K090398

## 510(k) Summary

APR - 3 2009

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| 510(k) Applicant: | Ventus Medical, Inc.<br>1301 Shoreway Road, Suite 425<br>Belmont, CA 94002<br>(650) 832-6118 (phone)<br>(650) 632-4198 (fax) |
| Contact: | Mary Rose, R.A.C.<br>Manager, Regulatory Affairs |
| Date Summary Prepared: | February 13, 2009 |
| Name of Device: | PROVENT™ Professional Sleep Apnea Therapy – 50 cm $H_2O$ sec/liter |
| Common Name: | Intraoral device |
| Classification Name: | Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570) |
| Product Code: | OHP |
| Predicate Device: | Provent™ Professional Sleep Apnea Therapy, K071560 |

**Device Description**

The PROVENT device is placed just inside the nostrils. The device directs expiratory flow through selected pathways, which increases intranasal pressure similar to the expiratory portion of the breathing cycle during CPAP use.

**Indications for Use**

For the treatment of obstructive sleep apnea (OSA).

**Performance Data**

Non-clinical and clinical testing demonstrated substantial equivalence of the PROVENT 50 device to the predicate device when used according to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ventus Medical
c/o Mary Rose
Manager, Regulatory Affairs
1301 Shoreway Road, Suite 425
Belmont, CA 94002

APR - 3 2009

Re: K090398
Trade/Device Name: PROVENT 50
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: Class II
Product Code: OHP
Dated: February 13, 2009
Received: February 17, 2009

Dear Ms. Rose :

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) 276-0115. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K090398

Device Name: PROVENT Professional Sleep Apnea Therapy Device - PROVENT 50

Indications for Use:

The PROVENT Professional Sleep Apnea Therapy Device – PROVENT 50 intended use is for the treatment of obstructive sleep apnea (OSA).

Prescription Use X (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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090398