



7th October 2024

Rest Assure[®] - US Food and Drug Authority (FDA) Update

SomnoMed Limited (ASX “SOM”, or the Company), the leading company in the provision of oral appliance treatment solutions for sleep-related breathing disorders and obstructive sleep apnea (‘OSA’), is pleased to announce that the FDA has cleared Rest Assure[®] as an oral device with in-built compliance monitoring. An additional feature, the monitoring of efficacy via an AHI measurement within Rest Assure[®]'s cloud-based system, was not cleared.

Whilst encouraged by the FDA's decision, SomnoMed is currently reviewing the requirements of a subsequent submission for the efficacy algorithm and the commercialisation pathway of the product over the medium term. SomnoMed's Rest Assure[®] strategy was predicated on both compliance (usage of device) and efficacy to enable clinical validation of the therapy and align with data currently available from most CPAP therapies.

Co-CEO's Karen Borg and Amrita Blickstead noted, “This is a significant achievement for SomnoMed. The team has worked tirelessly to develop the Rest Assure[®] system over the last four years. Rest Assure[®] technology will provide objective data that will address many of the questions our physician, dentist and patient customers have about oral device therapy. We are confident this data will positively shape the OSA industry in the years to come.”

SomnoMed's Rest Assure[®] product is a device with sensors, software and a cloud-based computing system, developed by the company over the last four years, delivering the first technology enabled oral appliance.

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This release has been approved by the Board of SomnoMed Limited.

For further information please contact

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About SomnoMed

SomnoMed is a public company providing treatment solutions for sleep-related breathing disorders including obstructive sleep apnea, snoring and bruxism. SomnoMed was commercialised 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 910,000 patients in over 20 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>

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