



## **SomnoMed USA receives 510K for SomnoDent® Fusion**

**24<sup>th</sup> June 2014**, SomnoMed Limited (ASX:SOM) announced today that it received today the FDA 510(k) approval from the US Department of Health & Human Services for its new SomnoDent® Fusion Classic and SomnoDent® Fusion Flex oral appliances. The new designs were introduced at the AADSM and AASM conventions in Minneapolis at the beginning of June and received positive customer reactions.

The SomnoDent® Fusion is a patented design, which allows greater titration. It has exchangeable wings, which makes adjustments of the forward position of the SomnoDent® device easier for the practitioner and patient.

“Both our new products, SomnoDent® Fusion and SomnoDent® Herbst Advance, are now approved by the FDA. Sales will be commencing in July. We believe both products represent another step forward in strengthening SomnoMed’s global leadership position in oral appliance therapy for obstructive sleep apnea. Both products offer improvements over existing devices and a greater level of patient comfort. Patient comfort is at the centre of SomnoMed’s mission and product philosophy, as it has a direct impact on compliance. We believe the more comfortable the treatment, the more compliant the patient, which is a precondition for better medical treatment outcome. The high level of compliance is giving oral appliance therapy a distinct advantage over CPAP for the majority of patients,” said Dr. Peter Neustadt, Chairman and CEO of SomnoMed.

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### **About SomnoMed**

SomnoMed is a public company providing diagnostic and treatment solutions for Sleep-related Breathing Disorders including obstructive sleep apnea, snoring and bruxism. SomnoMed was commercialized on the basis of extensive clinical research. Supporting independent clinical research, continuous innovation and instituting medical manufacturing standards has resulted in SomnoDent® becoming the state-of-the-art and clinically proven medical oral appliance therapy for obstructive sleep apnea. SomnoDent® is the most comfortable and effective design and treatment solution for over 175,000 patients in 24 countries.

For additional information, visit SomnoMed at <http://www.somnomed.com.au>