PARCUS Medical, LLC

SURGICAL INNOVATION >> VALUE DRIVEN

SEP 30 2009

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) 746-8665

Date Prepared: April 13, 2009

Trade Name: Parcus V-LoX™ PEEK CF 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 Titanium Suture Anchor (K090075)
- Smith & Nephew TWINFIX FT PK (K072785)

Device Description:

The Parcus V-LoX PEEK CF Suture Anchor is a threaded, tapered fastener for use in attachment of soft tissue to bone. The device is made from Carbon Fiber Reinforced Polyetheretherketone (PEEK CF). It comes preloaded with two #2 sutures either with or without attached needles, and is available in two different diameters, 5.5mm and 6.5mm.

Intended Use:

The Parcus V-LoX™ PEEK CF 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.

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 V-LoX PEEK CF Suture Anchors are essentially the same as the Parcus V-LoX Titanium Suture Anchors aside from the difference in material.

The only difference between the materials for the Parcus V-LoX PEEK CF Suture Anchor and the Smith & Nephew TWINFIX FT PK is that the Parcus Suture Anchor is carbon reinforced. Carbon fibers have been used clinically for more than 20 years as a reinforcement component for implant materials without obvious leachable-related biocompatibility reactions. Furthermore, there are currently several medical device implants on the market made from PEEK CF (e.g. Zimmer Spine BAK® Vista® Radiolucent Interbody Fusion System and the Depuy Spine OCELOT™ Stackable Cage System).

Therefore the Parcus V-LoX PEEK CF Suture Anchor is substantially equivalent to the predicate devices listed above in which the basic features and intended uses are the same. Any differences between the V-LoX PEEK CF Suture Anchor and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness.

Summary Performance Data:

The Parcus V-LoX PEEK CF Suture Anchors were placed in prepared holes and the pull out strength and insertion torque was measured. Test results were compared to the results for the Parcus V-LoX Titanium Suture Anchors and demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

SEP 30 2009

Parcus Medical, LLC
c/o Mr. Barton Bracy
VP Marketing and Product Development
839 South Neenah Avenue
Sturgeon Bay, Wisconsin 54235

Re: K091094
Trade/Device Name: Parcus V-Lox™ PEEK CF Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: September 23, 2009
Received: September 30, 2009

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 such 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); 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 (240) 276-3150 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): K091094

Device Name: Parcus V-LoX™ PEEK CF Suture Anchor

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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)

for MXM Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091094