K033759

FEB 1 9 2004

SECTION 9

510(K) SUMMARY

Official Contact / Address of Manufacturing facility	Zita A. Yurko Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Proprietary Name	C2 Nasal Mask
Common/Usual Name	Nasal mask
Classification Reference	21 CFR 868.5905
Classification	Class II
Appropriate Classification Panel	Anesthesiology Devices
Product Code	BZD – non-continuous ventilator
Predicate Devices	Worldwide Medical Technologies, Inc. Spiritus Respiratory System (K020641)
Reason for submission	New Device

Substantial Equivalence

This premarket notification submission demonstrates that the C2 Nasal Mask is substantially equivalent to the Worldwide Medical Technologies, Inc. Spiritus Respiratory System (K020641).

Design verification tests were performed on the C2 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 mask. In summary, the mask described in this submittal is substantially equivalent to the predicate mask.

Intended Use/Indications for Use

The Respironics C2 Nasal Mask is intended to provide an interface for application of prescribed CPAP or Bi-level positive airway pressure therapy.

Patient Population/Environment of Use

The mask is reusable and for single patient use only. It is intended for adult patients and may be used in a home or hospital/institutional environment.

Device Description

The C2 Nasal Mask consists of a tubular mask body, nasal interface cradle with cushion, two nasal interface cradle adapters, two exhalation devices, elbow with swivel, single split strap headgear, headgear clips and cloth cover. Standard 22 mm flexible tubing provided with a CPAP or Bi-level device connects to the mask at the elbow with swivel.

The headgear provided with the mask is a single strap that splits to wrap around the top and back portions of the user's head. Velcro tabs at each end of the headgear are used to secure a clip that is used to fasten the headgear to the mask body. To remove the mask from the user's face, the user may slide the stretchable headgear over their head, unfasten the Velcro tabs and slide the straps through the clips that are attached to the mask, or release a clip from the mask body.

(End of Section.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 2004

Ms. Zita Yurko
Regulatory Affairs Manager
Respironics, Incorporated
1001 Murry Ridge Lane
Murrysville, PA 15668

Re: K033759
Trade Name: C2 Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 1, 2003
Received: December 2, 2003

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.

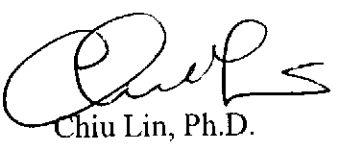
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.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): K033759

Device Name: C2 Nasal Mask

Indications for Use:

The C2 Nasal Mask is intended to provide an interface for application of prescribed CPAP or Bi-level therapy.

The mask is reusable and for single patient use only. It is intended for adult patients in a home or hospital/institutional environment.

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)

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

510(k) Number: K033759