August 29, 2024

Ortho-Design (Pty) Ltd
Dian Peach
Managing Director
17 Dely Road
Hazelwood, Pretoria 0081
South Africa

Re: K242296
Trade/Device Name: VersaTap™ Suture Anchor (ADP050); VersaPEEK™ Suture Anchor (APP002); MicroTi™ Suture Anchor (ATP003-M); VersaLat™ Ti Suture Anchor (ADP021-TI); VersaLat™ Suture Anchor (ADP021-PK)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 3, 2024
Received: August 2, 2024

Dear Dian Peach:

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,

Christopher Ferreira -S

Christopher Ferreira, MS
Assistant Director, Biomedical Engineer
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242296

Device Name

VersaTap™ Suture Anchor (ADP050);
VersaPEEK™ Suture Anchor (APP002);
MicroTi™ Suture Anchor (ATP003-M);
VersaLat™ Ti Suture Anchor (ADP021-TI);
VersaLat™ Suture Anchor (ADP021-PK)

Indications for Use *(Describe)*

VersaTap™ Suture Anchor

The VersaTap™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The VersaTap™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as:

- Shoulder: Rotator cuff repair, biceps tenodesis, SLAP repair, Bankart repair
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus
- Elbow: Tennis elbow repair
- Knee: Medial and lateral collateral ligament repair.
- Wrist: Scapholunate ligament reconstruction

VersaPEEK™ Suture Anchor

The VersaPEEK™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The VersaPEEK™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as:

- Shoulder: Rotator cuff repair, biceps tenodesis, SLAP repair, Bankart repair
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus
- Elbow: Tennis elbow repair
- Knee: Medial and lateral collateral ligament repair.
- Wrist: Scapholunate ligament reconstruction

MicroTi™ Suture Anchor

The MicroTi™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The MicroTi™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as:

- Elbow: Ulnar/Medial Collateral Ligament Repair
- Foot/Ankle: Achilles Tendon Repair, Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-foot Reconstruction, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.
- Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/ Radial Collateral Ligament Reconstruction.

VersaLat™ Ti Suture Anchor

The VersaLat™ Ti Suture Anchor is intended to use for fixation of soft tissue and ligaments to bone/ healthy tissue during tendon and ligament repairs, during procedures such as:

• Shoulder: Rotator Cuff Repair, Biceps Tenodesis
• Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction.
• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis
• Foot/Ankle: Lateral stabilization, medial stabilization, Achilles tendon repair, mid-foot reconstruction, hallux valgus reconstruction, metatarsal ligament repair, metatarsal tendon repair, bunionectomy, and digital tendon transfers.

VersaLat™ Suture Anchor

The VersaLat™ Suture Anchor is intended to use for fixation of soft tissue and ligaments to bone/ healthy tissue during tendon and ligament repairs, during procedures such as:

• Shoulder: Rotator Cuff Repair, Biceps Tenodesis
• Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction.
• Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis.
• Foot/Ankle: Lateral stabilization, medial stabilization, Achilles tendon repair, mid-foot reconstruction, hallux valgus reconstruction, metatarsal ligament repair, metatarsal tendon repair, bunionectomy, and digital tendon transfers.

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

The following information is provided in accordance with 21CFR 807.92 for the Premarket 510(k) Summary:

Submitter Information: Ortho-Design (Pty) Ltd
17 Dely Road
Hazelwood, Pretoria, 0081 South Africa

Date: 26 August 2024

Contact Person: Dian Peach, Managing Director
Telephone: (+27) 12 807 1902
Email: dianpeach@ortho-design.co.za

Table 1: Subject devices and their respective submission K212381 predicate devices.

