DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

American Sleep Dentistry
Ryan Gregerson
President
1957 West Royal Hunte Drive
Ste 250
Cedar City, Utah 84720-1903

June 8, 2017

Re: K163580
Trade/Device Name: ASD 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: Class II
Product Code: LRK
Dated: May 5, 2017
Received: May 9, 2017

Dear Ryan 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Mary S. Runner -A

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163580

Device Name
American Sleep Dentistry (ASD) Oral Appliances

Indications for Use *(Describe)*
The ASD Oral Appliances are intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in individuals 18 years of age or older.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K163580

510(k) Summary

Date: May 31, 2017

Sponsor:
American Sleep Dentistry, LLC
1957 West Royal Hunte Dr, Ste 250
Cedar City, UT 84720-1903
Phone: 800-555-1518

Contact Person: Ryan Gregerson, Manager

Trade Names: American Sleep Dentistry (ASD) Oral Appliances

Device Classification: Class II

Classification Name: Device, Anti-Snoring and device, jaw repositioning

Regulation: 21 CFR 872.5570, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea

Device Product Code: LRK

Device Description: The American Sleep Dentistry (ASD) Oral Appliances include five device models: the ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic, and ASD Lateral Mezzo. All are removable, intraoral devices which reposition the mandible and each is patient specific to individual patient anatomy.

The devices are comprised of thermoformed polymer splints (copolyester or EVA), which are connected via a hook and base mechanism or elastic bands or straps.

Intended Use: The ASD Oral Appliances are intended for the reduction of night time snoring and mild to moderate Obstructive Sleep Apnea (OSA) in individuals 18 years of age or older.

Primary Predicate Device:

American Sleep Association (ASA) Oral Appliances (K130504)

Reference Predicate Devices:

Removable Acrylic Herbst (K070327)

TAP III (K062951)

EMA (K971794)

Technological Characteristics:

The ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic, and ASD Lateral Mezzo Oral Appliances possess the same technological characteristics as one or more of the predicate devices.

These include:

- Anatomic location (intraoral),
- Intended Use, to treat mild to moderate sleep apnea.
- Basic design (mandibular repositioning using upper and lower polymer trays with a hook and base mechanism),
- Principles of Operation
- Materials (polymer and/or stainless steel), and
- Manufacture (appliance is patient specific fabricated by prescription to the specific requirements of a single patient).

The ASD Anterior model and predicate device, Tap III are both patient specific made Oral Appliances that include a hook and base mechanism placed on the anterior of the front teeth. The actual design differs slightly, but no new or different questions of safety and efficacy are raised by the differences.

The ASD Mezzo model and predicate devices Removable Acrylic Herbst and Tap III are all patient specific made Oral Appliances that include a hook and base mechanism like the TAP III, but are placed bilaterally like that of the Herbst appliance. The actual design differs slightly, but no new or different questions of safety and efficacy are raised by the differences.

The ASD Lateral model and predicate device Tap III are both patient specific made Oral Appliances that include a hook and base mechanism and is located the same as the TAP III, but the ASD Lateral model adds the additional anchors to the canine teeth for advanced stability. The actual design differs slightly, but no new or different questions of safety and efficacy are raised by the differences.

The ASD Lateral Mezzo model and predicate devices Removable Acrylic Herbst and Tap III are all patient specific made Oral Appliances that include a hook and base mechanism. The ASD Lateral Mezzo hook and base mechanism is like the TAP III, but are placed bilaterally like that of the Herbst appliance. The actual design differ slightly, but no new or different questions of safety and efficacy are raised by the differences.

The ASD Elastic model and predicate device EMA are both patient specific made Oral Appliances that include varying lengths of elastic bands or straps and are both placed bilaterally. The ASD Elastic, however anchors the straps in by stainless steel, while the EMA uses plastic anchors. The actual material differs slightly, but no new or different questions of safety and efficacy are raised by the differences.

The fundamental scientific technology of the ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic, and ASD Lateral Mezzo Oral Appliances is the same as previously cleared devices.

B. Substantial Equivalence Comparison Table:

Substantial Equivalence Comparison Features	ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic and ASD Lateral Mezzo	ASA Oral Appliances [Primary Predicate]	Removable Acrylic Herbst [Reference Predicate]	Tap III [Reference Predicate]	EMA [Reference Predicate]
510k #	**K163580**	**K130504**	**K070327**	**K062951**	**K971794**
Intended use/ Indications for use:	Intended for the reduction of nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in individuals 18 years of age or older.	Intended for the reduction of nighttime snoring and mild to moderate obstructive sleep apnea (OSA) in individuals 18 years of age or older.	Intended for the reduction of snoring and mild to moderate obstructive sleep apnea (OSA) by moving the lower jaw into a prescribed relationship to the upper jaw.	Intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea, OSA.	Treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where repositioning of the mandible can increase the patient's air space
Prescription/ OTC Use	Prescription	Prescription	Prescription	Prescription	Prescription
Principle of Operation	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate

Substantial Equivalence Comparison Features	ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic and ASD Lateral Mezzo	ASA Oral Appliances [Primary Predicate]	Removable Acrylic Herbst [Reference Predicate]	Tap III [Reference Predicate]	EMA [Reference Predicate]
510k #	**K163580**	**K130504**	**K070327**	**K062951**	**K971794**
	Obstructive Sleep Apnea (OSA).	Obstructive Sleep Apnea (OSA).	Obstructive Sleep Apnea (OSA).	Obstructive Sleep Apnea (OSA).	Obstructive Sleep Apnea (OSA).
Design: ASD Anterior	Mandibular repositioner having upper and lower polymer trays with hook and base mechanism placed on the anterior of the front teeth.	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms with bilateral, reclosable, polymer fasteners or both	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms	Mandibular repositioner having upper and lower trays with a Hook and Base mechanism placed on the anterior of the front teeth.	
Design: ASD Mezzo	Mandibular repositioner having upper and lower polymer trays with a hook and base mechanism placed bilaterally	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms with bilateral, reclosable, polymer fasteners or both	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms	Mandibular repositioner having upper and lower trays with a Hook and Base mechanism placed on the anterior of the front teeth.	

