DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 23, 2016

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

Re: K161832
Trade/Device Name: O_2 Vent T
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: August 23, 2016
Received: August 25, 2016

Dear Dr. M.W. 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,

Michael J. Ryan -S

for 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)*
K161832

Device Name
O2VENT T

Indications for Use *(Describe)*
The O2Vent 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.

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 T
prepared in accordance to 21CFR 807.92

Date Prepared	23rd September 2016
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 T
Common Name	Oral Appliance – Anti snoring device
Classification	Class II
Classification Name	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.
Classification Code	LRK
Classification Regulation	21 CFR 872.5570
Device Model Number(s)	O2VTDL, O2VTOV
Predicate Device	OVENT – Oventus Manufacturing Pty Ltd TAP-III – Airway Management
Device Description	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 ***O_2Vent T*** is made up of three 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 2. The Lower Tray fitted over the lower teeth, positions the jaw for mandibular advancement. The Upper and Lower Trays have a "landing area" customized to the pati ent's teeth and made from medical grade polymers.

	3. The Upper and Lower Trays are connected together with a connector. A hook mechanism attached to the Upper Tray fits into a socket attached to the Lower Tray and positions the lower jaw forward, preventing the soft tissue of the throat from collapsing and obstructing the airway. An Adjustment Key for the ***O_2Vent T*** allows the patient and their Clinician to adjust the protrusion of the lower jaw to the most effective and comfortable position.
Intended Use of the Device	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.
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 T	OVENT	TAP-III
510k Number	Not yet received.	K160234	K062951
Device Photo			
Intended Use	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 reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea (OSA).
Product Codes	LRK	LRK	LRK
Regulation	21CFR 872.5570	21CFR 872.5570	21CFR 872.5570
Use of device	Removable intraoral device. Multiple use. Prescription use only.	Removable intraoral device. Multiple use. Prescription use only.	Removable intraoral device. 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.
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.
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.
	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.

Feature	O_2Vent T	OVENT	TAP-III
Device Functionality	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.
	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].
	Retains the top and bottom teeth using rigid trays.	Retains the top and bottom teeth using rigid trays.	Retains the top and bottom teeth using rigid trays.
Device Design	Customized for each patient in a dental laboratory.	Customized made for each patient in a dental laboratory.	Customized made for each patient in a dental laboratory.
Adjustment	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].
Supplied Sterile/Non-Sterile	Non-Sterile	Non-sterile	Non-sterile
Materials Use - 1	Medical grade metal used[5].	Medical grade metal used[5].	Medical grade metals used[5].
Materials Use - 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.
Biocompatibility*	Not performed as the materials are identical as in the OVENT.	Passes Part 5 and Part 10 of ISO10993.	Passes Part 5 and Part 10 of ISO10993.
Mechanical safety	Can withstand mechanical forces without significant degradation.	Can withstand mechanical forces without significant degradation.	Can withstand mechanical forces without significant degradation.

* This is assumed as the 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 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 T and OVENT both 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 TAP-III 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 T and TAP device can be adjusted by the clinician or patient.

Note (5) The O_2Vent T and OVENT uses titanium and the TAP-III uses stainless steel.

Summary of Non Clinical Tests	The non-clinical testing included risk assessment of the physical properties of the O_2Vent T and its ability to achieve its intended use. The only new material that was incorporated in the O_2Vent T is the connector assembly made from special grade 316 stainless steel. The material and design specifications of the connector assembly is already used in as the predicate TAP-III device. No other risks are introduced in the device. The O_2Vent T 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 device (OVENT). No new risks are introduced in the new device apart from the connector assembly, which are not present in the predicate OVENT device, however is present in the TAP-III predicate device and the new material has no patient tissue contact in the new device. The device is deemed to be biocompatible, based on the similarity of the materials of constructions to the predicate devices (OVENT & TAP-III).
Summary of Clinical Tests	Human clinical studies were not deemed necessary to evaluate the substantial equivalence of the O_2Vent T as the O_2Vent T 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 OVENT and TAP-III. 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 T and predicate device OVENT is the method of adjustment. O_2Vent T allows protrusion of the mandible from the original treatment position via a screw mechanism without requiring additional impressions or laboratory procedures as required for OVENT. The adjustments can be made by the clinician or patient for the O_2Vent T device, however it is not possible in case of the OVENT device. Additionally, in order to facilitate the ability to titrate the device, the O_2Vent T has separate upper and lower trays connected via the screw mechanism, while the OVENT has a monobloc design. No new risks are introduced in the new device apart from the connector assembly and separate trays, which are not present in the predicate OVENT device, however are present in the TAP-III predicate device. The treatment outcomes for 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. Hence the differences mentioned are unlikely to adversely or otherwise affect the expected clinical outcomes for patients using the O_2Vent T device as compared to those using the OVENT, thus not affecting the substantial equivalency of the proposed device.
Conclusion on Non Clinical and Clinical Tests	The O_2Vent T 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.