K212381	The enclosed submission
VersaTap™ Suture Anchor	VersaTap™ Suture Anchor (Device A)
	VersaPEEK™ Suture Anchor (Device B)
MiniTi™ Suture Anchor	MicroTi™ Suture Anchor (Device C)
VersaLat™ Suture Anchor	VersaLat™ Ti Suture Anchor (Device D)
	VersaLat™ Suture Anchor (Device E)

Table 2: DEVICE A – VersaTap™ Suture Anchor

	Subject Device	Predicate Device (Cleared in K212381)
Device Trade Name:	VersaTap™ Suture Anchor	VersaTap™ Suture Anchor (Cleared in K212381)
Regulation Description:	Smooth or threaded metallic bone fixation fastener.	Smooth or threaded metallic bone fixation fastener.
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number:	21 CFR 888.3040	21 CFR 888.3040
Device Classification:	Class II	Class II
Product Code:	MBI	MBI
Reference Device(s):	KINSA RC Suture Anchor (K070908), manufactured by Smith & Nephew	K061665; K173788; K063453, K130274, K070758

Device Description:	The VersaTap™ Suture Anchor is a self-tapping suture anchor. This anchor is designed to combine the advantages of both PEEK and Titanium. The titanium tip makes the product self-tapping, whilst the majority of the anchor is manufactured from PEEK to minimize post-operative imaging effects.	The VersaTap™ Suture Anchor is a self-tapping suture anchor mostly used as a medial row anchor in rotator cuff repair surgery. This anchor is ingeniously designed to combine the advantage of both PEEK and Titanium. The titanium tip allows for self-tapping ability whilst the majority of the anchor is manufactured from PEEK which minimizes post-operative imaging effects.
Indications for Use:	The VersaTap™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The VersaTap™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator cuff repair, biceps tenodesis, SLAP repair, Bankart repair • Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus • Elbow: Tennis elbow repair • Knee: Medial and lateral collateral ligament repair. • Wrist: Scapholunate ligament reconstruction.	The VersaTap™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The VersaTap™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator cuff repair, biceps tenodesis, SLAP repair, Bankart repair • Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus • Elbow: Tennis elbow repair • Knee: Medial and lateral collateral ligament repair. • Wrist: Scapholunate ligament reconstruction
Relationship to the Device:	The subject and predicate devices (cleared in K212381) have the same intended use, materials, function, packaging, and similar design features.	

Technological Differences:	The subject and predicate devices (cleared in K212381) have similar engineering designs with minor dimensional changes. The subject device has a reduced diameter and a reduced length compared to the predicate device (cleared in K212381).
Clinical Characteristics:	The subject and predicate devices (cleared in K212381) are intended to be used for soft tissue fixation during general orthopedic surgery.
Technical Equivalence:	The subject and predicate devices (cleared in K212381) have similar designs, development methods, principles of operations and performance.
Mechanical Testing and Disclosure of Performance and Safety Deviation:	Substantial equivalence is supported by the results of mechanical testing including insertion torque and static pullout testing, and by justification for dynamic pullout (fatigue), component interconnection, and corrosion testing according to the FDA Guidance: 'Bone Anchors - Premarket Notification (510(k)) Submissions'. Ortho-Design's suture anchors support safety and effectiveness and can be considered substantially equivalent to the predicate device (cleared in K212381).
Biocompatibility:	The subject and predicate devices (cleared in K212381) are manufactured using the same approved suppliers, manufacturing facilities, manufacturing processes, chemicals, materials, and cleaning processes. All manufacturing is conducted according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have been used in the previously cleared device(s). Therefore biocompatibility of the subject device is substantially equivalent to the predicate device. The subject devices have been tested to be non-pyrogenic.

Quality Control Measures	For both the subject and predicate device (cleared in K212381) the methods, thresholds and criteria of the following are identical: • Sterility • Self-Life • Packaging • Pyrogenicity / Endotoxin Testing
Conclusion:	The subject device demonstrates substantial equivalence by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests and adheres to the minimum requirements set out in FDA's guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions.

