July 15, 2022

BioCircuit Technologies, Inc.
℅ Jack Griffis
Scientific and Regulatory Advisor
1819 Peachtree Road NE, Suite 205
Atlanta, Georgia 30309

Re: K210665
Trade/Device Name: Nerve Tape
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: April 6, 2022
Received: April 7, 2022

Dear Jack Griffis:

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)*
K210665

Device Name
Nerve Tape

Indications for Use *(Describe)*
Nerve Tape is indicated for the repair of peripheral nerve discontinuities where gap closure can be 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Number: K210665

Date Submitted: July 15th, 2022

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:
BioCircuit Technologies, Inc.
1819 Peachtree Rd NE, Suite 205
Atlanta, Georgia 30309
470-698-2117

B. Company Contact:
Jack Griffis
Scientific Advisor
(404) 583-6889 (direct)
jackgriffisiii@gmail.com

C. Device Information:
Trade Name: Nerve Tape
Common Name: Nerve Cuff

D. Classification: Nerve Cuff
21 CFR §882.5275 (Product Code: JXI)
Class II

E. Primary Predicate Device:
Cook Biotech Inc. AxoGuard® Nerve Connector (K162741)

F. Additional Predicate Device:
Cook Biotech Inc. Nerve Cuff (Marketed as AxoGuard® Nerve Protector) (K132660)

G. Physical Description:
The Nerve Tape device is composed of a bioabsorbable, extracellular collagen matrix derived from small intestinal submucosa (SIS). Microhooks made of a nickel-titanium alloy (NiTiNOL) are integrated into the nerve contacting side of the SIS for mechanical fixation and apposition of nerve ends. The device is packaged in a dried state and supplied sterile, and is rehydrated prior to use.

H. Indications for Use: Nerve Tape™ is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

I. Comparison to Predicate Device:

The subject Nerve Tape device is substantially equivalent in intended use to the predicate Cook Biotech Inc. AxoGuard® Nerve Connector and Cook Biotech Inc. Nerve Cuff devices in surgical repair of peripheral nerves. The subject and predicate devices are surgically fabricated with similar or identical bioresorbable porcine SIS material (certified to ISO 22442) which serves as scaffold that protects protection and supports remodeling while the injured nerve heals. The Nerve Tape differs from the predicates in the method of nerve cuff fixation. The Nerve Tape contains embedded microhooks,

whereas the predicate devices require suturing to maintain coaptation strength. A comparison of subject and predicate devices is provided in **Table 1**.

Table 1. Table of Substantial Equivalence

Parameter	**Nerve Tape** ***(Proposed)***	**AxoGuard® Nerve Connector (Predicate, K162741)**	**Nerve Cuff (Predicate, K132660)**
Manufacturer	*BioCircuit Technologies, Inc.*	*Cook Biotech Inc.*	*Cook Biotech Inc.*
510(k) Number	*K210665*	*K162741*	*K132660*
Product Code	*JXI*	*JXI*	*JXI*
Classification Number	*21 CFR 882.5275*	*21 CFR 882.5275*	*21 CFR 882.5275*
Common name	*Cuff, Nerve*	*Cuff, Nerve*	*Cuff, Nerve*
Intended use	*Intended for peripheral nerve injuries where a gap closure is achieved by flexion of the extremity.*	*Intended for peripheral nerve injuries where a gap closure is achieved by flexion of the extremity.*	*Intended for peripheral nerve injuries where there is no gap or where a gap closure is achieved by flexion of the extremity.*
Materials of Fabrication	*Porcine small intestinal submucosa; primarily collagen types I, III, IV, & VI (manufactured by Cook Biotech Inc.), NiTiNOL*	*Porcine small intestinal submucosa; primarily collagen types I, III, IV, & VI (manufactured by Cook Biotech Inc.)*	*Porcine small intestinal submucosa; primarily collagen types I, III, IV, & VI (manufactured by Cook Biotech Inc.)*
Shape	*Rectangular wrap (rolls into a hollow tube)*	*Hollow tube*	*Hollow tube with a slit*
Supplied Sterile?	*Yes*	*Yes*	*Yes*
Sterilization method	*Ethylene Oxide (cycle by Cook Biotech Inc.)*	*Ethylene Oxide (cycle by Cook Biotech Inc.)*	*Ethylene Oxide (cycle by Cook Biotech Inc.)*
Intended for single use?	*Yes*	*Yes*	*Yes*
Packaging Configuration	*Clamshell tray in Tyvek-poly pouch with an outer box (packaged by Cook Biotech Inc.)*	*Clamshell tray in Tyvek pouch with an outer box (packaged by Cook Biotech Inc.)*	*Clamshell tray in Tyvek pouch with an outer box (packaged by Cook Biotech Inc.)*
Shelf Life	*18 months*	*18 months*	*18 months*
Intended use	*Intended for peripheral nerve injuries where a gap closure is achieved by flexion of the extremity.*	*Intended for peripheral nerve injuries where a gap closure is achieved by flexion of the extremity.*	*Intended for peripheral nerve injuries where there is no gap or where a gap closure is achieved by flexion of the extremity.*
Dimensions (Wrapped)	*2-7mm diameter x 1.4-2.2cm length*	*1.5-10mm diameter x 1-5 cm length*	*1.5-10mm diameter x 1-5 cm length*
Thickness (Wrapped)	*100-750 µm*	*100-1000 µm*	*100-1000 µm*
Method of fixation	*NiTiNOL microhooks*	*Suture*	*Suture*

