

ASX release

Oventus Medical Receives FDA clearance for the O₂Vent W

Key Points:

- **US 510k FDA clearance for the O₂Vent W – winged or dorsal flex appliance – achieved; allowing sale of the appliance into the US.**
- **The O₂Vent W will be distributed exclusively in the US by Oventus’ distribution partner Modern Dental – which covers approximately one quarter of US dentists through 34,000 dental offices.**
- **First sales are planned for this quarter and expected to ramp up from the October 2017 quarter.**
- **The Winged device will allow dentists who prefer this type of mandibular advancement mechanism, to deliver appliances with the proprietary Oventus Airway Technology.**
- **Oventus now has O₂Vent appliances on the US market with the two (2) most popular mandibular advancement mechanisms.**

Brisbane, Australia 12th July 2017: Australian medical device company, Oventus Medical Ltd. has received FDA 510k clearance for its O₂Vent W device, an oral appliance intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnoea (OSA).

The clearance marks an important milestone for Oventus: With a US distribution partner recently signed, and appliances with the two most popular mandibular advancement mechanisms now cleared for sale, the company will focus on ramping up US sales. The US National Institute of Health estimate 12-18 million US adults have sleep apnoea¹ with at least 80% of these estimated to be outside of care or not treated effectively with other therapies.

Oventus Managing Director and Chief Executive Officer, Neil Anderson said: “The O₂Vent W is important to the Company’s product plans and follows the recent signing of Modern Dental as a global distribution partner.”

He added, “We now have the right product mix and right distribution partner to accelerate our launch into the lucrative US market. First sales of the winged appliance are planned for this quarter with ramp up from next quarter.” Oventus will continue to expand its product range, noting that the Oventus Positive Airway Pressure (PAP) connection currently in an advanced stage of development will be compatible with O₂Vent W appliance for low pressure combination therapy.

¹<http://www.nhlbi.nih.gov/news/spotlight/fact-sheet/sleep-disorders-insufficient-sleep-improving-health-through-research>

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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.*