February 12, 2024

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

Re: K233533
Trade/Device Name: NerveTape
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: November 2, 2023
Received: November 2, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S
Digitally signed by Adam D. Pierce -S
Date: 2024.02.12 17:00:53 -05'00'

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)*
K233533

Device Name
NerveTape

Indications for Use *(Describe)*
NerveTape 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.

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510(k) Summary

510(k) Number: K233533

Date: February 12, 2024

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
(800) 905-2204

B. Company Contact:

Jack Griffis
Scientific Advisor
(404) 583-6889 (direct)
jgriffis@biocircuit.com

C. Device Information:

Trade Name: *NerveTape*
Common Name: Nerve Cuff

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

E. Predicate Device:

PRIMARY: BioCircuit Technologies, Inc. Nerve Tape™ (K210665)
REFERENCE: AxoGuard® Nerve Connector (K162741)

F. Physical Description:

The proposed BioCircuit Technologies, Inc. *NerveTape* device is composed of a bioabsorbable, extracellular collagen matrix (small intestinal submucosa, SIS) with integrated microhooks made of a nickel-titanium alloy, commonly referred to as NiTiNOL (identical to the predicate), for mechanical fixation and apposition of nerve ends. The *NerveTape* is implanted around an injured nerve to provide a scaffold which becomes infiltrated and remodeled by the patient's cells. The device protects the damaged or severed nerve while the nerve heals.

The device is packaged and supplied sterile in a clamshell container inside a sealed pouch. The device is identical to the predicate, except for the SIS substrate manufacturer and the addition of a smaller size. The dimensions of the finished device range from 11mm x 12mm to 45mm x 22mm. The device is intended for the repair of nerves of diameters ranging from 1.5mm to 7mm.

G. Indications for Use:

NerveTape is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Comparison to Predicate Device(s):

The BioCircuit Technologies *NerveTape* device is substantially equivalent with respect to intended use, structure, and technological characteristics to the BioCircuit Technologies device

cleared under K210665. The devices both have a porcine small intestinal submucosa (SIS) backing (certified to ISO 22442) and operate under the same principle of axonal growth support with an identical form factor (tubular wrap with embedded microhook columns).

The devices differ in the source of the SIS backing substrate and the addition of a smaller sized option (1.5mm nerve compatible), which is equivalent to the original predicate (K162741). The proposed *NerveTape* device is manufactured with SIS supplied by Smithfield Bioscience, Inc., while the predicate and reference devices are composed of SIS supplied by Cook Biotech, Inc. BioCircuit Technologies, Inc., asserts that any differences from the predicate device do not affect safety or efficacy.

Table 1. Table of Substantial Equivalence

Parameter	***NerveTape* (BioCircuit Proposed)**	***Predicate* (BioCircuit)**	***Reference Predicate* (AxoGuard® Nerve Connector)**
Manufacturer	*BioCircuit Technologies, Inc.*	*BioCircuit Technologies, Inc.*	*Cook Biotech Inc.*
510(k) Number	*K233533*	*K162741*	*K162741*
Product Code	*JXI*	*JXI*	*JXI*
Material (wrap)	*Porcine small intestinal submucosa: primarily collagen types I, III, IV, and VI (manufactured by Smithfield Bioscience)*	*Porcine small intestinal submucosa: primarily collagen types I, III, IV, and VI (manufactured by Cook Biotech)*	*Porcine small intestinal submucosa: primarily collagen types I, III, IV, and VI (manufactured by Cook Biotech)*
Material (hook)	*NiTiNOL **(NO CHANGE)***		*N/A – device is secured to nerves using non-resorbable nylon sutures*
Shape	*Rectangular wrap (rolls into a hollow tube) **(NO CHANGE)***		*Hollow tube with a slit*
Supplied Sterile?	*Yes **(NO CHANGE)***		*Yes*
Sterilization method	*Ethylene Oxide (cycle by Parter Sterilization Services via Bioseal Inc. validated cycle)*	*Ethylene Oxide (validated cycle by Cook Biotech Inc.)*	*Ethylene Oxide (validated cycle by Cook Biotech Inc.)*
Intended for single use?	*Yes **(NO CHANGE)***		*Yes*
Packaging Configuration	*Clamshell tray in Tyvek-poly pouch with an outer box (packaged by Bioseal Inc.)*	*Clamshell tray in Tyvek-poly pouch with an outer box (packaged by Cook Biotech)*	*Clamshell tray in Tyvek pouch with an outer box (packaged by Cook Biotech)*
Shelf Life	*18 months **(NO CHANGE)***		*18 months*
Intended use	*Intended for peripheral nerve injuries where a gap closure is achieved by flexion of the extremity **(NO CHANGE)***		*Intended for peripheral nerve injuries where there is no gap or where a gap closure is achieved by flexion of the extremity.*
Dimensions (Wrapped)	*1.5 – 7mm diameter nerve* *1.2 – 4.5cm width x 1.1 – 2.2cm length* ***(ADDITION OF SMALLER SIZE)***	*2 – 7mm diameter nerve* *1.4 x 4.5cm width x 1.4 – 2.2cm length*	*1.5 – 7mm diameter nerve* *1.5 – 7mm diameter tube x 1 – 1.5 cm length*
Thickness (Wrapped)	*100-650 µm*[1]	*100-750 µm*	*100-1000 µm*
Microhook Height	*360 – 550 µm* *(**ADDITION OF SMALLER SIZE USING SHORTER MICROHOOKS**)*	*400 – 550 µm*	*N/A – device is secured to nerves using non-resorbable nylon suture*
Microhook Column Qty	*3 – 8 Columns* ***(ADDITION OF SMALLER SIZE USING 3 COLUMNS)***	*4 – 8 Columns*	*N/A – device is secured to nerves using non-resorbable nylon suture*

