December 6, 2021

Ortho-Design (Pty) Ltd
℅ Daniel Johnson
Senior Design Engineer
JALEX Medical
27865 Clemens Rd. Suite 3
Westlake, Ohio 44145

Re: K212381
Trade/Device Name: VersaTap™ Suture Anchor, VersaLat™ Suture Anchor, DueLock™ Suture Anchor, VersaTi™ Suture Anchor, MiniTi™ 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: July 23, 2021
Received: August 2, 2021

Dear Daniel Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely,

for

Laura C. Rose, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212381

Device Name
VersaTap™ Suture Anchor
VersaLat™ Suture Anchor
DueLock™ Suture Anchor
VersaTi™ Suture Anchor
MiniTi™ Suture Anchor

Indications for Use *(Describe)*

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 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

The DueLock™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The DueLock™ 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, Bankart Repair, SLAP Lesion Repair, Capsular Shift and Capsulolabral Reconstruction, Subscapularis Tendon Tears
Elbow: Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair
Foot/Ankle: Lateral Stabilization, Medial Stabilization, Mid-foot Reconstruction, Hallux Valgus Reconstruction, Metatarsal Ligament Repair, Metatarsal Tendon Repair.
Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/ Radial Collateral Ligament Reconstruction.
Hip: Acetabular labral repair.

The VersaTi™ 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, Joint capsule closure
Wrist: Scapholunate ligament reconstruction
Hip: Capsular Repair, acetabular labral repair

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.

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 21 CFR 807.92 for the Premarket 510(k) Summary:

Submitter Information:	Ortho-Design (Pty) Ltd 472 Botterklapper Street Die Wilgers, Pretoria, 0184 South Africa
Date:	01/12/2021
Contact Person:	Dian Peach, Managing Director
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DEVICE A

Device Trade Name:	VersaTap™ Suture Anchor
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Classification Name:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Device Classification:	Class II
Product Code:	MBI
Primary Predicate Device:	Parcus Twist PEEK Suture Anchor (K120942)
Secondary Predicates:	Arthrex FT Suture Anchor (K061665) Arthrex 6.5mm x 14.7mm PEEK Corkscrew FT Suture Anchor (K173788)
Reference Devices:	K063453, K130274, K070758

Device description:

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:

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- 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

Predicate device comparison:

Primary Predicate Device Manufacturer:	Parcus Medical, LLC 6423 Parkland Drive Sarasota, FL USA 34243
Relationship to the device:	Similar intended use, materials, design features, dimensions, and function as the VersaTap™ Suture Anchor
Technological Differences:	Proposed modifications consist of a smaller diameter, shorter length, additional material (self-tapping titanium tip), and minor dimensional changes.
Regulatory Status:	FDA Cleared – K120942

Clinical Characteristics:

Suture Anchors are intended to be used for soft tissue fixation during general orthopedic surgery.

Disclosure of performance and safety deviation: None

Technical Equivalence:

Similar design:	Yes, except for the tip of the VersaTap being made of titanium
Similar deployment methods:	Yes
Similar principles of operation and critical performance requirements:	Yes
Disclosure of performance and safety deviation:	No characteristics
Similar materials or substances in contact with the same human tissues:	Yes
Disclosure of performance and safety deviation:	Yes

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Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing including static pull-out, insertion torque, fatigue, and corrosion testing as per FDA Guidance Document: Bone Anchors—Premarket Notification (510(k)) Submissions. This testing was done on the subject device and the primary predicate device. The comparison shows that the subject device has similar or improved pull out force compared to the primary predicate.

Biocompatibility:

The reference devices selected for biocompatibility evaluation (510(k) numbers) are manufactured by Elite Surgical Supplies, at the same manufacturing facility producing the subject devices, using the same manufacturing processes, chemicals, materials, and cleaning processes as the subject devices. An OEM manufacturing contract is in place between Elite Surgical Supplies and Ortho-Design, stating that all manufacturing done for Ortho-Design, by Elite Surgical Supplies, is done according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have previously been cleared by the FDA for the reference device.

Sterility:

After reviewing the results of the IQ, OQ and PQ results, it can be concluded that the Overkill Method was successfully conducted in order to achieve a SAL of 10-6 based on the parameters and tolerances identified during the validation study.

