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PARCUS MEDICAL, LLC.

SURGICAL INNOVATION
VALUE DRIVEN

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:	April 8, 2011

Trade Name:	Parcus MiTi 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 Anchors (K090075)
- Smith & Nephew Twinfix Ti 2.8 Suture Anchor (K053344)
- Smith & Nephew MINITAC Ti 2.0 Suture Anchor (K000797)

Device Description:

The Parcus MiTi Suture Anchor is a threaded, tapered fastener for use in attachment of soft tissue to bone. The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136). The product family includes devices that come preloaded with either one or two sutures between #3-0 and #2 in size either with or without attached needles, and a driver, and is available in three different diameters, 2.0mm, 2.5mm and 3.5mm. The 2.0mm anchor is offered in the following suture configurations: two #3-0 and one or two #2-0 sutures. The 2.5mm anchor is offered in the following suture configurations: two #3-0, two #2-0 and one #2 sutures. The 3.5mm anchor is offered in the following suture configurations: two #3-0, two #1 and two #2 sutures. All configurations are offered in multiple color variations and with or without attached needles.

Intended Use:

The Parcus MiTi 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.

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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 MiTi Suture Anchor is substantially equivalent to the predicate devices listed above in which the basic features and intended uses are very similar. Any differences between the MiTi Suture Anchor and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness.

Summary Performance Data:

The pull out strength and insertion torque was measured for the Parcus MiTi Suture Anchors. The published literature was reviewed and side by side comparisons were done with the Parcus Medical and Smith & Nephew predicate devices. The results of the insertion torque testing, pullout force, and the literature review demonstrated that there were no significant differences between the Parcus MiTi Suture Anchors and the predicate devices.

Fax 1.920.746.2974 PARCUSMEDICAL.COM Call 1.877.746.2972
839 S. Neenah Ave, Sturgeon Bay, WI 54235

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
Vice President Marketing and Product Development
839 South Neenah Avenue
Sturgeon Bay, Wisconsin 54235

JUL 28 2011

Re: K111000
Trade/Device Name: Parcus MiTi 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: July 19, 2011
Received: July 20, 2011

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

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Indications for Use

510(k) Number (if known): 1

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Elbow	Tennis Elbow Repair, Biceps Tendon Reattachment.
Hand/Wrist	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

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

510(k) Number K 111000

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)