June 7, 2023

Suzhou Endophix Co., Ltd.
Jaun Wu
RA Specialist
NO. 151, Fengli Road
Suzhou, Jiangsu 215000
China

Re: K231002
Trade/Device Name: Javelot PK-S suture anchor, Javelot PK-S suture anchor (Knotless), Javelot PK-P suture anchor, Javelot PK-P suture anchor (Knotless), Javelot PK-L suture anchor (Knotless)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 7, 2023
Received: April 7, 2023

Dear Jaun Wu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jesse Muir -S

Jesse Muir, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231002

Device Name
Javelot PK-S suture anchor

Indications for Use *(Describe)*
The Javelot PK-S suture anchor is intended for the reattachment of soft tissue to bone for the following indications:
Shoulder:
-Bankart lesion repair
-SLAP lesion repair
-Acromioclavicular separation repair
-Rotator cuff tear repair
-Capsular shift or capsulolabral reconstruction
-Biceps tenodesis
-Deltoid repair

Foot/Ankle:
-Hallux Valgus repair
-Medial or lateral instability repair/reconstruction
-Achilles tendon repair/reconstruction
-Midfoot reconstruction
-Metatarsal ligament/tendon repair/reconstruction

Elbow:
-Ulnar or radial collateral ligament reconstruction
-Lateral epicondylitis repair
-Biceps tendon reattachment

Knee:
-Extra-capsular repair
  Medial collateral ligament
  Lateral collateral ligament
  Posterior oblique ligament
-Iliotibial band tenodesis
-Patellar realignment and tendon repair
  Vastus medialis obliquus advancement

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231002

Device Name
Javelot PK-S suture anchor (Knotless)

Indications for Use *(Describe)*
The Javelot PK-S suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications:
Shoulder:
-Bankart repair
-SLAP lesion repair
-Acromioclavicular separation repair
-Rotator cuff repair
-Capsular shift or capsulolabral reconstruction
-Biceps tenodesis
-Deltoid repair

Foot/Ankle:
-Hallux Valgus reconstruction
-Medial stabilization
-Lateral stabilization
-Achilles tendon repair
-Mid-foot reconstruction
-Metatarsal ligament/ tendon repair
-Bunionectorny

Elbow:
-Ulnar/ radial collateral ligament reconstruction
-Biceps tendon reattachment
-Lateral epicondylitis repair

Hand/Wrist:
-Scapholunate ligament reconstruction
-Ulnar/Radial collateral ligament reconstruction

Knee:
-Medial collateral ligament repair
-Lateral collateral ligament repair
-Posterior oblique ligament repair
-Iliotibial band tenodesis
-Patellar tendon repairs
-Anterior cruciate ligament repair (4.75-5.5mm anchors only)
-Secondary or adjunct fixation for ACL/PCL reconstruction or repair (4.75-5.5mm anchors only)
-Quadriceps tendon repair (4.75 mm anchors only)
-Meniscal root repair (4.75 mm anchors only)

Hip:
-Capsular Repair
-Acetabular labral repair

-Proximal hamstring repair (4.75-5.5mm anchors only)
-Gluteus Medius Repair (4.75-5.5mm anchors only)

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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement below.

510(k) Number *(if known)*
K231002

Device Name
Javelot PK-P suture anchor

Indications for Use *(Describe)*
The Javelot PK-P suture anchor is intended for the reattachment of soft tissue to bone for the following indications:
Shoulder:
-Rotator cuff repair
-Bankart repair
-SLAP lesion repair
-Biceps tenodesis
-Acromioclavicular 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

Knee:
-Medial collateral ligament repair
-Lateral collateral ligament repair
-Patellar tendon repair
-Posterior oblique ligament repair
-Iliotibial band tenodesis

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

Hip:
-Capsular repair
-Acetabular labral 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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231002

Device Name
Javelot PK-P suture anchor (Knotless)

Indications for Use *(Describe)*
The Javelot PK-P suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications:
Shoulder:
-Bankart repair
-SLAP lesion repair
-Acromioclavicular separation repair
-Rotator cuff repair
-Capsular shift or capsulolabral reconstruction
-Biceps tenodesis
-Deltoid repair

Foot/ Ankle:
-Hallux Valgus reconstruction
-Medial stabilization
-Lateral stabilization
-Achilles Tendon Repair
-Mid-foot reconstruction
-Metatarsal ligament repair/ tendon repair
-Digital tendon transfers (2.5mm anchor only)
-Bunionectomy (2.9-4.5mm anchors only)

Elbow:
-Ulnar or radial collateral ligament reconstructions
-Biceps tendon reattachment
-Lateral epicondylitis repair (2.9-4.5mm anchors only)

