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

March 17, 2016

Oventus Manufacturing Pty. LTD
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K160234
Trade/Device Name: OVENT
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: February 23, 2016
Received: March 2, 2016

Dear Mr. Job:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

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)*
K160234

Device Name

OVENT

Indications for Use *(Describe)*

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.

The OVENT is for prescription use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

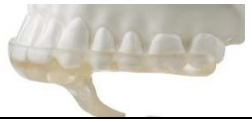
OVENT 510(k) Summary

Date Prepared:	25th January 2016
Owner Information [807.92(b)(1)]	Oventus Pty. Ltd. Suite 8, Level 17, 141 Queen Street, Brisbane QLD 4000 AUSTRALIA Tel +61 7 3210 2913 Fax +61 7 3229 9949 Official Contact: Neil Anderson
Device Name [807.92(b)(2)]	
Proprietary or Trade Name: Common / Usual Name: Regulation: Classification: Classification Name: Product codes: Device:	OVENT Oral Appliance - anti snoring device. 21 CFR 872.5570 II Intraoral devices for snoring and/or obstructive sleep apnea. LRK Anti-Snoring Device Oventus OVENT Device
Predicate Device [807.92(b)(3)]	• Airway Management - TAP III - K062951 • Dynaflex – LISA - K103076
Device Description [807.92(b)(4)]	The OVENT device is for the treatment of snoring and/or obstructive sleep apnea and is comprised of: • A titanium bimaxillary oral appliance which comprises, in one device, a lower tray fitted over the lower teeth and an upper tray fitted over the upper teeth. • A dental polymer material in each tray which is in contact with and retaining in position, the user's top and bottom teeth. • The lower jaw is retained in an advanced position to help open up the natural airway and alleviate the user's snoring condition. • A breathing port at the front of the appliance with an enclosed airway on each side which passes between the teeth and the cheek. Each airway delivers the air at the rear of the mouth typically between the last teeth. The airways allow the user to breathe with the mouth closed.

Intended Use [807.92(b)(5)]

Indicated Use:	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. The OVENT is for prescription use only.
Target population:	Adult patients 18 years and older
Environment of Use:	Home Use and sleep laboratories

Comparison to Predicate Devices

Feature	OVENT (Oventus)	TAPIII (Airway Management	LISA (Dynaflex)
510(k) Number	This application	K062951	K103076
Photo			
Intended Use	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).	Dynaflex® Anti-Snoring & Sleep Apnea Devices are intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.
Product Codes	LRK	LRK	LRK
Regulation	21 CFR 872.5570	21 CFR 872.5570	21 CFR 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	OVENT (Oventus)	TAPIII (Airway Management Repositions	LISA (Dynaflex)
Device Functionality	Repositions the lower jaw forward.	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.
	Has a lingual flange for holding the mandible forward[1].	Does not have a lingual flange for holding the mandible forward[1].	Has a lingual flange for holding the mandible forward[1].
	Permits patient to breathe through their mouth[2].	Permits patient to breathe through their mouth[2].	Does not permit patient to breathe through their mouth[2].
	Retains the top and bottom teeth using rigid trays[3].	Retains the top and bottom teeth using rigid trays[3].	Does not retain the top and bottom teeth using rigid trays[3].
Device Design	Custom made for each patient in a dental laboratory.	Custom made for each patient in a dental laboratory.	Custom made for each patient in a dental laboratory.
Adjustment	Cannot be adjusted by the clinician or patient[4].	Can be adjusted by the clinician or patient[4].	Cannot be adjusted by the clinician or patient[4].
Supplied Sterile/ Non-sterile	Non-sterile	Non-sterile	Non-sterile
Materials Used	Medical grade metals used[5].	Medical grade metals used[5].	No metal parts used[5].
	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*	Passses Part 5 and Part 10 of ISO 10993	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.

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 moulded polymer insert, the LISA relies on the lingual component for holding the mandible forward.

Note (2) The OVENT has 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 allows users to open their mouth to a degree, whereas for the LISA, if the user opens their mouth the lingual structure no longer supports the mandible and the lower jaw moves back.

Note (3) The OVENT and the TAP retain the top and bottom teeth in rigid trays whereas the LISA only retains the top teeth

Note (4) The OVENT requires a new insert to be made for mandibular adjustment, the TAP device can be adjusted by the clinician or patient and the LISA requires a whole new device to be made

Note (5) The OVENT uses titanium, the TAP stainless steel and the LISA has no metal parts

Non-Clinical Tests Performed [807.92(b)(1)]

a. Biocompatibility testing was performed as outlined in the FDA-modified "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" for a surface device that contacts intraoral (i.e., mucosal, gingival, and palatal) surfaces for prolonged contact. Testing was conducted as described in Parts 5 and 10 of ISO-10993 the standard at a certified, independent laboratory. The OVENT passed all 4 tests as per the pass/fail criteria of the standards – cytotoxicity, skin sensitization, intraoral mucosa irritation and intracutaneous reactivity.

b. Peel/Bond strength was determined for the titanium to the acrylic and the acrylic to the dental laminate materials before and after accelerated aging in an oral simulation solution. Aging duration was calculated to be equivalent to 1 year of nightly use. The bond strength pass/fail criterion was set at 1N/mm or 10N overall strength for a 10mm interface length. The peel strength was tested as per DD253-2001: Mouth guards for use in sport and recreation - Requirements and test methods. All the OVENT materials - before and after aging - had peak strengths greater than 1N/mm (>10N for a 10mm wide sample) and consequently have suitable bond strengths for the device application**.

** The key objective was to ensure that any degradation at the interfaces did not result in oral fluid ingression. All strengths were well above the set value and no fluid ingression resulted. If the inserts were removable for cleaning rather adhered to the titanium – mechanical retention would be required and the peel strength would be substantially less.

Clinical Tests Performed [807.92(b)(2)]

Human clinical studies were not deemed necessary to evaluate the performance of the device to determine substantial equivalence as the OVENT 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 intramandibular repositioning devices for snoring and/or obstructive sleep apnea;
- Deviate from the indications for use identified in the predicate devices: the TAPIII and the LISA.

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". In addition, adequate warnings and precautions are found in the "Instructions for Use".

Conclusion [807.92(b)(3)]

The OVENT is considered to be substantially equivalent to the predicate devices based on the following:

- Differences in the wording of intended uses between the subject and predicate devices are not critical to the intended therapeutic use of the device.
- It has equivalent technological characteristics to the predicates.
- The device is as safe, as effective and performs as well as than the legally marked devices identified above.