September 18, 2023

Parcus Medical
Calen Souther
Manager, Regulatory Affairs
6455 Parkland Drive
Sarasota, Florida 34243

Re: K232513
Trade/Device Name: X-Twist Biocomposite Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI
Dated: August 18, 2023
Received: August 18, 2023

Dear Calen Souther:

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,

Sara S. Thompson -S

For

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)*
K232513

Device Name
X-Twist Biocomposite Suture Anchor

Indications for Use *(Describe)*
The X-Twist Biocomposite Suture Anchors are indicated for attachment of soft tissue to bone. These products are intended for the following indications:

Shoulder: Rotator Cuff Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair

Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair, Meniscal Root Repair, Secondary or adjunct fixation for ACL/PCL reconstruction or repair, MPFL Repair/Reconstruction

Elbow: Ulnar/Radial Collateral Ligament Reconstruction, Lateral Epicondylitis 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

The information contained herein is being provided in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared:	September 12, 2023
Applicant:	Parcus Medical, LLC. 6423 Parkland Dr. Sarasota, FL 34243 USA
Official Correspondent:	Calen Souther, MS Manager, Regulatory Affairs Phone: (781) 457-9541 Email: csouther@anika.com
Trade/Proprietary Name:	X-Twist Biocomposite Suture Anchor
Common Name:	Fastener, fixation, biodegradable, soft tissue
Regulation Name:	Single/multiple component metallic bone fixation appliances and accessories
Device Class:	Class ll
Regulation Number:	21 CFR 888.3030
Product Code:	MAI
Predicate Device Information:	X-Twist PEEK Suture Anchor – K221135 - cleared May 19, 2022 Twist AP Suture Anchor – K183501 – cleared March 15, 2019
Reference Device Information:	Arthrex SwiveLock – K101823 – cleared January 7, 2011
Reason for 510(k) submission:	The purpose of this Special 510(k) is to obtain clearance for the X-Twist Biocomposite Suture Anchor, as an extension of the Parcus Medical X-Twist Suture Anchor portfolio, for use in the fixation of soft tissue to bone.
Device Description:	The X-Twist Biocomposite Suture Anchor consists of the implants (anchor and anchor tip) and the anchor driver assembly. The anchor and anchor tip are provided assembled to the driver and sterile. The X-Twist Biocomposite anchor is molded using a composite of βTCP (beta-tricalcium-phosphate) and PLGA (poly-lactic-co-glycolic acid). The anchor tip is molded using PEEK (polyetheretherketone). The anchor is fully threaded, double-helical, cannulated, and has inline fenestrations on each quarter-turn face. The anchor tip is retained on the driver via retention suture(s) or suture tape(s) that are passed through the driver cannulation, looped over the retention bridge within the tip, and returned out the proximal end of the driver handle

and cleated. These devices are to be used with a drill, awl, and/or bone tap. The X-Twist Biocomposite Suture Anchors are provided sterile and in 4.75mm, 5.5mm, or 6.25mm diameters.

Device Characteristics

	X-Twist Biocomposite Suture Anchor	X-Twist PEEK Suture Anchor	Twist AP (Biocomposite) Suture Anchor
510(k) clearance	Subject Device	K221135	K183501
Manufacturer	Parcus Medical	Parcus Medical	Parcus Medical
Common Name	Fastener, fixation, biodegradable, soft tissue	Fastener, fixation, non-degradable, soft tissue	Fastener, fixation, biodegradable, soft tissue
Regulation	21 CFR 888.3030	21 CFR 888.3040	21 CFR 888.3030
Class Name	Single/multiple component metallic bone fixation appliances and accessories	Smooth or threaded metallic bone fixation fastener	Single/multiple component metallic bone fixation appliances and accessories
Class	Class II	Class II	Class II
Product Code	MAI	MBI	MAI
Indications for Use	The X-Twist Biocomposite Suture Anchors are indicated for attachment of soft tissue to bone. These products are intended for the following indications: Shoulder: Rotator Cuff Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair Knee: Anterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair, Meniscal Root Repair, Secondary or adjunct fixation for ACL/PCL reconstruction or repair, MPFL Repair/Reconstruction Elbow: Ulnar/Radial Collateral Ligament Reconstruction, Lateral	The X-Twist PEEK Suture Anchors are indicated for attachment of soft tissue to bone. These products are intended for the following indications: Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment. Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar	The Parcus Twist AP Suture Anchors are indicated for the attachment of soft tissue to bone. This product is intended for the following indications: Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment. Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar

	Epicondylitis Repair	or Radial Collateral Ligament Reconstruction, TFCC.	or Radial Collateral Ligament Reconstruction, TFCC.
Implant Material	B-TCP/PLGA LT1- PEEK UHMWPE	LT1- PEEK UHMWPE	B-TCP/PLGA UHMWPE
Single use only	Yes	Yes	Yes
Sterility	Sterile, EO	Sterile, EO	Sterile, EO
Shelf-life	5-years	5-years	5-years

Non-clinical Testing

The non-clinical testing was conducted to evaluate the biocompatibility and performance of the subject device. The testing was performed using the same methods and protocols as that used for the predicate devices. The results of the testing were assessed against the results obtained with the predicate devices to determine substantial equivalency for design, performance, and safety.

Final devices were subjected to bacterial endotoxin testing in accordance with USP <85> and USP <161>.

Test	**Test Article**	**Negative Control**	**Standard Curve**	**PPC**	**Acceptance Criteria**	**Results**
Evaluation of the USP Limulus Amebocyte Lysate (LAL) Test - Kinetic-Turbidimetric Method - as an End-Product Endotoxin Test	Ten (10) disassembled devices, each submerged in 100ml LAL reagent water (LRW), extracted in a shaker incubator at 37°C for one (1) hour	Sterile LRW	Control Standard Endotoxin (CSE) at 10, 1.0, 0.1, 0.01 EU/ml	Test article spiked with 0.1 EU/ml	Standard Curve Correlation Coefficient: ≥0.98 Slope of curve between -0.400 and -0.100. PPC: 50-200% Test Article Endotoxin Concentration: ≤20 EU/device	Standard Curve Correlation Coefficient: 1.00 Slope: -0.213 PPC: 173% Test Article Endotoxin Concentration: <1.0 EU/device

Clinical Data

Clinical testing was deemed not necessary for demonstrating substantial equivalence to the predicate devices.

Conclusion

The X-Twist Biocomposite Suture Anchor is substantially equivalent to the predicate devices in which the design features, materials, packaging, sterility, shelf life, and intended uses are the same.

The testing data and comparisons of the technological characteristics within this submission demonstrate that the subject device is substantially equivalent to the predicate devices when used in accordance with the intended use.