Hand/ Wrist:
-Scapholunate ligament reconstruction
-UInar collateral ligament reconstruction (2.9-4.5mm anchors only)
-Radial collateral ligament reconstruction (2.9-4.5mm anchors only)
-Carpal ligament reconstruction (2.5mm anchors only)
-Repair/Reconstruction of collateral ligaments (2.5mm anchors only)
-Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits (2.5mm anchors only)
-Digital tendon transfers (2.5mm anchors only)

Knee:
-Medial collateral ligament repair
-Lateral collateral ligament repair
-Posterior oblique ligament repair
-Iliotibial band tenodesis
-Patellar tendon repairs

Hip: (2.9-4.5mm anchors only)

-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)

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231002

Device Name
Javelot PK-L suture anchor (Knotless)

Indications for Use *(Describe)*
The Javelot PK-L suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications:
Shoulder:
-Bankart lesion repair
-SLAP lesion repair
-Acromioclavicular separation repair
-Rotator cuff tear repair
-Capsular shift or capsulolabral reconstruction
-Biceps tenodesis
-Deltoid repair
-Anterior shoulder instability (3.7mm anchors only)

Foot/ Ankle:
-Hallux Valgus repair
-Medial or lateral instability repair
-Midfoot reconstruction
-Metatarsal ligament/tendon repair/reconstruction
-Achilles tendon repair/reconstruction
-Bunionectomy (3.7mm anchors only)

Elbow:
-Ulnar or radial collateral ligament reconstruction
-Biceps tendon reattachment
-Lateral epicondylitis repair (3.7mm anchors only)

Hand/Wrist:
-Scapholunate ligament reconstruction
-Ulnar collateral ligament reconstruction
-Radial collateral ligament reconstruction

Knee:
-Medial collateral ligament repair
-Lateral collateral ligament repair
-Posterior oblique ligament repair
-Iliotibial band tenodesis
-Patellar tendon repair

Hip: (3.7mm anchors only)
-Hip capsule repair
Acetabular labrum reattachment/ reconstruction

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)

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510(k) Summary

I Submitter

Device submitter:	Suzhou Endophix Co., Ltd. NO.151, Fengli Road, SIP, 215000 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
Primary contact person:	Juan Wu Regulatory Affairs Specialist Phone: +86-17521559984 Email: Juan.Wu@microport.com

Date of preparation: 2023-04-07

II Device

Trade Name of Device:	Javelot PK-S suture anchor, Javelot PK-S suture anchor (Knotless), Javelot PK-P suture anchor, Javelot PK-P suture anchor (Knotless), Javelot PK-L suture anchor (Knotless)
Common Name:	suture anchor
Classification Name:	Fastener, Fixation, Non-degradable, Soft Tissue
Regulatory Class:	II
Product Code:	MBI
Review Panel:	Orthopedic
Regulation Number:	888.3040

III Predicate Devices

Trade Name:	TWINFIX™ Ultra PK Suture Anchor
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K093228
Manufacturer:	Smith & Nephew, Inc., Endoscopy Division

Trade Name:	Arthrex Swivelock Anchors
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040, 21 CFR 888.3030
Product Code:	MAI, HWC
Premarket Notification:	K101823

Manufacturer:	Arthrex, Inc.

Trade Name:	Arthrex SwiveLock Suture Anchor
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040, 21 CFR 888.3030
Product Code:	MAI, MBI
Premarket Notification:	K203495
Manufacturer:	Arthrex, Inc.

Trade Name:	Arthrex SutureTak Suture Anchors
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040, 21 CFR 888.3030
Product Code:	MAI, MBI
Premarket Notification:	K140855
Manufacturer:	Arthrex, Inc.

Trade Name:	Arthrex PushLock™
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040, 21 CFR 888.3030
Product Code:	HWC, JDR, MAI, MBI
Premarket Notification:	K061863
Manufacturer:	Arthrex, Inc.

Trade Name:	Arthrex 2.5mm PushLock™
Common Name:	Fastener; Screw, Fixation, Bone
Classification:	Class II, 21 CFR 888.3040, 21 CFR 888.3030
Product Code:	HWC, MAI, MBI
Premarket Notification:	K063479
Manufacturer:	Arthrex, Inc.

Trade Name:	FOOTPRINT Ultra PK Suture Anchor
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K093897
Manufacturer:	Smith & Nephew, Inc., Endoscopy Division

Trade Name:	BIORAPTOR™ Knotless Suture Anchor
Common Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Classification:	Class II, 21 CFR 888.3040, 21 CFR 888.3030
Product Code:	MAI, MBI

Premarket Notification:	K121018
Manufacturer:	Smith & Nephew, Inc.

