April 1, 2024

Surgical Fusion Technologies GmbH
% Kelliann Payne
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K240288
Trade/Device Name: SF Push- in Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI, HTY, GAT
Dated: January 31, 2024
Received: February 1, 2024

Dear Kelliann Payne:

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.

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,

Maziar Shah Mohammadi

Digitally signed by Maziar Shah Mohammadi
Date: 2024.04.01 10:52:53 -04'00'

For: Jesse Muir, Ph.D.
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)*

K240288

Device Name

SF Push- in Anchor

Indications for Use *(Describe)*

The SF Push-in Anchor is intended to be used for suture or tissue fixation in the foot, ankle, hand, wrist, elbow, hip, knee and shoulder. The SF Push-in Anchor is designed only to be inserted with the SupraFuser Generator.

SF Push-in Anchor 1.6mm:
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Bankart Repair, SLAP Lesion Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair

SF Push-in Anchor 2.3mm:
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral epicondylitis repair

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, Achilles Tendon Repair, Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hip: Acetabular labral repair, capsular repair

SF Push-in Anchor 3.0mm and 3.6mm:
Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/ Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and

MCP joints for all digits, digital tendon transfers

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, lateral epicondylitis repair

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, Metatarsal tendon repair, Bunionectomy

Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon repair, posterior oblique ligament repair, and iliotibial band tenodesis

Hip: Acetabular labral repair, capsular 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.

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Surgical Fusion Technologies GmbH's SF-Push-in Anchors

510(k) Summary

Surgical Technology's SF Push-in Anchor Portfolio

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

Surgical Fusion Technologies GmbH
Wagistrasse 6 Schlieren, Switzerland

Phone: +41 44 204 60 18
Facsimile: +41 44 204 61 2820
Contact Person: Joerg Mayer, CTO
Date Prepared: March 29, 2024

Name of Device and Name

SF Push-in Anchor

Common or Usual Name

Fastener, fixation, biodegradable, soft tissue (MAI), class II Pin, fixation, smooth (HTY), class II
Suture, nonabsorbable, synthetic, polyethylene (GAT), class II

Classification Name

Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) Nonabsorbable poly(ethylene terephthalate) surgical suture (21 CFR 878.5000)

Predicate Devices

- K171228 SportWelding's Fiji Anchor (Primary Predicate)
- K063479 Arthrex's Bio-PushLock (Secondary Predicate)
- K082810 Arthrex's Bio Composite Pushlock (Secondary Predicate)
- K183091 SpineWelding's Elaris Pedicle Screw System (Reference Device)

Indications for Use

The SF Push-in Anchor is intended to be used for suture or tissue fixation in the foot, ankle, hand, wrist, elbow, knee, hip and shoulder. The SF Push-in Anchor is designed only to be inserted with the SupraFuser Generator.

SF Push-in Anchor 1.6mm:

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Bankart Repair, SLAP Lesion Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair

SF Push-in Anchor 2.3mm:

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, Lateral epicondylitis repair

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Metatarsal Ligament Repair, Hallux Valgus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, Achilles Tendon Repair, Bunionectomy

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hip: Acetabular labral repair, capsular repair

SF Push-in Anchor 3.0mm and 3.6mm:

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction, lateral epicondylitis repair

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus and Varus reconstruction, Digital Tendon Transfers, Mid-foot Reconstruction, Metatarsal tendon repair, Bunionectomy

Knee: Medial collateral ligament repair, lateral collateral ligament repair, patellar tendon repair, posterior oblique ligament repair, and iliotibial band tenodesis

Hip: Acetabular labral repair, capsular repair

Technological Characteristics

The SF Push-in Anchor system consists of implantable anchors with 1.6, 2.3, 3.0, and 3.6mm diameter, an ultrasonic system, a sonotrode, dedicated anchor size specific drills and stoppers, a handpiece front cover, and a guide with integrated wrench.

