November 2, 2019

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

Re: K192824
Trade/Device Name: Parcus Knotless AP Suture Anchors
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: October 1, 2019
Received: October 2, 2019

Dear Mr. 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,

Laurence D. Coyne, Ph.D.
Acting 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)*

K192824

Device Name

Parcus Knotless AP Suture Anchors

Indications for Use *(Describe)*

The Parcus Knotless 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 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.

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PARCUS MEDICAL, LLC.

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510(k) Summary - K192824

Submitter:	Parcus Medical, LLC 6423 Parkland Dr Sarasota, FL 34243
Company Contact:	Paul Vagts Phone: (941)755-7965 Fax: (941)755-6543
Date Prepared:	October 1st, 2019

Device Trade Name:	Parcus Knotless AP Suture Anchor
Common Name:	Suture Anchor
Device Class:	Class II
Classification Name:	Fastener, Fixation, Biodegradable, Soft Tissue 21 CFR 888.3030 - Product Code MAI

Predicate Device: The predicate device is the:

- Parcus Medical Twist AP Suture Anchor (K183501 cleared March 15, 2019).

Device Description:

The Parcus Knotless AP Suture Anchors consist of ribbed anchor bodies in 2.8mm, 4.5mm, and 5.5mm diameters. The anchor body is comprised of Parcus Medical's Advanced Polymer (AP) which is a formulation of β-TCP and PLGA that has a proven record as a safe and effective absorbable material that has been used in the industry for over 10 years. This material has been developed such that it will maintain the necessary strength to insert successfully and provide the necessary resistance to pull-out long enough for the body to heal and then, over time, break down, be absorbed into the body and eventually replaced by bone. The presence of the osteoconductive β-TCP will allow for boney replacement at the insertion site as the anchor is absorbed.

Knotless AP Suture Anchors are provided with a single use suture threader and a single use driver. These devices are individually packaged and provided sterile.

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Intended Use:

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Elbow	Tennis Elbow Repair, Biceps Tendon Reattachment.
Hand/Wrist	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

Substantial Equivalence Summary:

The Parcus Knotless AP Suture Anchors are very similar to the predicate devices in that they are comprised of the same materials, have identical intended use, and have identical indications for use. Pyrogenicity testing was conducted on a representative device from the Parcus AP Suture Anchor product line. The results of this testing met the acceptance criteria described in the FDA recognized standard and therefore it was concluded that the Knotless AP Suture Anchors do not raise any additional concerns regarding pyrogenicity. Extensive biocompatibility and mechanical testing has been conducted on the Knotless AP Suture Anchors or representative devices of the same material and has demonstrated substantial equivalence between the Parcus Knotless AP Suture Anchors and the predicate devices.

Summary Performance Data:

The entire scope of the proposed Knotless AP Suture Anchor product family was considered and worst-case scenarios for various concerns were identified. Devices, or representative devices of the same material, were subjected to biocompatibility and benchtop testing such as pull-out strength and cyclic loading studies. Based on the results of this testing and comparison with the performance of the predicate devices or published acceptance criteria, the Parcus Knotless AP Suture Anchors are determined by Parcus Medical to be substantially equivalent to the predicate devices.