April 9, 2026

KLISBio S.r.l.
% Scott Bruder
Founder and CEO
Bruder Consulting and Venture Group
38 True Harbour Way
West Islip, New York 11795

Re: K260245
Trade/Device Name: SILKBridge
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: Class II
Product Code: JXI
Dated: January 22, 2026
Received: January 27, 2026

Dear Scott Bruder:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.04.09 16:54:58 -04'00'

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.

510(k) Number *(if known)*
K260245

Device Name
SILKBridge

Indications for Use *(Describe)*
SILKBridge is indicated for the surgical repair of peripheral nerve discontinuities of up to 10 mm.

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.

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SILKBridge® 510(k) Summary

1. CONTACT DETAILS

1.1. APPLICANT

Name: KLISBio Srl
Address: Via Ludovico Ariosto 21, Bresso 20091, Milan, Italy
Contact person: Gabriele Grecchi
Contact telephone: 0039 392 1751186
Contact email: g.grecchi@klis.bio
Date summary preparation: January 22, 2026

1.2. CORRESPONDENT

Name: Bruder Consulting and Venture Group
Address: 38 True Harbour Way, West Islip, NY 11795 United States
Contact person: Scott Bruder
Contact telephone: 201-874-9701
Contact email: scott@bruderconsulting.com

2. DEVICE

Device trade name: SILKBridge®
Common name: Nerve Cuff
Classification name: Cuff, Nerve
Regulation number: 882.5275
Product code: JXI
Regulatory class: II

3. PREDICATE DEVICE

Predicate 510(k) number: K112267
Predicate trade name: NEUROLAC® TW NERVE GUIDE
Product code: JXI

4. DEVICE DESCRIPTION SUMMARY

SILKBridge® Biointegrative Nerve Guide (SILKBridge®) is a bioabsorbable implant for the surgical repair of peripheral nerve discontinuities.

SILKBridge is a semi-permeable non-constrictive implant, designed to guide and structurally support axonal growth across a nerve gap, isolating and protecting the injured nerve while ensuring nutrients influx. As a conduit, SILKBridge® has a hollow tubular shape with open ends for placement of severed nerve extremities.

SILKBridge is derived from silkworm fibroin (*Bombyx mori*) and is designed for enzymatic bioabsorption aligning with neovascularization and native tissue ingrowth, eventually replacing the implant.

SILKBridge contains up to 24 mg of silk fibroin bioengineered in two tailored formats: native fibers textile structure in the intermediate layer, and regenerated electrospun fibers in the inner and outer layers, forming a biomimetic matrix with a macro- and micro-porous wall design.

SILKBridge is supplied sterile for single use only in a variety of lengths designed to match the size of the nerve injury.

The product is not made with natural rubber latex.

SILKBridge is supplied sterile for single use only.

SILKBridge® 510(k) Summary

5. INDICATIONS FOR USE

SILKBridge® is indicated for the surgical repair of peripheral nerve discontinuities of up to 10 mm.

6. TECHNOLOGICAL COMPARISON

A comparison of the subject device and the predicate device demonstrated equivalent technological characteristics. The subject and predicate devices have the same intended use, indications for use, operating principle, fundamental scientific technology, and performance. Minor technological characteristic differences do not raise new questions of safety and effectiveness. Minor differences include 1) the wall design, with the subject device being comprised of three layers of materials, whereas the predicate device is comprised of one homogenous layer, and 2) materials of construction, with the subject device being made from Silk Fibroin, whereas the predicate is made from Poly (DL-lactide-co-ε-caprolactone).

7. NON-CLINICAL TEST SUMMARY & CONCLUSIONS

The non-clinical performance testing, relied on in this 510(k) for a determination of substantial equivalence between the SILKBridge® and its predicate device, consisted of the following analyses and evaluations:

Biocompatibility:
Biocompatibility testing was conducted on the final finished SILKBridge® in accordance with ISO 10993-1. The device was evaluated for:

- Cytotoxicity per ISO 10993-5
- Intracutaneous reactivity per ISO 10993-23
- Sensitization per ISO 10993-10
- Acute Systemic Toxicity per ISO 10993-11
- Material-Mediated Pyrogenicity per ISO 10993-11 and USP <151>
- Hemolysis per ISO 10993-4, ASTM F619, and ASTM F756
- Implantation per ISO 10993-6
- Chemical characterization and Toxicological Risk Assessment per ISO 10993-18 and ISO 10993-17.

Performance Testing – Bench:
Characterization of mechanical properties was performed on both the subject and predicate devices and included the following:

- Wall Thickness
- Compression resistance
- Suture retention strength
- Tensile properties
- Kink resistance

Performance Testing – Animal:
In vivo animal testing, consisting of a 12-month study on a sciatic nerve injury model in rats, with endpoints related to animal health, histopathology and immunohistochemistry of tissue response, and functional recovery by sensorimotor assessment was performed on both proposed and predicate devices.

The non-clinical performance testing supported the following conclusions:

- Biocompatibility testing: the biological risk assessment concludes that the SILKBridge® meets the biological safety requirements as per ISO 10993-1 and the FDA guidance “Use of International Standard ISO 10993-1”;
- Bench testing: SILKBridge® and Neurolac® TW Nerve Guide possess comparable physical and mechanical properties;
- Animal testing: SILKBridge® is as safe and as effective as Neurolac® TW Nerve Guide in terms of animal health, tissue response and functional recovery.

SILKBridge® 510(k) Summary

The information collected supports the substantial equivalence between the SILKBridge® and its predicate device, Neurolac® TW Nerve Guide, justifies that the different technological characteristics (wall design and constituent material) of the subject device do not raise new questions of safety and effectiveness, and that SILKBridge® is as safe as effective as the legally marketed predicate device.

In conclusion, based on the SILKBridge® information, and the results of non-clinical testing including biocompatibility testing, performance bench testing, and animal testing, it can be concluded that the SILKBridge® is substantially equivalent to Neurolac® TW Nerve Guide.