ASX Release
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Compumedics announces US FDA 510(K) approval for the World's First of its kind Neuro/EEG high-density amplifier Okti®

Highlights:

- **Okti® is the world's first of its kind high-density ambulatory EEG amplifier**
- **Sales of this next generation neurological monitoring device can now commence in the USA**
- **USA EEG market estimated at $400 million USD with a CAGR of 9%**
- **A significant milestone for the Company's core business growth goal of expanding its neurological monitoring market share in the USA**
- **Company targets 1% to 2% share of USA market in the medium term**
- **Company will leverage recent expansion of its selling team in the US to fully maximise the Okti® sales opportunity**

Compumedics Limited (ASX: CMP) ("Compumedics" or **"Company")** is pleased to announce that it has recently received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its Okti® high-density EEG amplifier range. This news will allow the newly expanded sales team in the USA to actively pursue sales of Okti® across the USA EEG market, which is estimated at $400 million USD with a CAGR of 9%. Compumedics targets taking a 1% to 2% share of this market in the medium term.

Okti® is the culmination of decades of experience in EEG monitoring and a deep understanding of patient care. Okti® is the world's first of its kind high-density ambulatory EEG amplifier. Electroencephalogram (EEG) is the measurement of electrical activity in the brain, critical for monitoring and diagnosing disorders of the brain such as epilepsy. As such, Okti® can also be used for Routine and Long-Term EEG epilepsy monitoring (LTM). By combining several different channel interfaces into a compact hand-held format, Okti® enables patients to undergo high resolution studies with the flexibility to be mobile within the Hospital or Clinic. Okti's wireless and high-definition capabilities will improve clinical workflows and the patient experience.

Okti® allows for high-density EEG recordings, for LTM and Clinical Routine EEG studies in the USA. Okti® is a modular, multi-functional design with interchangeable 32, 64 and 128 channel interfaces. Okti®is approved for both pediatric and adult applications and has up to 72 hours battery life, with hot swappable batteries, to ensure continuous recording. Typically, Okti® will be used in a clinical or hospital setting, where neurological departments are based. When a patient goes into one of these facilities they would be wired to the device and monitored over a period of time. Okti®'s wireless capability enables the patient to freely move around with the device whilst the data is continuously captured.

Neurological or EEG monitoring and measurement is typically a subset of the data captured in sleep diagnostic studies. As such, the Company has focused on building its capability in the market so as to double the market size opportunity in the USA. This device will enable the Company to focus and expand its market share in neurology in the USA.

With the FDA approval in place, the Company may now enter the lucrative US clinical EEG market, with its expanded sales team. Okti®systems will typically sell for around USD 50k to USD 250k depending on the number of devices and the final Okti®configuration, with large LTM sites in the USD 1m plus range. These large LTM sites have previously not been accessible to Compumedics with its past product offering. Okti®is already CE marked and TGA approved with regulatory submissions for other territories to be completed in due course.

Dr David Burton, Chairman and CEO of Compumedics said:

"Compumedics is pleased to have achieved this important milestone for the Okti® EEG amplifier range. Receiving 510(K) clearance from the FDA, whilst expected, is nevertheless satisfying, and validating. In addition to the technical accomplishments achieved by the Company, it represents a key milestone in relation to a major objective to expand our EEG market share in the USA."

About Compumedics Limited

Compumedics Limited [ASX: CMP] is a medical device company involved in the development, manufacture, and commercialisation of diagnostics technology for the sleep, brain, and ultrasonic blood flow monitoring applications. The Company owns US based Neuroscan, and Germany based DWL Elektronishe GmbH. In conjunction with these two subsidiaries, Compumedics has a broad international reach, including the Americas, Australia and Asia Pacific, Europe, and the Middle East.

Executive Chairman Dr. David Burton founded Compumedics in 1987. In the same year the Company successfully designed and installed the first Australian, fully computerised sleep clinic at Epworth Hospital in Melbourne. Following this early success, Compumedics focused on the development of products that sold into the growing international sleep clinic and home monitoring markets.

Compumedics listed on the Australian Securities Exchange in 2000. Over the years, Compumedics has received numerous awards, including Australia's Exporter of the Year, and has been recognised as a Top 100 Innovator by both German and Australian Governments.

About Okti®

Okti®* is the culmination of decades of experience in EEG monitoring and a deep understanding of patient care. Okti is the world's first high-density ambulatory EEG amplifier that can also be used for Routine & Long-Term EEG. By combining several different channel interfaces into a compact hand-held format, Okti® enables patients to undergo high resolution studies without being tethered to fixed equipment.

The Okti is a next generation of wireless products, developed to provide greater flexibility to the physicians and comfort for the patients. This wireless capability gives physicians the option of monitoring a patient's physiological data while the patients are out of bed, helping to ensure they capture critical clinical events on the recording. This allows the hospitals to utilise almost any bed as a virtual sleep/EEG clinic or monitoring bed.

Okti's application and possibilities are limited only by your imagination.

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Authorised for lodgement by Compumedics Limited's Board of Directors