



Compumedics Portable System Given Go-ahead by US FDA

Tuesday 28th January 2003: Australian medical technology company Compumedics Ltd (ASX:CMP) today announced that the US FDA has granted approval to market the company's portable Somté sleep-cardiology recording system in the United States.

The potential market for Somté in the United States is estimated to be of the order of US\$130 million per annum. This announcement follows recent approval to market Somté in Canada and last year's European Union, Australian and Japanese regulatory approvals.

Somté is a first of its kind, lightweight medical recorder that combines features of diagnostic sleep systems and cardiac recorders. The combination of the technologies addresses the mounting evidence of the correlation between sleep disordered breathing and cardiovascular disease. It is estimated that as many as 40% of the 58 million Americans suffering some form of cardiovascular disease also have a sleep disorder.

Compumedics executive chairman, David Burton hailed the FDA approval for Somté as a major leap forward for the company, "We are now able to sell the world's foremost technology in portable sleep-cardiology recorders into the world's biggest market," he said.

In the United States, Somté will be sold to over 2400 specialty sleep centers as well as to private physicians and clinics where significant interest is building for rapid detection of sleep disordered breathing in their patients. With its current sales structure in the United States, Compumedics has become one of the market leaders in the rapidly growing sleep diagnostic market.

Somté offers both financial and clinical benefits to patients and the health system generally. "Early detection of sleep disorders such as obstructive sleep apnea (OSA) and potentially associated cardiovascular disease allows for the earliest and least costly intervention. As Somté is portable, the patient study can be conducted at home, thus also eliminating the expense of hospitalization," Mr Burton said.

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About Compumedics: www.compumedics.com

Compumedics Limited, founded in 1987, is a global leader in the design and manufacture of diagnostic technology for sleep disorders, neurophysiology and cardiology. Compumedics was listed on the Australian Stock Exchange in December 2000. The company has corporate headquarters in Melbourne, Australia and offices in the United States, Asia and Europe. Compumedics holds 70% of the Australian sleep diagnostic market in Australia and is fast becoming a major presence in the US marketplace for both its sleep diagnostic as well as its neuro-diagnostic products.