AUG 9 - 2005

510(k) Summary **Silent Partner, K051014**

Date:	3 August 2005
Applicant: (Also manufacturing site)	DreamWRx Dental Laboratory 1911 Colorado Boulevard Los Angeles, CA 90041
Registration number:	3005034462
Contact person:	Nicolaas Besseling
Phone numbers: (Contact person)	(949) 466-7472 mobile (949) 448-0312 fax
Email address:	bestechconsulting@cox.net
Device name:	Silent Partner™ series OSA appliances
Common name:	Intraoral devices for snoring and obstructive sleep apnea
Classification:	Class II
Product Code:	LRK anti-snoring device
Regulation number:	21CFR872.5570
Predicate devices:	TOA, K972061 TAP, K962516 OASYS –Oral Airway System K030440
Device description:	The device consists of a lower tray fitted over the lower teeth, an upper tray over the upper teeth, and a mechanism to attach the lower to the upper tray. The device allows the practitioner to determine the advancement of the mandible and the vertical opening for desired results. This technology platform consists of a stylus, slider, and the channels into which they are placed; these parts are identical in both models. The device has a 10 mm long channel in the lower tray behind the anterior teeth that is perpendicular to the patient's tongue. This allows the upper component, which locks into the channel, to provide lateral excursion for the patient's comfort. Prior to final insertion the upper and lower trays are connected together by keying the stylus into the lower channel. The device's upper component consists of a 16 mm long titanium channel into which a nine-position latched slider will let the practitioner place the stylus in the optimum position. Both the slider and the stylus are placed into the channel's frontal opening and securely locked into place by tension attachment.
Intended use:	The device is intended to reduce nighttime snoring and/or mild to moderate obstructive sleep apnea by repositioning of the mandible.

Substantial equivalence comparison

Attribute \ Device	Silent Partner This submission, K051014	TOA K972061	TAP K962516	OASYS K030440
Intended use				
Intraoral device	yes	yes	yes	yes
Reduce snoring	yes	yes	yes	yes
Reduce obstructive sleep apnea	yes	yes	yes	yes
Design				
Removable device	yes	yes	yes	yes
Custom fit	yes	yes	yes	yes
Adjustable forward movement	yes	yes	yes	yes
Adjustable vertical movement	yes	no	no	no
Separate trays	yes	yes	yes	yes
Holds lower jaw forward	yes	yes	yes	yes
Permits lateral jaw movement	yes	yes	yes	yes
Permits vertical jaw movement	no	yes	yes	yes
Upper and lower trays can be separated by patient	yes	yes	no	yes
Permits patient to breathe through mouth	yes	yes	yes	yes
Specialized tools needed	no	no	no	yes
Materials				
Vacuum formed trays	Model A	yes	yes	yes
Thermoplastic trays	Model B	yes	yes	yes
Ti stylus and critical parts	yes	no	no	no

Conclusion

To the best of our knowledge, the device is substantially equivalent to the predicate devices, and no additional risks are created.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Nicolaas Besseling
Principal
DREAMWRX Dental Laboratory
1911 Colorado Blvd.
Los Angeles, California 90041

Re: K051014
Trade/Device Name: Sleep Partner Series OSA Appliances
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral devices for snoring and obstructive sleep apnea
Regulatory Class: II
Product Code: LRK
Dated: June 24, 2005
Received: June 30, 2005

Dear Mr. Besseling:

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

3 Indications for use

510(k) number: K051014

Device name: Silent Partner series OSA appliances

Intended use: Reduce nighttime snoring and/or mild to moderate obstructive sleep apnea by repositioning of the mandible.

Concurrence of CDRH, Office of Device Evaluation

Prescription use X or Over-The-Counter use _____
(Per 21CFR801.109)

Sara Runyon

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

510(k) Number: K051014