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K110623

FEB 10 2012

Section 5.0 510(k) Summary

A. 510(k) Owner

Medtronic Xomed, Inc
6743 Southpoint Drive North
Jacksonville, FL 32216 USA
Tel: 904-296-9600
Fax: 904-296-2386
Registration Number: 1045254

B. Contact Information

Rozanne Paciej
Senior Regulatory Affairs Specialist
904-332-8233 (phone)
904-296-2386 (fax)
rozanne.paciej@medtronic.com

C. Date Submission Prepared

March 3, 2011

D. Proprietary Name

Pillar Palatal Implant System

E. Device Name

Trade Name:	Pillar Palatal Implant System
Common/Usual Name:	Anti-Snoring Device
Classification Name:	LRK- Device, Anti-Snoring 21 CFR 872.5570, Class II

F. Predicate Devices:

Trade Name:	Pillar Palatal Implant System
Common/Usual Name:	Anti-Snoring Device
Classification Name:	LRK- Device, Anti-Snoring 21 CFR 872.5570, Class II
Premarket Notification:	K011723

G. Purpose of Submission:

Updating the labeling to the currently cleared Pillar Palatal Implant System.

H. Device Description

The Pillar Palatal Implant System is intended as a treatment option for snoring. The Pillar Palatal Implant System consists of an implant and a delivery tool. The implants are designed to stiffen the tissue of the soft palate reducing the dynamic flutter which causes snoring.

The implant is a cylindrical shaped segment of braided polyester filaments. The delivery tool is comprised of a handle and needle assembly that allows for positioning and placement of the implant submucosally in the soft palate. The implant is designed to be permanent while the delivery tool is disposable.

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I. Intended Use/Indications for Use

Indications for Use:

The Pillar System is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals

Intended Use

Indications for use of the System include: symptomatic, habitual, and social snoring due to palatal flutter.

J. Substantial Equivalence

The Pillar Palatal Implant System is identical in intended use, indications for use, design, intended anatomical site, and target population to the previously cleared Pillar Palatal Implant System (Anti-Snoring Device).

	Pillar Palatal Implant System	Pillar Palatal Implant System (Anti-Snoring Device)
510(k) Number	TBD	K011723
Substantial Equivalence Date	TBD	December 18, 2002
Regulation Number	21 CFR 872.5570	21 CFR 872.5570
Product Code/Classification	LRK; Class II	LRK; Class II
Intended Use/Indications for Use	Intended for use in stiffening the soft palate tissue which may reduce the severity of snoring in some individuals	Intended for use in stiffening the soft palate tissue which may reduce the severity of snoring in some individuals
Device Description	Intended as a treatment option for snoring. The System consists of an implant and a delivery tool. The implants are designed to stiffen the tissue of the soft palate reducing the dynamic flutter which causes snoring. The implant is a cylindrical shaped segment of braided polyester filaments. The delivery tool is comprised of a handle and needle assembly that allows for positioning and placement of	Intended as a treatment option for snoring. The System consists of an implant and a delivery tool. The implants are designed to stiffen the tissue of the soft palate reducing the dynamic flutter which causes snoring. The implant is a cylindrical shaped segment of braided polyester filaments. The delivery tool is comprised of a handle and needle assembly that allows for positioning and placement of the implant

	the implant submucosally in the soft palate. The implant is designed to be permanent while the delivery tool is disposable.	submucosally in the soft palate. The implant is designed to be permanent while the delivery tool is disposable.
Intended Anatomical Site	Soft Palate	Soft Palate
Target Population	Patients seeking treatment for snoring	Patients seeking treatment for snoring

J. Conclusion

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" a direct comparison of key characteristics demonstrates that the proposed Pillar Palatal Implant System is substantially equivalent to the predicate device since it is identical in intended use, indications for use, design, intended anatomical site, and target population. The Pillar Palatal Implant System is as safe, as effective, and performs as well as the 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

Ms. Rozanne Paciej
Senior Regulatory Affairs Specialist
Medtronic Xomed, Inc.
6743 Southpoint Drive, North
Jacksonville, Florida 32216

FEB 10 2012

Re: K110623
Trade/Device Name: Pillar Palatal Implant System
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: February 1, 2012
Received: February 2, 2012

Dear Ms. Paciej

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" (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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

Enclosure

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Section 4.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Pillar Palatal Implant System

Indications for Use:

The Pillar Palatal Implant System is intended for use in stiffening the soft palate tissue which may reduce the severity of snoring in some individuals.

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)

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: K110623