

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 <u>Federal Register</u>.

K231002 - Jaun Wu Page 2

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-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">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
-Metatrasal ligament/tendon repair/reconstruction
National information reputitive and responsible and responsibl
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)

FORM FDA 3881 (6/20) Page 1 of 2 PSC Publishing Services (301) 443-6740 EF

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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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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: 06/30/2023

Expiration Date: 06/30/2023 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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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-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)

Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)
Type of Use (Select one or both, as applicable)	
-Capsular repair	
Congular rangin	
-Acetabular labral repair	

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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 (Se	elect 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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Page 2 of 2

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 Javelot PK-S suture anchor, Javelot PK-S suture anchor

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

		T .	
	instability	-Medial or lateral	
	repair/reconstruction	instability	
	-Achilles tendon	repairs/reconstructions	
	repair/reconstruction	-Achilles tendon	
	-Midfoot reconstruction	repairs/reconstruction	
	-Metatarsal	-Midfoot reconstructions	
	ligament/tendon	-Metatarsal	
	repair/reconstruction	ligament/tendon	
	Elbow:	repairs/reconstructions	
	-Ulnar or radial collateral	Elbow:	
	ligament reconstruction	-Ulnar or radial collateral	
	-Lateral epicondylitis	ligament reconstructions	
	repair	-Lateral epicondylitis	
	-Biceps tendon	repair	
	reattachment	-Biceps tendon	
	Knee:	reattachment	
	-Extra-capsular repair	Knee:	
	Medial collateral	-Extra-capsular repairs	
	ligament	Medial collateral	
	• Lateral collateral	ligament	
	ligament	Lateral collateral	
	Posterior oblique	ligament	
	ligament	Posterior oblique	
	-Iliotibial band tenodesis	ligament	
	-Patellar realignment and	-Iliotibial band tenodesis	
	tendon repair	-Patellar realignment and	
	 Vastus medialis 	tendon repairs	
	obliquus	Vastus medialis	
	advancement	obliquous	
		advancement	
Composition	Implantable part: Anchor,	Implantable part: Anchor,	Identical as
	suture	suture	predicate
	Non-implantable part:	Non-implantable part:	device.
	inserter	inserter	
Key Patient	Anchor: PEEK	Anchor: PEEK	Identical as
Contacting	Suture: UHMWPE	Suture: UHMWPE	predicate
Material			device.
Dimensional	Anchor diameter:	Anchor diameter:	Substantially
Verification	4.5mm, 5.5mm, 6.5mm	4.5mm, 5.5mm, 6.5mm	equivalent.
	Anchor length: 19mm	Anchor length: 19mm	•
Anchor type	Screw-in suture anchor	Screw-in suture anchor	Identical as
		1	

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

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

Characteristics	Subject	Device	Predicate De	evice	Remarks
	(Javelot PK-S	suture	K101823,	SwiveLock	
	anchor (Knotle	ss))	suture ancho	r	
			(Primary Pred	dicate)	
			K203495,	SwiveLock	
			suture ancho	r	
			(Secondary F	Predicate)	
Product Code	MBI		K101823: MA	AI, HIWC	Different as
			K203495: MA	N, MBI	predicate
					device
					includes
					absorbable
					devices

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

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

	K231002
	-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
<u> </u>	, · · ·

		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:	Implantable part: Anchor,	Identical as
	Anchor, suture	suture	predicate
	Non-implantable part:	Non-implantable part:	device.
	inserter	inserter	
Key Patient	Anchor: PEEK	Anchor: PEEK	Identical as
Contacting	Suture: UHMWPE	Suture: UHMWPE	predicate
Material			device.
Dimensional	Anchor diameter:	Anchor diameter: 3.5mm,	Substantially
Verification	3.5mm, 4.75mm, 5.5mm	3.9mm, 4.75mm, 5.5mm	equivalent.
Anchor type	Screw-in knotless suture	Screw-in knotless suture	Substantially
	anchor	anchor	equivalent.
	Two-component anchor	Two-component anchor	
	comprised of an eyelet	comprised of an eyelet	
	and a hollow anchor	and a hollow anchor body	
	body		
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 refixed 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	Predicate Device	Remarks
	(Javelot PK-P suture	K140855, SutureTak	
	anchor)	Suture Anchor	
Product Code	MBI	MBI, MAI	Different as
			predicate
			device
			includes
			absorbable
			devices
			whose code
			is MAI.
Regulation	21 CFR 888.3040	21 CFR 888.3040	Different as
Number		21 CFR 888.3030	predicate
			device
			includes
			absorbable

