November 2, 2023

Suzhou Endophix Co., Ltd.
Juan Wu
Regulatory Affairs Specialist
No. 151, Fengli Road, SIP
Suzhou, Jiangsu 215000
China

Re: K232725
Trade/Device Name: Javelot Ti Suture Anchor, Javelot Ti-D Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 4, 2023
Received: September 6, 2023

Dear Mr. 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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2023.11.02 16:08:18 -04'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K232725

Device Name
Javelot Ti Suture Anchor, Javelot Ti-D Suture Anchor

Indications for Use *(Describe)*
The Javelot Ti and Javelot Ti-D Suture Anchor are intended for connection and fixation of soft tissue to bone in the knee, hip, shoulder, elbow, ankle, foot, wrist and hand for the following indications:
Shoulder:
• Bankart lesion repair
• SLAP lesion repair
• Acromio-clavicular separation repair
• Rotator cuff tear repair
• Capsular shift or capsulolabral reconstruction
• Biceps tenodesis
• Deltoid repair

Foot and Ankle:
• Hallux valgus repair
• Medial or lateral instability repair/reconstruction
• Achilles tendon repair/reconstruction
• Midfoot reconstruction
• Metatarsal ligament/tendon repair/reconstruction

Elbow, Wrist and Hand:
• Ulnar or radial collateral ligament reconstruction
• Lateral epicondylitis repair
• Biceps tendon reattachment
• Scapholunate ligament reconstrontion (not for 4.5-6.5mm pro anchors)

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

Hip: (2.8-6.5mm anchors only)
• 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: 2023-09-04

II Device

Trade Name:	Javelot Ti Suture Anchor, Javelot Ti-D Suture Anchor
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

1. Predicates for Javelot Ti Suture Anchor

Primary predicate

Trade Name:	TWINFIX Ultra Ti Suture Anchor
Common Name:	Suture Anchor
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K100159
Manufacturer:	Smith & Nephew, Inc., Endoscopy DIV.

Reference device

Trade Name:	OBL 2.0 MM MINI TAC ANCHOR, MODEL 10-1629-01
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K152566
Manufacturer:	Smith & Nephew, Inc., Endoscopy DIV.

2. Predicates for Javelot Ti-D Suture Anchor

Primary predicate

Trade Name:	PeBA Anchor/ Suture Combination
Common Name:	suture anchor
Classification:	Class II, 21 CFR 888.3040
Product Code:	MBI
Premarket Notification:	K152566
Manufacturer:	Smith & Nephew, Inc., Endoscopy DIV.

Reference device

Trade Name:	TWINFIX Ti Suture Anchor
Common Name:	Suture Anchor
Classification:	Class II, 21 CFR 888.3040
Product Code:	HWC, JDR, MAI, MBI
Premarket Notification:	K053344
Manufacturer:	Smith & Nephew, Inc., Endoscopy DIV.

IV Device description

Javelot titanium anchors and sutures are preassembled onto an inserter, which enables insertion of the anchor into bone. After the anchor is fully seated, the inserter is removed from the implant site, leaving the anchor in the bone and the suture looped through the anchor. Javelot titanium suture anchors come in various configurations, including: with attached non-absorbable needle(s). In certain configurations, the Javelot titanium suture anchors are packaged with a drill, a drill guide and a drill guide handle. The anchors are offered in titanium material. The sutures are offered in non-absorbable USP braid Ultra High Molecular Weight Polyethylene (UHMWPE) material. The preassembled inserter consists of an insertion rod and an insertion handle, the insertion rods are offered in stainless steel material, the insertion handles are offered in polycarbonate (PC) material. The needles are offered in 302 stainless steel material, the drills are offered in 630 stainless steel material, the drill guides are offered in 304 stainless steel material, and the drill guide handles are offered in polyphenylsulfone (PPSU) material. Javelot titanium suture anchors are provided sterile, non-absorbable, for single use only.

V Indications for use

The Javelot Ti and Javelot Ti-D Suture Anchor are intended for connection and fixation of soft tissue to bone in the knee, hip, shoulder, elbow, ankle, foot, wrist and hand for the following indications:

Shoulder:

- Bankart lesion repair
- SLAP lesion repair

- Acromio-clavicular separation repair
- Rotator cuff tear repair
- Capsular shift or capsulolabral reconstruction
- Biceps tenodesis
- Deltoid repair

Foot and Ankle:

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

Elbow, Wrist and Hand:

- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair
- Biceps tendon reattachment
- Scapholunate ligament reconstrontion (not for 4.5-6.5mm pro anchors)

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

Hip: (2.8-6.5mm anchors only)

