NOV 26 1999

K990659

XI. 510(K) Summary

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By: Breathing Technologies Corp.
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Waycross, GA 31501

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Date Prepared: November 16, 1999

Contact Person: Tom Wood, CEO

Device Name: Ventilator accessory mask,
Ventilator nasal mask
Ventilator nasal insert
(common names)

Ventilator Accessory
(classification names)

Nasal-Aire™
(proprietary trade name)

Predicate Device: The Monarch® Mini Mask manufactured by Respironics, Inc.
Cleared for market by 510(k) #K945938

Indications for Use and Description of Subject Device:

Nasal-Aire is intended for use as an accessory to respiratory ventilators. Nasal-Aire is a nasal insert with attached tubing for connection with non-continuous ventilation devices. The simplicity of the Nasal-Aire design allows easy manipulation of the device. Soft, pliable silicone is used for the nasal insert portion of the device facilitates a comfortable fit of the device when in use. Ventilation is indicated for patients who require mechanical assistance with breathing.

The Nasal-Aire accessory and associated tubing is intended for use in delivering ventilation to patients. The device consists of a hollow silicone elastomer under nose strip with molded nasal insert sleeves made from silicone elastomer. The under nose strip is fitted bilaterally with 3/8" Tygon® tubing which serves as conduits for ventilation. The tubing is joined to form a single ventilation conduit by a silicone elastomer "Y" coupling. The system is completed by the leg of the "Y" coupling connected to an adapter for connection to the main ventilators supply line. When the device is worn by the patient the under nose strip is positioned across the patient's upper lip and the silicone nasal inserts are inserted in the patient's nares. The tubing drapes over the patient's ears in the manner of standard nasal cannulae used for administering oxygen with the "Y" coupling positioned in front of the patient.

A limited clinical study was conducted using the device to assess unintended leakage of respiratory gases during clinical use. In vivo tests with healthy subjects ventilated with up to 2 Liters at inspiration rates of 100Lpm confirmed that unintended leakage was negligible and did not adversely impact the effectiveness of the device.

The materials of which the device is manufactured are all standard medical grade materials with an established history of safe clinical use in similar therapeutic respiratory devices. Patient contact with all materials includes mucosal membrane contact for limited contact duration. The patient contacting materials used in the device are specified to meet the biocompatibility requirements identified in the FDA's Blue Book Memorandum G95-1 and in ANSI/AAMI/ISO Standard 10993 (Part 1) for both surface devices with limited skin contact of less than 24 hours and surface devices with limited duration mucosal membrane contact.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 1999

Mr. Tom Wood
Breathing Technologies, Corp.
1909 Tebeau Street
Waycross, GA 31501

Re: K990659
Nasal-Aire
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: Undated
Received: September 16, 1999

Dear Mr. Wood:

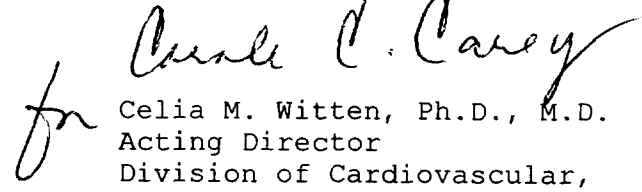
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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



for 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

K990659

Nasal Aire
by
Breathing Technologies

Intended Use

Nasal Aire is an accessory to positive pressure ventilation devices (e.g. CPAP, Bi-level). It may also be used in respiratory insufficiencies if the patient can tolerate the excess dead space.

The Nasal-Aire cannot exhaust exhaled air therefore this device must be used with a ventilator that contains an active exhalation valve or with an intentional leak port added into the breathing circuit

Carol C. Cory

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990659

✓ prescription use