MAY 24 1999

SECTION 1

SUMMARY OF SAFETY & EFFECTIVENESS

RESPIRONICS INC.®

1001 Murry Ridge Drive, 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	MNT – continuous ventilator, minimal ventilatory support
Common/Usual Name	nasal mask
Proprietary Name	Stick-On Disposable Nasal Mask
Predicate Device	Disposable Contour Nasal Mask As cleared with Respironics BiPAP S/T-D System (K951264)
Reason for submission	New Device

Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the Stick-On Disposable Nasal Mask is substantially equivalent to, and has the same intended use as, the Respironics Disposable Contour Nasal Mask, as cleared with the Respironics BiPAP S/T-D System.

Testing was performed to demonstrate that the performance of the Stick-On Disposable Nasal Mask in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of the Stick-On Disposable Nasal Mask were verified through performance-related testing. The Stick-On Disposable Nasal Mask was tested and found compliant

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

Device Description/Intended Use/Indications for Use

The Disposable Nasal Stick-On Mask is intended to provide an interface for application of Respironics BiPAP and CPAP therapy to patients. The mask consists of a faceplate with a contoured skin-contacting foam seal. The inlet connector of the faceplate has a pre-assembled, 22mm extendible inlet tube that attaches to a Respironics 22mm circuit. The faceplate has an integrated supplemental exhalation port and strap tabs to accommodate a strap that facilitates holding the mask in place under pressure. The mask is single use, however it can be repositioned on a patient during application and use.

The Stick-On Mask is molded of a soft thermoplastic elastomer, allowing it to flex to fit most adults. The skin-contacting portion is a soft foam material that is bonded to the faceplate of the mask. The foam seal is a laminate of three layers: a skin-contacting layer of a pressure sensitive adhesive material, a center contouring layer made of a soft, mostly closed cell foam, and an interfacing bonding the foam to the faceplate.

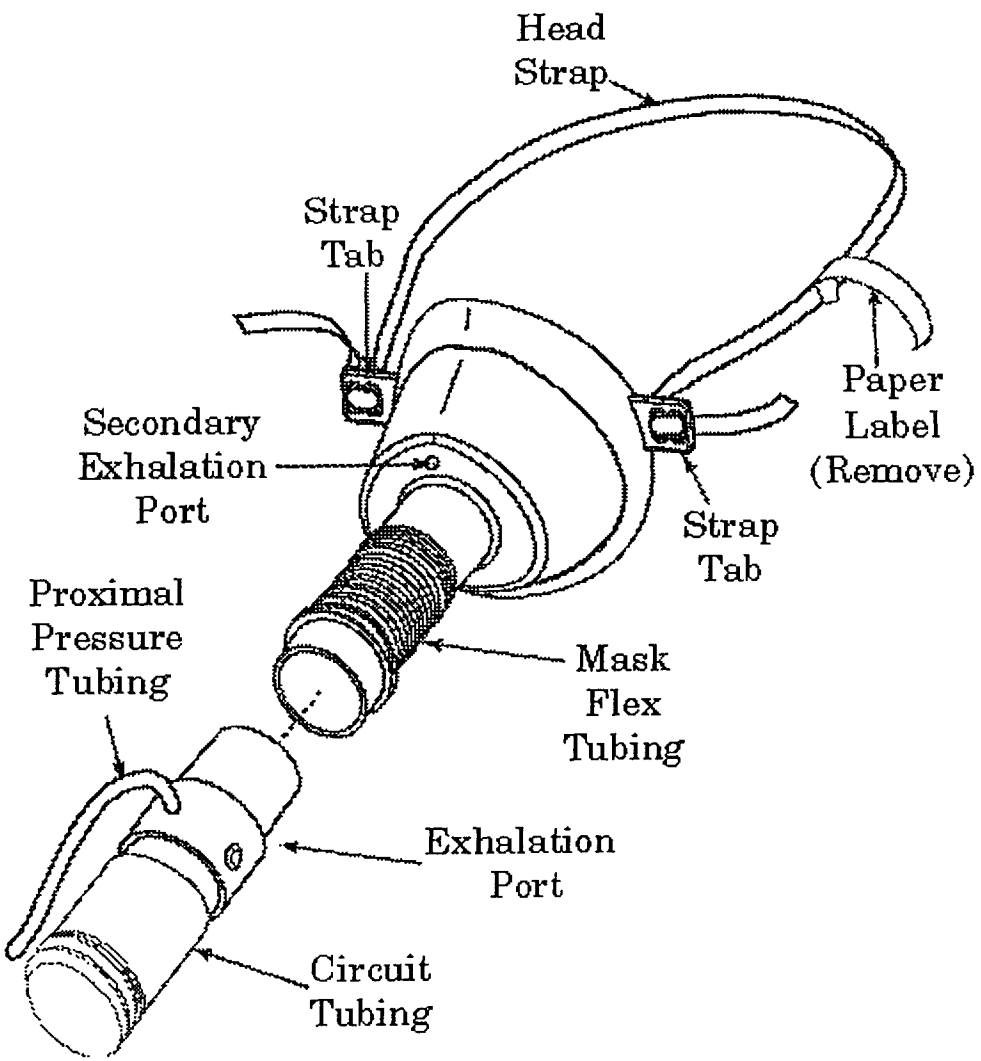


Figure 1-1. Stick-On Disposable Nasal Mask.

Environment of Use/Patient Population

The Stick-On Disposable Nasal Mask is intended for short-term, single use in a hospital or institutional environment. The mask is to be used on adult patients (> 30 kg) under the following conditions:

- Patients for whom BiPAP or CPAP has been prescribed, using a Respironics BiPAP or CPAP system.
- Intact, external skin surfaces only.

(End of Section.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 1999

Mr. David J. Vanella
Manager, Regulatory Affairs
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550

Re: K990574
Stick-On Disposable Nasal Mask
Regulatory Class: II (two)
Product Code: MNT
Dated: February 22, 1999
Received: February 23, 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.

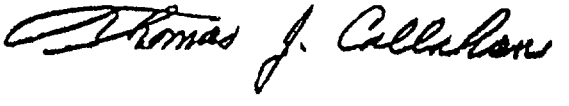
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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, ²Misbranding by reference to premarket notification² (21CFR 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): _____

Device Name: Stick-On Disposable Nasal Mask

Intended Use/Indications for Use

The Respironics Stick-On Disposable Nasal Mask is intended to provide an interface for application of Respironics BiPAP and CPAP support therapy to patients.

Environment of Use/Patient Population

For short-term, single use in a hospital or institutional environment. The mask is to be used on adult patients (> 30kg) under the following conditions:

- ☐ Patients for whom BiPAP or CPAP has been prescribed, using a Respironics BiPAP or CPAP system.
- ☐ Intact, external skin surfaces only.

(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 K980574