Table 3: DEVICE B – VersaPEEK™ Suture Anchor

	Subject Device	Predicate Device (Cleared in K212381)
Device Trade Name:	VersaPEEK™ Suture Anchor	VersaTap™ Suture Anchor (Cleared in K212381)
Regulation Description:	Smooth or threaded metallic bone fixation fastener.	Smooth or threaded metallic bone fixation fastener.
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number:	21 CFR 888.3040	21 CFR 888.3040
Device Classification:	Class II	Class II
Product Code:	MBI	MBI
Reference Device(s):	KINSA RC Suture Anchor (K070908), manufactured by Smith & Nephew	K061665; K173788; K063453, K130274, K070758
Device Description:	The VersaPEEK™ Suture Anchor is manufactured completely from PEEK. This material composition minimizes post-operative imaging effects. The suture anchor is designed for ultimate mechanical properties (pullout strength, tensile strength, etc). The VersaPEEK™ Suture Anchor also has a variety of suture/suture tape configurations.	The VersaTap™ Suture Anchor is a self-tapping suture anchor mostly used as a medial row anchor in rotator cuff repair surgery. This anchor is ingeniously designed to combine the advantage of both PEEK and Titanium. The titanium tip allows for self-tapping ability whilst the majority of the anchor is manufactured from PEEK which minimizes post-operative imaging effects.
Indications for Use:	The VersaPEEK™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The VersaPEEK™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator cuff repair, biceps tenodesis, SLAP repair, Bankart repair.	The VersaTap™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The VersaTap™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator cuff repair, biceps tenodesis,

	• Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus • Elbow: Tennis elbow repair. • Knee: Medial and lateral collateral ligament repair. • Wrist: Scapholunate ligament reconstruction. *The above-mentioned indications for use are identical to those of the predicate device, VersaTap™ Suture Anchor, cleared in submission K212381.	SLAP repair, Bankart repair • Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus • Elbow: Tennis elbow repair • Knee: Medial and lateral collateral ligament repair. • Wrist: Scapholunate ligament reconstruction
Relationship to the Device:	The subject and predicate devices (cleared in K212381) have the same intended use, materials, function, packaging, and similar design features.	
Technological Differences:	The subject and predicate devices (cleared in K212381) have similar engineering designs and minor dimensional changes. The subject device has a reduced diameter compared to the predicate device (cleared in K212381). The subject device is also composed fully composed of PEEK whereas the predicate device (cleared in K212381) is composed of a PEEK body and a titanium tip.	
Clinical Characteristics:	The subject and predicate device (cleared in K212381) are intended to be used for soft tissue fixation during general orthopedic surgery.	
Technical Equivalence:	The subject and predicate devices (cleared in K212381) have similar designs, development methods, principles of operations and performance.	
Mechanical Testing and Disclosure of Performance and Safety Deviation:	Substantial equivalence is supported by the results of mechanical testing including insertion torque and static pullout testing, and by justification for dynamic pullout (fatigue), component interconnection, and corrosion testing according to the FDA Guidance: 'Bone Anchors - Premarket Notification (510(k)) Submissions'. Ortho-Design's suture anchors support safety and effectiveness and can be considered substantially equivalent to the predicate device (cleared in K212381).	

Biocompatibility:	The subject and predicate devices (cleared in K212381) are manufactured using the same approved suppliers, manufacturing facilities, manufacturing processes, chemicals, materials, and cleaning processes. All manufacturing is conducted according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have been used in the previously cleared device(s). Therefore biocompatibility of the subject device is substantially equivalent to the predicate device. The subject devices have been tested to be non-pyrogenic.
Quality Control Measures	For both the subject and predicate device (cleared in K212381) the methods, thresholds and criteria of the following are identical: • Sterility • Self-Life • Packaging • Pyrogenicity / Endotoxin Testing
Conclusion:	The subject device demonstrates substantial equivalence by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests and adheres to the minimum requirements set out in FDA's guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions.

