August 29, 2019

Oventus Manufacturing PTY LTD
% M.W. (Andy) Anderson
Regulatory Consultant for Oventus Medical
Regulatory and Clinical Research Institute
5353 Wayzata Blvd, Ste 505
Minneapolis, Minnesota 55416

Re: K190236
Trade/Device Name: O2Vent Optima
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: July 31, 2019
Received: August 1, 2019

Dear M.W. (Andy) Anderson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190236

Device Name
O2 Vent Optima

Indications for Use *(Describe)*
The O2Vent Optima is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA). The device is indicated for use during sleep to aid in the treatment of these conditions.

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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K190236

510(k) SUMMARY FOR O_2VENT OPTIMA
prepared in accordance to 21CFR 807.92

Date Prepared	July 31,2019
510 (k) Owner Details Name: Address Phone:	 Oventus Manufacturing Pty Ltd 1 Swann Road, Indooroopilly, QLD 4068, Australia. +61 7 3180 3196
Name of Contact Person	Robyn Woidtke
Device Trade name	O_2Vent Optima
Common Name	Oral Appliance – Anti snoring device
Classification	Class II
Classification Name	Intraoral devices for snoring and obstructive sleep apnea.
Classification Code	LRK
Classification Regulation	21 CFR 872.5570
Device Model Number(s)	O2VB
Primary Predicate Device	K171316 O_2Vent W – Oventus Manufacturing Pty Ltd The primary predicate was chosen as it has the same principal design features as the O_2Vent Optima and indications for use
Reference Device(s)	K143244 The Panthera Anti-Snoring Device – Panthera Dental Inc This reference device was chosen as the material is the same as that used in the O_2Vent Optima K971794 EMA Appliance – Myerson LLC This reference device was chosen for the straps/bands
Device Description	The ***O_2Vent Optima*** is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA). The ***O_2Vent Optima*** consists of the following parts: Upper tray (upper teeth) Lower tray (lower teeth) Connector bands • The upper tray is fitted over the upper teeth, with the breathing port at the front leading to the airways on each side to the rear of the appliance. The upper nylon tray has two side protrusions (lugs) that engage a connector that when attached, extends to the lower tray and attaches to a similar lug stabilizing and advancing the lower jaw • The lower tray, is customized to the bottom teeth, which when attached to the same connector via a side protrusion (lug) together with the upper tray, positions the lower jaw forward,

	preventing the tongue and soft tissues of the throat from collapsing and obstructing the airway. • In order to adjust the trays to the specific needs of the user, various length bands (13-21mm) are used to move the lower jaw (i.e. adjust the trays) forward or backward • The shorter the connector band, the further the lower jaw is moved forwards. • The O_2Vent Optima is delivered fully assembled with the 19mm connector band as the recommended starting titration length for all new users. • The upper and lower trays of the O_2Vent Optima are made with PA2200 (i.e. Nylon) • The straps which connect the upper and lower trays together are made of 100% thermoplastic polyurethane/cured elastomer
Indications for Use	The O_2Vent Optima is a removable oral appliance that is fitted in the mouth and is intended to reduce or alleviate snoring and mild to moderate OSA. The Optima is indicated for use during sleep to aid in the treatment of these conditions.
Target Population	Adult patients 18 years and older.
Environment of Use	Home Use and Sleep laboratories.
Summary of Comparison of Technological Characteristics of the Device to Predicate Device	The following table displays a comparison between the O_2Vent Optima and the O_2Vent W (predicate) and reference devices

Feature	O_2Vent Optima	*Primary Predicate* O_2Vent W	*Reference Device* The Panthera Anti-Snoring Device	*Reference Device* Elastic Mandibular Advancement (EMA) Appliance	Compared to Subject Device
510k Number	K190236	K171316	K143244	K971794	
Device Photo					
Indications for Use	The O_2Vent Optima is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA). The device is indicated for use during sleep to aid in the treatment of these conditions..	The O_2Vent W is a removable medical device that is fitted in the patient's mouth and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA). The device is indicated for use during sleep to aid in the treatment of these conditions.	The Panthera anti snoring device is Intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	Treatment of nasal respiratory dysfunction of obstructive sleep apnea and snoring in those patients where repositioning of the mandible and opening the bite can increase the patients air space	Similar to predicates
Product Codes	LRK	LRK	LRK	LRK	Same for all
Regulation	21CFR 872.5570	21CFR 872.5570	21CFR 872.5570	21CFR 872.5570	Same for all
Common Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea	
Classification	Class II	Class II	Class II	Class II	Same for all
Use of device	Removable intraoral device. Single patient multiple use. Prescription use only.	Removable intraoral device. Single patient multiple use. Prescription use only.	Removable intraoral device. Multiple use. Prescription use only.	Removable intraoral device. Single patient multiple use. Prescription use only.	Similar or same for all

