DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Oventus Manufacturing Pty Ltd
% M.W. Andy Anderson, Ph.D., RAC
Senior Principal Advisor
Regulatory and Clinical Research Institute, Inc.
5353 Wayzata Boulevard, #505
Minneapolis, Minnesota 55416

July 11, 2017

Re: K171316
Trade/Device Name: O_2Vent W
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: June 15, 2017
Received: June 16, 2017

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. 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

Lori Wiggins
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)*
K171316

Device Name
O2VENT W

Indications for Use *(Describe)*
The O2Vent 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.

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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510(k) SUMMARY FOR O_2VENT W
prepared in accordance to 21CFR 807.92 k171316

Date Prepared	June 29, 2017
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	Hemangi Malde
Device Trade name	O_2Vent W
Common Name	Oral Appliance – Anti snoring device
Classification	Class II
Classification Name	Intraoral devices for snoring and obstructive sleep apnea for snoring and obstructive sleep apnea.
Classification Code	LRK
Classification Regulation	21 CFR 872.5570
Device Model Number(s)	O2VWUS
Predicate Device	O_2Vent T – Oventus Manufacturing Pty Ltd - Primary OVENT – Oventus Manufacturing Pty Ltd SOMNODENT CLASSIC – Somnomed Inc.
Device Description	The ***O_2Vent W*** is an oral appliance and is intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA). The ***O_2Vent W*** is made up of two parts: 1. The Upper Tray 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, is made from medical grade titanium (3D printed). The upper titanium tray has two side protrusions (wings) that extend vertically down to interface with the lower acrylic tray for titration of the device. The upper tray is lined with acrylic insert, and is customized to patient bite and impression.

	2. The Lower Tray customized to the lower teeth, positions the lower jaw forward, preventing the soft tissue of the throat from collapsing and obstructing the airway. The lower tray features an adjuster assembly set into the acrylic, comprising of an adjuster block and also adjustment screws each located on either side of the lower arch. The adjuster block interfaces with the side protrusions on the upper tray to provide titration. The screws are adjusted with an Adjustment Key for mandibular adjustment to be set by the dentist and/or by the patient under the direction of the dentist.
Indications for Use	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.
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	As mentioned in the following pages.

Feature	O_2Vent W	O_2Vent T	OVENT	SOMNODENT CLASSIC
510k Number	K171316	K161832	K160234	K050592
Device Photo				
Indications for Use	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 ***O_2Vent T*** 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 OVENT 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.	To intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Product Codes	LRK	LRK	LRK	LRK
Regulation	21CFR 872.5570	21CFR 872.5570	21CFR 872.5570	21CFR 872.5570
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. Single patient multiple use. Prescription use only.	Removable intraoral device. Single patient multiple use. Prescription use only.
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.	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.
Environment of Use	To be used in the patient's home or in sleep laboratories.	To be used in the patient's home or in sleep laboratories.	To be used in the patient's home or in sleep laboratories.	To be used in the patient's home or in sleep laboratories.

Feature	O_2Vent W	O_2Vent T	OVENT	SOMNODENT CLASSIC
Cleaning Instructions	Should be cleaned daily in soap and water.	Should be cleaned daily in soap and water.	Should be cleaned daily in soap and water.	Should be cleaned daily in soap and water.
	Can be periodically cleaned in an ultrasonic cleaner with an effervescent denture cleaning tablet.	Can be periodically cleaned in an ultrasonic cleaner with an effervescent denture cleaning tablet.	Can be periodically cleaned in an ultrasonic cleaner with an effervescent denture cleaning tablet.	Cannot be cleaned in an ultrasonic cleaner.
Device Functionality	Repositions the lower jaw forward.	Repositions the lower jaw forward.	Repositions the lower jaw forward.	Repositions the lower jaw forward.
	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.	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.
	Does not have a lingual flange for holding the mandible forward.	Does not have a lingual flange for holding the mandible forward.	Has a lingual flange for holding the mandible forward[1].	Does not have a lingual flange for holding the mandible forward.
	Permits patient to breathe through their mouth[2].	Permits patient to breathe through their mouth[2].	Permits patient to breathe through their mouth[2].	Permits patient to breathe through their mouth[2].
	Retains the top and bottom teeth using rigid trays.	Retains the top and bottom teeth using rigid trays.	Retains the top and bottom teeth with monobloc.	Retains the top and bottom teeth using rigid trays.
Device Design	Customized for each patient in a dental laboratory.	Customized for each patient in a dental laboratory.	Customized for each patient in a dental laboratory.	Customized for each patient in a dental laboratory.
	Upper and lower trays are separate.	Upper and lower trays separate.	No upper and lower trays.	Upper and lower trays separate.
	The upper tray have protrusions (wings) at the rear on the titanium part to interface with the adjuster block in the lower tray.	The two trays are connected in the front of the device with a screw assembly.	The device is a one piece assembly.	The protrusions (wings) are at the rear of the bottom tray to interface with the adjuster block in the upper tray.

