March 27, 2026

Surgical Fusion Technologies GmbH
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market St.
23rd Floor
Philadelphia, Pennsylvania 19103

Re: K260294
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 29, 2026
Received: January 29, 2026

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 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,

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.	K260294	?

Please provide the device trade name(s). ?

SF Push-in Anchor

Please provide your Indications for Use below. ?

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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Triangular Fibrocartilage Complex (TFCC)
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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Triangular Fibrocartilage Complex (TFCC)
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.	
Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C) ?

Surgical Fusion Technologies GmbH's SF-Push-in Anchors
510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person

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: January 29, 2026

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

K240288 Surgical Fusion SF-Push-in Anchor (Primary Predicate)

K183091 SpineWelding Elaris Pedicle Screw System (Material reference)

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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)

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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Triangular Fibrocartilage Complex (TFCC)

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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Triangular Fibrocartilage Complex (TFCC)

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, a guide with integrated wrench, and a set of reamers.

The SF Push-in Anchors are delivered in a dedicated Implant Case to facilitate suture loading and suture handling during implantation.

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. The Geomax Reamer is used for the SF Push-in Anchors 1.6, 2.3 and 3.0 in cases of thick cortical bone or oblique insertion.

Performance Data

The following tests were performed to demonstrate the substantial equivalence of the SF Push-in Anchor:

- Gamma sterilization validation
- Packaging validation
- Shelf-life validation
- Anchor pull out testing

Substantial Equivalence

The SF Push-in Anchors are as safe and effective as the primary predicate SF Push-in Anchors. The SF Push-in Anchors have the same intended uses and similar indications, technological characteristics, and principles of operation. The minor technological differences between the subject and predicate 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 predicate. Thus, the SF Push-in Anchors are substantially equivalent.

Company	**Surgical Fusion Technologies**	**Surgical Fusion Technologies**
Device	SF- Push-in Anchor Portfolio	SF- Push-in Anchor Portfolio
FDA 510(K)	Subject submission	K240288
Indications	**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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), **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 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

Company	Surgical Fusion Technologies	Surgical Fusion Technologies
	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, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Triangular Fibrocartilage Complex (TFCC) **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, Carpometacarpal joint	**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

Company	Surgical Fusion Technologies	Surgical Fusion Technologies
	arthroplasty (basal thumb joint arthroplasty), Triangular Fibrocartilage Complex (TFCC) **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	**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
Device Diameter/Length	1.6mm/5.2mm 2.3mm/7.2mm 3.0mm/8.7mm 3.6mm/10.2mm	1.6mm/5.2mm 2.3mm/7.2mm 3.0mm/8.7mm 3.6mm/10.2mm
Material	PLDLLA: Resomer® LR 706 S	PLDLLA: Resomer® LR 706 S

Company	Surgical Fusion Technologies	Surgical Fusion Technologies
Manufacturing	Injection molding at Surgical Fusion Technologies GmbH	Injection molding at Samaplast AG
Sterilization	VDmax 25 kGy Gamma radiation	VDmax 17.5 kGy Gamma radiation
Acceptance Level for Molecular Weight (Inherent Viscosity) post sterilization	1.0 cm^3/g	1.2 cm^3/g
Sutures	Supplied with, or recommended sutures Non-resorbable polyethylene terephthalate sutures or UHMWPE sutures or a combination of UHMWPE and polyester sutures	Supplied with, or recommended sutures Non-resorbable polyethylene terephthalate sutures or UHMWPE sutures or a combination of UHMWPE and polyester sutures
Insertion Method	Insert anchor into predrilled hole while applying US energy	Insert anchor into predrilled hole while applying US energy
Fixation Methods	Ultrasonic melting of the polymer into the porous cancellous bone	Ultrasonic melting of the polymer into the porous cancellous bone
Length of ultrasound energy delivery	Not more than 6 seconds	Not more than 6 seconds
Packaging	Primary: Implant in Implant Case in Blister Secondary: Blister in Aluminum Pouch Tertiary: Product box	Primary: Implant in Aluminium Pouch Secondary: PE pouch Tertiary: Product box

Company	Surgical Fusion Technologies	Surgical Fusion Technologies
Shelf-life	3 years (test in process for 7 years)	7 years
SupraFuser Ultrasonic System		
Components	Ultrasound generator Handpiece Sonotrode S-PI	Ultrasound generator Handpiece Sonotrode S-PI
Power Source	100-240V AC ±10% Max. Power consumption: 50VA	100-240V AC ±10% Max. Power consumption: 50VA
Software	V3.1	V2.5
Sterilizable Instruments		
Drill Sizes	Drill S-PI A1.6 Drill S-PI A2.3 Drill S-PI A3.0 Drill S-PI A3.6 Drill S-PI A.1.6 extra short (length 5mm instead of 6.9mm in the Drill S-PI A1.6)	Drill S-PI A1.6 Drill S-PI A2.3 Drill S-PI A3.0 Drill S-PI A3.6
Drill Material	Stainless steel (1.4197 medical/X20CrNiMos13-1) Additional Laser marking on tip	Stainless steel (1.4112)
Manual Reamer	Geomax Reamer S-PI-A1.6 Geomax Reamer S-PI-A2.3 Geomax Reamer S-PI-A3.0	Not available

Company	Surgical Fusion Technologies	Surgical Fusion Technologies
Reamer Material	Reamer - Stainless steel grade 1.4197 Handle – Medical grade silicone with SS core	Nor available
Stopper/Front Cover	Stopper S-PI-A1.6 Stopper S-PI-A2.3 Stopper S-PI-A3.0 Stopper S-PI-A3.6 Front Cover	Stopper S-PI-A1.6 Stopper S-PI-A2.3 Stopper S-PI-A3.0 Stopper S-PI-A3.6 Front Cover
Stopper/Front Cover Material	Medical grade PEEK	Medical grade PEEK

Conclusions

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