

K122391

JAN 10 2013

510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Establishment Registration Number: 1045254

Address of Manufacturer: Medtronic Xomed, Inc.
6743 Southpoint Drive North
Jacksonville, FL 32216
(904) 296-9600 Phone
(904) 296-2386 Facsimile

Contact Person: Douglas Johnson

Date: December 19, 2012

Trade or Proprietary Name: AIRvance™ Bone Screw System

Product Code
Class
Common name(s):
Classification Name(s):

- LRK
- II
- Device, Anti-Snoring
- Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea. (21 CFR§ 872.5570)
- Repose™ Bone Screw System (K981677)

Predicate device to the AIRvance™ Bone Screw System (K122391)

System Description:

The AIRvance™ Bone Screw System consists of three main components: a bone screw attached to surgical suture material, a bone screw inserter, and a suture passer. The AIRvance™ bone screw is a sharp tipped, small diameter titanium screw with polypropylene monofilament no. 1 suture crimped into its base. The AIRvance™ Bone Screw Inserter is a disposable, battery operated, single use device. The AIRvance™ Suture Passer is designed to assist in passing the suture through the floor of the tongue in a tongue base advancement procedure or through the neck during a hyoid suspension procedure.

Technological Characteristics:

The AIRvance™ Bone Screw System like its predicate device, the Repose™ Bone Screw System (K981677), is based on suspending soft tissue to fixed bone by means of sutures attached to bone screw. In respect to the procedures, the AIRvance™ Bone Screw System procedures are based upon well accepted and commonly used procedures like Hyoid Bone Suspension, Chin Osteotomy and Genioglossal Advancement for the treatment of OSA and/or snoring. None of the Technological Characteristics are different from those of the Predicate.

Indication for Use:

The AIRvance™ Bone Screw System is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring. The AIRvance™ Bone Screw System is also suitable for the performance of a hyoid suspension procedure which can be used in combination with other procedures for the treatment of obstructive sleep apnea (OSA). It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring.

Non Clinical Information:

No additional nonclinical tests were conducted in support of this submission. The current device is identical to the predicate.

Clinical Information:

The clinical information consists of a summary of clinical studies involving hyoid suspension published in the peer-review literature, to show that this treatment is often used successfully to reduce hypopharyngeal airway compromise in the effective treatment of OSA and may be used in combination with other surgical procedures (e.g. nasal, tongue palatal) that address additional sites of obstruction in the airway.

Multilevel upper airway surgery has evolved over the past 20 years and includes a variety of procedures to both enlarge the lumen and reduce the collapsibility of the upper airway during sleep. Currently, there is no readily defined standard by which to decide which combinations of procedures work best for a given patient. Factors that go into surgical decision making include physiologic variables (e.g., BMI), anatomic factors (e.g., craniofacial structure, tongue and tonsil size), sleep apnea severity, findings on upper airway fiber-optic endoscopy, and patient preference and economic/ health insurance considerations.

Because the hyoid and its attendant musculature are integral to the base of the tongue and the supraglottic airway, various surgical techniques have been used to bring the hyoid forward in order to advance the hypopharyngeal tissues and therefore expand hypopharyngeal space, specifically at the inferior base of the tongue, vallecula, and epiglottis.

Clinical Conclusion:

The use of hyoid suspension is an effective method to treat hypopharyngeal-based obstructions and can be used in combination with other procedures to effectively treat OSA with or without tongue suspension.

Conclusion:

Because the new device is physically identical to the predicate device, justifying no new nonclinical testing, along with the evolution of upper airway surgery and the factors regarding the method of treatment identified in the clinical information, we conclude that this new device is safe and effective for its intended use and performs as well or better than the predicate device.



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

January 10, 2013

Mr. Douglas Johnson
Principal Regulatory Affairs Specialist
Medtronic Xomed, Incorporated
6743 Southpoint Drive North
JACKSONVILLE FL 32216

Re: K122391

Trade/Device Name: AIRvance™ Bone Screw System

Regulation Number: 21 CFR 872.5570

Regulation Name: Intraoral Oral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea

Regulatory Class: II

Product Code: LRK

Dated: January 2, 2013

Received: January 4, 2013

Dear Mr. Johnson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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" (21 CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K122391

Device Name: AIRvance™ Bone Screw System

Indications for Use:

The AIRvance™ Bone Screw System is intended for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring. The AIRvance™ Bone Screw System is also suitable for the performance of a hyoid suspension procedure which can be used in combination with other procedures for the treatment of obstructive sleep apnea (OSA). It is indicated for the treatment of obstructive sleep apnea (OSA) and/or snoring.

Prescription Use ✓
(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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K122391