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K031896

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name:	InnoMed Technologies Inc.
Submitter's Address:	506 Garden St. Greensburg PA 15601 USA
Telephone Number:	(724) 838-7880
Fax Number:	(724) 838-7886
Contact Person:	Frank Pelc
Date:	October 17, 2003
Proprietary Name:	Nasal-Aire Critical Care
Classification:	Class II, 1. CFR 868.5895 MNT 2. 868.5905 BZD
Classification Name:	1. Ventilator, Continuous, Non-Life Supporting 2. Accessory to Continuous Ventilator
Predicate Devices:	**K982454**, BiPAP Vision Ventilatory Support System and Whisper Swivel exhalation port as cleared with use for this ventilator; Manufacturer: Respironics Inc. **K003075**, Knightstar 330 Ventilator and Breeze Sleepgear Interface with Nasal Pillows Assembly as interface recommended for use by the manufacturer with this ventilator; Manufacturer: Puritan-Bennett. **K022465,** Nasal-Aire II, Innomed Technologies **K023244**, Mirage Full Face Mask Series, ResMed, Inc.

Device Description – Nasal-Aire Criticial Care is ventilator interface accessory intended for use with a CPAP or Bi-Level device to provide noninvasive ventilation in adult patients for the treatment of respiratory insufficiencies or obstructive sleep apnea. This single use disposable interface is intended for hospital settings.

Nasal-Aire Critical Care consists of a soft nosepiece with two exhaust ports and two soft nasal cannula for fitting into the nasal openings. Connected on each side of the nosepiece is a length of tubing. The two lengths of tubing are joined at the opposite ends by a "Y"-shaped coupling, forming a loop with the nosepiece at one end and the "Y" coupling at the other. At the base of the "Y" coupling is a port for connection of the Nasal-Aire Critical Care to a positive pressure ventilation device. The Nasal-Aire Critical Care is compatible with any positive pressure ventilator containing a 22mm connection. Nasal-Aire Critical Care will be offered in various sizes designed for a comfortable and compliant fit for a wide variety of nare sizes.

Substantial Equivalence – Biocompatability requirements and functional testing relative to the intended use of the Nasal-Aire Critical Care have been satisfactorily completed to show that it is as safe and effective as the predicate devices.

The table below, comparing the Nasal-Aire Critical Care to predicate devices, shows that it is comparable to other devices cleared for similar intended use.

Comparison of Features

Attribute	**Nasal-Aire Critical Care** (Subject device)	**KnightStar 330 Ventilator w/Breeze Interface**	**Mirage Full Face Mask Series**	**Vision Ventilator System w/Whisper Swivel**
Intended Use	Intended for use with CPAP or Bi-Level device to provide noninvasive ventilation for the treatment of respiratory insufficiency or obstructive sleep apnea.	Non-invasively treat spontaneously breathing patients weighing 30kg or more who suffer from respiratory insufficiency and/or obstructive sleep apnea.	Intended for multiple patient use for adult patients prescribed continuous positive airway pressure (CPAP) and bi-level therapy.	Intended to augment the breathing of spontaneously breathing adult patients suffering from respiratory failure, respiratory insufficiency, or obstructive sleep apnea.
Intended Environment: Hospital/Institutional Use	Yes	Yes	Yes	Yes
Offered in Various sizes	Yes	Yes (interface)	Yes	No
Intended for Single Patient Use	Yes	Yes (interface)	No, multiple patient	Yes (interface)
Provided Non-Sterile	Yes	Yes (interface)	Yes	Yes (interface)
Compatible with 22mm ventilator connection	Yes	Yes	Yes	Yes
Treatment delivered through Nasal Passages	Yes	Yes (interface)	Yes and mouth	N/A
CPAP Swivel Connection	Yes	Yes (interface)	Yes	Yes

Attribute	**Nasal-Aire Critical Care** (Subject device)	**KnightStar 330 Ventilator w/Breeze Interface**	**Mirage Full Face Mask Series**	**Vision Ventilator System w/Whisper Swivel**
Pressure delivery 3-35 cm H_2O	Yes	Yes	Yes	Yes
Allows for pressure monitoring	Yes	Yes	Yes	Yes
Intended Population	Adult	Adult	Adult	Adult
Patient Contact Material	Silicone	Silicone	Silicone	N/A
Interface:Tubing Length	7"	15/18"	unknown	N/A
Latex Free	Yes	Yes	Yes	N/A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2004

InnoMed Technologies Incorporated
Mr. Frank Pelc
Director, Regulatory Affairs
Northeast Division
506 Garden Street
Greensburg, Pennsylvania 15601

Re: K031896
Trade/Device Name: Nasal-Aire Critical Care
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNS, BZD
Dated: October 18, 2003
Received: October 21, 2003

Dear Mr. Pelc:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

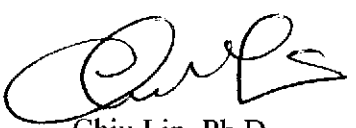
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K031896

Applicant: InnoMed Technologies

Device Name: *Nasal-Aire Critical Care*

Indications for Use:

Nasal-Aire Critical Care ventilator interface is intended for use with a CPAP or Bi-Level device to provide noninvasive ventilation in adult patients for the treatment of respiratory insufficiencies or obstructive sleep apnea. This single use disposable interface is intended for hospital settings.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)

Prescription Use X

Over-the counter Use_____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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