IV Device description

All Javelot PEEK suture anchors are preassembled onto an inserter, which enables insertion of the anchor into bone after creation of a pilot hole. The anchors are offered in a polyetheretherketone (PEEK) material with a screw-in, push-in (with or without lock-in) design. The sutures are offered in non-absorbable USP braid ultrahigh molecular weight polyethylene (UHMWPE) material. The preassembled inserter consists of an insertion rod and an insertion handle, the insertion rod is offered in stainless steel material, the insertion handle is offered in acrylonitrile butadiene Styrene copolymers (ABS) material. Javelot PEEK suture anchors come in various configurations, including: with attached non-absorbable suture(s). Javelot PEEK suture anchors are non-absorbable, provided sterile, for single use only.

V Indications for use

Javelot PEEK suture anchors - Javelot PK-S suture anchor

The Javelot PK-S suture anchor is intended for the reattachment of soft tissue to bone for the following indications:

Shoulder:

-Bankart lesion repair
-SLAP lesion repair
-Acromioclavicular separation repair
-Rotator cuff tear repair
-Capsular shift or capsulolabral reconstruction
-Biceps tenodesis
-Deltoid repair

Foot/Ankle:

-Hallux Valgus repair
-Medial or lateral instability repair/reconstruction
-Achilles tendon repair/reconstruction
-Midfoot reconstruction
-Metatarsal ligament/tendon repair/reconstruction

Elbow:

-Ulnar or radial collateral ligament reconstruction
-Lateral epicondylitis repair
-Biceps tendon reattachment

Knee:

-Extra-capsular repair

- Medial collateral ligament

- Lateral collateral ligament
- Posterior oblique ligament

-Iliotibial band tenodesis
-Patellar realignment and tendon repair

- Vastus medialis obliquus advancement

Javelot PEEK suture anchors - Javelot PK-S suture anchor (Knotless)

The Javelot PK-S suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications:

Shoulder:
-Bankart repair
-SLAP lesion repair
-Acromioclavicular separation repair
-Rotator cuff repair
-Capsular shift or capsulolabral reconstruction
-Biceps tenodesis
-Deltoid repair

Foot/Ankle:
-Hallux Valgus reconstruction
-Medial stabilization
-Lateral stabilization
-Achilles tendon repair
-Mid-foot reconstruction
-Metatarsal ligament/ tendon repair
-Bunionectorny

Elbow:
-Ulnar/ radial collateral ligament reconstruction
-Biceps tendon reattachment
-Lateral epicondylitis repair

Hand/Wrist:
-Scapholunate ligament reconstruction
-Ulnar/Radial collateral ligament reconstruction

Knee:
-Medial collateral ligament repair
-Lateral collateral ligament repair
-Posterior oblique ligament repair
-Iliotibial band tenodesis
-Patellar tendon repairs
-Anterior cruciate ligament repair (4.75-5.5mm anchors only)
-Secondary or adjunct fixation for ACL/PCL reconstruction or repair (4.75-5.5mm anchors only)

-Quadriceps tendon repair (4.75 mm anchors only)
-Meniscal root repair (4.75 mm anchors only)

Hip:

-Capsular Repair
-Acetabular labral repair
-Proximal hamstring repair (4.75-5.5mm anchors only)
-Gluteus Medius Repair (4.75-5.5mm anchors only)

Javelot PEEK suture anchors - Javelot PK-P suture anchor

The Javelot PK-P suture anchor is intended for the reattachment of soft tissue to bone for the following indications:

Shoulder:

-Rotator cuff repair
-Bankart repair
-SLAP lesion repair
-Biceps tenodesis
-Acromioclavicular 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

Knee:

-Medial collateral ligament repair
-Lateral collateral ligament repair
-Patellar tendon repair
-Posterior oblique ligament repair
-Iliotibial band tenodesis

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

Hip:

-Capsular repair

-Acetabular labral repair

Javelot PEEK suture anchors - Javelot PK-P suture anchor (Knotless)

The Javelot PK-P suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications:

Shoulder:

-Bankart repair

-SLAP lesion repair

-Acromioclavicular separation repair

-Rotator cuff repair

-Capsular shift or capsulolabral reconstruction

-Biceps tenodesis

-Deltoid repair

Foot/ Ankle:

-Hallux Valgus reconstruction

-Medial stabilization

-Lateral stabilization

-Achilles Tendon Repair

-Mid-foot reconstruction

-Metatarsal ligament repair/ tendon repair

-Digital tendon transfers (2.5mm anchor only)

-Bunionectomy (2.9-4.5mm anchors only)

Elbow:

-Ulnar or radial collateral ligament reconstructions

-Biceps tendon reattachment

-Lateral epicondylitis repair (2.9-4.5mm anchors only)

