K120665

JUN 12 2012

510(k) Summary

Date Summary Prepared: June 12, 2012

510(k) Owner: Ventus Medical, Inc.
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Principal, Domecus Consulting Services LLC
Consultant to Ventus Medical, Inc.
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Trade Name: InVent Snoring Device
Common Name: Nasal Dilator
Classification Name: 21 CFR 874.3900 Nasal Dilator; Product Code LWF
Predicate Device: BR2 Nasal Dilator

Device Description:
As with the predicate device, the subject device is a nasal dilator intended to reduce or eliminate snoring. While the predicate device is an internal nasal dilator, the subject device is an external nasal dilator in which the device is placed over the patient's nostrils. As with the predicate device, the subject device creates dilating pressure or expiratory positive airway pressure (EPAP) to dilate and open the nasal airway. The device directs expiratory flow though selected pathways, which maintain nasal airway pressure and help maintain nasal passage dilation.

Intended Use: The InVent Snoring Device is intended to reduce or eliminate snoring.

Technological Characteristics Comparison:
The predicate device and subject device have the same mechanism of action – expiratory resistance. Minor changes have been made to the dimensions and materials.

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Performance Data:
Bench testing of the subject device confirms that it meets pre-defined specifications and is substantially equivalent to the predicate device. Clinical testing also supports that the device is safe and effective for its intended use.

Conclusion:
The InVent Snoring Device is substantially equivalent to the BR2 predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ventus Medical, Incorporated
% Ms. Cindy Domecus, R.A.C. (US & EU)
Principal
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Re: K120665
Trade/Device Name: InVent Snoring Device
Regulation Number: 21 CFR 874.3900
Regulation Name: Nasal dilator
Regulatory Class: Class I
Product Code: LWF
Dated: May 2, 2012
Received: May 3, 2012

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.

We note that your device exceeded the Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 CFR Part 874.9), and therefore required the submission and clearance of a premarket notification prior to commercial distribution in the United States. Future devices of this same type that meet the exemption criteria and do not exceed the limitations of exemptions found in 21 CFR Part 874.9 will be exempt from the premarket notification requirements of the Act.

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); 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 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, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. Indications for Use Statement

Indications for Use Form

Indications for Use
510(k) Number (if known): _____
Device Name: _InVent Snoring Device

Indications for Use:

The InVent Snoring Device is intended to reduce or eliminate snoring.

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

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

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