K122805 pg 1/2

PARCUS MEDICAL, LLC.

510(k) Summary

FEB 05 2013

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

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

Date Prepared: February 4, 2013

Trade Name: Parcus Draw Tight Anchor

Common Name: Suture Anchor

Classification Name: Fastener, Fixation, Non-Degradable, Soft Tissue
21 CFR 888.3040 – Product Code MBI

Predicate Devices:

- Parcus 3.5mm PEEK CF Push-In Suture Anchors (K102326)
- Parcus Twist PEEK Suture Anchors (K120942)
- Biomet Sports Medicine Juggerknot™ Soft Anchor (K110145)

Device Description:

The Parcus Draw Tight Anchors are designed for use in attachment of soft tissue to bone. The devices are made from Ultra High Molecular Weight Polyethylene (UHMWPE) and Polyetheretherketone (PEEK). The construct of the Draw Tight Anchors is such that when inserted into bone and deployed via the included suture, a suture ball is created in the prepared socket that provides the necessary fixation. The Draw Tight Anchors are designed to accommodate both sliding and fixed sutures to be used for soft tissue fixation and are provided sterile.

Intended Use:

The Parcus Draw Tight 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.

K122805 #2/2

PARCUS MEDICAL, LLC.

Substantial Equivalence Summary:

The Parcus Draw Tight Anchors are similar to the predicate devices in that they are manufactured from the same or similar materials, presented to the end user in the same fashion and have the same or similar indications. When compared to the Parcus Twist PEEK Suture Anchors, the Draw Tight Anchors are identical in all of these aspects. While the method of fixation for the Draw Tight Anchor differs from that of the Parcus predicate devices, fixation due to a suture ball rather than a solid anchor body, it is very similar to that of the Biomet predicate device.

When compared to the Biomet predicate device, the specifications for the suture portion of the proposed device are included within that of the predicate. In addition, all of the indications for the proposed device are either identical or comparable to that of the predicate. As stated above, the method of fixation for both devices is similar in that it relies on the placement of suture into a prepared hole and the creation of a suture ball that holds the device in place.

From a performance point of view, the Draw Tight Anchors perform very comparably to that of the predicate devices. As shown in the data, the quality of the bone in which the device is implanted does affect the performance of the device. However, even in the worst case scenario the Draw Tight Anchors perform as intended and do not raise any concerns regarding the safety or efficacy of the device.

Therefore, the Parcus Draw Tight Anchors are substantially equivalent to the predicate devices listed above. Any differences between the Draw Tight Anchors and the predicate devices are considered minor and do not raise any safety and/or efficacy concerns.

Summary Performance Data:

The Parcus Draw Tight Anchors were placed in prepared holes and the pull out strength was measured. In addition to straight load to failure, the proposed device was also tested under cyclic loading conditions. Test results were compared to the results for the predicate devices and the Draw Tight Anchors demonstrated substantial equivalence in all aspects.

Call 1.941.755.7965 PARCUSMEDICAL.COM Fax 1.941.755.6543
6423 Parkland Drive, Sarasota, FL 34243

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Parcus Medical, LLC
% Mr. Paul Vagts
RA/QA Manger
839 South Neenah Avenue
Sturgeon Bay, Wisconsin 54235

Letter dated: February 5, 2013

Re: K122805
Trade/Device Name: Parcus Draw Tight 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 10, 2013
Received: January 30, 2013

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

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): K122805

Device Name: Parcus Draw Tight Anchors

Indications for Use:

The Parcus Draw Tight 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.

Prescription Use __X__ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

2013.02.05 13:37:13
-05'00'