February 10, 2022

Renerve Ltd
% Chris Sloan
President
Sloan Regulatory Consulting LLC
322 Hart Road
Gaithersburg, Maryland 20878

Re: K202234
Trade/Device Name: NervAlign Nerve Cuff
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: January 10, 2022
Received: January 11, 2022

Dear Chris Sloan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202234

Device Name
NervAlign® Nerve Cuff

Indications for Use *(Describe)*
The NervAlign® Nerve Cuff is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
NervAlign® Nerve Cuff
K202234

Submitter

Name	ReNerve Ltd
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Date Prepared	February 2, 2022

Device

Trade Name	NervAlign® Nerve Cuff
Common Name	Nerve Cuff
Classification Name	Nerve Cuff
Classification Number	21 CFR 882.5275
Product Code	JXI
Regulatory Class	II

Predicate Device

Name [510(k) Number]	AxoGuard Nerve Protector [K132660]

Device Description

The NervAlign® Nerve Cuff is a collagen membrane matrix derived from porcine pericardium. It is a sterile, whitish to light beige colored, freeze-dried, pre-cut, flat sheet of acellular collagen. The NervAlign® Nerve Cuff is available in three (3) different sizes: 10x10mm, 20x30mm and 30x40mm.

The collagen material that comprises the Nerve Cuff is derived from the same species as that of the predicate nerve cuff (AxoGuard Nerve Protector; K132660) manufactured by Cook Biotech Incorporated.

Like the predicate, the NervAlign® Nerve Cuff is implanted providing a scaffold which becomes infiltrated by the patient's cells and is remodelled into native tissue. The Nerve Cuff provides protection of the damaged nerve while the nerve heals.

The NervAlign® Nerve Cuff is packaged in a dried state, is for single use and provided sterile.

Indications for Use

The NervAlign® Nerve Cuff is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity.

Comparison of Technological Characteristics with the Predicate Device

The proposed device is substantially equivalent to the design and materials in the predicate device. The table below summarizes the comparison between the predicate device and the NervAlign® Nerve Cuff.

NervAlign® Nerve Cuff Comparison to AxoGuard Nerve Protector

Feature	NervAlign® Nerve Cuff [Proposed Device]	AxoGuard Nerve Protector [Predicate Device]
510(k)	K202234	K132660
Device Class	Class II	Class II
Classification Name and Number	Nerve Cuff; 21 CFR 882.5275	Nerve Cuff; 21 CFR 882.5275
Product Code	JXI	JXI
Indications for Use	The NervAlign® Nerve Cuff is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity.	The Nerve Cuff is indicated for the repair of peripheral nerve injuries in which there is no gap or where a gap closure is achieved by flexion of the extremity. The device is provided sterile and intended for one-time use.
Principles of Operation	Collagen matrix intended to wrap and repair damaged peripheral nerves	Collagen matrix intended to wrap and repair damaged peripheral nerves
Material	Collagen Matrix - Porcine Pericardium	Collagen Matrix – Porcine Small Intestinal Submucosa (SIS)
Sterile/Single Use	Sterile; single use	Sterile; single use
Sterilization Method	Gamma Irradiation	Ethylene Oxide (EtO)

Performance Data

The following testing was performed on the ReNerve NervAlign® Nerve Cuff.

