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NOV - 5 2009

510(k) Summary

Company Name:
InnoMed Technologies, Inc.
6601 Lyons Rd.
Suites B1-B4
Coconut Creek, FL 33073

Official Contact: Linda Magill Director of Quality and Regulatory Affairs

Telephone: (561) 208-3778

Fax: (888) 280-6607

Summary Date: March 20, 2009

Device Trade Name: Nasal-Aire II Pediatric

Common/Usual Name: Accessory to Non-Continuous Ventilator

Classification Name: Non-Continuous (Respirator) Ventilator (21 CFR 868.5905, Product Code BZD)

Predicate Devices:

510(k) Number: K060105
Manufacturer: ResMed
Trade Name: Kidsta Mask System

510(k) Number: K022465
Manufacturer: Innomed Technologies Inc..
Trade Name: Nasal-Aire II

510(k) Number: K002001
Manufacturer: Puritan Bennett Corp.
Trade Name: Breeze Sleepgear with Nasal Pillows

510(k) Number: K072993
Manufacturer: AEIOMed, Inc.
Trade Name: Reusable Headrest® with Nasal Seal

510(k) Number: unknown
Manufacturer: Hudson RCI
Trade Name: Infant Nasal CPAP Set

Device Description:

The Nasal-Aire II Pediatric has been modified from the Nasal-Aire II to meet the requirements of the pediatric population and adults requiring smaller sizes to achieve the proper fit and comfort. The Nasal-Aire II Pediatric provides therapy through the nose only.

The Nasal-Aire II Pediatric interface is an accessory to positive pressure ventilation devices (i.e. CPAP, Bi-Level) for both adult and pediatric patients aged seven and older or weighing more than 40 lbs, in hospital, clinic, or home environments.

For homecare applications, the Nasal-Aire II Pediatric may be reused multiple times by a single patient. For institutional applications (i.e. sleep lab, other clinical settings), the interface may be reused multiple times by multiple patients.

The Nasal-Aire II Pediatric interface has a soft nasal cannula to form a seal with the nasal openings. The nasal cannula has two nasal inserts and has integrated exhalation ports. The interface also has tubing, connectors to attach the tubing to the nasal cannula, and a swivel coupling that allows the interface to connect to the ventilation device. Headgear is attached to the device to secure the interface on the patient.

There are five nasal cannula sizes available, ranging from A (largest) to E (smallest).

The device is available by prescription only.

Intended Use:

The Nasal-Aire II Pediatric interface is an accessory to positive pressure ventilation devices (i.e. CPAP, Bi-Level) for both adult and pediatric patients aged seven and older or weighing more than 40 lbs, in the hospital, clinic or home environments.

The Nasal-Aire II Pediatric is intended for single-patient re-use in the home environment and multiple-patient re-use in the hospital / institutional environment.

Technology:

The Nasal-Aire II Pediatric has three significant components:

- Silicone Cannula with Nasal Inserts and Exhalation Ports
- Tubing with a "Y' shaped swivel coupling
- Headgear

Nasal-Aire II Pediatric is designed for patient comfort to facilitate patient compliance so that maximum benefit of the prescribed therapy can be derived. The headgear is adjustable by the user. Five different sizes of the cannula are available for a comfortable fit and a good seal. The swivel coupling connects to the ventilation device. The cannula provides the airflow pathway to the user's nasal openings.

Conclusion

The Nasal-Aire II Pediatric device is substantially equivalent to the predicate devices in intended use, environment of use, patient population, and frequency of use. Its basic method of operation and design are also substantially equivalent to the predicates. Materials information and functional testing relative to the intended use of the Nasal-Aire II Pediatric show that it is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Linda Magill
Director of Quality and Regulatory Affairs
Innomed Technologies, Incorporated /RespCare, Incorporated
6601 Lyons Road, Suites B1-B4
Coconut Creek, Florida 33073

NOV - 5 2009

Re: K090804
Trade/Device Name: Nasal-Aire II Pediatric Interface Accessory to Positive Pressure Ventilation Device
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator IPPB
Regulatory Class: II
Product Code: BZD
Dated: October 15, 2009
Received: October 16, 2009

Dear Ms. Magill:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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: _____ (To be assigned)

Device Name: Nasal-Aire II Pediatric Interface Accessory to Positive Pressure Ventilation Device

Indications for Use:

The Nasal-Aire II Pediatric interface is an accessory to positive pressure ventilation devices (i.e. CPAP, Bi-Level) for both adult and pediatric patients aged seven and older or weighing more than 40 lbs, in the hospital, clinic or home environments.

The Nasal-Aire II Pediatric is intended for single-patient re-use in the home environment and multiple-patient re-use in the hospital / institutional environment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K090804