The SF Push-in Anchors are made of biocompatible and fully bioresorbable Poly-L-lactide-co-D,L-lactide. The SF Push-in Anchors are fully bioresorbable implants designed for soft tissue reattachment to bone by means of suture materials. The implantation process employs ultrasonic energy to liquefy the polymeric components of the Push-in Anchors at the interface with bone tissue. The liquid polymer flows into the marrow space of the surrounding cancellous bone, where it is immediately quenched and provides anchorage of the implant.

The ultrasonic energy for the implantation of the Push-in Anchors is produced by the SupraFuser® ultrasonic generator and applied via the attached handpiece. The sonotrode is mounted on the handpiece. It transmits the ultrasonic vibrations to the Push-in Anchor. The drills and the stoppers are dedicated to be used with the Push-in Anchor of the respective size.

Performance Data

The following tests were performed to demonstrate the substantial equivalence of the Fiji Anchor:

- Software documentation and validation per FDA guidance
- IEC 60601-1 and 60601-1-2 testing
- Material characterization using GPC, inherent viscosity, GCMS, and ICP
- Static pullout testing before and after aging
- Dynamic pullout testing before and after aging
- Creep testing
- Insertion testing
- Degradation testing
- Biocompatibility risk assessment
- Lot-to-lot endotoxin testing is also performed per USP <85>

Substantial Equivalence

The SF Push-in Anchors are as safe and effective as the primary predicate device by the same manufacturer (Fiji Anchors). The SF Push-in Anchors have the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices (Arthrex's 2.5mm Bio PushLock, Bio-Composite PushLock). The minor technological differences between the SF Push-in Anchors and its predicate devices, summarized in the table below, raise no new issues of safety or effectiveness. Performance data demonstrate that the SF Push-in Anchors are as safe and effective as the Fiji Anchor as well as Arthrex's 2.5mm Bio PushLock or Bio-Composite PushLock. Thus, the SF Push-in Anchors are substantially equivalent. The reference device is cited to support testing methods and results.

Property	**SF Push- in Anchor**	**SportWelding Fiji Anchor/SF Push-in anchor 2.3**	**Arthrex 2.5 mm Bio-PushLock**	**Arthrex Bio-Composite PushLock**
Predicate	Subject	Primary Predicate	Secondary Predicate	Secondary Predicate
510(k)	Subject	K171228	K063497	K082810
Components	Anchor, suture, Sonotrode, US generator	Anchor, suture, sonotrode, US generator	PEEK eyelet, suture, anchor	PEEK eyelet, suture, anchor
Size	1.6mm/5.2mm 2.3mm/7.2mm 3.0mm/8.7mm 3.6mm/10.2mm	2.3 x 7.2 mm	2.5 x 8 mm	Diameter: 2.4-6.5mm/ Length: 5-18.5mm
Suture Sizes	1.6mm: #4-0 to #0 2.3mm: #4-0 to #2 3.0mm: #0 to #2, tape up to size 2mm 3.6mm: #2, tape up to size 2mm	#4-0 to #2	#2-0. #0	#2-0. #0, #2,tape up to size 2mm
Insertion Method	Insert anchor into predrilled hole while applying US energy	Insert anchor into predrilled hole while applying US energy	Insert eyelet into predrilled hole, then secure with bioresorbable anchor	Insert eyelet into predrilled hole, then secure with bioresorbable anchor

Property	SF Push- in Anchor	SportWelding Fiji Anchor/SF Push-in anchor 2.3	Arthrex 2.5 mm Bio-PushLock	Arthrex Bio-Composite PushLock
Fixation Method	Ultrasonic melting of the polymer into the porous cancellous bone	Ultrasonic melting of the polymer into the porous cancellous bone	Barbs in a mechanical press-fit	Barbs in a mechanical press-fit
Length of ultrasound energy delivery	Not more than 6 seconds	Not more than 6 seconds	N/A	N/A
Suture fixation	Manual knotting	Manual knotting	Knotless	Knotless
Material	PLDLLA	PLDLLA	PLLA and PEEK	PLLA, PLDLA/TCP, PEEK
Resorbable	Yes	Yes	Partly	Partly
Sterilization	Sterile	Sterile	Sterile	Sterile

Conclusions

The SF Push-in Anchors are substantially equivalent to the predicate devices.