K102162

PARCUS Medical, LLC

SURGICAL INNOVATION >> VALUE DRIVEN

NOV 10 2010

510(k) Summary

Submitter: Parcus Medical, LLC
839 South Neenah Ave.
Sturgeon Bay, WI 54234

Company Contact: Barton Bracy
Phone: (920) 746-2972
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Date Prepared: July 23, 2010

Trade Name: Parcus PEEK CF Push-In Suture Anchors

Common Name: Suture Anchor

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

Predicate Devices:

- Parcus V-LoX PEEK CF Suture Anchor (K091094)
- Smith & Nephew BioRaptor 2.9 (K031685, K053344)

Device Description:

The Parcus PEEK CF Push-In Suture Anchors are tapered fasteners with barbs for use in attachment of soft tissue to bone. The devices are made from Carbon Fiber Reinforced Polyetheretherketone (PEEK CF). The Push-In Suture Anchors are provided sterile in 3.0mm and 4.5mm diameters.

Intended Use:

The Parcus 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.

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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 (3.0mm only)

Substantial Equivalence Summary:

The Parcus PEEK CF Push-In Suture Anchors are similar to the Parcus V-LoX PEEK CF Suture Anchors in that they are made of the same material, manufactured in a similar manner, and have similar indications. While the method of fixation differs, push-in barbs versus threads, it does not raise any new concerns regarding safety and efficacy.

The Parcus PEEK CF Push-In Suture Anchors are similar in design to the Smith & Nephew BioRaptor 2.9. Both anchors are barbed and pushed in rather than threaded. Although the BioRaptor is listed as 2.9mm, this is the minor diameter and the actual outer diameter is 3.5mm while the Push-In Suture Anchors come in 3.0mm and 4.5mm outer diameters. Though the material differs, PEEK CF versus a bioabsorbable polymer, it does not raise any new concerns regarding safety and efficacy.

Therefore the Parcus PEEK CF Push-In Suture Anchors are substantially equivalent to the predicate devices listed above. Any differences between the Push-In Suture Anchors and the predicate devices are considered minor and do not raise any safety and efficacy concerns.

Summary Performance Data:

The Parcus PEEK CF Push-In Suture Anchors were placed in prepared holes and the pull out strength was measured. Test results were compared to the results for the Parcus V-LoX PEEK CF Suture Anchors as well as the Smith & Nephew BioRaptor 2.9 and demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Parcus Medical, LLC
% Mr. Barton Bracy
839 South Neenah Avenue
Sturgeon Bay, Wisconsin 54234

NOV 10 2010

Re: K102162
Trade/Device Name: Parcus 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: HWC, MBI
Dated: October 20, 2010
Received: October 20, 2010

Dear Mr. Bracy:

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
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102162

Device Name: Parcus PEEK CF Push-In Suture Anchors

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Elbow	Tennis Elbow Repair, Biceps Tendon Reattachment.
Hand/Wrist	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.
Hip	Acetabular Labral Repair (3.0mm only)

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)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102162