The technological characteristics of the subject Nerve Tape device are substantially equivalent to the predicate devices as demonstrated through bench, biocompatibility and animal testing.

J. Summary of Non-Clinical Tests:

Product characterization using known standards and/or relevant acceptance criteria were performed on the Nerve Tape device. A summary of this testing is provided in **Table 2**.

Table 2. Non-Clinical Bench Testing Information

Test	***Test Method Summary***	***Results***
User handling validation/ Ease of Use	Surgeon performance and handling of Nerve Tape, nylon suture and AxoGuard® Nerve Connector were assessed for ease of use in application to the transected rabbit tibial nerves	The ease of use characteristics of the Nerve Tape device are substantially equivalent to the predicate device. All samples met acceptance criteria.
Monotonic tensile strength	*Repair strength as assessed via device retention strength on repaired cadaveric nerve in comparison to standard suture repair according to the literature*	The tensile strength of the Nerve Tape device is substantially equivalent to standard suture for nerve repair. All samples met acceptance criteria.
Dimension Compliance	*Compliance with dimensional criteria for all components and assemblies*	Pass
Corrosion Resistance (for NiTiNOL components)	*ASTM F2129: Cyclic potentiodynamic polarization measurements for corrosion susceptibility*	*Pass*
Transformation temperature (DSC, for NiTiNOL components)	*Per the US FDA Guidance Document, "Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol", and ASTM F2004, Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis*	*Pass*
Magnetic resonance imaging safety and compatibility	*Per the US FDA Guidance Document, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"*	*Pass*

K. Biocompatibility Testing:

Biocompatibility of the Nerve Tape device has been established in accordance with ISO 10993-1:2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process to demonstrate that the device is safe for permanent contact (>30 days) implantation. The biocompatibility endpoints that were assessed include cytotoxicity, sensitization, irritation, acute systemic toxicity, subchronic/chronic systemic toxicity, pyrogenicity, implantation and genotoxicity.

L. Sterilization:

Ethylene oxide sterilization validation and ethylene oxide residuals testing of the Nerve Tape device are provided in **Table 4**.

Table 4. Sterilization Information

Test	***Test Method Summary***	***Results***
Sterilization validation	*Validation method in conformance with ISO 11135:2014, Sterilization of healthcare products with ethylene oxide, and AAMI TIR28:2016, Product adoption and process equivalence for ethylene oxide sterilization.*	*Pass*
EO Residuals	*ISO 10993-7:2008, Ethylene oxide sterilization residuals*	*Pass*

M. Animal Studies:

Testing using a rabbit tibial nerve transection model were evaluated for usability and tissue responses were assessed following implantation and treatment with either the Nerve Tape device, the AxoGuard® Nerve Connector or nylon suture, and evaluated at the 4-week or 16-week evaluation time points. Outcome measures included macroscopic assessment of the nerve implant sites, muscle weight and girth, and histological assessment of the implant sites and surrounding tissues. The studies demonstrated that the Nerve Tape device is as safe and effective as the AxoGuard® Nerve Connector and nylon suture in repairing peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

N. Clinical Studies:

No human studies were necessary to prove the safety and efficacy of the device.

Conclusion:

The Nerve Tape device has the same intended use as the predicate devices. Nonclinical testing demonstrated that the Nerve Tape is substantially equivalent to the predicate device(s).