April 2, 2025

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

Re: K242113
Trade/Device Name: Nerve Wrap (07-DW-001-TAB)
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: Class II
Product Code: JXI
Dated: July 19, 2024
Received: July 19, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.04.02 13:40:28 -04'00'

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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K242113 ? |

Please provide the device trade name(s). ?

Nerve Wrap (07-DW-001-TAB)

Please provide your Indications for Use below. ?

Nerve Wrap is indicated for the management of peripheral nerve injuries where there is no gap.

Please select the types of uses (select one or both, as applicable). ?

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

# 510(k) Summary

510(k) Number: K242113

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: *Nerve Wrap*
Common Name: Nerve Cuff

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

E. Predicate Device:
PRIMARY: AxoGuard® HA+ Nerve Protector (K223640)
REFERENCE: BioCircuit Technologies, Inc. Nerve Tape® (K233533)

F. Physical Description:
The proposed BioCircuit Technologies, Inc. *Nerve Wrap* device is composed of a bioabsorbable, layered extracellular collagen matrix (decellularized porcine small intestinal submucosa, SIS). The SIS material that comprises the *Nerve Wrap* is identical to the backing material of its reference predicate, Nerve Tape (K233533). The *Nerve Wrap* is implanted around a damaged peripheral nerve to provide a scaffold which becomes infiltrated and remodeled by the patient's cells. The device protects the nerve while the nerve heals and provides a non-constricting interface between the nerve and the surrounding tissue.

The device is packaged and supplied sterile in a clamshell container inside a sealed pouch. The dimensions of the finished device are 45mm x 22mm, with 2 - 3 layers of laminated SIS. The device is intended for implantation around nerves of diameters up to 7mm.

G. Indications for Use:
*Nerve Wrap* is indicated for the management of peripheral nerve injuries where there is no gap.

H. Comparison to Predicate Device(s):

The BioCircuit Technologies *Nerve Wrap* device is substantially equivalent, with respect to intended use and structure, to the Axogen, Inc. Axoguard HA+ Nerve Protector cleared under K223640. The devices are both composed of layered porcine small intestinal submucosa (SIS, certified to ISO 22442) and operate under the same principle of peripheral nerve injury management with an identical form factor (flat sheet). The proposed *Nerve Wrap* device is manufactured with decellularized porcine SIS which does not incorporate a coating. The

predicate device is composed of SIS that incorporates a coating composed of sodium hyaluronate and sodium alginate.

The BioCircuit Technologies *Nerve Wrap* device is substantially equivalent with respect to backing material characteristics and biocompatibility to the reference predicate BioCircuit Technologies Nerve Tape device cleared under K233533. The devices are composed of the same porcine small intestinal submucosa (decellularized porcine SIS, refer to MAF #3762) and operate under the same principle of peripheral nerve injury management with an identical form factor (tubular wrap) and size range. The devices differ in the presence of the NiTiNOL microhooks for nerve injury coaptation, which are present in the reference predicate NerveTape device, but not in the proposed *Nerve Wrap* device. In addition, the proposed *Nerve Wrap* is intended for use in peripheral nerve injuries where there is no gap and is only intended to serve as a non-constricting protection for non-transected peripheral nerve injuries. This is identical to the primary predicate, K223640 (refer to Axogen HA+ Nerve Protector Instructions for Use, LB-1082 REV01 in the attachments).

BioCircuit Technologies, Inc., asserts that any differences from the primary predicate and reference devices do not affect safety or efficacy.

**Table 1. Table of Substantial Equivalence**

| **Parameter** | ***Nerve Wrap (BioCircuit Proposed)*** | ***Predicate (AxoGuard® HA+ Nerve Protector)*** | ***Reference Predicate (Nerve Tape)*** |
|---|---|---|---|
| Manufacturer | *BioCircuit Technologies, Inc.* | *Cook Biotech Inc.* | *BioCircuit Technologies, Inc.* |
| 510(k) Number | *K242113* | *K223640* | *K233533* |
| Product Code | *JXI* | *JXI* | *JXI* |
| Material (wrap) | *Porcine small intestinal submucosa: primarily collagen types I, III, IV, and VI)* | *Porcine small intestinal submucosa: primarily collagen types I, III, IV, and VI) including a coating composed of sodium hyaluronate and sodium alginate* | *Porcine small intestinal submucosa: primarily collagen types I, III, IV, and VI)* |
| Shape | *Rectangular wrap (rolls into a hollow tube)* | *Rectangular wrap (rolls into a hollow tube)* | *Rectangular wrap (rolls into a hollow tube)* |
| Supplied Sterile? | *Yes* | *Yes* | *Yes* |
| Sterilization method | *Ethylene Oxide* | *Ethylene Oxide* | *Ethylene Oxide* |
| Intended for single use? | *Yes* | *Yes* | *Yes* |
| Packaging Configuration | *Clamshell tray in Tyvek-poly pouch with an outer box* | *Clamshell tray in Tyvek pouch with an outer box* | *Clamshell tray in Tyvek-poly pouch with an outer box* |
| Shelf Life | *18 months* | *18 months* | *18 months* |
| Intended use | *Intended for peripheral nerve injuries where there is no gap.* | *Intended for peripheral nerve injuries where there is no gap.* | *Intended for peripheral nerve injuries where a gap closure is achieved by flexion of the extremity.* |
| Dimensions | *22mm width x 4.5 cm length* | *10 – 40mm width x 2 – 8 cm length* | *11 – 22mm width x 1.2 – 4.5 cm length* |
| Configuration | *Flat Sheet* | *Flat Sheet* | *Flat Sheet* |
| Thickness (Wrapped) | *100-1000 µm* | *100-1000 µm* | *100-650 µm* |

| Parameter | *Nerve Wrap (BioCircuit Proposed)* | *Predicate (AxoGuard® HA+ Nerve Protector)* | *Reference Predicate (Nerve Tape)* |
|---|---|---|---|
| Mechanism of Action | *Maintains contact with nerve via cohesion of the SIS to itself, holding the wrap closed around the nerve, with optional non-resorbable nylon stay sutures if desired.* | *Maintains contact with nerve via non-resorbable nylon stay sutures used to hold the SIS closed around the nerve to complete entubulation.* | *Maintains coaptation via integrated microhooks within the SIS substrate layers; wrapped around the target site of nerve repair to complete entubulation of the positioned, severed nerve stumps.* |

