Abbreviated 510k Notification
Section 5

510K SUMMARY K101709

Submitter of 510k: Emily B. Rossiter on behalf of Steve Lamberg, DDS

Contact Person: Emily B. Rossiter
President, Regulatory Resources, Inc.
800 E. Leigh Street, Suite 206-5
Virginia Biotechnology Research Park
Richmond, VA 23219
804-370-9459
rri@infionline.net

AUG 1 8 2010

Date of Summary: June 18, 2010

Trade Name: LambergSleepWell-Smartrusion (LSW-S)

Classification Name: Anti-snoring device, Jaw Repositioning Device

Device Product Code: LRK, LQZ

Predicate Devices: Somnomed MAS RxA - K050592
Lamberg Sleep Well Device - K062333

Intended Use/Indication for Use: For the reduction of night-time snoring or mild to moderate obstructive sleep apnea in adults 18 years of age or older. Prescription use only.

Device Description:
The LSW-S is a removable intraoral device consisting of two custom fabricated trays that fit separately over the upper and lower dental arches and engage each other in the anterior area of the mouth by means of a protrusive element on the upper member relating to the protrusive element's mate on the lower member. This interface, and thus this device, functions as a mandibular anterior repositioner, which acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep. Every device is custom made, by prescription, for each patient and is adjustable at the time of delivery and anytime thereafter.

Comparison Table with Predicate Device:

The following table displays the differences and similarities between the new LambergSleepWell-Smartrusion and two other previously marketed devices. Equivalence is based on similarities in intended use, materials of construction, design, and operating principles, as summarized in the table on the following page.

2 of 2

K101709

Feature	LambergSleepWell-Smartrusion (LSW-S)	Lamberg Sleep Well Device K062333	Somnomed MAS RxA K050592
Intended Use	To reduce or alleviate night-time snoring and mild and moderate obstructive sleep apnea (OSA) in adults.	To reduce night-time snoring; for use in adults 18 years of age or older in a home or sleep laboratory environment	To reduce night-time snoring and mild to moderate obstructive apnea (OAS) in adults.
Materials of construction	Methyl methacrylate, copolyester, stainless steel	Methyl methacrylate, stainless steel	Dentocryl methylmethacrylate, stainless steel
Design	Two custom-molded components that fit separately over each of the dental arches inside the mouth. Adjustable by the dentist upon delivery to the patient and at any visit thereafter, as necessary.	One-piece custom molded appliance that is seated against the palate of the mouth, extends over the upper incisors, and is 2-3 mm thick.	Custom fitted acrylic trays fit onto the upper and lower teeth and are locked into place. The two trays are positioned in relation to each other by an adjustable mechanism, made of interlocking lugs and wings
Principle of operation/-means of mandibular advancement	The two component pieces are engaged in the anterior area by means of a protrusive element and its mate, in complementary arches. The jaws are repositioned in an anterior-posterior relationship, moving the mandible forward; the vertical opening of the jaw is not fixed in a single position.	Single piece device is placed in the mouth and secured to the upper front molars with Adams clasps. A central protrusive element makes contact with the lingual surface of the mandibular incisors, repositioning the mandible and tongue forward; the vertical opening of the jaw is not fixed in a single position.	Adjustment of the relative position of the trays advances the mandible forward, enlarging the airway while the appliance is in place. The vertical opening of the jaw is not fixed in a single position.
Fixed/Removable	Removable	Removable	Removable
Adjustment	Adjusted by the prescribing dentist by the addition of dental acrylic material to the anterior protrusive element.	Adjusted by the prescribing dentist by the addition of dental acrylic to the anterior protrusive element.	Adjusted via the use of interlocking lugs and wings placed on both sides of the trays with stainless steel screws.
Supplied Sterile?	No	No	No
Single Use?	No; custom designed for each patient; reusable	No; custom designed for each patient; reusable	No; custom designed for each patient; reusable
By prescription only?	Yes	Yes	Yes

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

Steven B. Lamberg, DDS
C/O Ms. Emily B. Rossiter
Regulatory Resources, Incorporated
800 East Leigh Street, Suite 206-5
Richmond, Virginia 23219

AUG 1 8 2010

Re: K101709
Trade/Device Name: LambergSleep Well-Smartrusion (LSW-S)
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: LQZ
Dated: July 22, 2010
Received: July 22, 2010

Dear Ms. Rossiter:

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

1561

Indications for Use

510(k) Number (if known): K101709

Device Name: LambergSleepWell-Smartrusion (LSW-S)

Indications for Use:

The LambergSleepWell-Smartrusion is used to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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

510(k) Number K101709

(Posted November 13, 2003)