K110164 (1/2)

FEB - 7 2011

510(k) Summary

ArthroCare Corporation
Spartan™ PEEK Suture Implant System

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	January 18, 2011

Device Description

Trade Name:	ArthroCare Spartan PEEK Suture Implant System
Generic/Common Name:	Screw, Fixation, Bone
Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)
Device Classification:	Class II, 21 CFR 888.3040 Product Code MBI

Predicate Device

Arthrocare 5.5mm Spartan PEEK Suture Implant System	K102262 (October 21, 2010)

Product Description

The ArthroCare Spartan PEEK (polyether-etherketone) Suture Implant is a fully-threaded, corkscrew shape anchor available in 5.5mm diameter size. The suture anchor comes preconfigured with MagnumWire® sutures for traditional knot tying and is mounted on a disposable delivery driver. The device is supplied sterile and is available with our without needles. Associated instruments (Punch Tap and Extraction Tool) for implantation and removal of the implant are available separately and altogether are referred to as the ArthroCare Spartan PEEK Suture Implant System.

Intended Uses/Indications for Use

The ArthroCare Spartan PEEK Suture Implant is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:

Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis, and deltoid repair

Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction, and midfoot reconstruction

Foot: Hallux valgus reconstruction

Elbow: Tennis elbow repair, biceps tendon reattachment

Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare compared the intended use, device design, technology, and device components of the subject device with the predicate device. Bench performance testing has been completed to demonstrate the substantial equivalence of the ArthroCare Spartan PEEK Suture Implant in accordance with FDA Guidance Document Testing for Bone Anchors. The *in vitro* testing performed involved insertion of the anchors in a simulated human bone substrate followed by both ultimate strength and cyclic loading tests. The performance testing and device comparison demonstrate that the subject device is substantially equivalent to the predicate device, and is safe and effective for its intended use.

Summary of Safety and Effectiveness

The proposed modifications to the Spartan PEEK Suture Implant System are not substantial changes, and do not significantly affect the safety or efficacy of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

ArthroCare Corporation
% Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085-3523

FEB - 7 2011

Re: K110164
Trade/Device Name: ArthroCare® Spartan™ PEEK Suture Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: January 18, 2011
Received: January 19, 2011

Dear Mr. Defiesta-Ng:

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,

for

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): K110164

Device Name: ArthroCare® Spartan™ PEEK Suture Implant System

Indications For Use:

The ArthroCare Spartan PEEK Suture Implant is indicated for use in fixation of soft tissue to bone. Examples of such procedures include:

Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis, and deltoid repair

Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction, and midfoot reconstruction

Foot: Hallux valgus reconstruction

Elbow: Tennis elbow repair, biceps tendon reattachment

Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

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)

M. Melkerson

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

510(k) Number K110164