



SURGICAL INNOVATION &gt;&gt; VALUE DRIVEN

NOV 15 2010

**510(k) Summary**

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

**Company Contact:** Barton Bracy  
Phone: (920) 746-2972  
Fax: (920) 746-2974

**Date Prepared:** August 13, 2010

**Trade Name:** Parcus 3.5mm PEEK CF Push-In Suture Anchor

**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 3.5mm 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.

**Intended Use:**

The Parcus 3.5mm 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.

#### **Substantial Equivalence Summary:**

The Parcus 3.5mm 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 3.5mm 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 a 3.5mm outer diameter. Though the material differs, PEEK CF versus a bioabsorbable polymer, it does not raise any new concerns regarding safety and efficacy.

Therefore the Parcus 3.5mm 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 3.5mm 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.



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 15 2010

Re: K102326

Trade/Device Name: Parcus 3.5mm PEEK CF Push-In Suture Anchor  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: MBI, HWC  
Dated: August 13, 2010  
Received: August 17, 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.

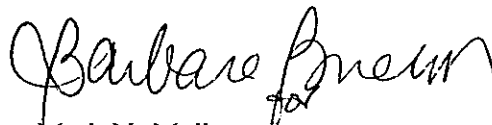
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (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 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,

A handwritten signature in black ink that reads "Barbara for Melkerson". The signature is written in a cursive style.

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): K102326 (pg 1/1)

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Device Name: Parcus 3.5mm PEEK CF Push-In Suture Anchor

**Indications for Use:**

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- 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   
(Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use \_\_\_\_\_  
(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)

[Signature] for mxm  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K102326