- Capsular repair
- Acetabular labral repair

VI Comparison of technological characteristics with the predicate devices

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

Table 1 Substantial equivalence discussion - Javelot Ti Suture Anchor

Characteristics	**Subject Device (Javelot Ti Suture Anchor)**	**Predicate Device** **K100159**, TWINFIX Ultra Ti Suture Anchor	**Remarks**

		(Primary Predicate) **K152566**, OBL 2.0 MM MINI TAC ANCHOR, MODEL 10-1629-01 (Reference Device)	
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.
Indications for use	The Javelot Ti and Javelot Ti-D Suture Anchor are intended for connection and fixation of soft tissue to bone in the knee, hip, shoulder, elbow, ankle, foot, wrist and hand for the following indications: **Shoulder:** • Bankart lesion repair • SLAP lesion repair • Acromio-clavicular separation repair • Rotator cuff tear repair • Capsular shift or capsulolabral reconstruction • Biceps tenodesis • Deltoid repair **Foot and Ankle:** • Hallux valgus repair • Medial or lateral instability repair/reconstruction • Achilles tendon repair/reconstruction • Midfoot reconstruction	**Primary Predicate:** TWINFIX Ultra Ti Suture Anchor (**K100159)** is intended for use for the reattachment of soft tissue to bone for the following indications: **Shoulder:** Bankart lesion repairs, SLAP lesion repairs, Acromio-clavicular separation repairs, Rotator cuff tear repairs, Capsular shift or capsulolabral reconstructions, Biceps tenodesis, Deltoid repairs **Foot and Ankle:** Hallux valgus repairs, Medial or lateral instability repairs, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions	Identical as predicate device.

	• Metatarsal ligament/tendon repair/reconstruction **Elbow, Wrist and Hand:** • Ulnar or radial collateral ligament reconstruction • Lateral epicondylitis repair • Biceps tendon reattachment • Scapholunate ligament reconstrontion (not for 4.5-6.5mm pro anchors) **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 **Hip: (2.8-6.5mm anchors only)** • Capsular repair • Acetabular labral repair	**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, including vastus medialis obliquous advancement **Reference Device:** The OBL Preloaded Series Anchor (**K152566**) is intended for use only for the fixation of nonabsorbable synthetic suture material for the following indications: **Shoulder:** Bankart lesion repairs, SLAP lesion repairs, Acromio-clavicular separation repairs, Rotator cuff tear repairs, Capsular shift or capsulolabral reconstructions, Biceps tenodesis, Deltoid repairs **Foot and Ankle:** Hallux valgus repairs, Medial or lateral instability repairs, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal	

		ligament/tendon repairs/reconstructions **Elbow, Wrist, and Hand:** Scapholunate ligament reconstructions, 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, including vastus medialis obliquous advancement	
Composition	Implantable parts: anchor, suture Non-implantable parts: inserter, instruments, needles	Implantable parts: anchor, suture Non-implantable parts: inserter, instruments, needles	Identical as predicate device.
Key Patient Contacting Material	Anchor: Titanium alloy TI6AL4VELI Suture: UHMWPE	**K100159** (TWINFIX Ultra Ti Suture Anchor) Anchor: Titanium alloy TI6AL4VELI Suture: UHMWPE **K152566** (OBL Preloaded Series Anchor) Anchor: Titanium alloy TI6AL4VELI Suture: UHMWPE, polyester.	Substantially equivalent.
Anchor picture			Similar as predicate device.

			
Anchor thread	Single thread	Single thread	Identical as predicate device.
Dimensional Verification	Anchor diameter: 4.5mm, 5.5mm, 6.5mm Anchor length: 19.3mm, 19.4mm, 19.5mm Suture size: #2 suture Anchor diameter: 2.0mm Anchor length: 6.8mm Suture size: #2-0 suture	**K100159** (TWINFIX Ultra Ti Suture Anchor) Anchor diameter: 4.5mm, 5.5mm, 6.5mm Anchor length: 19.2mm, 19.4mm, 19.5mm Suture size: #2 suture **K152566** (OBL Preloaded Series Anchor) Anchor diameter: 2.0mm Anchor length: 6.8mm Suture size: #3-0 suture, #2-0 suture	Substantially equivalent.
Sterilization	EO sterilization	EO sterilization, Irradiation sterilization	Substantially equivalent, 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	Implant the anchor into the bone to form an anchorage with the bone. The suture connected to the anchor can	Identical as predicate device.

	re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	re-suture and fix the soft tissues such as tendons and ligaments, so that they can be re-fixed on the surface of bone.	
Environment of Use	Hospitals/clinics	Hospitals/clinics	Identical as predicate device.

