

## ReNerve's NervAlign® Nerve Cuff receives FDA market clearance

**11<sup>th</sup> of February 2022; Melbourne Australia:** ReNerve Ltd (ReNerve) today announced that it has received market clearance from the FDA for its NervAlign® Nerve Cuff device. This means that the company can now market and sell the product in the United States. The NervAlign Nerve Cuff is a Class II medical device.

“Well done to the team. This is a major step forward for ReNerve as it progresses from an R&D orientation towards building a portfolio of commercialised products focussed on the nerve repair market” said Chair Mr Stephen Cooper.

ReNerve has existing logistics in place and has partnered with Emerging Surgical to initiate the launch of the NervAlign Nerve Cuff product. Over the coming months the company will commence customer outreach and product promotion as well as building its inventory in the US with a focus on getting first sales and product use in the US.



NervAlign Nerve Cuff is cleared for use in the repair of peripheral nerve injuries in which there is no gap or where a gap closure can be achieved by flexion of the extremity. The nerve cuff is manufactured using a patented technology called supercritical CO<sub>2</sub> which results in a clean, safe material that has had no exposure to highly toxic chemicals and therefore has no toxic residues yet retains its natural pliability and conformality, which is desirable for nerve repairs and good patient outcomes. The product is bio-absorbed and promotes tissue regrowth around the surgical site, whilst protecting the regenerating nerve.

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### About ReNerve

ReNerve is a medical device company specialising in biomaterial based medical devices for repair of peripheral nerve injury and related medical conditions. ReNerve's portfolio includes a range of cleaner, safer, tissue engineered surgical products designed to enhance nerve regeneration and provide better patient outcomes. The Company's NervAlign® Nerve Cuff has been through extensive testing and is currently in review at the FDA for marketing clearance. The NervAlign® Nerve Graft is an 'off-the-shelf', next generation product under development for the replacement of damaged nerves. ReNerve wishes to acknowledge AusIndustry support through the Accelerating Commercialisation program that has supporting many of the activities required to take the product through to clearance to market the device.