# SomnoDent®G2 FDA 510(k) cleared

**7th June 2012**: SomnoMed Limited (SOM:ASX) is pleased to announce that it has received a 510(k) from the US Food and Drug Administration ("FDA") and will now begin marketing its unique SomnoDent® G2 in the USA. The SomnoDent® G2 technology (patent pending) has been developed over several years, after extensive research and development, following US quality system requirements and the FDA regulatory process.

SomnoDent® G2 will be launched at the 21st Annual Meeting of the Academy of Dental Sleep Medicine and 26th Annual Meeting of the Associated Professional Sleep Society, LLC (APSS) from 7- 13 June 2012 in Boston.

SomnoDent® G2 incorporates modular adjustment parts, which are uniquely identified and provide instant and accurate advancement of the G2 splints. This revolutionary design "Click to Fit" will provide a controlled measurement of a patient's mandible position to treat OSA. The device's range of motion has also been extended providing more treatment options. The SomnoDent® G2 includes SomnoMed's proprietary materials, is metal free and is 20% smaller than SomnoMed's current range of sleep apnea devices, thereby increasing patient comfort.

SomnoDent® G2 will be available through qualified SomnoMed Preferred Dental Network partners only. A newly designed premium packaging and travel case will also protect the device when not in use. Accompanied by an adjustment kit, which stores and organizes the modular adjustment parts, the SomnoDent® G2 represents a new standard of care for Obstructive Sleep Apnea (OSA) patients.

"With the innovative SomnoDent® G2 and Somnomed MATRx® both now FDA cleared we are able to offer state-of-the-art oral appliance treatment and diagnostic solutions for OSA patients never seen before," says CEO Ralf Barschow. "These revolutionary, premium product innovations continue our focus on evidence based, quality clinical outcomes for patients".

For more information please visit SomnoMed at www.somnomed.com or contact:

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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 100,000 patients in 22 countries.