September 30, 2025

Arthrex Inc.
Emmarie Halteman
Senior Regulatory Affairs Specialist
1370 Creekside Boulevard
Naples, Florida 34108

Re: K251690
Trade/Device Name: Arthrex SpeedFLEX™ Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWY, GAT
Dated: August 29, 2025
Received: August 29, 2025

Dear Emmarie Halteman:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, 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

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.	K251690

Please provide the device trade name(s).

Arthrex SpeedFLEX™Implant

Please provide your Indications for Use below.

The Arthrex SpeedFLEX™ Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The Arthrex SpeedFLEX™ Implant is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including but not limited to reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. The Arthrex SpeedFLEX™ Implant is not intended to replace normal body structures or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to bone, provide mechanical strength for the tendon repair.

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

Date Prepared	5/30/2025
Submitter	Arthrex Inc. 1370 Creekside Boulevard Naples, FL 34108-1945
Contact Person	Name: Emmarie Halteman Title: Senior Regulatory Affairs Specialist Phone: 1-239-643-5553 ext. 74232 Email: emmarie.halteman@arthrex.com
Trade Name	Arthrex SpeedFLEX™ Implant
Common Name	Mesh, Surgical, Collagen, Orthopaedics, Reinforcement of Tendon
Product Code	Primary: OWY Additional: GAT
Classification Name	**CFR 878.3300: Mesh, Surgical, Collagen, Orthopaedics, Reinforcement of Tendon** CFR 878.5000: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class	Class II
Primary Predicate Device	K103787: Medeor™ Matrix
Reference Device	K120479: MTF Fascia
Purpose of Submission	This Traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex SpeedFLEX™ Implant.
Device Description	The Arthrex SpeedFLEX™ Implant consists of a decellularized human allograft dermis that is pre-sutured with FiberWire® suture (passing suture) and TigerLink™ SutureTape (implanted). The allograft implant will be offered in four (4) sizes. The Arthrex SpeedFLEX™ Implant is sold sterile, single use.
Indications for Use	The Arthrex SpeedFLEX™ Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The Arthrex SpeedFLEX™ Implant is also intended for reinforcement of soft tissues that are repaired by suture or suture anchors, during tendon repair surgery including but not limited to reinforcement of rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. The Arthrex SpeedFLEX™ Implant is not intended to replace normal body structures or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, or quadriceps tendons. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to bone, provide mechanical strength for the tendon repair.
Performance Data	The subject device Arthrex SpeedFLEX™ Implant consists of a decellularized human allograft dermis that is pre-sutured with FiberWire® suture (passing suture) and TigerLink™ SutureTape (implanted). The submitted biomechanical test data, Tensile and

	Suture Retention, was performed to address the risks of decreased biomechanical strength of the suture materials in the subject device Arthrex SpeedFLEX™ Implant. Bacterial Endotoxin Testing (BET) was performed on the Arthrex SpeedFLEX implant utilizing the Kinetic Chromogenic Method in accordance with ANSI/AAMI ST72:2019, USP <161>, USP <85>. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. The testing conducted demonstrates that the Arthrex SpeedFLEX implant meets pyrogen limit specifications. All donors have been screened and tissues recovered, processed, stored, tested, and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270 and 1271, current Standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required. This allograft was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed). All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. The following test criteria were met for the donor of this allograft bio-implant: Hepatitis B virus (HBV) surface antigen, HBV core antibody, Hepatitis C virus (HCV) antibody, HIV-1/12 antibody, Syphilis, HIV-1 NAT, HCT NAT, and HBV NAT. Cytotoxicity, Sensitization, Irritation, Genotoxicity, Acute Systemic Toxicity, Implantation, Material Mediated Pyrogenicity, and Material Chemical Characterization was conducted on the Arthrex SpeedFLEX™ implant in accordance with ISO 10993-1:2018 and deemed biocompatible when used as intended.
Technological Comparison	Compared to the predicate device Medeor™ Matrix (K103787), the subject Arthrex SpeedFLEX™ Implant has the same fundamental scientific technology, sterility, and shelf-life. The subject Arthrex SpeedFLEX™ Implant is comprised of decellularized human allograft dermis that is pre-sutured with FiberWire® suture (K021434) and TigerLink™ SutureTape (K122374); whereas the predicate device is composed of decellularized porcine-dermis-derived collagen

	surgical mesh and is not pre-sutured. Additionally, the reference device MTF Fascia (K120479) surgical mesh is made of decellularized human allograft and complies with all requirements in 21 CFR 1271 to reduce the risk of the introduction, transmission, and spread of communicable diseases by human cells, tissues, and cellular and tissue-based products (HCT/Ps) analogously to the Arthrex SpeedFLEX™ Implant. Both the predicate and subject devices are sterilized to a sterility assurance level of 10^{-6}. Any differences between the subject device and the predicate device are considered minor and do not raise new or different questions concerning safety or effectiveness. The submitted biomechanical test data demonstrates that the Arthrex SpeedFLEX™ Implant results are statistically equivalent to the predicate device Medeor™ Matrix (K103787) for the desired indications. The predicate device submitted two in vivo animal studies (sheep and rabbit) to assess the tissue response when used to repair a defect. For the subject device, the results of 22 peer-reviewed human clinical data, inclusive of local tissue response for the subject device when the three components (decellularized dermis, TigerLink SutureTape, and FiberWire suture) are assembled in the operating room by the surgeon to repair the indicated defects. The data supports an analogous conclusion to the predicate. Based on the fundamental scientific technology and the summary of data submitted, Arthrex Inc. has determined that the subject device is substantially equivalent to the currently marketed predicate device Medeor™ Matrix (K103787).
Conclusion	The Arthrex SpeedFLEX™ Implant is substantially equivalent to the predicate device in which the intended orthopedic use/indications (OHT6) are the same. Any difference between the subject device and the predicate device are considered minor and do not raise different questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and the summary of data submitted, Arthrex Inc. has determined that the subject device is substantially equivalent to the currently marketed predicate device.