Table 4: DEVICE C – MicroTi™ Suture Anchor

	Subject Device	Predicate Device (Cleared in K212381)
Device Trade Name:	MicroTi™ Suture Anchor	MiniTi™ Suture Anchor (Cleared in K212381)
Regulation Description:	Smooth or threaded metallic bone fixation fastener.	Smooth or threaded metallic bone fixation fastener.
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number:	21 CFR 888.3040	21 CFR 888.3040
Device Classification:	Class II	Class II
Product Code:	MBI	MBI
Reference Device:	Depuy Mitek QuickAnchor (K071257)	K061665; K111000; K173788; K063453, K200523, K070758
Device Description:	The MicroTi™ Suture Anchor is a small screw-in suture anchor used in a variety of small-joint applications. Despite its small diameter, the specially engineered thread combines with cortical bone to provide tremendous pull-out strength.	The MiniTi™ Suture Anchor is a small screw-in suture anchor used in a variety of small-joint applications. Despite its small diameter, the specially engineered thread combines with cortical bone to provide tremendous pull-out strength.
Indications for Use:	The MicroTi™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The MicroTi™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Elbow: Ulnar/Medial Collateral Ligament Repair. • Foot/Ankle: Achilles Tendon Repair, Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid-foot Reconstruction, Hallux Valgus Reconstruction,	The MiniTi™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The MiniTi™ Suture Anchor is intended for use in arthroscopic or open surgical approaches for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Elbow: Ulnar/Medial Collateral Ligament Repair • Foot/Ankle: Achilles Tendon Repair, Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Mid- foot Reconstruction, Hallux Valgus Reconstruction,

	Metatarsal Ligament Repair. • Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/ Radial Collateral Ligament Reconstruction. *The above-mentioned indications for use are identical to those of the predicate device, MiniTi™ Suture Anchor, cleared in submission K212381.	Metatarsal Ligament Repair. • Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/ Radial Collateral Ligament Reconstruction.
Relationship to the Device:	The subject and predicate devices (cleared in K212381) have the same intended use, materials, function, packaging, and similar design features.	
Technological Differences:	The subject and predicate devices (cleared in K212381) have similar engineering designs and minor dimensional changes. The subject device has a reduced diameter compared to the predicate device (cleared in K212381).	
Clinical Characteristics:	The subject and predicate devices (cleared in K212381) are intended to be used for soft tissue fixation during general orthopedic surgery.	
Technical Equivalence:	The subject and predicate devices (cleared in K212381) have similar designs, development methods, principles of operations and safety performance.	
Mechanical Testing and Disclosure of Performance and Safety Deviation:	Substantial equivalence is supported by the results of mechanical testing including insertion torque and static pullout testing, and by justification for dynamic pullout (fatigue), component interconnection, and corrosion testing according to the FDA Guidance: 'Bone Anchors - Premarket Notification (510(k)) Submissions'. Ortho-Design's suture anchors support safety and effectiveness and can be considered substantially equivalent to the predicate device (cleared in K212381).	

Biocompatibility:	The subject and predicate devices (cleared in K212381) are manufactured by the same approved suppliers, and use the same manufacturing facilities, manufacturing processes, chemicals, materials, and cleaning processes. All manufacturing is conducted according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have been used in the previously cleared device(s). Therefore biocompatibility of the subject device is substantially equivalent to the predicate device. The subject devices have been tested to be non-pyrogenic.
Quality Control Measures	For both the subject and predicate device (cleared in K212381) the methods, thresholds and criteria of the following are identical: • Sterility • Self-Life • Packaging • Pyrogenicity / Endotoxin Testing
Conclusion:	The subject device demonstrates substantial equivalence by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests and adheres to the minimum requirements set out in FDA's guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions.

