K050171

MAY - 4 2005

InnoMed Technologies

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

InnoMed IT Nasal Mask

InnoMed Technologies
506 Garden Street
Greensburg, PA 15601

March 9, 2005

Official Contact

Frank Pelc
Director, Regulatory Affairs
InnoMed Technologies
506 Garden Street
Greensburg, PA 15601

(After April 1, 2005):
6601 Lyons Road Suites B1-B4
Coconut Creek, FL 33073

Classification Name 21 CFR 868.5895, 73 MNS

Common/Usual Name Ventilator, continuous, non-life supporting (accessory to)

Proprietary Name IT Nasal Mask

Predicate Devices

K991648 -- Respironics Contour Nasal Mask

K974453 -- Respironics Comfort Classic Nasal Mask

K984428 -- ResMed Mirage Nasal Mask

K984407 -- Respironics Bipap Harmony S/T, and accessories cleared with said ventilator

K962517 – HealthDyne Model 7700 Quantum Pressure Support Ventilator and accessories cleared with said ventilator

InnoMed IT Nasal Mask

Substantial Equivalence

This premarket notification section 510(k) submission demonstrates that the InnoMed IT Nasal Mask is substantially equivalent to the Respironics Contour and Comfort Classic Nasal Masks, and the ResMed Mirage Nasal Mask. Each of these devices is used as a patient interface accessory for currently-marketed CPAP and bi-level ventilatory devices. These devices are constructed of equivalent materials, have similar designs and configurations, and operate in the same manner.

Testing was conducted to demonstrate that the performance of the InnoMed IT Nasal Mask, when used as prescribed, is as safe and effective as that of the legally marketed predicate device. Testing demonstrated that the important clinical performance characteristics were equivalent to those of the predicate devices. The characteristics tested included exhalation port flow rate, exhalation port resistance, and mask volume (or "deadspace").

The major functional components of the InnoMed IT Nasal Mask are constructed of the same materials (polycarbonate plastic and silicone elastomer) as the predicate devices. These materials have been demonstrated to meet industry standards for patient-contact biocompatibility. The cleaning methods prescribed for the InnoMed IT Nasal Mask are the same as those provided for the predicate devices, and have been shown to be effective for single-patient use.

General Description

Intended Use/Indications for Use

The InnoMed Technologies IT Nasal Mask is intended to be used as a patient interface for currently-marketed CPAP and Bi-Level positive-pressure ventilation devices capable of generating pressures up to 20cm H_2O. It is indicated for use in non-critical care applications such as treatment of adult obstructive sleep apnea and ventilatory support during respiratory insufficiency.

The InnoMed Technologies IT Nasal Mask is available by prescription, and is intended for single patient use only for adult patients (>30kg) in home or hospital settings.

Manufacturer

The IT Nasal Mask is commercially distributed in the United States by InnoMed Technologies, Inc.

Summary Device Description

The IT Nasal mask consists of a polycarbonate faceplate shaped to fit around the patient's nose, and a silicon cushion covering the edge of the faceplate where the mask makes contact with the patient's face. At the front of the mask's faceplate is a 90-degree elbow attached so as to allow it to rotate 360 degrees relative to the faceplate.

The other end of the elbow is configured as a standard female 22mm fitting for the attachment of a separate exhalation port/swivel that is supplied with each IT Nasal Mask. This exhalation port is configured so as to sufficiently exhaust exhaled air from the patient at a proper flow rate. The other end of the exhalation port/swivel allows connection to a CPAP or bi-level positive pressure ventilator's flexible breathing circuit tubing.

The IT Nasal mask is available in seven different sizes in order to accommodate a broad range of facial feature variations.

The IT Nasal Mask is secured to the patient by a single-piece nylon cloth headset. The headset has four straps which allow the mask to be adjusted for proper fit and patient comfort, and provide for quick removal of the mask.

To use the IT Nasal Mask, the exhalation port/swivel is attached to the mask, then connected to the ventilatory device's breathing circuit per the manufacturer's instructions. The headset is secured to the mask, and the mask placed over the patient's face with the ventilator running. The headset is adjusted so that the mask fits comfortably and provides an adequate seal.

The patient can now breathe normally and receive the prescribed therapy. Upon inhalation, pressurized air from the breathing circuit enters the mask and is breathed in through the patient's nose. As the patient exhales, exhaled air passes through the mask and out into the breathing circuit. The patient can continue to wear the mask for the prescribed period as long as the ventilatory device continues to operate properly.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

Mr. Frank Pelc
Regulatory Affairs Director
InnoMed Technologies, Incorporated
6601 Lyons Road, Suites B1-B4
Coconut Creek, Florida 33073

Re: K050171
Trade/Device Name: InnMed Technologies IT Nasal Mask
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 13, 2005
Received: April 14, 2005

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.

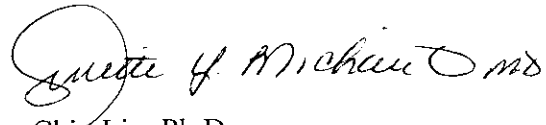
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.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

510(k) Number (if known): K050171

Device Name: InnoMed Technologies IT Nasal Mask

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for AAG

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

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