K130504

510(k) Summary

Date:	16 September 2013
Sponsor:	American Sleep Association, LLC 1957 Royal Hunte Drive, Ste. 250 Cedar City, UT 84720 Phone: 866.620.3670
Contact Person:	Ryan Gregerson, Manager
Trade Names:	American Sleep Association (ASA) Oral Appliances
Device Classification:	Class II
Common Name:	Oral Appliance
Classification Name:	Device, Anti-Snoring
Regulation:	872.5570, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Device Product Code:	LRK
Device Description:	The American Sleep Association (ASA) Oral Appliances include three devices: the ASA Herbst and Herbst/Hilsen Hybrid devices. All are removable, intraoral devices which reposition the mandible and each is custom-fabricated to individual patient specifications. The devices are comprised of thermoformed polymer splints (copolyester or EVA) which are connected bilaterally via a stainless steel telescoping Herbst mechanism, reclosable fasteners or both.
Intended Use:	The ASA Oral Appliances are intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.
Predicate Devices:	Removable Acrylic Herbst (K070327) Hilsen Anti-Snoring Device (K963591) Silent Nite® sl (K972424)
Technological Characteristics:	The ASA Herbst and Herbst/Hilsen Hybrid devices possess the same technological characteristics as one or more of the predicate devices. These include: • Anatomic location (intraoral), • Basic design (mandibular repositioning using upper and lower polymer trays with bilateral connecting mechanism), • Materials (polymers and/or stainless steel) and • Manufacture (appliance is fabricated by prescription to the specific requirements of a single patient) The fundamental scientific technology of the ASA Herbst and Herbst/Hilsen Hybrid devices is the same as previously cleared devices.

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Conclusion:

In comparison to the predicate devices, the ASA Oral Appliances have

- the same intended use and
- the same technological characteristics and so do not raise new questions of safety and effectiveness.

Therefore the ASA Herbst and Herbst/Hilsen Hybrid devices can be found substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 18, 2013

American Sleep Association, LLC
Mr. Ryan Gregerson
Manager
1957 Royal Hunte Drive, Suite 250
CEDAR CITY UT 84720

Re: K130504
Trade/Device Name: American Sleep Association (ASA) Oral Appliances
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: September 16, 2013
Received: September 20, 2013

Dear Mr. Gregerson:

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 contact 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. 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,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 - Indications for Use Statement

510(k) Number: K130504

Device Name: **American Sleep Association (ASA) Oral Appliances**

Indications for Use:

The ASA Oral Appliances are intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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