JUL 8 2004

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K040417

SUBMITTER: Restore Medical Inc.
2800 Patton Road
St. Paul, MN 55113

CONTACT PERSON: Edward W. Numainville

DATE PREPARED: February 17, 2004

TRADE NAME: Pillar™ Palatal Implant System

COMMON NAME: Palatal Implant System

CLASSIFICATION: Unclassified

PRODUCT CODE: LRK

PREDICATE DEVICE(S):

Pillar™ Palatal Implant System (a/k/a Anti-Snoring Device), manufactured by Restore Medical Inc, and cleared via 510(k) Notification K011723 on December 18, 2002 for the treatment of snoring.

Somnoplasty System, manufactured by Gyrus PLC (formerly Somnus Medical Technologies, Inc.) and cleared via 510(k) Notification K982717 on November 2, 1998 for the reduction of the incidence of airway obstructions in patients suffering from UARS (Upper Airway Resistance Syndrome) or OSAS (Obstructive Sleep Apnea Syndrome).

Sleep-In Bone Screw System, manufactured by Influence, Inc. cleared via 510(k) Notification K972023 on August 25, 1997 for the treatment of obstructive sleep apnea and/or snoring.

DEVICE DESCRIPTION: The Pillar™ Palatal Implant System ("System") is intended as a treatment option for snoring and obstructive sleep apnea. 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. Additionally, the implants reduce the incidence of airway obstruction caused by the soft palate.

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.

INTENDED USE: The System is intended for use in stiffening the soft palate tissue, which may reduce the severity of snoring in some individuals and reduce the incidence of airway obstructions in patients suffering from mild to moderate OSA (Obstructive Sleep Apnea).

EQUIVALENCE TESTING: The System has been clinically evaluated in support of expanding the current snoring indication to include the treatment of patients with OSA. The clinical results were compared to the clinical results of other products which have an indication for the treatment of OSA. The results were comparable in terms of performance.

CONCLUSION: The Pillar™ Palatal Implant System with the additional OSA indication is substantially equivalent to the current commercially available System which is indicated for snoring in terms of its design and materials and to the Influence Screw In Bone System (K972023) and the Gyrus PLC (formerly Somnus Medical Technologies) Somnoplasty System (K982717) in their indications for use in the treatment of those patients suffering from OSA.

Clinical data demonstrates the device performs as anticipated and raises no new questions of safety and effectiveness over the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Edward W. Numainville
Vice President, Regulatory and Clinical Affairs
Restore Medical, Incorporated
2800 Patton Road
Saint Paul, Minnesota 55113

JUL 2 8 2004

Re: K040417
Trade/Device Name: Pillar™ Palatal Implant System
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: June 7, 2004
Received: June 8, 2004

Dear Mr. Numainville:

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.

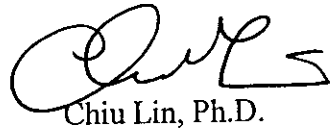
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
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): K040417

Device Name: Pillar™ Palatal Implant System

Indications for Use: The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (Obstructive Sleep Apnea).

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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