Hand/ Wrist:

-Scapholunate ligament reconstruction

-UInar collateral ligament reconstruction (2.9-4.5mm anchors only)

-Radial collateral ligament reconstruction (2.9-4.5mm anchors only)

-Carpal ligament reconstruction (2.5mm anchors only)

-Repair/Reconstruction of collateral ligaments (2.5mm anchors only)

-Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits (2.5mm anchors only)

-Digital tendon transfers (2.5mm anchors only)

Knee:

-Medial collateral ligament repair

-Lateral collateral ligament repair

-Posterior oblique ligament repair
-Iliotibial band tenodesis
-Patellar tendon repairs
Hip: (2.9-4.5mm anchors only)
-Acetabular labral repair
-Capsular repair

Javelot PEEK suture anchors - Javelot PK-L suture anchor (Knotless)

The Javelot PK-L suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications:

Shoulder:
-Bankart lesion repair
-SLAP lesion repair
-Acromioclavicular separation repair
-Rotator cuff tear repair
-Capsular shift or capsulolabral reconstruction
-Biceps tenodesis
-Deltoid repair
-Anterior shoulder instability (3.7mm anchors only)
Foot/ Ankle:
-Hallux Valgus repair
-Medial or lateral instability repair
-Midfoot reconstruction
-Metatarsal ligament/tendon repair/reconstruction
-Achilles tendon repair/reconstruction
-Bunionectomy (3.7mm anchors only)
Elbow:
-Ulnar or radial collateral ligament reconstruction
-Biceps tendon reattachment
-Lateral epicondylitis repair (3.7mm anchors only)
Hand/Wrist:
-Scapholunate ligament reconstruction
-Ulnar collateral ligament reconstruction
-Radial collateral ligament reconstruction
Knee:
-Medial collateral ligament repair
-Lateral collateral ligament repair
-Posterior oblique ligament repair
-Iliotibial band tenodesis
-Patellar tendon repair
Hip: (3.7mm anchors only)

-Hip capsule repair

- Acetabular labrum reattachment/ reconstruction

VI Comparison of technological characteristics with the predicate devices

Javelot PEEK suture anchors have similar technological characteristics and fundamental design as the predicate device. The differences between the subject device and predicate device do not alter suitability of the proposed device for its intended use.

Table 5.1 Substantial equivalence discussion - Javelot PK-S suture anchor

Characteristics	**Subject Device (Javelot PK-S suture anchor)**	**Predicate Device K093228**, TWINFIX™ Ultra PK Suture Anchor	**Remarks**
Product Code	MBI	MBI	Identical as predicate device.
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Intended Use	The Javelot PK-S suture anchor is intended for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Bankart lesion repair -SLAP lesion repair -Acromioclavicular separation repair -Rotator cuff tear repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair **Foot/Ankle:** -Hallux Valgus repair -Medial or lateral	The Smith & Nephew TWINFIX Ultra PK Suture Anchor is intended for use for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Bankart lesion repairs -SLAP lesion repairs -Acromioclavicular separation repairs -Rotator cuff tear repairs -Capsular shift or capsulolabral reconstructions -Biceps tenodesis -Deltoid repairs **Foot/Ankle:** -Hallux Valgus repairs	Identical as predicate device.

	instability repair/reconstruction -Achilles tendon repair/reconstruction -Midfoot reconstruction -Metatarsal ligament/tendon repair/reconstruction **Elbow:** -Ulnar or radial collateral ligament reconstruction -Lateral epicondylitis repair -Biceps tendon reattachment **Knee:** -Extra-capsular repair • Medial collateral ligament • Lateral collateral ligament • Posterior oblique ligament -Iliotibial band tenodesis -Patellar realignment and tendon repair • Vastus medialis obliquus advancement	-Medial or lateral instability repairs/reconstructions -Achilles tendon repairs/reconstruction -Midfoot reconstructions -Metatarsal ligament/tendon repairs/reconstructions **Elbow:** -Ulnar or radial collateral ligament reconstructions -Lateral epicondylitis repair -Biceps tendon reattachment **Knee:** -Extra-capsular repairs • Medial collateral ligament • Lateral collateral ligament • Posterior oblique ligament -Iliotibial band tenodesis -Patellar realignment and tendon repairs • Vastus medialis obliquous advancement	
Composition	Implantable part: Anchor, suture Non-implantable part: inserter	Implantable part: Anchor, suture Non-implantable part: inserter	Identical as predicate device.
Key Patient Contacting Material	Anchor: PEEK Suture: UHMWPE	Anchor: PEEK Suture: UHMWPE	Identical as predicate device.
Dimensional Verification	Anchor diameter: 4.5mm, 5.5mm, 6.5mm Anchor length: 19mm	Anchor diameter: 4.5mm, 5.5mm, 6.5mm Anchor length: 19mm	Substantially equivalent.
Anchor type	Screw-in suture anchor	Screw-in suture anchor	Identical as

			predicate device.
Sterilization	EO sterilization	EO sterilization	Identical as predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 5.2 Substantial equivalence discussion - Javelot PK-S suture anchor (Knotless)

