May 19, 2022

Parcus Medical LLC
Calen Souther, MS
Senior Specialist, Regulatory Affairs
6423 Parkland Drive
Sarasota, Florida 34243

Re: K221135
Trade/Device Name: X-Twist PEEK 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: April 15, 2022
Received: April 19, 2022

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221135

Device Name

X-Twist PEEK Suture Anchor

Indications for Use *(Describe)*

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 or Radial Collateral Ligament Reconstruction, TFCC.

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.

510(k) Summary

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

Date Prepared:	May 17, 2022
Applicant:	Parcus Medical, LLC. 6423 Parkland Dr. Sarasota, FL 34243 USA
Official Correspondent:	Calen Souther, MS Senior Specialist, Regulatory Affairs Phone: (770) 616-1389 Email: csouther@anika.com
Trade/Proprietary Name:	X-Twist PEEK Suture Anchor
Common Name:	Fastener, Fixation, Non-degradable, Soft Tissue
Regulation Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	Class ll
Regulation Number:	21 CFR 888.3040
Product Code:	MBI
Predicate Device Information:	Parcus Slik Anchor - K170327 - cleared March 30, 2017 Parcus Twist PEEK Suture Anchor – K120942 – cleared April 20, 2012
Reason for 510(k) submission:	The purpose of this Special 510(k) is to obtain clearance for the X-Twist PEEK Suture Anchor, as an extension of the Parcus suture anchor portfolio, for use in the fixation of soft tissue to bone.
Description of Device:	The X-Twist PEEK Suture Anchor consists of an implantable anchor and anchor tip that are provided assembled to a driver. Retention suture(s) or suture tapes(s) are preloaded through the driver cannulation to secure the anchor tip onto the driver shaft. The anchor tip can be loaded with additional suture(s) or suture tapes(s) if needed for the intended surgical procedure. Clockwise rotation of the driver allows for advancement of the fully threaded anchor and anchor tip into the prepared bone socket to serve as the point of fixation for soft tissue repair.

Device Characteristics

	X-Twist PEEK Suture Anchor	Parcus Slik Anchor Parcus Twist PEEK Suture Anchor
510(k) clearance	Subject Device	K170327 K120942
Manufacturer	Parcus Medical	Parcus Medical
Common Name	Fastener, Fixation, Non-degradable, soft tissue	Fastener, Fixation, Non-degradable, soft tissue
Regulation	21 CFR 888.3040	21 CFR 888.3040
Class Name	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener
Class	Class ll	Class ll
Product Code	MBI	MBI
Indication for Use	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 or Radial Collateral Ligament Reconstruction, TFCC.	The Parcus Slik Anchors and 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 or Radial Collateral Ligament Reconstruction, TFCC.
Implant Material	LT1- PEEK UHMWPE	LT1- PEEK UHMWPE
Single use only	Yes	Yes
Sterility	Sterile, EO	Sterile, EO
Shelf-life	5-years	5-years

Non-clinical Testing

Benchtop testing was performed to evaluate cycle loading and elongation, insertion torque, and anchor pullout force. The testing was performed using the same methods and protocols as that used for the predicate devices. The results of the testing met the defined acceptance criteria and were assessed against the results obtained with the predicate devices to determine substantial equivalency for design and performance.

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
USP <85> and <161> Inhibition/ Enhancement Single Lot Validation for the Kinetic Turbidimetric Limulus Amebocyte Lysate (LAL) Test	Ten (10) disassembled devices, each submerged in 1000ml LAL reagent water (LRW), extracted at room temperature for one (1) hour	Sterile LRW	Control Standard Endotoxin (CSE) at 1.23, 0.25, 0.05, 0.01 EU/ml	Test article spiked with 0.05 EU/ml	Standard Curve Correlation Coefficient: ≥0.98 Neg. Control Onset Time: Onset time > lowest Cal Standard PPC: 50-200% Test Article Endotoxin Concentration: ≤20 EU/device	Standard Curve Correlation Coefficient: 1.00 Neg. Control Onset Time: >6000 seconds PPC: 58% Test Article Endotoxin Concentration: <1 EU/device

The results of the bacterial endotoxin test met the requirements of the FDA-recognized standards USP <85> and USP <161>.

Clinical Data

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

Conclusion

The X-Twist PEEK Suture Anchor is substantially equivalent to the predicate devices in which the basic 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.