K050592

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510(k) Summary

Contact Person: Elaine Duncan

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JUL 12 2005

Brand Name: **SOMNOMED MAS RXA**

Common Name: Mandibular advancement device

Classification Name: Device, anti-snoring (21CFR872.5570])

Product Code: LRK

Predicate Device: MDSA K042161

Date Prepared: 3 March 2005

Description Of The Device: The Somnomed MAS RxA is an intraoral device used for treating Snoring and Sleep Apnea. It consists of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable lugs. The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep. The device is custom made for each patient and has the adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device.

Indications For Use: The SomnoMed MAS RxA is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Summary of Equivalence: The Somnomed MAS RxA is considered to be substantially equivalent to the Bird MDSA device. Both the Somnomed MAS RxA and the MDSA are prescription Custom Made titratable mandibular repositioning devices for the dental treatment of patients suffering snoring and mild to moderate obstructive sleep apnea.

The technical designs and manufacture of the two devices are almost identical, being composed of custom fitted acrylic trays which fit onto the upper and lower teeth and which are positioned in relation to each other by an adjustable mechanism. The only design difference is in the nature of the adjustable mechanisms in the two devices. The MDSA device achieves mandibular advancement by means of a locking clasp placed at the front centre of the two acrylic trays, whereas the Somnomed RxA uses interlocking lugs and wings placed on the sides of the trays. The dental acrylic, adjustment screws and ball clasps used to manufacture the Somnomed MAS RxA have all been granted prior 510(k) approval for use in manufacture of dental appliances

A risk assessment concluded that there were no new safety concerns raised by the design of the Somnomed MAS RxA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Somnomed Limited
C/O Ms. Elaine Duncan
Paladin Medical Incorporated
P.O. Box 560
Stillwater, Minnesota 55082

Re: K050592
Trade/Device Name: MAS RxA
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: June 9, 2005
Received: June 15, 2005

Dear Ms. Duncan:

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 (240) 276-0115. 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/industry/support/index.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): K050592

Device Name: MAS RxA

Indications For Use:

The SomnoMed MAS RxA is intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (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)

for MSR

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

510(k) Number K050592