Test	Test Method Summary	Results
Suture retention strength	A suture was placed through aged and unaged devices and the force required to pull free was measured.	Test was completed and met specification. Like predicate the device has sufficient strength for its intended use.
Thickness	Direct measurement of the device with micrometer when hydrated according to IFU.	Thickness measurements of device showed substantially equivalent to predicate.
Tensile Strength	Direct measurement of the device. Device placed between two grips and the separation force required to reach device failure was measured.	Test was completed and met specification. Like predicate device is suitable for intended use.
Cytotoxicity	The device was evaluated for potential cytotoxic effects using a mammalian cell line following ISO 10993-5 guidelines.	The test article extract showed no cytotoxic potential.
Sensitization	The device was evaluated for the potential to cause delayed dermal contact sensitization in guinea pigs based on ISO 10993-10.	Extracts of the test article showed no evidence of inducing delayed contact sensitization in the guinea pig.
Acute intracutaneous reactivity (Irritation)	The device was evaluated for the potential to cause irritation following intracutaneous injection in rabbits based on ISO 10993-10.	Extracts of the test article show no evidence of irritation.
Acute systemic toxicity	The device was evaluated for acute systemic toxicity in mice based on ISO 10993-11.	No mortality or evidence of systemic toxicity from both extracts, injected into mice.
Pyrogenicity	The device was evaluated for the potential to induce a pyrogenic response following intravenous injection in rabbits. Study conducted according to the United States Pharmacopeia (USP 41 - NF36, General Chapter <151>).	The test article met the requirements and is judged non-pyrogenic.
Hemolysis	The device was evaluated for hemolytic potential when in contact with blood based on ASTM F756 and requirements of ISO 10993-4.	The direct contact of the test article was slightly hemolytic. The extracts at 25, 12.5 and 6.25% were non-hemolytic. Device is suitable for intended indication.
Genotoxicity (AMES)	The device was evaluated for the potential to induce reverse mutations in *Salmonella typhimurium* and	Extracts of the device were considered to be non-mutagenic to tester strains.

Test	Test Method Summary	Results
	Escherichia coli tester strains per ISO 10993-3.	
Genotoxicity (mouse lymphoma assay)	The device was evaluated to determine its mutagenic potential using the mouse lymphoma forward gene mutation assay per ISO 10993-3.	Test article considered non-mutagenic.
Endotoxin	Bacterial endotoxin testing is conducted per USP 85 and European Pharmacopoeia 2.6.14	Device is produced and released with endotoxin level <2.15EU/device.
Subacute Systemic Toxicity & Local effects of Implantation	The device was surgically implanted in the subcutaneous tissue of rats for 4 weeks to evaluate its potential systemic toxicity and local tissue response.	The device showed no evidence of systemic toxicity. Device appeared as a well-integrated scaffold with remodelling responses. Microscopically the test article demonstrated minimal reaction to the tissue.
Sub-chronic Systemic Toxicity & Local effects of implantation	The device was surgically implanted in the subcutaneous tissue of rats for 8 and 13 weeks to evaluate potential systemic toxicity after 13 weeks and local tissue responses after 8 and 13 weeks.	On subcutaneous implantation the device showed no evidence of systemic toxicity after 13 weeks. Microscopically the test article demonstrated minimal tissue reaction compared to control. Device was bioresorbing at 13 weeks as expected.
6-Month Nerve Wrap Study in New-Zealand White Rabbits	The device was surgically implanted around the sciatic nerve of rabbits for 1, 2 & 6 months. The effects and compatibility of the wrapping material on the nerve and surrounding tissues were assessed.	The device was well tolerated with no device related clinical signs, changes in body weight, food consumption, neurological parameters, NCV, clinical pathology, or organ weights up to 6 months post-implantation. No adverse macroscopic or microscopic changes in the nerve and surrounding tissues were observed. No device related axonal degeneration was observed.
Rat transected sciatic nerve model	The device was surgically implanted around the transected sciatic nerve of the rat and compared to nerves wrapped with marketed predicate control material. Data were collected at 1, 4 and 13 weeks.	At all time points the changes observed in the nerve were similar between device and predicate control material and were typical of changes in a nerve after transection. At all time points the device was considered to elicit no or minimal reaction in comparison to the predicate control.

Test	Test Method Summary	Results
	Local tissue responses and device degradation were evaluated, and motor and sensory neurological assessments were conducted.	The reactivity scores for device and predicate control decreased at later time points indicating healing. The device was markedly or completely degraded at 13 weeks, compared with the control device which was not degraded. Neuromas were not observed in any animal.

Conclusions

The NervAlign® Nerve Cuff has the following similarities to the predicate device:

- Same intended use,
- Same basic design,
- Similar material,
- Similar safety and performance characteristics, and
- Same operating principles.

Based on the similarities of the intended use/indications for use, device design, principles of operation, technological characteristics and the results of the non-clinical performance testing, the subject device, NervAlign® Nerve Cuff, is substantially equivalent to the legally marketed predicate device.