Feature	O_2Vent Optima	*Primary Predicate* O_2Vent W	*Reference Device* The Panthera Anti-Snoring Device	*Reference Device* Elastic Mandibular Advancement (EMA) Appliance	Compared to Subject Device
Target Population	People over 18 years of age who snore and/or have sleep apnea.	People over 18 years of age who snore and/or have sleep apnea.	Adults	Not indicated	Same or similar
Device Functionality (Please note trays and splints are synonymous)	Repositions the lower jaw forward.	Repositions the lower jaw forward.	A mandibular repositioner, maintaining the lower jaw in a forward position during sleep.	Advance the mandible to an anterior and inferior position with regard to the maxilla.	Description similar for all devices
	Acts by increasing the pharyngeal space to improve the patient's ability to exchange air.	Acts by increasing the pharyngeal space to improve the patient's ability to exchange air.	This mechanical protrusion acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep.	Repositioning of the mandible pulls the tongue forward and increased the patient's airspace thereby decreasing upper airway obstruction.	Same as predicate, similar to references
	Permits patient to breathe through their mouth via a proprietary built in airway	Permits patient to breathe through their mouth via a proprietary built in airway	NA	NA	Same as primary predicate
	Retains the top and bottom teeth using rigid trays.	Retains the top and bottom teeth using rigid trays.	The upper and lower splints are adapted for the upper and lower teeth, respectively	Upper and lower trays for tooth retention	Same as primary predicate; similar for references
	Upper and lower trays are separate.	Upper and lower trays are separate.	Two customized splints that fit separately over the upper and lower teeth inside the mouth.	Upper and lower trays are separate	Same as primary, similar for references

Feature	**O_2Vent Optima**	***Primary Predicate*** **O_2Vent W**	***Reference Device*** **The Panthera Anti-Snoring Device**	***Reference Device*** **Elastic Mandibular Advancement (EMA) Appliance**	**Compared to Subject Device**
Device Design and Principle of Operation	The trays have protrusions (lugs) at the side of the upper and lower parts with a connector between the upper and lower parts to stabilize and/or advance the lower jaw.	The upper tray has protrusions (wings) at the rear on the titanium part to interface with the adjuster block in the lower tray.	The lower splint contains a triangular protrusion, allowing the splints to engage by means of interlocking rods on the sides	Removable replacement adjustable bands which attach by protrusions to the side of the upper and lower trays	Same as reference devices, similar to predicate device
Means of advancing the mandible	Lower jaw adjusted by attaching connectors of varying lengths	Lower jaw adjusted using titration of the adjustment screws equally on both sides with an adjustment key.	Adjusted via the use of interlocking rods placed on the sides of the splints. The shorter the rod, the further the mandible is advanced The length of the rods can vary from 19 to 36 mm and can be adjusted in 0.5-mm increments for a highly accurate and customized advancement	Lower jaw adjusted by attaching connectors of varying lengths	Same as reference devices; similar to predicate device
Adjustment	Can be adjusted by the clinician and patient.	Can be adjusted by the clinician and patient.	The dentist/patient can simply select a shortened connecting rod until optimal advancement is achieved	Can be adjusted by the clinician and patient.	Same for all

Feature	O_2Vent Optima	*Primary Predicate* O_2Vent W	*Reference Device* The Panthera Anti-Snoring Device	*Reference Device* Elastic Mandibular Advancement (EMA) Appliance	Compared to Subject Device
Design CAD/CAM	Customized for each patient in a dental laboratory located at the manufacturing site based on the dentist prescription Use of computer aided design (CAD) and computer aided manufacturing (CAM) and is made through additive manufacturing using laser sintering of PA2200 Polymide 12 nylon material. The use of these technologies provides for customization according to the unique characteristics of the patient oral anatomy based on the prescription provided by the clinician	Customized for each patient in a dental laboratory based on the dentist prescription. Use of computer aided design (CAD) and computer aided manufacturing (CAM). Dental plastic laminates and acrylics are used for upper and lower trays. The titanium component of the device is 3D printed using the additive manufacturing. EBM (Electron Bean Melting) method of 3D printing. The use of these technologies provides for customization according to the unique characteristics of the patient oral anatomy based on the prescription provided by the clinician	The device is a prescription customized for each patient and has an adjustment mechanism enabling the amount of mandibular advancement to be set by the dentist or physician at the time of fitting the device. Use of computer aided design (CAD) and computer aided manufacturing (CAM). Uses CAD that enables a high degree of customization according to the physician or dentist prescription to accommodate complex dental anatomy of individual patients. The CAM and selective laser sintering guarantees precision, accuracy and consistency for each patient	This custom oral appliance is available to dental and medical professionals through authorized dental laboratories.	Same as for reference device; similar to the predicate
Adjustment Accessory	Replacement/re-supply connectors (13-21 mm)	NA	Replacement/re-supply connectors (19-36 mm)	Replacement/re-supply connectors	Similar to reference devices
Supplied Sterile/Non-Sterile	Non-Sterile	Non-sterile	Non-sterile.	Non-Sterile	Same for all

