K991648

MAY 28

ATTACHMENT 4

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

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

Official Contact	David J. Vanella Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668
Classification Reference	21 CFR 868.5895
Product Code	BZD – noncontinuous ventilator
Common/Usual Name	nasal mask
Proprietary Name	Reusable II Contour Nasal Mask
Predicate Device	Reusable Contour Nasal Mask As cleared with Respironics BiPAP S/T-D System (K951264)
Reason for submission	Change in design; change in materials

Substantial Equivalence

Verification testing has shown the modified mask has the following similarities to the previously cleared predicate device:

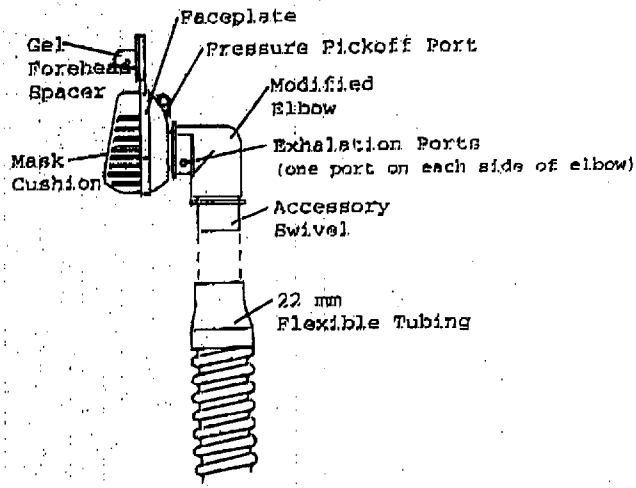
- ☐ Same indicated use.
- ☐ Same operating principle.
- ☐ Same skin-contacting mask cushion materials.
- ☐ Same technology.
- ☐ Same manufacturing process.

In summary, the mask described in this submission is, in our opinion, 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 Reusable Contour II Nasal Mask is intended to provide a single-patient use interface for adult patients (>30 kg) receiving Respironics CPAP or bi-level therapy. It consists of a silicone skin-contacting cushion, a polycarbonate faceplate and a polycarbonate elbow (to which 22 mm flexible tubing is attached). The mask elbow swivels 360 degrees relative to the faceplate.



Reusable Contour II Nasal Mask.

The Reusable Contour II Nasal mask has two permanently fixed exhalation ports (vent holes), one on each side of the mask elbow, which eliminate the need for a separate exhalation device. An accessory swivel allows rotation of the flexible tubing about its center axis. Thus the elbow swivels at both the faceplate and the tubing connection. The mask cushion material varies in thickness for better seal and fit. The cushion material is thinnest where the cushion contacts the nose.

The faceplate has a streamlined, compact shape to reduce mask volume. The gel forehead spacer is mounted on the mask's forehead extension. Because it distributes force more evenly than the current foam spacer, it allows the patient or caregiver to increase strap tension without jeopardizing patient comfort. The Reusable Contour II Nasal Mask (with an optional headstrap) is available in three sizes to fit a broad range of facial structures. *(End of Section.)*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1999

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

Re: K991648
Reusable Contour Nasal Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: May 12, 1999
Received: May 13, 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991648

Device Name: Reusable Contour II Nasal Mask

Intended Use/Indications for Use

The Respironics Reusable Contour II Nasal Mask is intended to provide an interface for application of Respironics bi-level or CPAP 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 (>30kg) for whom bi-level or CPAP therapy has been prescribed using a Respironics bi-level or CPAP 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 K991648