[1] NOTE: change in thickness is due to the qualification of the L and L+ sizes of the proposed *NerveTape* device with only two (2) SIS layers (which is identical to all other sizes). The original (predicate) Nerve Tape device cleared under K210665 utilized three (3) SIS layers for the L and L+ sizes and only two (2) SIS layers for all other sizes.

Parameter	*NerveTape (BioCircuit Proposed)*	*Predicate (BioCircuit)*	*Reference Predicate (AxoGuard® Nerve Connector)*
Mechanism of Action	*Maintains coaptation via integrated microhooks within the SIS substrate layers, and wrapped around the target site of nerve repair to complete entubulation of the positioned, severed nerve stumps (**NO CHANGE**)*		*Maintains coaptation via non-resorbable nylon sutures used to reconnect the ends of the nerves while the SIS is positioned around the repair site to complete entubulation of the sutured nerve stumps.*

H. Summary of Non-Clinical Tests:

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

Table 2. Non-Clinical Testing Information

Test	*Test Method Summary*	*Results*
Performance Verification: Ease of Use (Simulated Use in Cadaver)	*Surgeon handling of representative final product; acceptance criteria: product possesses acceptable characteristics for handling, trimming and implantation*	The handling characteristics of the subject device are substantially equivalent or superior to the predicate device based on acceptability to the end user. All samples met acceptance criteria.
Performance Verification: 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 ultimate tensile strength of the proposed device nerve repairs is substantially equivalent or superior to the predicate device. All samples met acceptance criteria.
Specification Compliance	*Compliance with go/no-go dimensional and visual inspection criteria for all components and assemblies*	All samples met acceptance criteria.

I. Biocompatibility Testing:

Biocompatibility of the predicate 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 as detailed in **Table 3**.

Table 3a. Device Biocompatibility Information (*all testing performed on sterile product of largest size*)

Test	*Test Method Summary*
ANSI/AAMI/ISO 10993-5:2009/(R)2014 – Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity	The purpose of the in vitro study was to assess the cytotoxicity potential of extract from the proposed device using the Elution test and the mouse cell line L929. The cytotoxic potential of the test article extract was assessed by the change in morphology of the cell line, which was evaluated microscopically. Based on the criteria of the protocol, the proposed device met the requirements of the test.
ANSI/AAMI/ISO 10993-23:2021 – Biological evaluation of medical devices – Part 23: Tests for Irritation	Intracutaneous reactivity test was conducted with rabbits to determine the potential for the proposed device to produce irritation from intradermal injections. Under the conditions of this study, the proposed device met the requirements of the test. The positive response observed in the historical positive control validation study with Hexyl Cinnamic Aldehyde (HCA) validates the test system used in this study.
ANSI/AAMI/ISO 10993-10:2021 – Biological evaluation of medical devices – Part 10: Tests for Skin Sensitization	A guinea pig maximization sensitization test was conducted with guinea pigs to determine the potential for the proposed device to invoke a dermal skin sensitization reaction. The study was conducted using a two-stage induction phase and a challenge phase. An emulsion of 50% v/v Freund's Complete Adjuvant (FCA) in saline and sesame oil was used during the intradermal injection induction phase. Based on the results of this study, the proposed device met the requirements of the test.
ANSI/AAMI/ISO 10993-11:2017 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	An acute systemic toxicity test in mice was conducted to determine the potential for the proposed device to produce acute systemic toxicity from a single dose administered by intravenous (IV) and intraperitoneal (IP) injection. Under the conditions of this study, the proposed device met the requirements of the test.

