



Food and Drug Administration
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October 29, 2015

OravanOSA, LLC
Ms. Deborah Stein
Vice President
769 Northfield Avenue, Suite 160
West Orange, New Jersey 07052

Re: K152159
Trade/Device Name: Oravan Herbst
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: July 22, 2015
Received: August 3, 2015

Dear Ms. Stein:

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 yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology,

General Hospital, Respiratory, Infection
Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152159

Device Name
Oravan Herbst

Indications for Use (Describe)

Oravan Herbst is intended to reduce snoring and mild to moderate sleep apnea in adults.

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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SECTION 5

510(k) Summary

1. Submitter's Name and Contact Information

Company Name: OravanOSA, LLC
Address: 769 Northfield Avenue, Suite 160
West Orange, NJ 07052

Contact Person: Deborah Stein
Vice President, OravanOSA LLC

Email: debbie481@comcast.net
Telephone: 973-886-6855
Fax: 973-325-6442

Summary Preparation Date: July 15, 2015

2. Device Identification:

Proprietary Name: Oravan Herbst
Common Name: Anti-snoring device
Classification: Class II
Product Code: LRK
Regulation Number: 21 CFR 872.5570
Review Panel: Dental

3. Description of the Device:

The Oravan Herbst is intended to reduce snoring and mild to moderate sleep apnea in adults. It is made of orthodontic acrylic trays and herbst assembly. It has two acrylic pieces - the upper acrylic tray that fits over the top posterior teeth and the lower acrylic tray that fits over the bottom posterior teeth. The herbst assembly provides a standard titration mechanism and enables mandibular advancement. With this design, the Oravan Herbst allows the physician to increase the patient's pharyngeal opening, improving their ability to exchange air during sleep and reduce vibrations. Each Oravan Herbst device is patient-specific (customized for each patient).

4. Indications for Use:

Oravan Herbst is intended to reduce snoring and mild to moderate sleep apnea in adults

5. Predicate Devices:

The Oravan Herbst is substantially equivalent to the following devices:

- i. SomnoDent Herbst (by SomnoMed Inc.), K130558
- ii. Oravan OSA (by New Jersey Snoring Solutions), K121285

6. Summary of Similar Technological Characteristics

The proposed 'Oravan Herbst' and the predicate devices are Anti-snoring devices intended to reduce snoring and mild to moderate sleep apnea in adults. Their fundamental scientific technology, design, technological characteristics and materials are also comparable, as outlined in the following table:

	Subject Device	Predicate Device K121285	Reference Predicate Device K130558
Device Name	Oravan Herbst	Oravan OSA	SomnoDent Herbst
Submitter	OravanOSA, LLC	New Jersey Snoring Solutions (n.b.a OravanOSA, LLC)	SomnoMed Inc.
Characteristics / Features			
Indications for Use	Oravan Herbst is intended to reduce snoring and mild to moderate sleep apnea in adults.	Oravan OSA is intended to reduce snoring and mild to moderate sleep apnea in adults.	The SomnoDent Herbst is intended for the treatment of nighttime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.
Prescription / OTC Use	Prescription only <u>Note:</u> Custom-fitted to each patient, based on dental impressions	Prescription only <u>Note:</u> Custom-fitted to each patient, based on dental impressions	Prescription only <u>Note:</u> Custom-fitted to each patient, based on dental impressions