Characteristics	**Subject Device (Javelot PK-S suture anchor (Knotless))**	**Predicate Device** **K101823**, SwiveLock suture anchor (Primary Predicate) **K203495**, SwiveLock suture anchor (Secondary Predicate)	**Remarks**
Product Code	MBI	K101823: MAI, HIWC K203495: MAI, MBI	Different as predicate device includes absorbable devices

			whose code is different.
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Indications for use	The Javelot PK-S suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Bankart repair -SLAP lesion repair -Acromioclavicular separation repair -Rotator cuff repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair **Foot/Ankle:** -Hallux Valgus reconstruction -Medial stabilization -Lateral stabilization -Achilles tendon repair -Mid-foot reconstruction -Metatarsal ligament/ tendon repair -Bunionectorny **Elbow：** -Ulnar/ radial collateral ligament reconstruction -Biceps tendon reattachment -Lateral epicondylitis	(**K101823**) The Arthrex SwiveLock Anchors are intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in the following procedures: **Shoulder:** -Bankart repair -SLAP lesion repair -Acromio-clavicular separation repair -Rotator cuff repairs -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair **Foot/Ankle:** -Hallux Valgus reconstruction -Medial stabilization -Lateral stabilization -Achilles tendon repair -Mid-foot reconstruction -Metatarsal ligament repair/ tendon repair -Bunionectorny. **Elbow：** -Ulnar or radial collateral ligament reconstruction	Substantially equivalent.

	repair **Hand/Wrist:** -Scapholunate ligament reconstruction -Ulnar/Radial collateral ligament reconstruction **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repairs -Anterior cruciate ligament repair (4.75-5.5mm anchors only) -Secondary or adjunct fixation for ACL/PCL reconstruction or repair (4.75-5.5mm anchors only) -Quadriceps tendon repair (4.75 mm anchors only) -Meniscal root repair (4.75 mm anchors only) **Hip:** -Capsular Repair -Acetabular labral repair -Proximal hamstring repair(4.75-5.5mm anchors only) -Gluteus Medius Repair (4.75-5.5mm anchors only)	-Biceps tendon reattachment -Tennis elbow repair -Lateral epicondylitis repair **Hand/Wrist:** -Scapholunate ligament reconstruction -Ulnar or Radial collateral ligament reconstruction -Radial collateral ligament reconstruction **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repairs **Hip:** -Capsular Repair -Acetabular labral repair (**K203495**) The Arthrex SwiveLock Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in skeletally mature pediatric and adult patients for the following procedures: **Shoulder:** -Bankart repair -SLAP lesion repair -Acromio-clavicular separation repair	

		-Rotator cuff repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis capsulolabral reconstruction -Deltoid repair **Foot/ Ankle:** -Hallux Valgus repair -Medial stabilization -Lateral stabilization -Achilles tendon reconstruction, -Mid-foot reconstruction -Metatarsal ligament/ tendon repair -Bunionectorny. **Elbow：** -Ulnar/ radial collateral ligament reconstruction -Biceps tendon reattachment -Lateral epicondylitis repair **Hand/Wrist:** -Scapholunate ligament reconstruction -Ulnar/Radial collateral ligament reconstruction **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repairs -Anterior cruciate ligament repair(4.75-5.5	

		SwiveLock Only) -Secondary or adjunct fixation for ACL/PCL reconstruction or repair (4.75-5.5 SwiveLock Only) -Quadriceps tendon repair (4.75 SwiveLock C Only) -Meniscal root repair (4.75 SwiveLock C Only) -MPFL repair/ reconstruction (3.9 SwiveLock Only) **Hip:** -Capsular Repair -Acetabular labral repair -Proximal hamstring repair(4.75-5.5mm PEEK SwiveLock suture anchors only)) -Gluteus Medius Repair(4.75-5.5mm PEEK SwiveLock suture anchors only))	
Composition	Implantable part: Anchor, suture Non-implantable part: inserter	Implantable part: Anchor, suture Non-implantable part: inserter	Identical as predicate device.
Key Patient Contacting Material	Anchor: PEEK Suture: UHMWPE	Anchor: PEEK Suture: UHMWPE	Identical as predicate device.
Dimensional Verification	Anchor diameter: 3.5mm, 4.75mm, 5.5mm	Anchor diameter: 3.5mm, 3.9mm, 4.75mm, 5.5mm	Substantially equivalent.
Anchor type	Screw-in knotless suture anchor Two-component anchor comprised of an eyelet and a hollow anchor body	Screw-in knotless suture anchor Two-component anchor comprised of an eyelet and a hollow anchor body	Substantially equivalent.
Sterilization	EO sterilization	EO sterilization	Identical as

			predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 5.3 Substantial equivalence discussion - Javelot PK-P suture anchor