Table 2 Substantial equivalence discussion - Javelot Ti-D Suture Anchor

Characteristics	**Subject Device (Javelot Ti-D Suture Anchor)**	**Predicate Device** **K152566**, PeBA Anchor/ Suture Combination (Primary Predicate) **K053344**, TwinFix 2.8mm, 3.5mm and BioRaptor 2.9mm Suture Anchors (Reference Device)	**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.
Indications for use	The Javelot Ti and Javelot Ti-D Suture Anchor are intended for connection and fixation of soft tissue to bone in the knee, hip, shoulder, elbow, ankle, foot, wrist and hand for the following indications: **Shoulder:** • Bankart lesion repair • SLAP lesion repair • Acromio-clavicular separation repair	**Primary Predicate:** The PeBA Series Anchor/ Suture (**K152566**) Combination is intended for the fixation of surgical suture material for the following indications: **Shoulder:** Bankart lesion repairs, SLAP lesion repairs, Acromio-clavicular separation repairs, Rotator cuff tear repairs,	Substantially equivalent.

	• Rotator cuff tear repair • Capsular shift or capsulolabral reconstruction • Biceps tenodesis • Deltoid repair **Foot and Ankle:** • Hallux valgus repair • Medial or lateral instability repair/reconstruction • Achilles tendon repair/reconstruction • Midfoot reconstruction • Metatarsal ligament/tendon repair/reconstruction **Elbow, Wrist and Hand:** • Ulnar or radial collateral ligament reconstruction • Lateral epicondylitis repair • Biceps tendon reattachment • Scapholunate ligament reconstrontion (not for 4.5-6.5mm pro anchors) **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 **Hip: (2.8-6.5mm anchors only)**	Capsular shift or capsulolabral reconstructions, Biceps tenodesis, Deltoid repairs **Foot and Ankle:** Hallux valgus repairs, Medial or lateral instability repairs, Achilles tendon repairs/ reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions **Elbow, Wrist, and Hand:** Scapholunate ligament reconstructions, 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, including vastus medialis obliquous advancement **Reference Device:** TwinFix Ti 2.8 & 3.5mm Suture Anchor (**K053344**) is intended for use for the reattachment of soft tissue to bone for the following indications:	

	• Capsular repair Acetabular labral repair	**Shoulder:** Bankart lesion repairs, SLAP lesion repairs, Acromio-clavicular separation repairs, Rotator cuff tear repairs, Capsular shift or capsulolabral reconstructions, Biceps tenodesis, Deltoid repairs, Anterior Shoulder Instability Repair **Foot and Ankle:** Hallux valgus repairs, Medial or lateral instability repairs, 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, including vastus medialis obliquous advancement **Hip:** Capsular repair, Acetabular	

		labral repair	
Composition	Implantable parts: anchor, suture Non-implantable parts: inserter, needle	Implantable parts: anchor, suture Non-implantable parts: inserter, needle	Identical as predicate device.
Key Patient Contacting Material	Anchor: Titanium alloy TI6AL4VELI Suture: UHMWPE	Anchor: Titanium alloy TI6AL4VELI Suture: UHMWPE	Substantially equivalent.
Anchor picture	  	  	Similar as predicate device.
Anchor thread	Double thread	Double thread	Identical as predicate device.
Dimensional Verification	Anchor diameter: 2.8mm, 3.5mm, 5.0mm, 6.5mm Anchor length: 8.9mm, 13.2mm, 15.7mm, 18.9mm Suture size: #2-0 suture, #2 suture	Anchor diameter: 2.8mm, 3.5mm, 5.0mm, 6.5mm Anchor length: 8.9mm, 13.2mm, 15.7mm, 18.9mm Suture size: #2-0 suture, #2 suture	Substantially equivalent.
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 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 metallic surgical implants.

We have complied with the following material standards:

ISO 5832-3:2021 Implants for surgery - Metallic materials Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

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

ASTM F899-20: Standard Specification for Wrought Stainless Steels for Surgical Instruments

ASTM F702-18: Standard Specification for Polysulfone Resin for Medical Applications

Biocompatibility testing

Biocompatibility of the Javelot titanium suture anchor 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.

The Subject devices are not labeled as non-pyrogenic or pyrogen free.

Mechanical performance testing

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

1. Insertion torque
2. Failure torque
3. Static pullout strength
4. Cyclic pullout strength

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 anchors of Javelot titanium suture anchors have been evaluated for safety in the MR environment. These titanium anchors were evaluated based on the FDA Guidance Document – *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* and applicable ASTM standards, and worst-case devices were selected for testing. Devices were tested for magnetically induced force, magnetically induced torque, heating by RF fields, and image artifact.

The sutures of Javelot titanium suture anchors are MR safe as 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.

VIII Conclusion

The Javelot titanium suture anchor is 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.