	Subject Device	Predicate Device K121285	Reference Predicate Device K130558
Device Name	Oravan Herbst	Oravan OSA	SomnoDent Herbst
Submitter	OravanOSA, LLC	New Jersey Snoring Solutions (n.b.a OravanOSA, LLC)	SomnoMed Inc.
Characteristics / Features			
Device components/ parts	<ul style="list-style-type: none"> • Orthodontic Acrylic trays • Herbst Assembly • Wire with ball clasps • Allen key 	<ul style="list-style-type: none"> • Orthodontic Acrylic trays • Expansion Screws • Wire with ball clasps • Allen key 	<ul style="list-style-type: none"> • Orthodontic Acrylic trays • Herbst Assembly • Wire with ball clasps • Allen key
Device configuration	<p>Two-piece design:</p> <p>Upper acrylic tray covers top posterior teeth</p> <p>Lower acrylic tray covers bottom posterior teeth</p>	<p>Two-piece design:</p> <p>Upper acrylic tray covers top posterior teeth</p> <p>Lower acrylic tray covers bottom posterior teeth</p>	<p>Two-piece design:</p> <p>Upper acrylic tray covers top teeth</p> <p>Lower acrylic tray covers bottom teeth</p>
Device Functionality	<p>The device allows for increase in the patient's pharyngeal opening, improving their ability to exchange air during sleep and reduce vibrations.</p> <p>Works by mandibular advancement using adjustable mechanism (a standard Herbst style titration mechanism). The Herbst assembly includes</p> <ul style="list-style-type: none"> – Fixing Elements with Allen Screws and Wrench – Long Herner Guiding Telescope <p>Lower jaw advancement is adjustable using a supplied adjustment key</p>	<p>The device allows for increase in the patient's pharyngeal opening, improving their ability to exchange air during sleep and reduce vibrations.</p> <p>Works by mandibular advancement using component advancement screws. Extension wings hold maxillary and mandibular sections in relative approximation once advancement is fixed.</p> <p>Lower jaw advancement is adjustable using a supplied adjustment key</p>	<p>The device allows for increase in the patient's pharyngeal opening, improving their ability to exchange air during sleep and reduce vibrations.</p> <p>Works by mandibular advancement using adjustable mechanism (a standard Herbst style titration mechanism). The Herbst assembly includes</p> <ul style="list-style-type: none"> – Fixing Elements with Allen Screws and Wrench – Long Herner Guiding Telescope <p>Lower jaw advancement is adjustable using a supplied adjustment key</p>

	Subject Device	Predicate Device K121285	Reference Predicate Device K130558
Device Name	Oravan Herbst	Oravan OSA	SomnoDent Herbst
Submitter	OravanOSA, LLC	New Jersey Snoring Solutions (n.b.a OravanOSA, LLC)	SomnoMed Inc.
Characteristics / Features			
Mandibular Advancement range	Up to 5 mm	Up to 6 mm	Up to 5 mm
Materials			
• Orthodontic Acrylic	Two part Polymethylmethacrylate supplied by Dentaureum; (Medical grade, biocompatible)	Two part Polymethylmethacrylate supplied by Dentaureum; (Medical grade, biocompatible)	Two part Polymethylmethacrylate (Medical grade, biocompatible)
• Colorants	No colorants	No colorants	Not specified
• Wire with ball clasps	Medical Grade Stainless Steel	Medical Grade Stainless Steel	Medical Grade Stainless Steel
• Advancement Mechanism - herbst assembly	Medical Grade Stainless Steel	Not Applicable	Medical Grade Stainless Steel
• Advancement Mechanism - expansion screws	Not Applicable	Medical Grade Stainless Steel	Not Applicable

The Oravan Herbst is a modification to Oravan OSA (K121285), the main difference being the type of adjustment mechanism. The Oravan OSA works by mandibular advancement using component advancement screws. In contrast, the Oravan Herbst has a herbst style titration mechanism which is the same as that in the SomnoDent Herbst.

The Oravan Herbst and the predicate devices enable mandibular advancement through adjustment mechanism. At the time of fitting the device, the advancement mechanism can be adjusted up to 5 mm (in case of Oravan Herbst and SomnoDent Herbst) and up to 6 mm (in case of Oravan OSA), after placement. This difference is minor and does not raise any new concerns of equivalence as the purpose of this adjustment mechanism is to increase the patient's pharyngeal opening, thus improving ability to exchange air during sleep and reduce vibrations.

7. Non-Clinical Data

The submission includes data regarding the physical properties of the Orthodontic Acrylic material used in the Oravan Herbst. These physical properties are in accordance with the requirements and limits specified in standard ISO 20795-2:2005 - Dentistry -- Base polymers -- Part 2: Orthodontic base polymers. This performance data is the same as submitted in K121285 for predicate Oravan OSA. In addition, risk analysis was performed for the Oravan Herbst per standard ISO 14971. The potential risks/hazards include improper fit (due to incorrect registry and impression), minor discomfort due to rigid positioning, component/device failure, material reaction and risks resulting from failure to follow instructions for use. Based on the use of biocompatible materials, well characterized design, labeling, performance testing; the results of the risk analysis demonstrate that the hazards associated with the use of the Oravan Herbst are acceptable in regard to the product's intended use and the risk acceptance criteria.

8. Clinical Testing

The submission does not rely on any clinical data; therefore no clinical testing was performed

9. Conclusion:

Based on the intended use, design, technological characteristics and non-clinical information provided in the submission; the proposed 'Oravan Herbst' is substantially equivalent to the referenced predicate devices.