ATTACHMENT 4

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	David J. Vanella Manager, Regulatory Affairs 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® Total™ Face Mask
Predicate Device	Total Face Mask (K925920)
Reason for submission	Modified design; modified materials.

Substantial Equivalence

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

- ❑ Same intended use.
- ❑ Same operating principle.
- ❑ Same technology.
- ❑ Same manufacturing process.

Design verification tests were performed on the Total Face Mask as a result of the risk analysis assessment, and acceptance criteria were met. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the mask described in this submission is substantially equivalent to the predicate device.

The modified mask complies with the applicable standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

Device Description/Intended Use

The Total Face Mask is intended to provide a single-patient-use interface for adult patients (>30 kg) receiving Respironics CPAP or BiPAP therapy. The mask (Figure 1) fits over the entire face, with the rim of the mask framing the face along the hairline and jawline. The mask consists of a polycarbonate faceplate and a thin silicone cushion that folds inward, creating a flap on the inner perimeter of the mask to improve seal. The faceplate has four Velcro® hooks to which the headgear tabs attach.

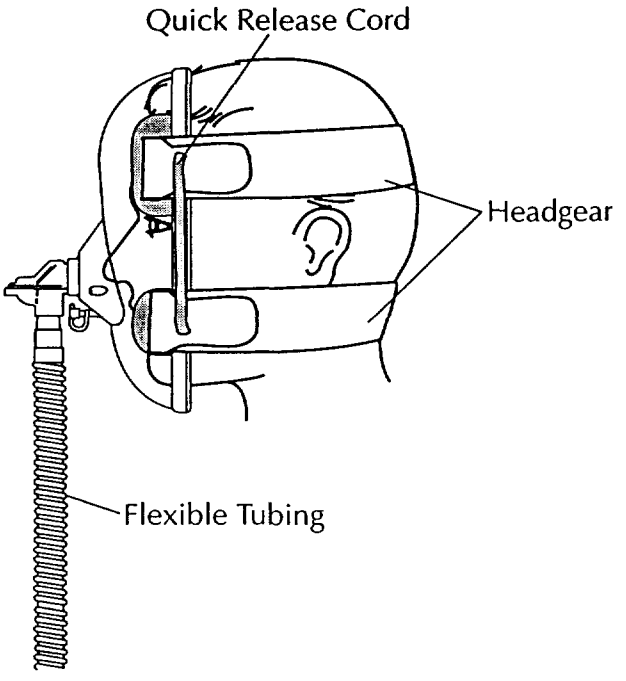


Figure 1. Respironics® Total™ Face Mask & headgear

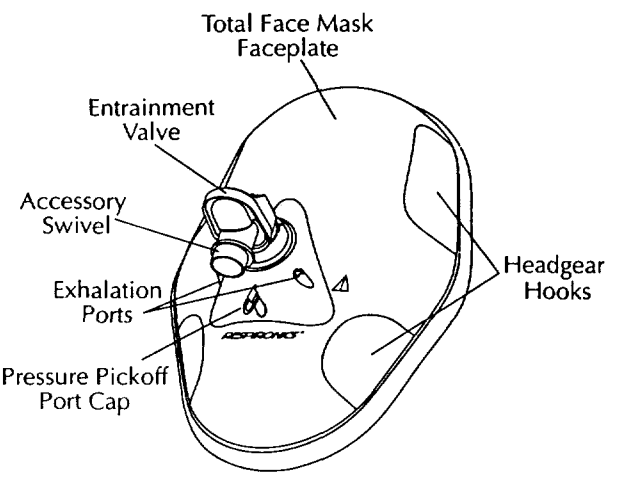


Figure 2. Respironics® Total™ Face Mask

The modified faceplate (Figure 2) is smaller, rounder, and has a streamlined profile. (Predicate mask is larger, primarily round, with the exception of the eye area, which is squared off.) Modified mask volume is smaller at 1550 ml. (Predicate volume is 2300 ml.) Modified mask cushion material is silicone. (Predicate cushion is urethane.)

Modified faceplate (Figure 2) has a nosepiece with 22-mm entrainment valve, whose accessory swivel connects to patient circuit. (Predicate faceplate has a 22-mm elbow, to which patient circuit is connected.) Entrainment valve opens to ambient air if pressure should cease. (Predicate requires use of a non-rebreathing valve (NRV).) Two built-in exhalation ports are located on the nosepiece. (Predicate's ports are located on the mask.) Nosepiece has one pressure pickoff port. (Predicate elbow has two.) The headgear consists of Velcro® straps. (Predicate headgear is a cap with Velcro straps.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 10 1999

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K992969
Total Face Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: October 8, 1999
Received: October 12, 1999

Dear Mr. Vanella:

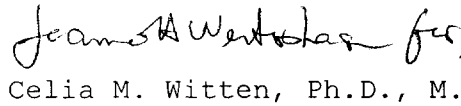
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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,



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992969

Device Name: Respironics® Total™ Face Mask

Intended Use/Indications for Use

The Respironics® Total™ Face Mask is intended to provide an interface for application of Respironics CPAP or BiPAP therapy to patients.

Environment of Use/Patient Population

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ 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 K992969