May 29, 2025

Arthrex Inc.
Tiffany Mentzel
Principal Regulatory Affairs Specialist
1370 Creekside Blvd.
Naples, Florida 34108

Re: K243480
Trade/Device Name: SuturePatch Tissue Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWX, FTL
Dated: May 1, 2025
Received: May 1, 2025

Dear Tiffany Mentzel:

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,

Thomas Mcnamara -S

For: Christopher Ferriera, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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)*

K243480

Device Name

SuturePatch Tissue Reinforcement Device

Indications for Use *(Describe)*

The SuturePatch Tissue Reinforcement is intended for the management and protection of soft tissue injuries. The SuturePatch Tissue Reinforcement is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of the rotator cuff, patellar, achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and sutures, or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. The SuturePatch Tissue Reinforcement device reinforces and protects healing soft tissues.

The SuturePatch Tissue Reinforcement device is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, achilles, biceps, quadriceps, or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to bone, provide mechanical strength for the repair.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared	May 28, 2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Tiffany Mentzel Title: Principal Regulatory Affairs Specialist Phone: 239-566-5833 Email: tiffany.mentzel@arthrex.com
Trade Name	SuturePatch Tissue Reinforcement Device
Common Name	Surgical Mesh
Product Code	OWX, FTL
Classification Name	21 CFR 878.3300 Surgical Mesh
Regulatory Class	II
Primary Predicate Device	K070961 Biomerix Surgical Mesh
Additional Predicate Devices	K122374 Arthrex Suture K190707 Arthrex SoftStitch
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex SuturePatch Tissue Reinforcement device.
Device Description	The Arthrex SuturePatch Tissue Reinforcement device is a non-absorbable, permanent, implantable orthopedic surgical mesh intended for the reinforcement of soft tissue/tendon repair. It is manufactured from embroidered polyester yarns with integral reinforcements across its width and around its perimeter to provide improved stability and high suture retention strength. The SuturePatch is available in rectangular and trapezoidal patterns and configurable sizes. Sutures passed through soft tissue can also be passed throughout the SuturePatch with needles or suture passer.
Indications for Use	The SuturePatch Tissue Reinforcement is intended for the management and protection of soft tissue injuries. The SuturePatch Tissue Reinforcement is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of the rotator cuff, patellar, achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and sutures, or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. The SuturePatch Tissue Reinforcement device reinforces and protects healing soft tissues.

	The SuturePatch Tissue Reinforcement device is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, achilles, biceps, quadriceps, or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to bone, provide mechanical strength for the repair.
Performance Data	To demonstrate adequate product performance, Arthrex has conducted benchtop performance testing for suture unraveling, suture retention, tensile strength and stiffness, mesh thickness, and density. Animal testing demonstrates the ability of the mesh to support tissue ingrowth and mechanically reinforce the repair as compared to surgical controls, without any adverse clinical effects. Biocompatibility testing was conducted in accordance with ISO 10993-1:2018.
Technological Comparison	The proposed Arthrex SuturePatch and predicate devices have the same basic design, similar materials, performance and intended use. Any differences in the above characteristics have been adequately tested to support substantial equivalence.
Conclusion	Based on the intended use, fundamental scientific technology, and the data provided in this Traditional 510(k), Arthrex has determined that SuturePatch is substantially equivalent to the predicate device, Biomerix Surgical Mesh (K070961). Any differences between the proposed and predicate devices are considered minor and do not raise different questions concerning safety and effectiveness.