Feature	O_2Vent Optima	*Primary Predicate* O_2Vent W	*Reference Device* The Panthera Anti-Snoring Device	*Reference Device* Elastic Mandibular Advancement (EMA) Appliance	Compared to Subject Device
Materials of construction: Components **Top and Bottom trays**	Made from polymers (100% polyamide type 12 [aka Nylon]) Highly resilient and durable biocompatible polymer material	Medical grade titanium (top air channel only) Dental plastic laminates and acrylics used for upper and lower trays which are in contact with the patient's teeth. Erkoloc-pro Dual Laminate and Orthocryl (Bottom and top trays only)	Made from polymers (polyamide type 12 [aka Nylon]), Highly resilient and durable biocompatible polymer material.	Proprietary thermoplastic polymer that delivers superior impact strength to acrylic.	Same as the reference device; different from predicate as subject device uses additive manufacturing for teeth contact materials
Materials of construction Component. **Connectors/straps**	100% thermoplastic Polyurethane/cured elastomer	NA	Same as above per labeling	100% thermoplastic Polyurethane/cured elastomer	Same as the reference devices
Cleaning Instructions	Clean the device daily in lukewarm water with a soft toothbrush. Rinse, dry, and store in the case provided.	Clean the device with a soft clean toothbrush (not the same toothbrush you use to brush your teeth as toothpaste can damage the device). Rinse well with lukewarm water.	Clean the device daily in lukewarm water with a soft toothbrush. Rinse, dry, and store in the case provided.	Clean your appliance every morning in cool or lukewarm water with a denture toothbrush and toothpaste. We suggest using denture toothpaste such as DentuCreme® or Fresh 'N Brite; If white film begins to form on the appliance or if it picks up odors, soak it in a denture cleaning solution such as Polident® or Efferdent® in warm, not hot, water	Same as reference device and similar to predicate

Feature	**O_2Vent Optima**	***Primary Predicate*** **O_2Vent W**	***Reference Device*** **The Panthera Anti-Snoring Device**	***Reference Device*** **Elastic Mandibular Advancement (EMA) Appliance**	**Compared to Subject Device**
	Clean twice a week with chlorine free antibacterial cleanser	Clean twice a week with an effervescent denture cleaning tablet.	Twice weekly use chlorine free antibacterial orthodontic cleaning solution.	Once per week clean the device with a commercial denture cleaner in cool water.	Same as reference; similar to predicate
Biocompatibility - Passes Part 5 and Part 10 of ISO 10993	Yes, passed all tests	Not performed as the materials are identical as in the OVENT T (K160234).	Information could not be verified. Statement in K143244 "The device is biocompatible, based on the similarity of the materials of construction to the predicate device (Narval CC) marketed by ResMed"	Information could not be verified.	Same as predicate and reference devices per available information

Differences between the proposed device, predicate device and reference device(s).	As summarized above, the main functional differences between the subject (O_2Vent Optima) and predicate (O_2Vent W) and/or reference devices (The Panthera Anti-Snoring Device and Elastic Mandibular Advancement (EMA) Appliance) are: - Predicate: The predicate device does not use PA2200 in the additive manufacturing process - Reference: The Panthera Anti-Snoring Device and the Elastic Mandibular Advancement (EMA) Appliances **do not** contain an airway
Conclusion on Non-Clinical and Clinical Tests	The O_2Vent Optima is considered to be substantially equivalent to the predicate and reference devices based on the following: - It has the same intended use and is indicated for the same user population. - It has equivalent technological characteristics to the predicate or reference devices. - The device is as safe, as effective and performs comparatively to the legally marked devices identified above.