Test	*Test Method Summary*
ANSI/AAMI/ISO 10993-7:2008(R)2012 – *Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*	Quantification of sterilant gas residue was performed for the proposed device having been exposed to 100% Ethylene oxide (EO). Samples received post sterilization underwent immersion and exhaustive extractions using purified water and evaluated using gas chromatography. Extractions taken every 24 hours post sterilization were pooled and reported for total mg EO and ECH (Ethylene chlorohydrin). Reported values were compared against the ISO standard for acceptable limits at or below the recommended average daily dose for residuals in permanent implants. Under the conditions of this study, the proposed device met the requirements of the test.
ANSI/AAMI ST72:2019, USP <161>, USP <85>, EP 2.6.14, and JP 4.01	A Bacterial Endotoxins Test (BET), or Limulus Amebocyte Lysate (LAL) test, was performed to detect and quantify bacterial endotoxin, a component of the cell wall of Gram-negative bacteria. Standard controls and a positive product control (PPC) demonstrate a compliant assay. Acceptable detected endotoxins must not exceed the maximum allowable limit for permanent implants as per the FDA Guidance Document Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile. Under the conditions of this study, the proposed device met the requirements of the test.

Table 3b. Decellularized Porcine Small Intestine Submucosa Biocompatibility Information (*all testing performed on non-sterile, decellularized porcine small intestine raw material - SIS*)

Test	*Test Method Summary*
ANSI/AAMI/ISO 10993-5:2009/(R)2014 – Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity	The purpose of the in vitro study was to assess the cytotoxicity potential of extract from the SIS material using the Elution test and the mouse cell line L929. The cytotoxic potential of the test article extract was assessed by the change in morphology of the cell line, which was evaluated microscopically. Based on the criteria of the protocol, the SIS material met the requirements of the test.
	The purpose of the in vitro study was to assess the cytotoxicity potential of extract from the SIS material using the XTT dye method and the mouse cell line L929. The cell viability and cytotoxic potential of the test article extracts were determined by quantification of a formazan dye formed in active mitochondria of living cells. Based on the criteria of the protocol, the SIS material met the requirements of the test.
ANSI/AAMI/ISO 10993-23:2021 - Biological evaluation of medical devices – Part 23: Tests for Irritation	Intracutaneous reactivity test was conducted with rabbits to determine the potential for the SIS material to produce irritation from intradermal injections. Under the conditions of this study, the SIS material met the requirements of the test and is a non-irritant for both polar and nonpolar extracts.
ANSI/AAMI/ISO 10993-10:2021 – Biological evaluation of medical devices – Part 10: Tests for Skin Sensitization	A guinea pig maximization sensitization test was conducted with guinea pigs to determine the potential for the SIS material to invoke a dermal skin sensitization reaction. Based on the results of this study, the SIS material met the requirements of the test and is not considered to be a contact skin sensitizer.
ANSI/AAMI/ISO 10993-11:2017 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	An acute systemic toxicity test in mice was conducted to determine the potential for the SIS material to produce acute systemic toxicity from a single dose administered by intravenous (IV) and intraperitoneal (IP) injection. Under the conditions of this study, the SIS material met the requirements of the test.
ANSI/AAMI/ISO 10993-11:2017 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	A subacute / subchronic toxicity test in mice was conducted to determine the potential for the SIS material to produce systemic toxicity in male and female rats that is likely to arise from repeated exposure via a dual route approach, intraperitoneal (IP) injection and intravenous (IV) administration, over a period of at least 14 days. Under the conditions of this study, and based on the toxicological endpoints evaluated, there is no potential toxicity of the SIS material from repeated exposure via 10 mL/kg/day via intravenously once per day or 5 mL/kg/day via intraperitoneally every three days for both male and female Sprague Dawley rats.
ANSI/AAMI/ISO 10993-11:2017 – Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	A material-mediated pyrogenic response test in rabbits was conducted to determine the potential for the SIS material to produce a pyrogenic response due to intravenous exposure. Under the conditions of this study, there were no signs of gross toxicity, adverse clinical effects, or abnormal behavior. None of the animals showed increases in temperature of 0.5°C or more than their respective control temperatures following administration of the SIS material extract. Therefore, and

