesiology
Product Code	BZD
Predicate Devices	Respironics Nasal Interface Model 7910 (K974453) Respironics Monarch II Mini Mask (K992336) ResMed Nasal Jacks Mask (K032433)
Reason for submission	Modified design

Substantial Equivalence

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

- ❑ 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 devices.

Intended Use

The ComfortLite Nasal Mask is intended to provide an interface for application of CPAP or bi-level therapy for the treatment of Obstructive Sleep Apnea. The mask is for use in the home or hospital/institutional environment on adults.

Device Description

The ComfortLite Nasal Mask is a nasal interface for application of non-invasive CPAP or bi-level therapy. The mask 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.

The mask is available with three types of nasal interface: simple cushion, direct seal cushion, and nasal pillow. The nasal interface may be adjusted vertically by an extension tube twist mechanism and horizontally by an angle selector. In addition, a thin, bendable support stabilizer arm is located on the outer body of the direct seal cushion and nasal pillow to allow for more fine adjustment of these nasal interfaces. The mask has a built-in exhalation device, thus no separate exhalation device is needed.

The mask directs standard 6 ft. 22 mm tubing, provided with a CPAP or Bi-level device, over the user's head.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2006

RESPIRONICS, INC.
C/O Ms. Zita A. Yurko
Respironics, Incorporated
Sleep and Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K053352
Trade/Device Name: ComfortLite Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: February 3, 2006
Received: February 10, 2006

Dear Ms. Yurko:

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.

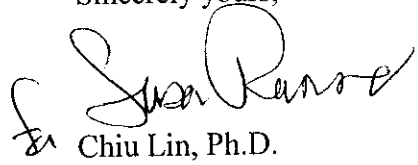
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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: ___ComfortLite Nasal Mask_____

Indications for Use:

The ComfortLite Nasal Mask is intended to provide an interface for application of Respironics CPAP or bi-level therapy for the treatment of Obstructive Sleep Apnea. The mask is for use in the home or hospital/institutional environment on adults.

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)

[illegible] Division of Cardiovascular, General Hospital, Infection Control, Dental Devices

510(k) Number K053352