Shelf-Life:

The VersaTap™ Suture Anchor has a shelf-life of 3 years, which has been validated with accelerated aging techniques listed above in 016_Sterilization and Shelf-Life Table 2. Real-time aging is being conducted and the design history file will be updated with this information when completed. The implant components are manufactured from PEEK OPTIMA conforming to ASTM F2026 and Titanium Alloy conforming to ASTM F136. All materials have been historically used in implant devices and have demonstrated not to be mechanically affected by aging within the 3 year shelf life , so no additional aging testing is required for the implants.

Packaging:

The VersaTap™ Suture Anchor will be boxed individually in EtO sterilized double peel pouches to allow for easy transfer into the sterile operative field. Both the inner and outer pouch is a 60g/m_2 medical plastic film and paper peel pouch. Each package includes external package labeling, an instruction leaflet, and individual patient labels. Instruments are provided non-sterile in steam sterilization trays separately from the implants.

Endotoxin/pyrogenicity:

The device has been tested to be non-pyrogenic.

Conclusion:

From the non-clinical testing results and summaries, it is clear that the VersaTap™ Suture Anchor demonstrates substantial equivalence and adheres to minimum requirements set out in the guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions laid out by the FDA. This was demonstrated by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests.

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DEVICE B

Device Trade Name:	VersaLat™ Suture Anchor
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Classification Name:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Device Classification:	Class II
Product Code:	MBI
Primary Predicate Device:	DePuy Mitek Healix Advance Knotless BR Anchor (K130917)
Secondary Predicates:	Arthrex Swivelock (K190728) Arthex Swivelock SP 5.5 x 24.5mm – AR-2323SLM (K203495)
Reference devices:	K130274, K070758

Device description:

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
- Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction.
- Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, and Iliotibial Band Tenodesis

Predicate device comparison:

Primary Predicate Device Manufacturer:	DePuy 325 Paramount Dr Raynham, MA 02767
Relationship to the device:	Similar intended use, design features, dimensions, and function as the VersaLat™ Suture Anchor
Technological Differences	Similar design, indications for use, and engineering principles with

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addition of small titanium tip and sutures loop, instead of eyelid, for insertion of external sutures.

Regulatory Status: FDA cleared – K130917

Clinical Characteristics:

Suture Anchors are intended to be used for soft tissue fixation during general orthopedic surgery.

Disclosure of performance and safety deviation: None

Technical Equivalence:

Similar design: Yes

Similar deployment methods: Yes

Similar principles of operation and critical performance requirements: Yes

Disclosure of performance and safety deviation: No characteristics

Similar materials or substances in contact with the same human tissues: Yes

Disclosure of performance and safety deviation: Yes

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing including static pull-out, insertion torque, fatigue, and corrosion testing as per FDA Guidance Document: Bone Anchors—Premarket Notification (510(k)) Submissions. This testing was done on the subject device and compared to the data found in literature (Cyclic Biomechanical Testing of Biocomposite Lateral Row Knotless Anchors in a Human Cadaveric Model, A. Barberl et al, 2013, p3, Table 1). The comparison shows that the subject device has similar or improved pull out force compared to the primary predicate.

Biocompatibility:

The reference devices selected for biocompatibility evaluation (510(k) numbers) are manufactured by Elite Surgical Supplies, at the same manufacturing facility producing the subject devices, using the same manufacturing processes, chemicals, materials, and cleaning processes as the subject devices. An OEM manufacturing contract is in place between Elite Surgical Supplies and Ortho-Design, stating that all manufacturing done for Ortho-Design, by Elite Surgical Supplies, is done according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have previously been cleared by the FDA for the reference device.

Sterility:

After reviewing the results of the IQ, OQ and PQ results, it can be concluded that the Overkill Method was successfully conducted in order to achieve a SAL of 10-6 based on the parameters and tolerances identified during the validation study.

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Shelf-Life:

The VersaLat™ Suture Anchor has a shelf-life of 3 years, which has been validated with accelerated aging techniques listed above in 016_Sterilization and Shelf-Life Table 2. Real-time aging is being conducted and the design history file will be updated with this information when completed. The implant components are manufactured from PEEK OPTIMA conforming to ASTM F2026 and Titanium Alloy conforming to ASTM F136. All materials have been historically used in implant devices and have demonstrated not to be mechanically affected by aging within the 3 year shelf life, so no additional aging testing is required for the implants.

Packaging:

The VersaLat™ Suture Anchor will be boxed individually in EtO sterilized double peel pouches to allow for easy transfer into the sterile operative field. Both the inner and outer pouch is a 60g/m_2 medical plastic film and paper peel pouch. Each package includes external package labeling, an instruction leaflet, and individual patient labels. Instruments are provided non-sterile in steam sterilization trays separately from the implants.

Endotoxin/pyrogenicity:

The device has been tested to be non-pyrogenic.

Conclusion:

From the non-clinical testing results and summaries, it is clear that the VersaLat™ Suture Anchor demonstrates substantial equivalence and adheres to minimum requirements set out in the guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions laid out by the FDA. This was demonstrated by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests.

DEVICE C

Device Trade Name:	DueLock™ Suture Anchor
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Classification Name:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Device Classification:	Class II
Product Code:	MBI
Primary Predicate Device:	Arthrex PEEK Mini Pushlock Anchor (K201786)
Secondary Predicates:	Arthrex PEEK Pushlock (K101679) Parcus Knotless PEEK CF Push-in 3.5 x 10mm – 10313 (K193295) Smith and Nephew 2.9mm BioRaptor (K121018)
Reference Devices:	K130274, K070758

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Device description:

The DueLock™ Suture Anchor is a flexible anchor that combines the functionality of two conventional push-in anchors into one multi-purpose suture anchor. This anchor can be used as a knotless suture anchor as well as a push-in, pre-loaded suture anchor used in both small and large-joint repairs.

Indications for Use:

The DueLock™ Suture Anchor is intended to be used for soft tissue fixation during general orthopedic surgery. The DueLock™ 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, Bankart Repair, SLAP Lesion Repair, Capsular Shift and Capsulolabral Reconstruction, Subscapularis Tendon Tears
- Elbow: Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair
- Foot/Ankle: Lateral Stabilization, Medial Stabilization, Mid-foot Reconstruction, Hallux Valgus Reconstruction, Metatarsal Ligament Repair, Metatarsal Tendon Repair.
- Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/ Radial Collateral Ligament Reconstruction.
- Hip: Acetabular labral repair.

Predicate device comparison:

Primary Predicate Device Manufacturer:	Arthrex Inc.Orbison Street 1370 Creekside Boulevard Naples, Florida 34108-1945
Relationship to the device:	Similar intended use, materials, design features, dimensions, and function as the DueLock Suture Anchor
Technological Differences:	Proposed modifications consist of a shorter length and minor dimensional changes.
Regulatory Status:	FDA Cleared – K201786

Clinical Characteristics:

Suture Anchors are intended to be used for soft tissue fixation during general orthopedic surgery.

Disclosure of performance and safety deviation: None

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Technical Equivalence:

Similar design:	Yes
Similar deployment methods:	Yes
Similar principles of operation and critical performance requirements:	Yes
Disclosure of performance and safety deviation:	No characteristics
Similar materials or substances in contact with the same human tissues:	Yes
Disclosure of performance and safety deviation:	Yes

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing including static pull-out, insertion torque, fatigue and corrosion testing as per FDA Guidance Document: Bone Anchors—Premarket Notification (510(k)) Submissions. This testing was done on the subject device and compared to the data found in literature (Pull-out Strength of Various Knotless Hip Suture Anchors (arthrex.com)). The comparison shows that the subject device has similar or improved pull out force compared to the primary predicate.

Biocompatibility:

The reference devices selected for biocompatibility evaluation (510(k) numbers) are manufactured by Elite Surgical Supplies, at the same manufacturing facility producing the subject devices, using the same manufacturing processes, chemicals, materials, and cleaning processes as the subject devices. An OEM manufacturing contract is in place between Elite Surgical Supplies and Ortho-Design, stating that all manufacturing done for Ortho-Design, by Elite Surgical Supplies, is done according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have previously been cleared by the FDA for the reference device.

Sterility:

After reviewing the results of the IQ, OQ and PQ results, it can be concluded that the Overkill Method was successfully conducted in order to achieve a SAL of 10-6 based on the parameters and tolerances identified during the validation study.

Shelf-Life:

The DueLock™ Suture Anchor has a shelf-life of 3 years, which has been validated with accelerated aging techniques listed above in 016_Sterilization and Shelf-Life Table 2. Real-time aging is being conducted and the design history file will be updated with this information when completed. The implant components are manufactured from PEEK OPTIMA conforming to ASTM F2026 and Titanium Alloy conforming to ASTM F136. All materials have been historically used in implant devices and have demonstrated not to be mechanically affected by aging within the 3 year shelf life, so no additional aging testing is required for the implants.

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Packaging:

The DueLock™ Suture Anchor will be boxed individually in EtO sterilized double peel pouches to allow for easy transfer into the sterile operative field. Both the inner and outer pouch is a 60g/m_2 medical plastic film and paper peel pouch. Each package includes external package labeling, an instruction leaflet, and individual patient labels. Instruments are provided non-sterile in steam sterilization trays separately from the implants.

Endotoxin/pyrogenicity:

The device has been tested to be non-pyrogenic.

Conclusion:

From the non-clinical testing results and summaries, it is clear that the DueLock™ Suture Anchor demonstrates substantial equivalence and adheres to minimum requirements set out in the guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions laid out by the FDA. This was demonstrated by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests.

DEVICE D

Device Trade Name:	VersaTi™ Suture Anchor
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Classification Name:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Device Classification:	Class II
Product Code:	MBI
Primary Predicate Device:	Arthrex corkscrew™ FT ll Anchor (K050358) = Parcus V-Lox 4.5 x 13.9mm – 10353T (K201083)
Reference Devices:	K063456, K130274

Device description:

The VersaTi™ Suture Anchor is a self-tapping suture anchor mostly used as a medial row anchor in rotator cuff repair surgery. The anchor is designed for ultimate mechanical properties (pull-out strength, tensile strength, etc.) and ease of use. VersaTi™ Suture Anchor is recommended for use in small and large-joint repairs without the need for tapping or drilling.

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Indications for Use:

The VersaTi™ 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, Joint capsule closure
- Wrist: Scapholunate ligament reconstruction
- Hip: Capsular Repair, acetabular labral repair

Predicate device comparison:

Primary Predicate Device Manufacturer:	Arthrex Inc.Orbison Street 1370 Creekside Boulevard Naples, Florida 34108-1945
Relationship to the device:	Similar intended use, materials, design features, dimensions, and function as the VersaTi Suture Anchor
Technological Difference	The thread of the subject device is designed for optimal pull-out strength and mechanical stability. Thread design for cancellous and cortical fixation.
Regulatory Status:	FDA cleared – K050358

Clinical Characteristics:

Suture Anchors are intended to be used for soft tissue fixation during general orthopedic surgery.

Disclosure of performance and safety deviation: None

Technical Equivalence:

Similar design: Yes

Similar deployment methods: Yes

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Similar principles of operation and critical performance requirements: Yes

Disclosure of performance and safety deviation: No characteristics

Similar materials or substances in contact with the same human tissues: Yes

Disclosure of performance and safety deviation: Yes

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing including static pull-out, insertion torque, fatigue and corrosion testing as per FDA Guidance Document: Bone Anchors—Premarket Notification (510(k)) Submissions. This testing was done on the subject device and compared to the data found in literature (Suture Anchor Materials, Eyelets, and Designs: Update 2008, A. Barber et al, 2008, p6, Table 2). The comparison shows that the subject device has similar or improved pull out force compared to the primary predicate.

Biocompatibility:

The reference devices selected for biocompatibility evaluation (510(k) numbers) are manufactured by Elite Surgical Supplies, at the same manufacturing facility producing the subject devices, using the same manufacturing processes, chemicals, materials, and cleaning processes as the subject devices. An OEM manufacturing contract is in place between Elite Surgical Supplies and Ortho-Design, stating that all manufacturing done for Ortho-Design, by Elite Surgical Supplies, is done according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have previously been cleared by the FDA for the reference device.

Sterility:

After reviewing the results of the IQ, OQ and PQ results, it can be concluded that the Overkill Method was successfully conducted in order to achieve a SAL of 10-6 based on the parameters and tolerances identified during the validation study.

Shelf-Life:

The VersaTi™ Suture Anchor has a shelf-life of 3 years, which has been validated with accelerated aging techniques listed above in 016_Sterilization and Shelf-Life Table 2. Real-time aging is being conducted and the design history file will be updated with this information when completed. The implant components are manufactured from PEEK OPTIMA conforming to ASTM F2026 and Titanium Alloy conforming to ASTM F136. All materials have been historically used in implant devices and have proven not to be mechanically affected by aging within the 3 years shelf life, so no additional aging testing is required for the implants.

Packaging:

The VersaTi™ Suture Anchor will be boxed individually in EtO sterilized double peel pouches to allow for easy transfer into the sterile operative field. Both the inner and outer pouch is a 60g/m_2 medical plastic film and paper peel pouch. Each package includes external package labeling, an instruction leaflet, and individual patient labels. Instruments are provided non-sterile in steam sterilization trays separately from the implants.

Endotoxin/pyrogenicity:

The device has been tested to be non-pyrogenic.

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Conclusion:

From the non-clinical testing results and summaries, it is clear that the VersaTi™ Suture Anchor demonstrates substantial equivalence and adheres to minimum requirements set out in the guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions laid out by the FDA. This was demonstrated by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests.

DEVICE E

Device Trade Name:	MiniTi™ Suture Anchor
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Classification Name:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Device Classification:	Class II
Product Code:	MBI
Primary Predicate Device:	De Puy Mitek MiniLok QuickAnchor (K071257)
Secondary Predicates:	Parcus Medical MiTi (K111000)
	Arthrex 2.2mm Micro Corkscrew FT Suture Anchor (K173788)
	Rejoin Medical 2mm Ti Anchor
Reference Devices:	K063453, K200523, K070758

Device description:

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 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.

ORTHO-DESIGN
ORTHOPAEDIC INNOVATION

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Predicate device comparison:

Primary Predicate Device Manufacturer:	DePuy 325 Paramount Dr Raynham, MA 02767
Relationship to the device:	Similar intended use, materials, design features, dimensions, and function as the MiniTi™ Suture Anchor
Technological Differences	Minor dimensional changes
Regulatory Status:	FDA cleared – K071257

Clinical Characteristics:

Suture Anchors are intended to be used for soft tissue fixation during general orthopedic surgery.

Disclosure of performance and safety deviation: None

Technical Equivalence:

Similar design:	Yes
Similar deployment methods:	Yes
Similar principles of operation and critical performance requirements:	Yes
Disclosure of performance and safety deviation:	No characteristics
Similar materials or substances in contact with the same human tissues:	Yes
Disclosure of performance and safety deviation:	Yes

Mechanical Testing:

Substantial equivalence is supported by the results of mechanical testing including static pull-out, insertion torque, fatigue, and corrosion testing as per FDA Guidance Document: Bone Anchors—Premarket Notification (510(k)) Submissions. This testing was done on the subject device and compared to the data found in literature (https://www.smith-nephew.com/global/assets/pdf/products/surgical/extremities_hand%20wrist_bro_f.pdf). The comparison shows that the subject device has similar or improved pull out force compared to the primary predicate.

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Biocompatibility:

The reference devices selected for biocompatibility evaluation (510(k) numbers) are manufactured by Elite Surgical Supplies, at the same manufacturing facility producing the subject devices, using the same manufacturing processes, chemicals, materials, and cleaning processes as the subject devices. An OEM manufacturing contract is in place between Elite Surgical Supplies and Ortho-Design, stating that all manufacturing done for Ortho-Design, by Elite Surgical Supplies, is done according to the processes defined by ISO 13485 and ISO 9001. All materials, processes, and cleaning agents used for the subject device have previously been cleared by the FDA for the reference device.

Sterility:

After reviewing the results of the IQ, OQ and PQ results, it can be concluded that the Overkill Method was successfully conducted in order to achieve a SAL of 10-6 based on the parameters and tolerances identified during the validation study.

Shelf-Life:

The MiniTi™ Suture Anchor has a shelf-life of 3 years, which has been validated with accelerated aging techniques listed above in 016_Sterilization and Shelf-Life Table 2. Real-time aging is being conducted and the design history file will be updated with this information when completed. The implant components are manufactured from PEEK OPTIMA conforming to ASTM F2026 and Titanium Alloy conforming to ASTM F136. All materials have been historically used in implant devices and have proven not to be mechanically affected by aging within the 3 years of shelf life, so no additional aging testing is required for the implants.

Packaging:

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Endotoxin/pyrogenicity:

The device has been tested to be non-pyrogenic.

Conclusion:

From the non-clinical testing results and summaries, it is clear that the MiniTi demonstrates substantial equivalence and adheres to minimum requirements set out in the guidance document for Bone Anchors – Premarket Notification (510(k)) Submissions laid out by the FDA. This was demonstrated by non-clinical testing consisting of mechanical, biocompatibility, sterility, shelf-life, packaging and pyrogenicity tests.