K080983

AUG - 7 2008

510(K) SUMMARY

510(k) Applicant:	Ventus Medical, Inc. 1301 Shoreway Rd., Suite 340 Belmont, CA 94002 (650) 632-4199 (phone) (650) 632-4198 (fax)
Contact:	Cindy Domecus, R.A.C. (US & EU) Domecus Consulting Services LLC (650) 343-4813
Date Summary Prepared:	July 17, 2008
Name of Device:	Provent™ Nasal Cannula
Common Name:	Nasal Cannula
Classification Name:	Breathing Frequency Monitor (21 CFR 868.2375, Product Code MNR)
Predicate Device:	Predicate devices included in the 510(k) Notification are as follows: K051313, Salter Labs Bi-NAPS Nasal Airflow and Snore Transducer K984431, Braebon Medical Ultima Airflow Sensor K971501, Bio-logic Airflow Pressure Transducer K053063, Pro-Flow Multipurpose Cannula

Device Description:
The Provent Nasal Cannula was developed to transmit pressure signals from the Provent Professional Sleep Apnea Therapy device to a pressure transducer of a physiologic recorder during sleep evaluations. The Provent Nasal Cannula is specifically designed to attach the Provent Professional Sleep Apnea Therapy (Provent PSAT, K071560) device to standard pressure transducers.

The Provent Nasal Cannula is essentially identical to standard nasal cannulae except for its custom connection to the Provent PSAT. The Provent Nasal Cannula is comprised of the same design elements as a standard nasal cannula:

1. a bifurcated tube with a luer lock connector,
2. an anti-microbial filter at one end, and
3. a component to hold the tubes in the correct location near the nostrils at the other end.

The Provent nasal cannula is worn in the same way as the standard nasal cannulae, with the proximal ends held in place in the path of nasal airflow and the tubing routed over the ears and under the chin.

Indications for Use:

The Provent Nasal Cannula is indicated for the transmission of respiratory airflow signals between the Provent Professional Sleep Apnea Therapy device and the pressure transducers used with physiologic recorders during sleep studies.

Comparison to Predicate Devices:

The table below shows a comparison the Provent Nasal Cannula to its predicates.

	Provent Nasal Cannula	**Salter Labs BI-NAPS Nasal Airflow and Snore Transducer**	**Biologic Airflow Pressure Transducer**	**Braebon Medical Ultima Airflow Sensor**	**Pro-Flow Multipurpose Cannula**
Indications for Use	The Provent Nasal Cannula is indicated for the transmission of respiratory airflow signals between the Provent Professional Sleep Apnea Therapy device and the pressure transducers used with physiologic recorders during sleep studies.	The Salter Labs Airflow Pressure Transducer is a reusable device intended for use during sleep disorder studies to detect respiratory airflow and snoring for recording onto a polysomnography recorder via nasal pressure changes.	The Bio-logic Airflow Pressure Transducer is indicated for use during sleep disorder studies to detect respiratory airflow for recording on a physiological recorder. It is a battery-powered device, with a disposable nasal cannula which attaches to the patient and plugs into the input of the Airflow Pressure Transducer device.	The Ulitma Airflow Pressure Sensor is intended for use during sleep disorder studies as a qualitative measure of respiratory airflow ... A disposable nasal cannula with a 0.2-micron hydrophobic filter attaches to the patient and connects to the input of the Ultima Airflow Pressure Sensor.	Intended for use for simultaneous detection of respiratory airflow and sampling, or delivery, of gases, such as EtCO2 or oxygen
Product Code	MNR	MNR	MNR	BZQ	CCK
Purpose	Carry nasal airflow signals	Carry and process nasal airflow signals	Carry and process nasal airflow signals	Carry and process nasal airflow signals	Carry nasal airflow signals and sample or deliver gas

	Provent Nasal Cannula	Salter Labs BI-NAPS Nasal Airflow and Snore Transducer	Biologic Airflow Pressure Transducer	Braebon Medical Ultima Airflow Sensor	Pro-Flow Multipurpose Cannula
Interface with nasal air flow	Two open tubing ends which attach to the Provent Professional Sleep Apnea Therapy device, which, in turn enters the nares	Two open tubing ends on nasal prongs which enter the nares	Two open tubing ends on nasal prongs which enter the nares	Two open tubing ends on nasal prongs which enter the nares	Two open tubing ends on nasal prongs which enter the nares
Cannula interface with pressure transducer	Single Luer fitting	Single Luer fitting	Single Luer fitting	Single Luer fitting	One Luer fitting for each purpose (one for airflow monitoring and one for gas delivery/sampling)
Method of pressure signal transmission	Hollow tubing	Hollow tubing	Hollow tubing	Hollow tubing	Hollow tubing
Reuse	Single use, disposable	Cannula portion is single use, disposable	Cannula portion is single use, disposable	Cannula portion is single use, disposable	Single use, disposable

Table 4-1. Comparison of the Provent Nasal Cannula with predicate devices

Performance Data:

Bench data were submitted to support the 510(k) Notification. The bench testing demonstrated that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ventus Medical, Incorporated
C/O Ms. Cindy Domecus
Principal
Domecus Consulting Services LLC
1301 Shoreway Road, Suite 340
Belmont, California 94002

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Re: K080983
Trade/Device Name: Provent™ Nasal Cannula
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: July 17, 2008
Received: July 21, 2008

Dear Ms. Domecus:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Chiu S. Lin, Ph. D
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 (if known):

Device Name: Provent™ Nasal Cannula

Indications for Use:

The Provent Nasal Cannula is indicated for the transmission of respiratory airflow signals between the Provent™ Professional Sleep Apnea Therapy device and the pressure transducers used with physiologic recorders during sleep studies.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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