Substantial Equivalence Comparison Features	ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic and ASD Lateral Mezzo	ASA Oral Appliances [Primary Predicate]	Removable Acrylic Herbst [Reference Predicate]	Tap III [Reference Predicate]	EMA [Reference Predicate]
510k #	**K163580**	**K130504**	**K070327**	**K062951**	**K971794**
Design: ASD Lateral	Mandibular repositioner having upper and lower polymer trays with hook and base mechanism placed on the anterior of the teeth. With anchors placed on the canine teeth.	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms with bilateral, reclosable, polymer fasteners or both	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms	Mandibular repositioner having upper and lower trays with a Hook and Base mechanism placed on the anterior of the front teeth.	
Design: ASD Lateral Mezzo	Mandibular repositioner having upper and lower polymer trays with a hook and base mechanism placed bilaterally	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms with bilateral, reclosable, polymer fasteners or both	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms	Mandibular repositioner having upper and lower trays with a Hook and Base mechanism placed on the anterior of the front teeth.	

Substantial Equivalence Comparison Features	ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic and ASD Lateral Mezzo	ASA Oral Appliances [Primary Predicate]	Removable Acrylic Herbst [Reference Predicate]	Tap III [Reference Predicate]	EMA [Reference Predicate]
510k #	**K163580**	**K130504**	**K070327**	**K062951**	**K971794**
Design: ASD Elastic	Mandibular repositioner having upper and lower polymer trays and elastic bands or straps with stainless steel anchors.				Mandibular repositioner having upper and lower trays with bilateral elastic bands or straps with plastic anchors.
Materials: ASD Anterior ASD Mezzo ASD Lateral ASD Lateral Mezzo					
Polymer Splint	PETG/TPU, EVA	PETG/TPU, EVA	Acrylic	Acrylic	
Connecting Mechanism	303/304 Stainless Steel	303/304 Stainless Steel	303/304 Stainless Steel	303/304 Stainless Steel	
Materials: ASD Elastic					
Polymer Splint	PETG/TPU, EVA				Acrylic
Connecting Mechanism	Latex free Poylmer				Latex free Polymer

Substantial Equivalence Comparison Features	ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic and ASD Lateral Mezzo	ASA Oral Appliances [Primary Predicate]	Removable Acrylic Herbst [Reference Predicate]	Tap III [Reference Predicate]	EMA [Reference Predicate]
510k #	**K163580**	**K130504**	**K070327**	**K062951**	**K971794**
Range and precision of adjustment	Front to back +/- 1 mm	Front to back +/- 1 mm	Front to back +/- 1 mm	Front to back +/- 1 mm	Front to back +/- 1 mm
Target Population	Patients diagnosed with mild to moderate Obstructive Sleep Apnea	Patients diagnosed with mild to moderate Obstructive Sleep Apnea	Patients diagnosed with mild to moderate Obstructive Sleep Apnea	Patients diagnosed with mild to moderate Obstructive Sleep Apnea	Patients diagnosed with mild to moderate Obstructive Sleep Apnea
Where Used:	Fitted by a clinician, used at home.	Fitted by a clinician, used at home.	Fitted by a clinician, used at home.	Fitted by a clinician, used at home.	Fitted by a clinician, used at home.
Energy Used/ Delivered:	None	None	None	None	None
Human Factors:	The device is fitted by the dentist. The patient is instructed in its use and care. Subsequent use by the patient is as directed by the dentist in accordance with the provided instructions for use.	The device is fitted by the dentist. The patient is instructed in its use and care. Subsequent use by the patient is as directed by the dentist in accordance with the provided instructions for use.	The device is fitted by the dentist. The patient is instructed in its use and care. Subsequent use by the patient is as directed by the dentist in accordance with the provided instructions for use.	The device is fitted by the dentist. The patient is instructed in its use and care. Subsequent use by the patient is as directed by the dentist in accordance with the provided instructions for use.	The device is fitted by the dentist. The patient is instructed in its use and care. Subsequent use by the patient is as directed by the dentist in accordance with the provided instructions for use.

Substantial Equivalence Comparison Features	ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic and ASD Lateral Mezzo	ASA Oral Appliances [Primary Predicate]	Removable Acrylic Herbst [Reference Predicate]	Tap III [Reference Predicate]	EMA [Reference Predicate]
510k #	**K163580**	**K130504**	**K070327**	**K062951**	**K971794**
Sterility:	Non-sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.	Non-sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.	Non-sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.	Non-sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.	Non-sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.

Conclusion:

In comparison to the predicate devices, the ASD 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 proposed ASD Anterior, ASD Mezzo, ASD Lateral, ASD Elastic and ASD Lateral Mezzo Oral Appliances are deemed substantially equivalent to the predicate devices based on a review of the descriptive characteristics of each device model.