Characteristics	**Subject Device (Javelot PK-P suture anchor)**	**Predicate Device K140855**, SutureTak Suture Anchor	**Remarks**
Product Code	MBI	MBI, MAI	Different as predicate device includes absorbable devices whose code is MAI.
Regulation Number	21 CFR 888.3040	21 CFR 888.3040 21 CFR 888.3030	Different as predicate device includes absorbable

			devices
Regulatory Class	Class II	Class II	Identical as predicate device.
Indications for use	The Javelot PK-P suture anchor is intended for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Rotator cuff repair -Bankart repair -SLAP lesion repair -Biceps tenodesis -Acromioclavicular 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 **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Patellar tendon repair -Posterior oblique ligament repair -Iliotibial band tenodesis **Hand/Wrist:** -Scapholunate ligament	The Arthrex SutureTak suture anchors are intended to be used for suture (soft tissue) fixation to bone in the foot, ankle, knee, hand, wrist, elbow, shoulder, and hip. **Shoulder:** -Rotator cuff repair -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 **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Patellar tendon repair -Posterior oblique ligament repair	Identical as predicate device.

	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 **Hip:** -Capsular repair -Acetabular labral repair	-Iliotibial band tenodesis **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 **Hip:** -Capsular repair -Acetabular labral repair	
Composition	Implantable part: Anchor, suture Non-implantable part: inserter	Implantable part: Anchor, suture Non-implantable part: inserter	Identical as predicate device.
Key Patient Contacting Material	Anchor: PEEK Suture: UHMWPE	Anchor: PEEK Suture: UHMWPE	Identical as predicate device.
Dimensional Verification	Anchor diameter: 2.0mm, 2.4mm, 3.0mm	Anchor diameter: 2.0mm, 2.4mm, 3.0mm	Substantially equivalent.
Anchor type	Push-in suture anchor	Push-in suture anchor	Identical as predicate device.
Sterilization	EO sterilization	EO sterilization	Identical as predicate device.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate

			device.
Operating Principle	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 5.4 Substantial equivalence discussion - Javelot PK-P suture anchor (Knotless)

Characteristics	**Subject Device (Javelot PK-P suture anchor (Knotless))**	**Predicate Device** **K061863**, Arthrex PushLock™ (Primary Predicate) **K063479**, Arthrex 2.5mm PushLock™ (Secondary Predicate)	**Remarks**
Product Code	MBI	K061863: HWC, MBI, JDR, MAI K063479: HWC, MAI, MBI	Different as predicate device includes absorbable devices whose code is different.
Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Indications for	The Javelot PK-P suture	**(K061863)**	Substantially

use	anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Bankart repair -SLAP lesion repair -Acromioclavicular separation repair -Rotator cuff repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair **Foot/ Ankle:** -Hallux Valgus reconstruction -Medial stabilization -Lateral stabilization -Achilles Tendon Repair -Mid-foot reconstruction -Metatarsal ligament repair/ tendon repair -Digital tendon transfers (2.5mm anchor only) -Bunionectomy (2.9-4.5mm anchors only) **Elbow:** -Ulnar or radial collateral ligament reconstructions -Biceps tendon reattachment -Lateral epicondylitis repair (2.9-4.5mm anchors only) **Hand/ Wrist:** -Scapholunate ligament reconstruction -Ulnar collateral	The Arthrex PushLock™, previously cleared under 510(k) K051219, is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, hip, and pelvis in the following procedures: **Shoulder:** -Bankart repair -SLAP lesion repair -Acromio-clavicular separation repair -Rotator cuff repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair **Foot/ Ankle:** -Hallux Valgus reconstruction -Medial stabilization -Lateral stabilization -Achilles Tendon Repair -Mid-foot reconstruction -Metatarsal ligament repair/ tendon repair -Bunionectomy **Elbow：** -Ulnar or radial collateral ligament reconstruction -Biceps tendon reattachment -Tennis elbow repair -Lateral epicondylitis repair **Hand/ Wrist:** -Scapholunate ligament	equivalent.

