4 August 2026

Control Bionics Completes US FDA Registration and Device Listing for NeuroStrip™

Melbourne, Australia: Control Bionics Limited (ASX: CBL) ("Control Bionics" or "the Company") is pleased to announce that its NeuroStrip™ surface EMG (sEMG) wearable platform has been registered and listed with the United States Food and Drug Administration (FDA) as a medical device. It formally establishes NeuroStrip within the US medical device regulatory framework.

Highlights

- NeuroStrip™ is now registered and listed with the FDA as a medical device, formally establishing its status within the US regulatory framework governing surface EMG devices. The FDA listing number is D605008 and registration number is 3006789226.
- The registration is a meaningful milestone in its own right, reinforcing NeuroStrip's credentials as a medical-grade device and supporting the Company's broader regulatory strategy.
- While not a prerequisite for NeuroStrip's existing use in sports performance and general rehabilitation, the registration adds further stature to the platform in commercial discussions with existing and prospective customers across all verticals.
- The registration will meaningfully support NeuroStrip's positioning for advanced clinical rehabilitation, medical research applications and prospective human-computer interface and medtech development partners, where recognised US regulatory status is typically a threshold condition of engagement.
- Control Bionics has also submitted applications for regulatory approval in additional key jurisdictions, including registration with the Therapeutic Goods Administration (TGA) in Australia, CE marking under the EU Medical Device Regulation (MDR), and registration under the UK MDR framework.

The FDA registration and listing formalises NeuroStrip's recognised status in the US medical device market, one of the world's largest and most influential healthcare markets. Registration with the FDA is an important credential in its own right, and while it is not required to support NeuroStrip's continued rollout across sports performance and everyday rehabilitation settings, it materially strengthens the Company's position in more advanced

applications. In particular, the registration is expected to support engagement with advanced clinical rehabilitation providers, medical research institutions and future human-computer interface and medtech development partners, where formal US regulatory recognition is often a baseline requirement for engagement.

The Company views this registration as an important step in accelerating its growth strategy across all three NeuroStrip application areas – performance, rehabilitation, and research and data – and as a further building block in Control Bionics' 25 year plus legacy as an innovative medtech business. Combined with the Company's pending applications for TGA registration, CE marking and UK MDR registration, this reflects the breadth and pace of Control Bionics' regulatory strategy as it continues to scale NeuroStrip into new markets and deepen adoption with existing partners.

Control Bionics CEO and Managing Director, Jeremy Steele, commented:

"This FDA registration is an important milestone for Control Bionics and for NeuroStrip. It is a significant credential in its own right, and while NeuroStrip already supports sports performance and everyday rehabilitation use without requiring this level of regulatory status, formal recognition under the US medical device framework meaningfully strengthens our position in advanced clinical rehabilitation, medical research and future human-computer interface applications, where customers and partners expect a recognised regulatory foundation.

"This registration builds on our 25 year plus legacy as an innovative medtech business and supports our strategy to accelerate growth across all three NeuroStrip application areas. Combined with our pending TGA, CE and UK MDR applications, it reflects the breadth of our regulatory strategy as we continue to scale NeuroStrip into new markets and deepen adoption with existing partners," said Mr Steele.

This announcement has been authorised for release by the Board of Control Bionics Limited.

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Forward-Looking Statements

This announcement contains forward-looking statements, including in relation to the anticipated timing and outcome of pending applications for TGA registration, CE marking and UK MDR registration. Forward-looking statements are based on current expectations, estimates and assumptions and are subject to known and unknown risks, uncertainties and other factors, many of which are beyond the Company's control, that may cause actual outcomes to differ materially from those expressed or implied. There is no certainty as to the timing or ultimate outcome of any pending regulatory application, and readers are cautioned not to place undue reliance on forward-looking statements.

About Control Bionics

Control Bionics Limited is a neurotechnology company commercialising objective, non-invasive neural-signal technology proven in clinical environments and built to scale across multiple markets. Its neural-signal platform captures the body's physiological signals, including the electrical activity generated by muscles, with medical-grade precision and converts them into measurable, decision-ready outcomes. A single underlying technology platform serves four applications: Performance, Rehabilitation, Research & Data, and Assistive Communication. The technology has historically been deployed in assistive communication and is now being extended into sports performance, rehabilitation, medical research, platform partnerships and broader human-computer interface applications. Control Bionics' technology does not require surgery or implantation, and holds regulatory clearances in the US, Australia and Europe. The Company is also a registered NDIS provider in Australia.