Feature	O_2Vent W	O_2Vent T	OVENT	SOMNODENT CLASSIC
Adjustment	Can be adjusted by the clinician and patient[4].	Can be adjusted by the clinician and patient[4].	Cannot be adjusted by the clinician or patient[4].	Can be adjusted by the clinician and patient[4].
	Lower jaw adjusted using titration of the adjustment screws equally on both sides with an adjustment key.	Lower jaw adjusted using titration of the adjustment screw with an adjustment key.	Lower jaw cannot be adjusted and there is no adjustment key.	Lower jaw adjusted using titration of the adjustment screws equally on both sides with an adjustment key.
Supplied Sterile/Non-Sterile	Non-Sterile	Non-sterile	Non-sterile	Non-sterile
Materials Used - 1	Medical grade metal used[5].	Medical grade metal used[5].	Medical grade metals used[5].	Medical grade metals used[5].
Materials Used - 2	Dental plastic laminates and acrylics used for upper and lower trays which is in contact with the patient's teeth.	Dental plastic laminates and acrylics used for upper and lower trays which is in contact with the patient's teeth.	Dental plastic laminates and acrylics used for upper and lower trays which is in contact with the patient's teeth.	Dental acrylics used for upper and lower trays which is in contact with the patient's teeth.
Biocompatibility*	Not performed as the materials are identical as in the OVENT.	Not performed as the materials identical as in the OVENT.	Passes Part 5 and Part 10 of ISO10993.	Information could not be verified.

* This is assumed as the predicate devices are FDA 510(k) cleared and are currently on the market. Only the OVENT device was tested as part of this submission. Biocompatibility was not performed on the O_2Vent T and O_2Vent W device as the materials used in the device were similar to that of OVENT.

Note (1) The OVENT has a choice of lingual flange (to be decided by the clinician) although for most cases adequate retention (in advanced position) is achieved by the molded polymer insert.

Note (2) The O_2Vent W, O_2Vent T and OVENT all have a dedicated breathing port (delivering air to the rear of the mouth) to allow the user to breathe through their mouth if they want, the SOMNODENT CLASSIC allows users to open their mouth to a degree.

Note (4) The OVENT requires a new insert to be made for mandibular adjustment, the O_2Vent W, O_2Vent T and SOMNODENT CLASSIC device can be adjusted by the clinician or patient through the adjustment screws and the adjustment key.

Note (5) The O_2Vent W, O_2Vent T and OVENT use 3D printed titanium trays and stainless steel screws (only for O_2Vent W and O_2Vent T) and the SOMNODENT CLASSIC uses stainless steel screws and ball clasps.