	ligament reconstruction (2.9-4.5mm anchors only) -Radial collateral ligament reconstruction (2.9-4.5mm anchors only) -Carpal ligament reconstruction (2.5mm anchors only) -Repair/Reconstruction of collateral ligaments (2.5mm anchors only) -Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits (2.5mm anchors only) -Digital tendon transfers (2.5mm anchors only) **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repairs **Hip:** (2.9-4.5mm anchors only) -Acetabular labral repair -Capsular repair	reconstruction -UInar collateral ligament reconstruction -Radial collateral ligament reconstruction **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repairs **Hip:** -Capsular repair -Acetabular labral repair **Pelvis:** Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency (**K063479)** The Arthrex PushLock™ is intended to be used for suture or tissue fixation in the foot, ankle, knee, hand, wrist, elbow, shoulder, and in select maxillofacial applications. Specific indications are listed below: **Skull:** -Stabilization and fixation of oral cranio-maxillofacial skeletal bone -Mandible and	

		maxillofacial bones -Lateral Canthoplasty -Repair of Nasal Vestibular Stenosis -Brow Lift -Temporomandibular Joint (TMJ) reconstruction -Soft tissue attachment to the parietal temporal ridge, frontal, zygoma, and perioorbital bones of the skull **Shoulder:** -Bankart repair -SLAP lesion repair -Acromio-clavicular separation repair -Rotator cuff repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair **Foot/ Ankle:** -Hallux Valgus reconstruction -Medial stabilization -Lateral stabilization -Achilles Tendon Repair -Mid-foot reconstruction -Metatarsal ligament repair -Digital tendon transfers **Elbow：** -Ulnar or radial collateral ligament reconstruction -Biceps tendon reattachment **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 **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repair	
Composition	Implantable part: Anchor Non-implantable part: inserter	Implantable part: Anchor Non-implantable part: inserter	Identical as predicate device.
Key Patient Contacting Material	Anchor: PEEK	Anchor: PEEK	Identical as predicate device.
Dimensional Verification	Anchor diameter: 2.5mm, 2.9mm, 3.5mm, 4.5mm	**K061863**, Anchor diameter: 2.9mm, 3.5mm, 4.5mm **K063479**, Anchor diameter: 2.5mm	Substantially equivalent.
Anchor type	Push-in knotless suture anchor Two-component anchor comprised of an eyelet and a hollow anchor body	Push-in knotless suture anchor Two-component anchor comprised of an eyelet and a hollow anchor body	Identical as predicate device.
Sterilization	EO sterilization	Irradiation sterilization	Different, but the sterilization is validated and subject

			device has a SAL of 10^{-6}.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	Implant the anchor into the bone to form an anchorage with the bone. Connect appropriate suture to the anchor to re-suture and fix the soft tissues such as tendons and ligaments, so that the soft tissues can be re-fixed on the surface of bone.	Implant the anchor into the bone to form an anchorage with the bone. Connect appropriate suture to the anchor to re-suture and fix the soft tissues such as tendons and ligaments, so that the soft tissues can be re-fixed on the surface of bone.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 5.5 Substantial equivalence discussion - Javelot PK-L suture anchor (Knotless)

Characteristics	**Subject Device (Javelot PK-L suture anchor (Knotless))**	**Predicate Device** **K093897**, FOOTPRINT Ultra Suture Anchor (Primary Predicate) **K121018**, BIORAPTOR Knotless Suture Anchor (Secondary Predicate)	**Remarks**
Product Code	MBI	MBI (K093897) MAI, MBI (K121018)	Different as K121018 includes other devices whose code is MAI.

Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
Regulatory Class	Class II	Class II	Identical as predicate device.
Indications for use	The Javelot PK-L suture anchor (Knotless) is intended for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Bankart lesion repair -SLAP lesion repair -Acromioclavicular separation repair -Rotator cuff tear repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair -Anterior shoulder instability (3.7mm anchors only) **Foot/ Ankle:** -Hallux Valgus repair -Medial or lateral instability repair -Midfoot reconstruction -Metatarsal ligament/tendon repair/reconstruction -Achilles tendon repair/reconstruction -Bunionectomy (3.7mm anchors only) **Elbow：** -Ulnar or radial collateral ligament reconstruction	The Smith & Nephew FOOTPRINT Ultra PK Suture Anchor (**K093897)** is intended for use for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Bankart repair -SLAP lesion repair -Acromio-clavicular separation -Rotator cuff repair -Capsular shift or capsulolabral reconstruction -Biceps tenodesis -Deltoid repair **Foot/Ankle:** -Hallux Valgus repairs -Medial stabilization -Lateral stabilization -Achilles tendon repair -Mid-foot reconstructions -Metatarsal ligament repair **Elbow：** -Ulnar or radial collateral ligament reconstruction -Biceps tendon reattachment **Hand/Wrist:** -Scapholunate ligament reconstruction -Ulnar collateral ligament	Substantially equivalent.