Table 5: DEVICE D – VersaLat™ Ti Suture Anchor

	Subject Device	Predicate Device (Cleared in K212381)
Device Trade Name:	VersaLat™ Ti Suture Anchor	VersaLat™ Suture Anchor (Cleared in K212381)
Regulation Description:	Smooth or threaded metallic bone fixation fastener.	Smooth or threaded metallic bone fixation fastener.
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number:	21 CFR 888.3040	21 CFR 888.3040
Device Classification:	Class II	Class II
Product Code:	MBI	MBI
Predicate Device:	VersaLat™ Suture Anchor (K212381), manufactured by Ortho-Design (Pty) Ltd	DePuy Mitek Healix Advance Knotless BR Anchor (K130917)
Reference Device:	K151342 - Arthrex Swivelock Anchors	K190728; K203495; K130274 K070758
Device Description:	The VersaLat™ Ti Suture Anchor is a knotless-/suture anchor. This titanium screw-in anchor can be combined with the VersaTap™ Suture Anchor in double rotator cuff repair surgery. Flexibility is what differentiates this anchor from its competitors with surgeons being able to fixate any number of sutures/tapes (K150438) by adjusting the size of the characteristic front loop. The extra suture provided by this anchor can also be used for the fixation of the biceps tendon or any ligament fragments.	The VersaLat™ Suture Anchor is an innovative knotless-/suture anchor inspired by a top orthopedic shoulder surgeon. This PEEK screw-in anchor can be combined with the VersaTap™ Suture Anchor in double rotator cuff repair surgery. Flexibility is what differs this anchor from its competitors with surgeons being able to fixate any number of sutures/tapes (K150438) by adjusting the size of the characteristic front loop. The extra suture provided by this anchor can also be used for the fixation of the biceps tendon or any ligament fragments
Indications for Use:	The VersaLat™ Ti Suture Anchor is intended to use for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator Cuff Repair, Biceps Tenodesis	The VersaLat™ Suture Anchor is intended to use for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator Cuff Repair, Biceps Tenodesis

	• Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction. • Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis • Foot/Ankle: Lateral stabilization, medial stabilization, Achilles tendon repair, mid-foot reconstruction, hallux valgus reconstruction, metatarsal ligament repair, metatarsal tendon repair, bunionectomy, and digital tendon transfers.	• Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction. • Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis.
Relationship to the Device:	The subject and predicate devices (cleared in K212381) have the same intended use, materials, function, packaging, and similar design features.	
Technological Differences:	The subject and predicate devices (cleared in K212381) have similar engineering designs and minor dimensional changes. The subject device has a reduced diameter and an increased length compared to the predicate device (cleared in K212381). The subject devices also features a titanium threaded body whereas the predicate device features a PEEK threaded body.	
Clinical Characteristics:	The subject and predicate devices (cleared in K212381) are intended to be used for soft tissue fixation during general orthopedic surgery.	
Technical Equivalence:	Both the subject and predicate devices (cleared in K212381) have similar designs, development methods, principles of operations and safety performance.	
Mechanical Testing and Disclosure of Performance and Safety Deviation:	Substantial equivalence is supported by the results of mechanical testing including insertion torque and static pullout testing, and by justification for dynamic pullout (fatigue), component interconnection, and corrosion testing according to the FDA Guidance: 'Bone Anchors - Premarket Notification (510(k)) Submissions'. Ortho-Design's suture anchors support safety and effectiveness and can be considered substantially equivalent to the predicate device (cleared in K212381).	

Biocompatibility:	The subject and predicate devices (cleared in K212381) are manufactured by the same approved suppliers, and use the same manufacturing facilities, manufacturing processes, chemicals, materials, and cleaning processes. All manufacturing is conducted according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have been used in the previously cleared device(s). Therefore biocompatibility of the subject device is substantially equivalent to the predicate device. The subject devices have been tested to be non-pyrogenic.
Quality Control Measures	For both the subject and predicate device (cleared in K212381) the methods, thresholds and criteria of the following are identical: • Sterility • Self-Life • Packaging • Pyrogenicity / Endotoxin Testing
Conclusion:	The subject device demonstrates substantial equivalence by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests and adheres to the minimum requirements set out in FDA's guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions.

