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	Monarch II Mini Mask
Predicate Device	Monarch Mini Mask (K945938)
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:

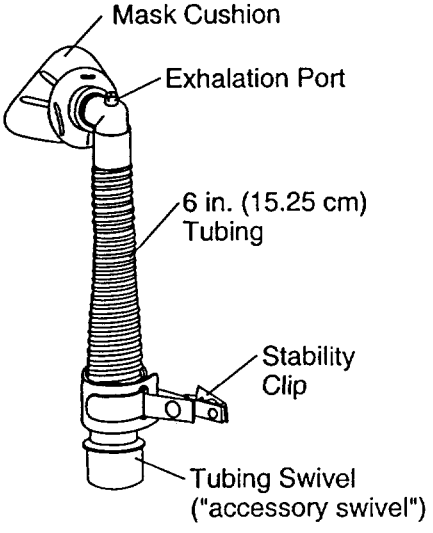
- ❑ Same indicated use.
- ❑ Same operating principle.
- ❑ Same skin-contacting mask cushion materials.
- ❑ Same technology.
- ❑ Same manufacturing process.

In summary, the mask described in this submission is 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 Monarch II Mini Mask is a single-patient-use interface for adult patients (> 30 kg) receiving Respironics CPAP or bi-level therapy. The mask consists of a removable silicone skin-contacting cushion, a polycarbonate faceplate, and a polycarbonate elbow (to which 15 mm flexible tubing is attached). The elbow fits on the faceplate at a 90° angle and swivels 360° about faceplate.



Monarch II Mini Mask

The Monarch II Mask incorporates a thin mask cushion that folds inward, creating a flap to improve seal. The mask fits over the tip of the nose (rather than under the nares). This improves the stability of the mask and also accommodates patients with various nose sizes and facial shapes. The shape of the modified cushion is that of a typical nasal mask (triangular). The mask is available in two sizes, small and medium, and is available with or without headgear. The mask does not come in contact with the nasal bridge area.

The faceplate is round and has three slots for the corresponding headgear attachment tabs. One exhalation port is on the elbow. The headgear material is Neoprene™ encased in nylon/polyester, a common material used for apparel products. It is safe for "next-to-skin" applications. The headgear has three attachment tabs.

Mask tubing is reusable, drapeable low-density polyethylene with EVA. Mask tubing is 6 inches long, 15 mm diameter at the mask, and gradually widens to 22 mm diameter at the opposing end. The 22-mm end of the mask tubing has an "accessory swivel" used to attach a 6-foot patient circuit.

(End of Section.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Drive
Murrysville, PA 15668-0299

Re: K992336
Monarch™ Mini Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: August 6, 1999
Received: August 9, 1999

Dear Mr. Ward:

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): K992336

Device Name: Monarch II Mini Mask

Intended Use/Indications for Use

The Respironics Monarch II Mini Mask is intended to provide an interface for application of Respironics CPAP or bi-level 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 bi-level therapy has been prescribed using a Respironics CPAP or bi-level system.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992336

(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)