

ASX release

Oventus Medical lodges FDA submission for the O₂Vent W

Key Points:

- **US 510k FDA submission for the O₂Vent W – winged or dorsal flex appliance – has been lodged; FDA clearance will allow this version of the device to be sold in the US**
- **The Winged device allows dentists who prefer this type of mandibular advancement mechanism, to deliver appliances with the proprietary Oventus Airway Technology**
- **O₂ Vent W was listed on the TGA's Australian Register of Therapeutic Goods (ARTG) in early March 2017 – the first appliances have now been shipped to Australian clinicians**
- **Once cleared, Oventus will have O₂Vent appliances on the US market with the two most popular advancement mechanisms**

Brisbane, Australia 5th May, 2017: Australian medical device company Oventus Medical Ltd., has lodged an FDA 510k submission for its O₂Vent W device - an oral appliance intended to reduce or alleviate snoring, mild to moderate obstructive sleep apnoea (OSA) and severe sleep apnoea when the patient is intolerant to Continuous Positive Airway Pressure Devices.

This is in line with the company's strategy of expanding its product portfolio to incorporate Oventus Airway technology into all of the main design variations of oral appliances for the treatment of sleep disordered breathing. It demonstrates that Oventus Airway Technology can be incorporated into any device design to give patients and clinicians the benefit of the airway no matter what type of oral appliance they prefer to use.

Oventus Managing Director and Chief Executive Officer, Neil Anderson said: "The O₂Vent W is important to the Company's positioning and ability to meet a wide range of needs in the dental marketing channel. Since the launch of the O₂Vent T, we have had a significant number of dentists who have requested a Winged version of the O₂Vent with an airway. This is often because they are used to delivering these types of appliances to their patients.

"We have been able to quickly develop and manufacture this device in response to these requests, and we are already shipping the first products to Australian clinicians for delivery to their patients."

Once FDA cleared, Oventus will have three devices for sale in the US market – O₂ Vent W, and O₂Vent Mono and O₂Vent T that already have 510k clearance.

Additionally, the Oventus PAP connection, which is currently in an advanced stage of development, will be compatible with the O₂Vent W and O₂Vent T appliances for low pressure combination therapy. It is anticipated the clearance for O₂ Vent W will be received in the 2nd half of the 2017 calendar year.

-ENDS-

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About Oventus

Oventus is a Brisbane based medical device company that is commercialising a suite of oral appliances for the treatment of sleep apnoea and snoring. Unlike other oral appliances, the Oventus devices have a unique and patented airway within the device that delivers air to the back of the mouth bypassing multiple obstructions from the nose, soft palate and tongue. They are particularly designed for the many people that have nasal obstructions and consequently tend to mainly breathe through their mouth. While it may seem counterintuitive, the device actually prevents oral breathing. The O₂Vent is designed to allow nasal breathing when the nose is unobstructed, but when obstruction is present, breathing is supplemented via the airways in the appliance.

According to a report published by the Sleep Health Foundation Australia, an estimated 1.5 million Australians suffer with sleep disorders and more than half of these suffer with obstructive sleep apnoea.¹

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, OSA, however many patients have difficulty tolerating CPAP². Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.³

¹ Deloitte Access Economics. *Reawakening Australia: the economic cost of sleep disorders in Australia, 2010*. Canberra, Australia.

² Beecroft, et al. *Oral continuous positive airway pressure for sleep apnea; effectiveness, patient preference, and adherence*. *Chest* 124:2200–2208, 2003

³ Sutherland et al. *Oral appliance treatment for obstructive sleep apnea: An updated Journal of Clinical Sleep Medicine*. February 2014.