Table 6: DEVICE E – VersaLat™ Suture Anchor

	Subject Device	Predicate Device (Cleared in K212381)
Device Trade Name:	VersaLat™ Suture Anchor	VersaLat™ Suture Anchor (Cleared in K212381)
Regulation Description:	Smooth or threaded metallic bone fixation fastener.	Smooth or threaded metallic bone fixation fastener.
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue	Fastener, Fixation, Nondegradable, Soft Tissue
Regulation Number:	21 CFR 888.3040	21 CFR 888.3040
Device Classification:	Class II	Class II
Product Code:	MBI	MBI
Predicate Device:	VersaLat™ Suture Anchor (K212381), manufactured by Ortho-Design (Pty) Ltd	DePuy Mitek Healix Advance Knotless BR Anchor (K130917)
Reference Device:	K151342 - Arthrex Swivelock Anchors	K190728; K203495; K130274 K070758
Device Description:	The VersaLat™ Suture Anchor is a knotless-/suture anchor. This titanium screw-in anchor can be combined with the VersaTap™ Suture Anchor in double rotator cuff repair surgery. Flexibility is what differentiates this anchor from its competitors with surgeons being able to fixate any number of sutures/tapes (K150438) by adjusting the size of the characteristic front loop. The extra suture provided by this anchor can also be used for the fixation of the biceps tendon or any ligament fragments.	The VersaLat™ Suture Anchor is an innovative knotless-/suture anchor inspired by a top orthopedic shoulder surgeon. This PEEK screw-in anchor can be combined with the VersaTap™ Suture Anchor in double rotator cuff repair surgery. Flexibility is what differs this anchor from its competitors with surgeons being able to fixate any number of sutures/tapes (K150438) by adjusting the size of the characteristic front loop. The extra suture provided by this anchor can also be used for the fixation of the biceps tendon or any ligament fragments
Indications for Use:	The VersaLat™ Suture Anchor is intended to use for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator Cuff Repair, Biceps Tenodesis	The VersaLat™ Suture Anchor is intended to use for fixation of soft tissue and ligaments to bone/healthy tissue during tendon and ligament repairs, during procedures such as: • Shoulder: Rotator Cuff Repair, Biceps Tenodesis

	• Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction. • Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis • Foot/Ankle: Lateral stabilization, medial stabilization, Achilles tendon repair, mid-foot reconstruction, hallux valgus reconstruction, metatarsal ligament repair, metatarsal tendon repair, bunionectomy, and digital tendon transfers.	• Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction. • Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis.
Relationship to the Device:	The subject and predicate devices (cleared in K212381) have the same intended use, materials, function, packaging, and similar design features.	
Technological Differences:	The subject and predicate devices (cleared in K212381) have similar engineering designs and minor dimensional changes. The subject device has a reduced diameter and an increased length compared to the predicate device (cleared in K212381).	
Clinical Characteristics:	The subject and predicate devices (cleared in K212381) are intended to be used for soft tissue fixation during general orthopedic surgery.	
Technical Equivalence:	The subject and predicate devices (cleared in K212381) have similar designs, development methods, principles of operations and safety performance.	
Mechanical Testing and Disclosure of Performance and Safety Deviation:	Substantial equivalence is supported by the results of mechanical testing including insertion torque and static pullout testing, and by justification for dynamic pullout (fatigue), component interconnection, and corrosion testing according to the FDA Guidance: 'Bone Anchors - Premarket Notification (510(k)) Submissions'. Ortho-Design's suture anchors support safety and effectiveness and can be considered substantially equivalent to the predicate device (cleared in K212381).	

Biocompatibility:	The subject and predicate devices (cleared in K212381) are manufactured by the same approved suppliers, and use the same manufacturing facilities, manufacturing processes, chemicals, materials, and cleaning processes. All manufacturing is conducted according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have been used in the previously cleared device(s). Therefore biocompatibility of the subject device is substantially equivalent to the predicate device. The subject devices have been tested to be non-pyrogenic.
Quality Control Measures	For both the subject and predicate device (cleared in K212381) the methods, thresholds and criteria of the following are identical: • Sterility • Self-Life • Packaging • Pyrogenicity / Endotoxin Testing
Conclusion:	The subject device demonstrates substantial equivalence by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests and adheres to the minimum requirements set out in FDA's guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions.