January 17, 2026

Auxilium Biotechnologies, Inc.
Jacob Koffler
CEO
333 Jackson Plaza
Ann Arbor, Michigan 48103

Re: K253363
Trade/Device Name: NeuroSpan Bridge
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve Cuff
Regulatory Class: Class II
Product Code: JXI
Dated: September 30, 2025
Received: December 19, 2025

Dear Jacob Koffler:

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,

Yen-chih Lin -S

Digitally signed by Yen-chih Lin -S
Date: 2026.01.17 14:20:50 -05'00'

for Jaime Raben, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K253363

Device Name

NeuroSpan Bridge 3 x 30 (PRT001-3030);
NeuroSpan Bridge 3 x 25 (PRT001-3025);
NeuroSpan Bridge 3 x 20 (PRT001-3020);
NeuroSpan Bridge 3 x 15 (PRT001-3015);
NeuroSpan Bridge 3 x 10 (PRT001-3010);
NeuroSpan Bridge 2.5 x 30 (PRT001-2530);
NeuroSpan Bridge 2.5 x 25 (PRT001-2525);
NeuroSpan Bridge 2.5 x 20 (PRT001-2520);
NeuroSpan Bridge 2.5 x 15 (PRT001-2515);
NeuroSpan Bridge 2.5 x 10 (PRT001-2510);
NeuroSpan Bridge 2 x 30 (PRT001-2030);
NeuroSpan Bridge 2 x 25 (PRT001-2025);
NeuroSpan Bridge 2 x 20 (PRT001-2020);
NeuroSpan Bridge 2 x 15 (PRT001-2015);
NeuroSpan Bridge 2 x 10 (PRT001-2010);
NeuroSpan Bridge 1.5 x 30 (PRT001-1530);
NeuroSpan Bridge 1.5 x 25 (PRT001-1525);
NeuroSpan Bridge 1.5 x 20 (PRT001-1520);
NeuroSpan Bridge 1.5 x 15 (PRT001-1515);
NeuroSpan Bridge 1.5 x 10 (PRT001-1510)

Indications for Use *(Describe)*

The NeuroSpan Bridge is indicated for the repair of peripheral nerve discontinuities where a tensionless repair can be made (i.e., 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.

510(k) SUMMARY
NeuroSpan Bridge

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Auxilium Biotechnologies, Inc.
333 Jackson Plaza
Ann Arbor, MI 48103
Phone: (858) 699-9443
Email: j.koffler@auxiliumbio.com

Contact: Dr. Jacob Koffler, CEO
Tel: Phone: (858) 699-9443
Email: j.koffler@auxiliumbio.com

Date Prepared: January 16, 2026

Name of Device

Trade name: NeuroSpan Bridge
Common name: Cuff, Nerve
Classification name: Nerve cuff (21 CFR 882.5275)
Regulatory class: II
Product code: JXI

Predicate Device

Trade name: NeuraGen Nerve Guide (K011168)
Regulation: 882.5275 - Nerve cuff
Regulatory class: II
Product code: JXI

Device Description

The NeuroSpan Bridge is a biodegradable micro-channeled implant for the repair of peripheral nerve discontinuities. The NeuroSpan Bridge provides a protective environment for peripheral nerve repair after injury, and is designed to be an interface between the two transected nerve stumps in order to provide a bridge for axonal growth across the nerve gap.

The NeuroSpan Bridge is flexible while being strong enough to hold sutures. The NeuroSpan Bridge is made from polycaprolactone (PCL) and features overhangs on

both ends for suturing, with marks showing the overhang depth. The overhang allows the surgeon to place the nerve stump with apposition to the internal microchannel structure and suture without damaging it. The NeuroSpan Bridge has multiple channels throughout the device for axon growth. The NeuroSpan Bridge is provided sterile, for single use, and in multiple diameter and length variations.

Indications for Use

The NeuroSpan Bridge is indicated for the repair of peripheral nerve discontinuities where a tensionless repair can be made (i.e., by flexion of the extremity).

Comparison of Technological Characteristics with the Predicate Device

The subject NeuroSpan Bridge device has similar technological characteristics to the predicate device. Both are flexible tubular implants made from biodegradable materials and are supplied sterile for single use in a range of sizes. Both devices are designed to support nerve regeneration after injury. Both subject and predicate devices are absorbed by the body over time. Both the subject and predicate devices come in a range of lengths and diameters. Both devices are implanted using the same techniques.

The subject device includes a microtubular structure in its interior lumen. The predicate device has an open lumen. The subject device is made from polycaprolactone. The predicate is made from collagen.

	NeuroSpan Bridge (Subject device)	**Neurogen Nerve Guide (K011168) (Predicate device)**	**Comparison**
Regulation	21 CFR 882.5275	21 CFR 882.5275	Same
Product Code	JXI	JXI	Same
Resorbable	Yes	Yes	Same
Suturable	Yes	Yes	Same
Material	Poly-Ɛ-caprolactone	Collagen	Equivalent function

Indications For Use	The NeuroSpan Bridge is indicated for the repair of peripheral nerve discontinuities where a tensionless repair can be made (i.e., by flexion of the extremity).	NeuroGen™ Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.	Same
Physical structure	Tubular structure with microchannels	Hollow tubular structure	Internal structure of the devices is different.
Mode of Action	Create microenvironment for neuron regeneration	Create microenvironment for neuron regeneration	Same
Size	1.5 – 3.0 mm ID 1-3 cm length Micro-channels: 200-300 μm ID	1.5 mm - 7mm ID 2-3 cm length	Equivalent function
Biocompatibility	Yes	Yes	Same
Preparation for use	Rehydration	Rehydration	Same
Reusable	No	No	Same
Sterilization Method	Ethylene oxide	Ethylene oxide	Same
Packaging	Thermoformed tray with Tyvek lining	Double blister packaging	Equivalent function
Shelf life	2 years	Unknown	Equivalent function

Performance Data

The technical characteristics of the subject and predicate devices have been tested using comparative bench tests, which showed very similar results. In addition,

performance testing, including biocompatibility testing and animal testing, demonstrates similar safety and performance of the subject device and its predicate. The following performance testing has been conducted:

Stability testing of the product and packaging

Stability of the NeuroSpan Bridge was demonstrated by the real-time and accelerated aging methodologies for the product and the packaging materials.

Transportation testing

The transportation testing was conducted to demonstrate the ability of the NeuroSpan Bridge and its packaging to withstand the distribution environment. The testing was conducted according to ASTM D4169-22.

Pyrogenicity testing

NeuroSpan Bridge is labeled as non-pyrogenic. Endotoxin testing was conducted to demonstrate that the product is non-pyrogenic.

Biocompatibility testing

Biocompatibility testing was conducted according to FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.""

Test	Test Summary	Conclusions
Cytotoxicity	The device was evaluated for potential cytotoxic effects following ISO 10993-5 guidelines.	The cytotoxicity test results do not raise any safety concerns.
Sensitization	The device was evaluated for the potential to cause sensitization in guinea pigs based on ISO 10993-10. The test animals showed no evidence of inducting sensitization.	Non-sensitizing
Irritation	The device was evaluated for the potential to cause irritation following intracutaneous injection in rabbits based on ISO 10993-23. The extracts of the test article show no evidence of irritation.	Non-irritant

Test	Test Summary	Conclusions
Pyrogenicity	The device was evaluated for the potential to induce a pyrogenic response following intravenous injection in rabbits based on ISO 10993-11. The total rise of temperature was within acceptable range.	Non-pyrogenic
Genotoxicity - Bacterial Reverse Mutation	The device was evaluated for the potential to induce reverse mutations in *bacteria* per ISO 10993-3. The result indicated that the extracts of the device were not genotoxic.	Non-genotoxic
Genotoxicity - Chromosomal Abnormality	The device was evaluated for the potential of clastogenicity per ISO 10993-3. It showed that this device is clastogenicity negative in cultured mammalian cells.	Non-genotoxic
Implantation Effects	The device was evaluated in a series of animal studies.	No adverse tissue responses
Acute systemic toxicity	The device was evaluated for acute systemic toxicity in mice based on ISO 10993-11. No change was observed in general conditions or in necropsy.	No acute systemic toxicity
Subacute/ Subchronic and Chronic toxicity	The device was evaluated for systemic effects following implant. No abnormality occurred in general conditions or surgical sites after implantation. Manufacturing residual testing was conducted	No systemic toxicity No added risk for manufacturing residuals

Test	Test Summary	Conclusions
Hemocompatibility - Hemolysis testing	The device was evaluated for hemolytic potential when in contact with blood based on ISO 10993-4 and ASTM F756 standard. The test article extracts demonstrated that the test article was non-hemolytic.	The test article is non-hemolytic
Carcinogenicity	Endpoint was addressed with a toxicological risk assessment approach.	Justified by risk assessment.
Neurotoxicity	Neurotoxicity was evaluated in a series of animal studies.	No neurotoxic effects

Sterility Testing

Sterilization of the NeuroSpan Bridge is based on ISO 11135:2014 Annex E Single Batch Release Process.