I. Summary of Non-Clinical Tests:

Product characterization using known standards and / or clinically relevant acceptance criteria (suture retention, bubble strength, seal strength, endotoxin, and end user validation) was performed on the device. Coefficients of friction testing were not performed due to *Nerve Wrap*'s lack of sodium hyaluronate / sodium alginate coating. All samples met their acceptance criteria.

J. Biocompatibility Testing:

Biocompatibility of the SIS backing material 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 2a and 2b** (ref. K233533 and MAF #3762).

**Table 2a. Biocompatibility Information (*all testing performed on sterile Nerve Tape of largest size*)**

| *Test* | *Test Method Summary* | *Results* |
|---|---|---|
| *In Vitro* Cytotoxicity | *The cytotoxic potential of the test article extract was assessed by the change in morphology of the cell line, which was evaluated microscopically per MEM Elution and XTT Dye Method - ANSI/AAMI/ISO 10993-5:2009/(R)2014 - Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity.* | *Based on the criteria of the protocol, the proposed device met the requirements of the test.* |
| 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 per ANSI/AAMI/ISO 10993-10:2021(£)- Biological evaluation of medical devices – Part 10: Tests for Skin Sensitization.*<br>*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.* |
| Intracutaneous Irritation / Reactivity | *Intracutaneous reactivity test was conducted with rabbits to determine the potential for the proposed device to produce irritation from intradermal injections per ANSI/AAMI/ISO 10993-23:2021 (E) - Biological evaluation of medical devices – Part 23: Tests for Irritation (normal saline and sesame oil extraction vehicles).* | *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.* |
| Acute 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 per ANSI/AAMI/ISO 10993-11:2017(E) - Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (normal saline and sesame oil extraction vehicles).* | *Under the conditions of this study, the proposed device met the requirements of the test.* |
| EO Residuals | *Per ISO 10993-7:2008, 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.* |

| *Test* | *Test Method Summary* | *Results* |
|---|---|---|
| Endotoxin | *Per USP <161>:2020, Medical Devices-Bacterial Endotoxin and Pyrogen Tests, 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 2b. Decellularized Porcine SIS Biocompatibility Information (*all testing performed on non-sterile, decellularized porcine small intestine submucosa raw material - SIS*)

| *Test* | *Test Method Summary* | *Results* |
|---|---|---|
| *In Vitro* Cytotoxicity | *The cytotoxic potential of the test article extract was assessed by the change in morphology of the mouse cell line L929, which was evaluated microscopically per MEM Elution and XTT Dye Method - ANSI/AAMI/ISO 10993-5:2009/(R)2014 - Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity.* | *Based on the criteria of the protocol, the proposed device met the requirements of the test.* |
| 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 per ANSI/AAMI/ISO 10993-10:2021(£)- Biological evaluation of medical devices – Part 10: Tests for Skin Sensitization.* | *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.* |
| Intracutaneous Irritation / Reactivity | *Intracutaneous reactivity test was conducted with rabbits to determine the potential for the proposed device to produce irritation from intradermal injections per ANSI/AAMI/ISO 10993-23:2021 (E) - Biological evaluation of medical devices – Part 23: Tests for Irritation (normal saline and sesame oil extraction vehicles).* | *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.* |
| Acute 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 per ANSI/AAMI/ISO 10993-11:2017(E) - Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (normal saline and sesame oil extraction vehicles).* | *Under the conditions of this study, the SIS material met the requirements of the test.* |
| Subacute/ Subchronic Toxicity | *A subacute/subchronic toxicity test in rats 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, per ANSI/AAMI/ISO 10993-11:2017(E) - Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.* | *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.* |
| Genotoxicity | *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) per ANSI/AAMI/ISO 10993-3:2014 - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.* | *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 per ANSI/AAMI/ISO 10993-3:2014 - Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity. 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.* |

| *Test* | *Test Method Summary* | *Results* |
|---|---|---|
| Intramuscular Implantation | *Test material implanted intramuscularly and explanted at 4 (acute) and 16 (chronic) weeks. Implantation site evaluated for histopathological irritation/reaction compared to control article per ISO 10993-6:2016 - Biological evaluation of medical devices - Part 6: Tests for local effects after implantation* | *Under the conditions of this study, the SIS material was well tolerated in comparison to the control article at both timepoints 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).* |
| Material Mediated Pyrogenicity | *Per 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 based on interpretation of the raw data according to USP- NF<151>, the SIS material met the requirements of the test.* |

K. Sterilization:

The method employed to ensure sterility of the proposed device is provided in **Table 3**. The sterilization process is identical for the subject and reference predicate device.

**Table 3. 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* |

L. Animal Studies:

In the animal study conducted, a statistically valid number of rabbits underwent implantation on an intact tibial nerve for 4 weeks and 12 weeks, respectively. The device met all acceptance criteria and was substantially equivalent or superior to the control device.

M. Clinical Studies:

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

N. Conclusion:

No new questions of safety or effectiveness were identified during device testing; therefore, the *Nerve Wrap* device is considered substantially equivalent to the predicate device(s) in terms of safety and effectiveness.