



FDA 510k approval for SomnoDent® Alpha

21st September 2016, SomnoMed Limited (ASX:SOM) announced today that it has received the FDA 510k approval for its new instant fit SomnoDent® Alpha device. SomnoDent® Alpha is an oral appliance based on the patented SomnoDent® family of devices. The approval is the result of a two year development project by SomnoMed's in house product development department in Sydney.

SomnoDent® Alpha can be used by medical and dental specialists to fit an oral appliance in a matter of minutes allowing follow up sleep tests with the device to show the level of efficacy of COAT™ in a particular patient. It fills the requirements of some medical specialists, hospitals or insurers who wish to test the impact of COAT™ before a permanent device is fitted to the patient. Patents have been lodged for Alpha in SomnoMed's key markets.

"SomnoDent® Alpha was designed as a result of our close co-operation with the medical side of our business. It will assist in broadening the acceptance of COAT™ as alternative treatment to CPAP as it allows medical specialists, either in their own practice or in co-operation with the dental sleep specialist, to check the efficacy of COAT™ immediately following the diagnosis of obstructive sleep apnea," said Dr Peter Neustadt, Chairman of SomnoMed.

"A number of insurers in the US are reimbursing the use of an interim device for the purpose of testing the treatment of OSA with an oral appliance. SomnoDent® Alpha will be available in all our global markets," said Dr Neustadt.

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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 over 275,000 patients in 27 countries.

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