MAR 2 8 2011

510(K) SUMMARY

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

Submitter Information: Bradley Southworth

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Date Summary Prepared: 8/31/2010

Contact Persons: Bradley Southworth

Device Name:
Trade Name(s): Pantino Pro Positioner
Classification Name: Intraoral Devices for Snoring and Intraoral Devices for Obstructive Sleep Apnea
Panel: Dental
Product Code: LRK

Predicate Device Information:

Device Name	Manufacturer	510(k) Reference
MAS RxA	SomnoMed Inc.	K050592
TAP-T	Airway Management Inc.	K061732
TAP III	Airway Management Inc.	K062951

Device Description: The Pantino Pro Positioner is an intraoral device used for treating snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older. It consists of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable components. The device functions as a mandibular repositioner, which acts to increase the patients Pharyngeal space during sleep and improves their ability to exchange air during sleep. The device is custom made for each patient and has adjustment mechanisms enabling the amount of mandibular advancement to be set by the dentist or physician at the time of the device fitting

The Pantino Pro Positioner is offered in two model designs. The Pantino Pro "A" has a single interlocking mechanism centrically located on the anterior occlusal surface of the upper and lower arches. This design offers lateral movement of the

maxillary and mandible for those patients who require this freedom of motion. The Pantino Pro "B" has dual interlocking mechanisms located parallel to one another on the left and right occlusal surfaces positioned as posterior as possible to maintain maximum protrusion and a comfortable fit for the patient. This model offers vertical adjustment control for those patients who require this dimension of vertical stability.

Intended Use: The Pantino Pro Positioner is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Comparison to Predicate Device: The Pantino Pro Positioner is considered to be substantially equivalent to the SomnoMed MAS RxA, TAP III, and TAP-T devices. The Pantino Pro Positioner and the MAS RxA, TAP III, and the TAP-T are prescription custom made titratable mandibular repositioning devices for the dental treatment of patients suffering from snoring and obstructive sleep apnea.

The technical designs and manufacture of these devices are very similar, 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 type of adjustable mechanisms used. The Pantino Pro Positioner, TAP III, and TAP-T use a male rail pin clasp on the upper portion of the device that insert into a a female interlocking rail clasp on the lower device that have a locking screw mechanism to set the correct amount of mandible protrusion. The SomnoMed RxA uses interlocking titratable screw lugs on the upper device aligned to the lower wings to achieve the correct amount of protrusion. The adjustment screws, hooks, and clasps used to manufacture the Pantino Pro Positioner have not been granted prior 510(k) approval for use in the manufacture of dental appliances; however the screws, hooks, and clasps are made of ATI Ti-6AI-4v ELI (Extra Low Inerstitals). This grade of titanium is used in biomedical applications such as surgical instruments and also orthopedic implants. The titanium screws, hooks, and clasps do not contain any lead, nickel, cadmium, or mercury in the alloy. The acrylic material used is the same as what is used to manufacture the SomnoMed MAS RxA and is cleared under K050592.. Also, the SMH Flex material used in the SomnoMed MAS RxA soft model and also will be used to manfucture the Pantino Pro "A" and "B" appliances is cleared under K073004.

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

Mr. Bradley Southworth
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MAR 28 2011

Re: K102521
Trade/Device Name: Pantino Pro Positioner
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring
Regulatory Class: II
Product Code: LRK
Dated: March 18, 2011
Received: March 18, 2011

Dear Mr. Southworth:

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

Indications for Use

510(k) Number (if known): K102521

Device Name: Pantino Pro Positioner

Indications for Use: The Pantino Pro Positioner is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (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)

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

510(k) Number: K102521