Summary of Non Clinical Tests	The non-clinical testing included risk assessment of the physical properties of the O_2Vent W and its ability to achieve its intended use. Preliminary testing was carried out to confirm that the design can withstand forces applied during normal use and also reasonable abuse in cases such as bruxing. The O_2Vent W met the specifications set. The only new material that was incorporated in the O_2Vent W are the adjustment screws which have been granted prior 510(k) approval, made of special grade stainless steel and have been widely used in manufacturing of dental appliances. The specifications of the adjuster screws are same as in the predicate SOMNODENT CLASSIC device. No other risks are introduced in the device. The O_2Vent W met the specifications as set. A biocompatibility assessment of the device was performed. The purpose of the biocompatibility assessment was to ensure that biocompatibility had been established for the device. No new materials are being used in the device; all materials are already used in the predicate devices (O_2Vent T & OVENT). No new risks are introduced in the new device apart from the two adjustment screws on the lower tray, which are not present in the predicate O_2Vent T & OVENT devices, however are present in the SOMNODENT CLASSIC predicate device. These screws have been granted prior 510(k) approval, made of special grade stainless steel and have been widely used in the manufacturing of dental appliances. Our conclusion is that biocompatibility testing of the adjustment screws is not warranted due to the source and nature of the component, it has long been used in intraoral environment (i.e. mucosal, gingival, and palatal) with prolonged contact and has been widely used in the manufacturing of dental appliances. The device is deemed to be biocompatible, based on the similarity of the materials of constructions to the predicate devices (O_2Vent T, OVENT & SOMNODENT CLASSIC).
Summary of Clinical Tests	Human clinical studies were not deemed necessary to evaluate the substantial equivalence of the O_2Vent W, as the O_2Vent W does not: • Use designs dissimilar from the predicate device and other previously-cleared devices under a 510(k); • Use new technologies different from legally-marketed intra-mandibular repositioning devices for snoring and/or obstructive sleep apnea;

	• Deviate from the indications for use identified in the predicate devices: the O_2Vent T, OVENT and SOMNODENT CLASSIC. In lieu of human clinical testing, the risks and mitigating controls associated with the use of mandibular repositioning devices, as identified by the FDA, have been addressed in the "Risk Assessment". The function of mandibular repositioning devices required that the prescribing dentist be aware of the potential for soreness caused by mandibular advancement. Management of these risks is achieved by advising the patients and dentists in the "Instructions for Use". The contraindications, warnings, precautions, storage, fitting and adjustment directions are written to avoid potential problems from arising or persisting caused by Mandibular Advancement Devices.
Differences between the proposed and predicate device(s).	As discussed in the comparison chart above, the main functional difference between the proposed O_2Vent W and predicate devices O_2Vent T & OVENT is the method of adjustment: - O_2Vent W allows protrusion of the mandible from the original treatment position via use of adjuster assembly located on both sides of the lower arch, whereas O_2Vent T allows protrusion via a single screw mechanism in the front of the device and additional impressions or laboratory procedures are required for OVENT. - The adjustments can be made by the clinician or by the patient under the direction of the clinician for the O_2Vent W and O_2Vent T device, however it is not possible in case of the OVENT device. - Additionally, in order to facilitate the titration of the device, the O_2Vent W have a separate upper tray with side protrusions (wings) and lower tray with the adjuster assembly on both the side that interface with the protrusions, while O_2Vent T has separate upper and lower trays connected via the screw mechanism in the front of the device, and the OVENT has a monobloc design. No new risks are introduced in the new device apart from the wings and two adjustment screws, which are not present in the predicate O_2Vent T and OVENT device, however are present in the SOMNODENT CLASSIC predicate device. The treatment outcomes for O_2Vent W, O_2Vent T and OVENT are expected to be equivalent as the final levels of mandibular protrusion and the provision for oral breathing via the customized airway is same for each device. The difference between the proposed O_2Vent W and predicate device SOMNODENT CLASSIC is the location of the wings and

	titration blocks, which is switched between the upper and lower trays. The purpose of the wings and the titration blocks is to stabilize the mandible in a more advanced position and thus be able to advance the mandible forward incrementally to reduce airway collapse during sleep. The fact that the wing is on the top part of the device as opposed to the bottom is inconsequential as it achieves the same purpose of mandibular advancement in this regard. Hence the differences mentioned are unlikely to adversely or otherwise affect the expected clinical outcomes for patients using the O_2Vent W device as compared to those using the predicate devices, thus not affecting the substantial equivalency of the proposed device.
Conclusion on Non Clinical and Clinical Tests	The O_2Vent W is considered to be substantially equivalent to the predicate 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 predicates. • The device is as safe, as effective and performs as well as or better than the legally marked devices identified above.