

Media release

Oventus Medical Receives FDA Clearance for the O2Vent™ T

Key Points:

- **The O2Vent™ T is the company's titratable device (patent pending) with an included airway (patent registered in Australia and pending overseas)**
- **FDA clearance marks a major milestone for Oventus**
- **The O2Vent™ T is the company's first product to be launched into the US through multiple clinical sites. Beta test sites being set up and the launch is planned for October.**
- **The O2Vent™ T is designed to treat patients that cannot, or are not, treated effectively with existing treatments Eg. Nasal obstructors and CPAP¹ intolerant**
- **Already registered with the TGA in Australia and has been on the market since 1st July 2016**

Brisbane, Australia 26th September 2016: Australian medical device company, Oventus Medical Ltd. has received clearance from the U.S. Food and Drug Administration (FDA) for the O₂VENT™ T 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 (CPAP) devices.

The clearance marks an important milestone for Oventus, allowing the company to now launch into the US. The [US National Institutes of Health](#) estimate 12-18 million US adults have sleep apnoea 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™ T is the Company's first product to be launched into the USA. Its FDA clearance is consequently an important milestone for us as we strive to bring our innovative product portfolio to the global market to benefit those that suffer from OSA or snore excessively."

The device, which was created by Brisbane dentist Dr Chris Hart, who founded Oventus and is the company's Clinical Director, is indicated for use during sleep to aid in the treatment of snoring and OSA.

The O₂VENT is a 3D printed titanium mandibular (jaw) advancement device fitted in a patient's mouth. It has an airway that directs air to the back of the throat and bypasses nasal, soft palate obstructions and tongue obstructions. The device is unique in its innovative design and is protected by a strong portfolio of patent applications (IP).

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The device already is registered with the Therapeutic Goods Administration (TGA) in Australia and is on market and generating revenue for the company. TGA registration also paves the way for launch into key European and Asian markets.

A clinical study² completed earlier this year showed the company's first generation product the O₂VENT™ Mono is successful in treating OSA and that snoring was either eliminated or significantly reduced in 100 per cent of patients². The positive results included those people who had nasal obstructions and mainly breathed through their mouths, including when they were asleep.

Dr Hart said: "The recent clinical data strongly supports its superior performance and clearly demonstrates its effectiveness in treating a range of sleep disorders. It also improves oxygen levels for patients."

"It means a greater number of patients who are CPAP intolerant or mild to moderate sufferers of sleep apnoea now have an alternative treatment option available," Dr Hart added.

The company is expecting the titratable version, the O2Vent™ T to have similar or even superior results as the jaw position can be more optimised through the titration mechanism.

¹ CPAP – Continuous Positive Airway Pressure - Patients wear a face or nasal mask during sleep. The mask, connected to a pump, provides a positive flow of air into the nasal passages in order to keep the airway open

² Oventus Clinical Trial Report. Data on file.

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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

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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.*