SECTION 1

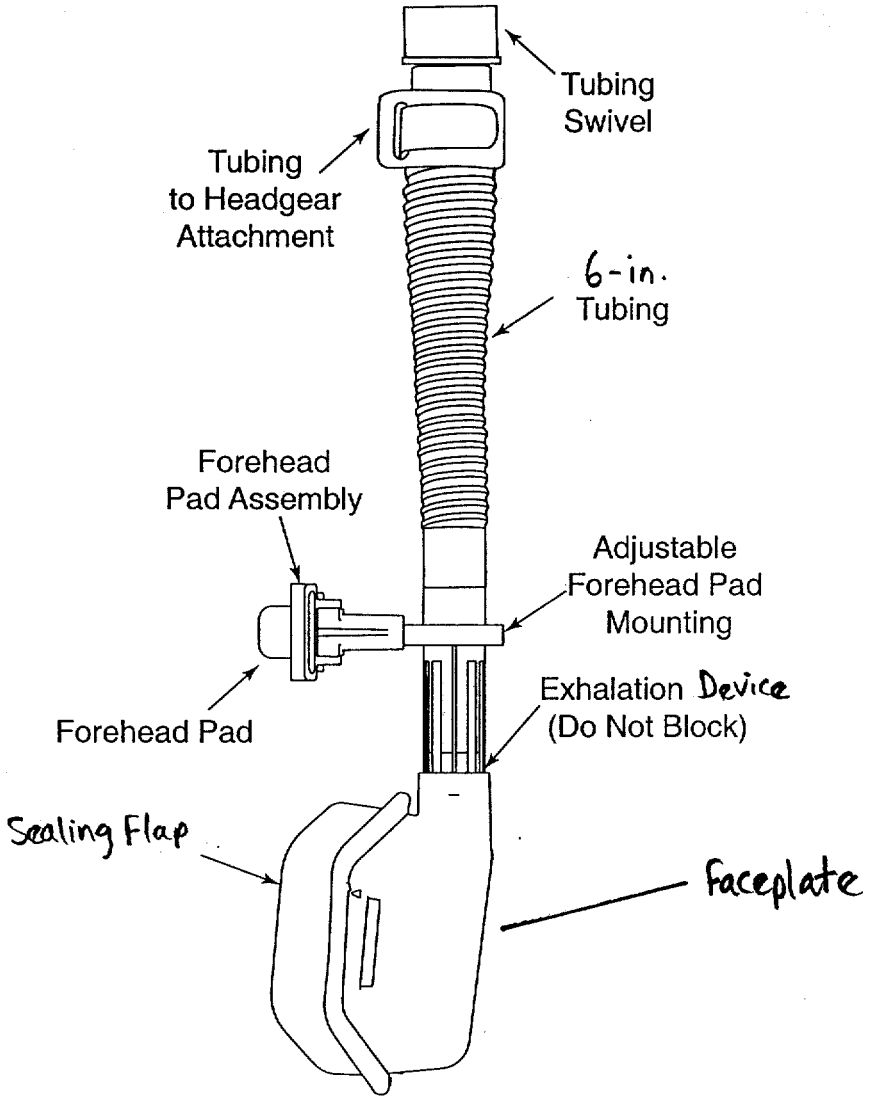
SUMMARY OF SAFETY & EFFECTIVENESS

RESPIRONICS INC.®
1001 Murry Ridge Lane, Murrysville, PA 15668

Official Contact	David J. Vanella Manager, Regulatory/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5905
Product Code	BZD – noncontinuous ventilator
Common/Usual Name	nasal mask
Proprietary Name	Respironics® Silhouette™ Nasal Mask
Predicate Device	Reusable Contour II Nasal Mask (K991648)
Reason for submission	New Device

Substantial Equivalence

This premarket notification section 510(k) shows that the Silhouette Nasal Mask is substantially equivalent to the Respironics Reusable II Contour Nasal Mask. The two masks have the same intended use, environment of use and patient population. The Silhouette, like the predicate, has a built-in exhalation device. Based on verification testing, we conclude that the differences (e.g., sealing flap, movable forehead pad, fewer sizes, over-the-head tubing) do not affect the safety and effectiveness of the Silhouette Nasal Mask.



Respironics Silhouette Nasal Mask

Intended Use/Indications for Use

The Respironics Silhouette Nasal Mask is intended to provide an interface for application of Respironics CPAP or bi-level therapy to patients. It is intended for multiple-patient-use in a home or hospital/institutional environment. The mask is to be used on adult patients (> 30 kg) for whom CPAP or bi-level therapy has been prescribed, using a Respironics CPAP or bi-level system.

Device Description

The mask consists of a faceplate and a cushion, which are molded together. A soft cover, called the sealing flap, fits over the cushion. The faceplate has a grooved tubing connector that mates with a grooved extension tube on the flexible patient tube. The mask is designed to direct the patient tube over the head (away from the face and neck). An adjustable forehead pad assembly can be placed higher or lower on the forehead for comfort. Adjusting the pad assembly can also put the mask closer to or further away from the face.

- ❑ Sealing flap is available in two sizes, small and medium.
- ❑ The connection of the mask and tube forms the built-in exhalation device.
- ❑ The forehead-pad mounting is designed not to interfere with the built-in exhalation device.
- ❑ The forehead pad assembly and the faceplate have slots for the headgear tabs.
- ❑ The mask was tested and found compliant with ISO 10993-1 "Biological Evaluation of Medical Devices – Guidance on Selections of Tests."

(End of Section.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2000

Mr. David J. Vanella
Respironics, Inc.
1000 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K000705
Respironics® Silhouette™ Nasal Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: August 9, 2000
Received: August 10, 2000

Dear Mr. Vanella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000705

Device Name: Respironics® Silhouette™ Nasal Mask

Intended Use/Indications for Use

The Respironics Silhouette Nasal Mask is intended to provide an interface for application of Respironics CPAP or bi-level therapy to patients.

Environment of Use/Patient Population

For multiple-patient use in the home or hospital/institutional environment. The mask ~~is to be~~ used on adult patients (> 30kg) for whom CPAP or bi-level therapy has been prescribed, using a Respironics CPAP or bi-level system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000705