Test	*Test Method Summary*
	based on interpretation of the raw data according to USP-NF<151>, the SIS material met the requirements of the test.
ANSI/AAMI/ISO 10993-3:2014 – Biological evaluation of medical devices – Part 3: Tests for Genotoxicity, Carcinogenicity, And Reproductive Toxicity	In Vitro micronucleus testing was conducted to evaluate the potential for extract of the SIS material to induce micronuclei (clastogenic response) or hypodiploidy (aneugenic response) in cultured Chinese Hamster Ovary (CHO) cells in the absence and presence of metabolic activation (S9). Under the conditions of this study, the SIS material extract did not induce micronuclei (via chromosome breaks and/or loss of whole chromosome(s)) or hypodiploidy (chromosome loss, sub-2n nuclei) in cultured CHO cells when tested up to the limit of cytotoxicity (4 hours in the presence of metabolic activation) and the maximum recommended extract concentration of 0.2 g/mL (4 and 23 hours in the absence of metabolic activation), and met the requirements of the test.
	Bacterial mutagenicity testing was conducted to evaluate the potential for extract of the SIS material to induce gene mutations in bacteria using the Ames assay. Point mutations which involve substitution, addition, or deletion of one or a few DNA base pairs are detected in amino acid-requiring strains of Salmonella typhimurium (S. typhimurium, ST) and Escherichia coli (E. coli, EC) by their ability to functionally reverse mutations. These reverse mutations result in revertant colonies of bacteria with restored capability to synthesize the essential amino acid. Under the conditions of this study, the SIS material extract did not elicit evidence of bacterial mutagenicity in the Ames assay and met the requirements of the test.
ANSI/AAMI/ISO 10993-6:2016 – Biological evaluation of medical devices – Part 6: Tests for Local Effects After Implantation	Acute intramuscular implantation (4 weeks) of the SIS material was conducted in rabbits and evaluated histologically. Under the conditions of this study, the SIS material was well tolerated in comparison to the control article and met the requirements of the test.
	Chronic intramuscular implantation (16 weeks) of the SIS material was conducted in rabbits and evaluated histologically. Under the conditions of this study, the SIS material was well tolerated in comparison to the control article and met the requirements of the test.
Histological Comparison between Native Intestinal Tissue to Decellularized Tissue	Histological evaluation was conducted for the proposed SIS material in comparison to native (non-decellularized) tissue via Hematoxylin & Eosin (H&E) to semi-quantitatively assess the absence of nuclei and cytoplasmic material in the sample, Masson's Trichrome to assess the integrity of the collagen network, and immunohistochemistry specific to galactose-α-1,3-galactose (α-gal IHC) to assess the level of the α-gal antigen present in the ECM. Under the conditions of the tests, the decellularization process of the SIS material was found to have removed any microscopic evidence of intact cells that could be detected by light microscopy and left no intact nuclei present in any decellularized section stained by H&E and Masson's Trichrome. In addition, decellularized SIS had significantly reduced positivity for galactose-α-1, 3-galactose (α-gal).

J. Sterilization:

The method employed to ensure sterility of the proposed device is provided in **Table 4**. The sterilization process is identical for the subject and predicate device.

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*

K. Animal Studies:

In the animal study conducted, a statistically valid number of rabbits underwent implantation of the proposed *NerveTape* device or the predicate device on an intact tibial nerve for 4 weeks and

12 weeks, respectively. The proposed device met all acceptance criteria and was substantially equivalent or superior to the predicate device.

L. Clinical Studies:
No human studies were necessary to prove the safety and efficacy of the device.

M. Conclusion:
No new questions of safety or effectiveness were identified during device testing; therefore, the Nerve Tape device is considered substantially equivalent to the predicate device in terms of safety and effectiveness.