August 12, 2026

Boston Scientific
Cary Percy
Regulatory Associate Director
4100 Hamline Ave. N.
Saint Paul, Minnesota 55112

Re: K262406
Trade/Device Name: EluPro Antibiotic-Eluting BioEnvelope
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, FTL, OXH, PIJ
Dated: July 14, 2026
Received: July 15, 2026

Dear Cary Percy:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

JESSICA L. BATISTA -S

Digitally signed by JESSICA L. BATISTA -S
Date: 2026.08.12 15:50:20 -04'00'

Jessica Batista Bertolini
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
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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)*
K262406

Device Name
EluPro Antibiotic-Eluting BioEnvelope

Indications for Use *(Describe)*
The EluPro Antibiotic-Eluting BioEnvelope is intended to securely hold a cardiac implantable electronic device or an implantable neurostimulator to create a stable environment when implanted in the body. The cardiac implantable electronic devices that may be used with the EluPro Antibiotic-Eluting BioEnvelope include pacemaker pulse generators, defibrillators, and other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the EluPro Antibiotic-Eluting BioEnvelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators, sacral nerve stimulators, and other neurostimulator devices.

The EluPro Antibiotic-Eluting BioEnvelope contains the antibiotics rifampin and minocycline, which have been shown in preclinical testing to reduce bacterial colonization on the envelope. Overall clinical benefit has not yet been evaluated.

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.

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510(k) Summary

This 510(K) Summary is provided per the requirements of Section 807.92(c)

Company Information

Company Name:	Boston Scientific 1100 Old Ellis Road, Suite 1200, Roswell, GA 30076
Contact Name:	Cary Percy
Contact Email:	Cary.Percy@bsci.com
Contact Title:	Regulatory Associate Director
Phone:	612-619-0824

Date Prepared: July 08, 2026

Device Information

Trade Name:	EluPro Antibiotic-Eluting BioEnvelope
Common Name:	Surgical Mesh Envelope
Classification Name:	Surgical Mesh
Regulation Number:	21 CFR 878.3300
Product Code:	FTM, FTL, OXH, PIJ
Device Class:	Class II

Predicate Device

The EluPro Antibiotic-Eluting BioEnvelope is substantially equivalent to the following device:

- EluPro Antibiotic-Eluting BioEnvelope, K233991

Device Description

The EluPro Antibiotic-Eluting BioEnvelope consists of decellularized, non-crosslinked, lyophilized extracellular matrix (ECM) and resorbable ring-shaped poly(lactide-co-glycolide) (PLGA) discs containing the antibiotics rifampin and minocycline. The ECM material is derived from porcine small intestinal submucosa (SIS). The envelope is constructed with four multilaminate sheets, perforated to allow for exudate. The drug-eluting polymer discs are secured between the multilaminate sheets on each side of the envelope.

The EluPro Antibiotic-Eluting BioEnvelope is intended to securely hold an implantable electronic device (IED) to create a stable environment when implanted in the body, while reducing bacterial colonization with rifampin and minocycline eluted from resorbable polymer discs in the envelope. The EluPro Antibiotic-Eluting BioEnvelope is based on the existing EluPro Antibiotic-Eluting BioEnvelope (K233991), with a change to the in vitro elution specification for minocycline.

The EluPro Antibiotic-Eluting BioEnvelope is provided sterile in two sizes and is intended for single use in a single patient only.

EluPro Antibiotic-Eluting BioEnvelope	Envelope Size W x L	# of discs	Rifampin	Minocycline
Size 2 (Medium)	6.9 cm x 6.5 cm	2	10.5 mg	9.3 mg
Size 3 (Large)	6.9 cm x 8.0 cm	2	10.5 mg	9.3 mg

Indications for Use

The EluPro Antibiotic-Eluting BioEnvelope is intended to securely hold a cardiac implantable electronic device or an implantable neurostimulator to create a stable environment when implanted in the body. The cardiac implantable electronic devices that may be used with the EluPro Antibiotic-Eluting BioEnvelope include pacemaker pulse generators, defibrillators, and other cardiac implantable electronic devices. The implantable neurostimulator devices that may be used with the EluPro Antibiotic-Eluting BioEnvelope include vagus nerve stimulators, spinal cord neuromodulators, deep brain stimulators, sacral nerve stimulators, and other neurostimulator devices.

The EluPro Antibiotic-Eluting BioEnvelope contains the antibiotics rifampin and minocycline, which have been shown in preclinical testing to reduce bacterial colonization on the envelope. Overall clinical benefit has not yet been evaluated.

Summary of Technological Characteristics

The EluPro Antibiotic-Eluting BioEnvelope is designed to hold IEDs securely to create a stable environment when implanted in the body. The intended use of the EluPro Antibiotic-Eluting BioEnvelope is identical to the predicate device (K233991) and its technical characteristics are substantially equivalent.

The EluPro Antibiotic-Eluting BioEnvelope is based on the previously cleared EluPro Antibiotic-Eluting BioEnvelope (K233991), with a change to the in vitro elution specification for minocycline. The device is otherwise unchanged.

The device and the predicate are both terminally sterilized via e-beam irradiation.

The performance of EluPro and the predicate device all have been assessed through bench, *in vitro*, and *in vivo* testing. The results demonstrate that EluPro does not raise any new questions of safety and effectiveness.

Performance Data

The following performance data is provided in support of the substantial equivalence determination.

Performance Standards:

No performance standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act.

Device Modification and Rationale for Testing:

The subject device is identical in every respect to the predicate device (K233991) except for a revision to the in vitro elution (IVE) specification for minocycline. No changes were made to the device design, materials, manufacturing process, sterilization method, or labeling. Because the device itself is

unchanged, the biocompatibility, bench, and animal testing previously submitted and reviewed in support of the predicate device's clearance (K233991) remain applicable and are not repeated in this submission.

Basis for Revised Minocycline IVE Specification:

The minocycline IVE specification was revised based on a review of existing post market stability and manufacturing data. No new testing was performed, and no changes were made to the device itself. This update does not raise new questions of safety or effectiveness.

Conclusion

Performance data utilizing *in vitr*o and *in vivo* testing demonstrates substantial equivalence to the predicate device (K233991). The EluPro device is as safe and as effective, with equivalent performance, to the legally marketed predicate device.