



## SomnoDent Avant™ receives FDA clearance

**13<sup>th</sup> May 2019, SomnoMed Limited (ASX:SOM)** announced today that its new digitally milled sleep apnea treatment product, SomnoDent Avant™, received full FDA 510k clearance.

The development of the digital manufacturing platform has been a transforming and rewarding process that will allow SomnoMed to showcase enduring quality with precision fit and unsurpassed patient comfort. The patented SomnoDent Avant™ has been developed through continuous innovation in design and materials and has a unique, easy to use titration mechanism. Preliminary clinical follow-up results indicate the SomnoDent Avant™ has an improved efficacy over previous products in the range.

“We are very proud of the Company’s achievement on the FDA approval of the SomnoDent Avant™,” said Mr Neil Verdal-Austin, Global CEO of SomnoMed. “We have invested significant time and resources to ensure that our new digital manufacturing process will enhance and improve the quality of the range of SomnoDent® products we produce. Our overarching deliverable will always be focused on treating patients who suffer from Obstructive Sleep Apnea (“OSA”) with a more comfortable alternative to CPAP and as such we will only offer products that with a high level of comfort and compliance,” Mr Verdal-Austin added.

“We are building on our heritage of almost 15 years experience, with more than 480,000 SomnoDent® devices sold globally, where we have a proven history of product innovation that has enhanced clinical and patient outcomes,” commented Mr Verdal-Austin. “The SomnoDent Avant™ will help us compete in the market segment of CAD/CAM produced oral appliances with pride. Our product in this growing segment will provide customers with greater precision, improved fit and shorter delivery times,” concluded Mr Verdal-Austin.

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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 more than 480,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>