March 15, 2019

Parcus Medical, LLC  
Paul Vagts  
Director of Regulatory Affairs  
6423 Parkland Drive  
Sarasota, Florida 34231

Re: K183501  
Trade/Device Name: Parcus Twist 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: December 13, 2018  
Received: December 17, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
### Indications for Use

**510(k) Number (if known)**
K183501

**Device Name**
Parcus Twist AP Suture Anchors

**Indications for Use (Describe)**

The Parcus Twist AP Suture Anchors are indicated for the attachment of soft tissue to bone. This product is intended for the following indications:

<table>
<thead>
<tr>
<th>Area</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoulder</td>
<td>Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.</td>
</tr>
<tr>
<td>Knee</td>
<td>Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.</td>
</tr>
<tr>
<td>Foot/Ankle</td>
<td>Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.</td>
</tr>
<tr>
<td>Elbow</td>
<td>Tennis Elbow Repair, Biceps Tendon Reattachment.</td>
</tr>
<tr>
<td>Hand/Wrist</td>
<td>Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.</td>
</tr>
</tbody>
</table>

**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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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510(k) Summary

Submitter: Parcus Medical, LLC
6423 Parkland Dr
Sarasota, FL 34243

Company Contact: Paul Vagts
Phone: (941)755-7965
Fax: (941)755-6543

Date Prepared: December 13th, 2018

Device Trade Name: Twist 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 devices are the:

- Parcus Medical Twist PEEK Suture Anchor (K120942 cleared April 20th, 2012),
- DePuy Mitek HEALIX BR Anchor (K073412 cleared January 17th, 2008),
- DePuy Mitek Healix Knotless BR (K130917 cleared May 24th, 2013), and
- DePuy Mitek Lupine BR Anchor (K070925 cleared May 2nd, 2007).

Device Description:
The Parcus Twist AP Suture Anchors consist of fully threaded anchor bodies in 4.5, 5.5, and 6.5mm diameters. The anchor body is comprised of a β-TCP and PLGA biocomposite that has a proven record as a safe and effective absorbable material that has been used in the industry for over 10 years. The anchor bodies feature an internal bar over which strands of UHMWPE suture and/or suture tape are suspended. This allows for free movement of the suture or suture tape in order to assist with the passing and securing of soft tissue. The anchor body material has been designed 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. While the UHMWPE suture and suture tape are non-absorbable, this does not create any problems and may remain implanted indefinitely. The presence of the osteoconductive β-TCP will allow for boney replacement at the insertion site as the anchor is absorbed.

Suture anchors are assembled with suture and/or suture tape provided with or without needles assembled on single use drivers and provided to the end user individually packaged and sterile.

**Intended Use:**
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 or Radial Collateral Ligament Reconstruction, TFCC.

**Substantial Equivalence Summary:**
The Parcus Twist AP Suture Anchors are very similar to the predicate devices in that they are comprised of the same materials (K073412, K130917 and K070925), have identical intended use (K120942, K073412, K130917 and K070925), have identical (K120942) or very similar (K073412, K130917 and K070925) indications for use and utilize similar designs (K120942 and K073412). Pyrogenicity testing was conducted on a representative device from the Twist AP Suture Anchor product family. The results of this testing met the acceptance criteria described in the FDA recognized standard and therefore it was concluded that the Twist AP Suture Anchors do not raise any additional concerns regarding pyrogenicity. Extensive biocompatibility, mechanical and cadaveric testing has been conducted and has demonstrated substantial equivalence between the Parcus Twist AP Suture anchors and the predicate devices.
Summary Performance Data:
The entire scope of the proposed Twist AP Suture Anchor product family was considered and worst-case scenarios for various concerns were identified. Devices were subjected to biocompatibility and benchtop testing such as pull-out strength, cyclic loading, insertion torque testing, in-vitro degradation, and animal implantation studies. Based on the results of this testing and comparison with the performance of the predicate devices or published acceptance criteria, the Parcus Twist AP Suture Anchors are determined by Parcus Medical to be substantially equivalent to the predicate devices.