For each sterilization batch, the testing conducted will include product sterility, method suitability (bacteriostasis and fungistasis), and ethylene oxide residuals. For final product release all sterility tests (comparative resistance, product sterility, bacteriostasis and fungi, and ethylene oxide residuals) will need to pass their respective assessment criteria.

A batch sterilization has been performed. This report is in Steris Batch Sterilization Validation Report and Appendices. There were no deviations reported in this testing.

Sterility validation testing included assessments of EO residuals and bacterial

endotoxins.

Bench Testing

Bench testing was conducted to assess the mechanical resilience of the NeuroSpan Bridge device in tension and compression, as well as its ability to retain sutures under load and the rate of biodegradation. Results were compared against the performance of the predicate device, NeuroGen, under the same conditions.

Test	Test Method Summary	Results
Tensile strength	The device is cut into a piece, and then pull both ends of the test piece and measure the strength when it breaks.	Pass

Suture retention strength	After passing a suture with a needle though the wetted specimen, the device is sutured to blocks. The specimen is pulled, and the strength at which the device breaks is measured.	Pass
Compression strength	A device is placed on a load cell and subjected to transverse compression cycles up to 50%. Devices were considered passing if channels remained open following compression.	Pass
Degradation	Devices chronically implanted in rat and rabbit animal models were assessed for material degradation after explantation.	Degradation profile characterized.

Animal Testing

Two GLP animal studies evaluated the effect of NeuroSpan Bridge on nerve regeneration. Study 1 was a comparison of the NeuroSpan Bridge, Neuragen Nerve Guide and an injury-only cohort using the Sprague Dawley rat sciatic nerve transection (10 mm defect) model at 3- and 6-month endpoints. A total of 72 animals were used across the two timepoints and three cohorts. Study endpoints included neurobehavioral assessments, functional assessments (e.g., cranial nerves, motor, sensory and coordination), retrograde nerve tracing, clinical pathology, gross pathology and histopathology for the assessment of safety, functional performance, nerve regeneration, inflammatory responses, and biodegradation. The results of functional testing were similar between the test (NeuroSpan Bridge) and control group (Neuragen Nerve Guide) at both timepoints, with some improvement in scores but there was no consistent trend noted for improvement in test (NeuroSpan Bridge) or control (Neuragen Nerve Guide) groups over the injury only group.

The gross and histological responses at the implantation sites were highly similar among all animals in both the test and control animals at the 3-month and 6-month time points. Histological observations of the test article demonstrated inflammation consistent with normal, expected bioresorption and healing from the surgical procedures with mean inflammation scores decreasing from 3 to 6 months.

Study 2 compared the subject device and predicate in a New Zealand white rabbit sciatic nerve transection (30 mm gap) model. A total of 39 rabbits were evenly distributed across three cohorts (test, control and injury-only) at a 5-month timepoint. Study endpoints included neurobehavioral assessments, functions assessments (e.g., posture, gait, toe spread, circumference of the limb under the knee), retrograde nerve tracing, clinical pathology, gross pathology, histopathology and bio-resorption for the assessment of safety and functional performance. The response to implant and functional outcomes were similar between the test and control groups. The gross and histological response at the test article implantation sites were highly similar among all animals and were similar between the test and control animals. Both test and control articles presented minimal to mild, common, and expected changes at the device/tissue interface related to

encapsulation of the test and control articles and healing from the surgical procedures. A similar level of nerve regeneration as assessed by muscle weight and histological evidence was observed in test (NeuroSpan Bridge) and control (Neuragen Nerve Guide) groups.

Conclusions

Performance testing demonstrated that the subject device performs similarly as the predicate device. Thus, the NeuroSpan Bridge is substantially equivalent to the predicate device.