	-Biceps tendon reattachment -Lateral epicondylitis repair (3.7mm anchors only) **Hand/Wrist:** -Scapholunate ligament reconstruction -Ulnar collateral ligament reconstruction -Radial collateral ligament reconstruction **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repair **Hip:** (3.7mm anchors only) -Hip capsule repair • Acetabular labrum reattachment/ reconstruction	reconstruction -Radial collateral ligament reconstruction **Knee:** -Medial collateral ligament repair -Lateral collateral ligament repair -Posterior oblique ligament repair -Iliotibial band tenodesis -Patellar tendon repair The Smith & Nephew Suture Anchors (**K121018)** are intended for the reattachment of soft tissue to bone for the following indications: **Shoulder:** -Capsular stabilization • Bankart repair • SLAP lesion repairs • Anterior shoulder instability • Capsular shift or capsulolabral reconstructions -Acromioclavicular separation repairs -Rotator Cuff repairs -Biceps tenodesis -Deltoid repairs **Foot/Ankle:** -Hallux valgus repairs -Medial or lateral instability repairs/ reconstructions -Achilles tendon repairs/reconstructions -Midfoot reconstructions	

		-Metatarsal ligament/tendon repairs/reconstructions -Bunionectomy **Elbow, Wrist, and Hand:** -Ulnar or radial collateral ligament reconstructions -Lateral epicondylitis repair -Biceps tendon reattachment **Knee:** -Extra-capsular repairs • Medial collateral ligament • Lateral collateral ligament • Posterior oblique ligament -Iliotibial band tenodesis -Patellar realignment and tendon repairs • Vastus medialis obliquous advancement **Hip:** -Hip capsule repair • Acetabular labrum reattachment/ reconstruction	
Composition	Implantable part: Anchor Non-implantable part: suture, inserter	Implantable part: Anchor Non-implantable part: suture, inserter	Identical as predicate device.
Key Patient Contacting Material	Anchor: PEEK Suture: UHMWPE	Anchor: PEEK Suture: Polyester	Different while both devices are evaluated according to ISO 10993-1.

Dimensional Verification	Anchor diameter: 3.7mm, 4.5mm, 5.5mm	Anchor diameter: 4.5mm, 5.5mm (K093897) Anchor diameter: 3.7mm (K121018)	Substantially equivalent.
Anchor type	Lock-in knotless suture anchor Two-component anchor comprised of an anchor body with eyelet and an inner core	Lock-in knotless suture anchor Two-component anchor comprised of an anchor body with eyelet and an inner core	Identical as predicate device.
Sterilization	EO sterilization	Irradiation sterilization	Different, but the sterilization is validated and subject device has a SAL of 10^{-6}.
Shelf-life	5 Years	5 Years	Identical as predicate device.
Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
Operating Principle	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	Identical as predicate device.
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

VII Performance data

Non-clinical bench tests were conducted in support of the substantial equivalence

determination.

Material Standards

The material standards are the essential part to be complied with first, as it is the basis of manufacturing surgical implants.

We have complied with the following material standards:

ASTM F2026-17: Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications

ASTM F2848-17: Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.

Biocompatibility testing

Biocompatibility of the Javelot PEEK suture anchors was evaluated in accordance with ISO 10993-1: 2018 for the body contact category of “Implant medical device - Tissue/ bone” with a contact duration of “Long term (> 30 d)” and “Externally communicating medical device - Tissue/ bone/ dentin” with a contact duration of “Limited (≤24 h)”.

Bacterial endotoxin testing

Bacterial endotoxins for the implantable components are determined using LAL testing to meet endotoxin limit specifications.

Mechanical performance testing

The following are the mechanical tests that have been performed on the Subject device (i.e. The Javelot PK-S suture anchor) and Predicate device (i.e. Smith & Nephew's TWINFIX™ Ultra PK Suture Anchor):

1. Insertion testing
2. Pullout testing
3. Component interconnection testing
4. Fatigue testing

Sterilization and Shelf-life testing

The sterilization method has been validated according to ISO 11135:2014 to a SAL of 10^{-6}, which has thereby determined the routine control and monitoring parameters, 5-year shelf-life of the device has been evaluated by accelerated ageing test.

Safety in MRI

The Javelot PEEK suture anchors are MR safe as the polyetheretherketone material and the ultrahigh molecular weight polyethylene material are nonmetallic, nonconducting materials that do not contain ferromagnetic materials or any other metallic markers that can interfere with magnetic resonance imaging (MRI). There are no concerns with the performance of the devices in an MRI environment. These devices are labeled MR safe

per ASTM F2503.

VIII Conclusion

The Javelot PEEK suture anchors are substantially equivalent to the predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.