			devices
Regulatory	Class II	Class II	Identical as
Class			predicate
			device.
Indications for	The Javelot PK-P suture	The Arthrex SutureTak	Identical as
use	anchor is intended for	suture anchors are	predicate
	the reattachment of soft	intended to be used for	device.
	tissue to bone for the	suture (soft tissue)	
	following indications:	fixation to bone in the	
	Shoulder:	foot, ankle, knee, hand,	
	-Rotator cuff repair	wrist, elbow, shoulder,	
	-Bankart repair	and hip.	
	-SLAP lesion repair	Shoulder:	
	-Biceps tenodesis	-Rotator cuff repair	
	-Acromioclavicular	-Bankart repair	
	separation repair	-SLAP lesion repair	
	-Deltoid repair	-Biceps tenodesis	
	-Capsular shift or	-Acromio-clavicular	
	capsulolabral	separation repair	
	reconstruction	-Deltoid repair	
	Foot/Ankle:	-Capsular shift or	
	-Lateral stabilization	capsulolabral	
	-Medial stabilization	reconstruction	
	-Achilles tendon repair	Foot/Ankle:	
	-Metatarsal ligament	-Lateral stabilization	
	repair	-Medial stabilization	
	-Hallux valgus	-Achilles tendon repair	
	reconstruction	-Metatarsal ligament	
	-Digital tendon transfers	repair	
	-Mid-foot reconstruction	-Hallux valgus	
	Knee:	reconstruction	
	-Medial collateral	-Digital tendon transfers	
	ligament repair	-Mid-foot reconstruction	
	-Lateral collateral	Knee:	
	ligament repair	-Medial collateral	
	-Patellar tendon repair	ligament repair	
	-Posterior oblique	-Lateral collateral	
	ligament repair	ligament repair	
	-Iliotibial band tenodesis	-Patellar tendon repair	
	Hand/Wrist:	-Posterior oblique	
	-Scapholunate ligament	ligament repair	

	ro con otm : -4: - :-	Histibial band tan-1:	
	reconstruction	-Iliotibial band tenodesis	
	-Carpal ligament	Hand/Wrist:	
	reconstruction	-Scapholunate ligament	
	-Repair/Reconstruction	reconstruction	
	of collateral ligaments	-Carpal ligament	
	-Repair of flexor and	reconstruction	
	extensor tendons at the	-Repair/Reconstruction	
	PIP, DIP, and MCP joints	of collateral ligaments	
	for all digits	-Repair of flexor and	
	-Digital tendon transfers	extensor tendons at the	
	Elbow:	PIP, DIP, and MCP joints	
	-Biceps tendon	for all digits	
	reattachment	-Digital tendon transfers	
	-Ulnar or radial collateral	Elbow:	
	ligament reconstruction	-Biceps tendon	
	Hip:	reattachment	
	-Capsular repair	-Ulnar or radial collateral	
	-Acetabular labral repair	ligament reconstruction	
		Hip:	
		-Capsular repair	
		-Acetabular labral repair	
Composition	Implantable part:	Implantable part: Anchor,	Identical as
	Anchor, suture	suture	predicate
	Non-implantable part:	Non-implantable part:	device.
	inserter	inserter	
Key Patient	Anchor: PEEK	Anchor: PEEK	Identical as
Contacting	Suture: UHMWPE	Suture: UHMWPE	predicate
Material			device.
Dimensional	Anchor diameter:	Anchor diameter: 2.0mm,	Substantially
Verification	2.0mm, 2.4mm, 3.0mm	2.4mm, 3.0mm	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	Single Use	Single Use	Identical as
Use/Reuse			predicate
	<u> </u>	<u> </u> -	

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

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

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

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

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

Composition	Implantable part: Anchor Non-implantable part: inserter	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 Implantable part: Anchor Non-implantable part: inserter	Identical as predicate device.
Material 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	device. 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
Chalf life	5 Years	E Vooro	SAL of 10 ⁻⁶ .
Shelf-life	5 rears	5 Years	
			predicate
Cinala	Cingle Hee	Cingle I lee	device.
Single	Single Use	Single Use	Identical as
Use/Reuse			predicate
0 "			device.
Operating	Implant the anchor into	Implant the anchor into	Identical as
Principle	the bone to form an	the bone to form an	predicate
	anchorage with the	anchorage with the bone.	device.
	bone. Connect	Connect appropriate	
	appropriate suture to the	suture to the anchor to re-	
	anchor to re-suture and	suture and fix the soft	
	fix the soft tissues such	tissues such as tendons	
	as tendons and	and ligaments, so that the	
	ligaments, so that the	soft tissues can be re-	
	soft tissues can be re-	fixed on the surface of	
	fixed on the surface of	bone.	
	bone.		
Environment of	Hospitals/clinics	Hospitals/clinics	Identical as
Use			predicate
			device.

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

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

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

-Biceps tendon reconstruction reattachment collateral -Radial ligament reconstruction epicondylitis -Lateral Knee: repair (3.7mm anchors -Medial collateral only) Hand/Wrist: ligament repair -Scapholunate ligament -Lateral collateral reconstruction ligament repair -Ulnar collateral ligament oblique -Posterior reconstruction ligament repair -Radial collateral -Iliotibial band tenodesis ligament reconstruction -Patellar tendon repair Knee: -Medial collateral The Smith & Nephew ligament repair Suture Anchors -Lateral collateral (K121018) are intended ligament repair for the reattachment of -Posterior oblique soft tissue to bone for the ligament repair following indications: -lliotibial band tenodesis Shoulder: -Patellar tendon repair -Capsular stabilization Hip: (3.7mm anchors Bankart repair SLAP lesion repairs only) -Hip capsule repair Anterior shoulder Acetabular labrum instability reattachment/ Capsular shift or reconstruction 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	Implantable part: Anchor	Identical as
Composition	Non-implantable part:	Non-implantable part:	predicate
	suture, inserter	suture, inserter	device.
Key Patient	Anchor: PEEK	Anchor: PEEK	Different
Contacting	Suture: UHMWPE	Suture: Polyester	while both
Material	Gataro. Or iivivvi L	Outure. I diyester	devices are
iviaterial			evaluated
			according to
			•
			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 refixed 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.