January 23, 2020

Parcus Medical, LLC
Paul Vagts
Director of Regulatory Affairs
6423 Parkland Drive
Sarasota, Florida 34243

Re: K193295
Trade/Device Name: Parcus Knotless PEEK and PEEK CF Push-In Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 7, 2020
Received: January 8, 2020

Dear Paul Vagts:

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,

Laura C. Rose, Ph.D.
Acting 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)*
K193295

Device Name
Parcus Knotless PEEK and PEEK CF Push-In Suture Anchor

Indications for Use *(Describe)*

The Parcus Knotless PEEK and PEEK CF Push-In Suture Anchors are indicated for 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 or Radial Collateral Ligament Reconstruction, TFCC.
Hip	Acetabular Labral Repair

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PARCUS MEDICAL, LLC.

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510(k) Summary – K193295

510(k) Owner & Submitter:	Parcus Medical, LLC 6423 Parkland Dr Sarasota, FL 34243
Company Contact:	Paul Vagts Phone: (941)755-7965 Fax: (941)755-6543
Date Prepared:	January 16th, 2020
Device Trade Name:	Knotless PEEK and PEEK CF Push-In Suture Anchor
Common Name:	Fastener, Fixation, Non-Degradable, Soft Tissue
Device Class:	Class II
Classification Name:	21 CFR 888.3040 - Product Code MBI
Predicate Device:	Parcus Knotless PEEK CF Suture Anchors, K113730, cleared 1/17/2012
Reference Devices:	Parcus Twist PEEK Suture Anchors, K120942, cleared 4/20/2012. Parcus SLiK Anchors, K170327, cleared 3/30/2017. Parcus SLiK Fix Screws, K170877, cleared 6/2/2017

Device Description:

The Parcus Knotless PEEK and PEEK CF Push-In Suture Anchors are tapered fasteners with an eyelet at the distal tip and circumferential barbs used to secure the implant in bone and provide suture fixation without the need for knot tying. After passing through the target tissue, sutures are passed through the distal eyelet of the anchor, it is pounded into place which secures both the anchor and the suture in place. This is the same design and insertion technique as the predicate Knotless PEEK CF Push-In Suture Anchors. The predicate device was originally provided in 3.5mm and 4.5mm diameters and this 510(k) will expand that size range to include 2.8mm and 5.5mm options. The Knotless PEEK Push-In Suture Anchor is made from polyetheretherketone (PEEK) and the Knotless PEEK CF Push-In Suture Anchors are made from carbon fiber polyetheretherketone (PEEK CF). The Parcus predicate device is comprised of carbon fiber polyetheretherketone (PEEK CF). The Parcus reference devices consist of devices comprised of either PEEK or PEEK CF. The Parcus Knotless PEEK and PEEK CF Push-In Suture Anchors are provided sterile with a single use suture passer and either with or without a single use inserter.

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Intended Use:

The Parcus Knotless PEEK and PEEK CF Push-In Suture Anchors are indicated for 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 or Radial Collateral Ligament Reconstruction, TFCC.
Hip	Acetabular Labral Repair

Substantial Equivalence Summary:

The Parcus Knotless PEEK and PEEK CF Push-In Suture Anchors are very similar to the predicate Parcus 35 and 45 Knotless PEEK CF Push-In Suture Anchors in that they both feature the same design, both utilize the same surgical technique, both are comprised of the same or similar material and both are intended for the same indications. In addition, the proposed and predicate devices are all packaged in the same fashion using the same materials, are sterilized using the same ETO sterilization cycle, and all share the same 5-year shelf life. An assessment of the biocompatibility of the proposed devices did not raise any concerns as they are comprised of the same material manufactured in the same fashion using the same equipment as the predicate and reference devices stated above that are currently marketed by Parcus Medical. LAL testing has been conducted on a representative devices comprised of the same materials and it was concluded that the Knotless PEEK and PEEK CF Push-In Suture Anchor meet the endotoxin limit specifications and do not raise any additional concerns regarding pyrogenicity.

Summary Performance Data:

The Knotless PEEK and PEEK CF Push-In Suture Anchors were evaluated and testing was conducted side by side with the predicate device. Devices were assembled to test blocks and placed in a test fixture. Devices were evaluated for strength and elongation under cycle loading and ultimate failure conditions. Results were compared with test data for the predicate device and demonstrated substantial equivalency.