ross creek medical

MAY 20 2009

510(k) Summary
(per 21CFR807.92)

General Company Information		
Name:	Ross Creek Medical, Inc.	
Contact:	Michael Kolber	
	Vice President, Regulatory Affairs	
Address:	16417 Peacock Lane Los Gatos, CA 95032	
Telephone:	408-505-6626	
Fax:	408-358-2381	
Date Prepared:	April 16, 2009	
General Device Information		
Product Name:	Spin-Loc Suture Anchor System	
Common Name:	Suture Anchor	
Classification: Device Class: Product Code:	Screw, fastener, fixation, non-degradable, soft tissue 21 CFR 888.3040 Product Code: MBI Class: II	
Predicate Devices		
Manufacturer	Device Name	510(k) Number
Arthrex	PushLock	K063479
Mitek	Versalok	K063478
Teleflex Medical	Force Fiber	K063778

Description

The Spin-Loc Suture Anchor System consists of a PEEK polymer and stainless steel or cobalt chromium alloy suture anchor loaded on an insertion handle. The Spin-Loc anchor is designed to facilitate fixation of soft tissue to bone. The design allows the surgeon to adjust the tension on the tissue after insertion of the anchor into bone. The Spin-Loc Suture Anchor System will be validated to a SAL of 10^{-6} using ethylene oxide. The ethylene oxide residuals will be tested according to ISO10993-7.

Intended Use (Indications)

The Spin-Loc Suture Anchor System is intended to be used for soft tissue fixation to bone in the shoulder, foot and ankle, knee, and elbow. The anchor is intended for use in the following procedures:

Shoulder
- Rotator Cuff Repair
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acromio-Clavicular Separation Repair
- Deltoid Repair
- Capsular Shift/Capsulolabral Reconstruction.

Knee
- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Tenodesis

Foot and Ankle ▪ Lateral Stabilization ▪ Medial Stabilization ▪ Achilles Tendon Repair ▪ Hallux Valgus Reconstruction ▪ Midfoot Reconstruction ▪ Metatarsal Ligament Repair	**Elbow** ▪ Biceps Tendon Reattachment

Substantial Equivalence

This submission supports the position that the Ross Creek Spin-Loc Suture Anchor System is substantially equivalent to a number of previously cleared devices, including the Arthrex PushLock [510(k) Number K063479], the Mitek Versalok [(510(k) K063478) and the Teleflex Medical Force Fiber [K063778].

The 510(k) notice contains summaries of *in vitro* studies that were conducted to evaluate the anchor pull-out strength as specified in the FDA Guidance Document for Testing Bone Anchor Devices (dated April 20, 1996). The data presented demonstrate that the anchor pull-out for the Ross Creek Spin-Loc Suture Anchor System compares favorably with the predicate devices. The failure modes observed for the Spin-Loc Suture Anchor were the same as those of the predicate devices.

The single patient use components of the bone anchor system are provided sterile.

Conclusions

Ross Creek Medical, Inc. believes that the information provided demonstrates that the proposed device is substantially equivalent to the predicate devices and do not raise any new issues of safety or efficacy. Based on the indications for use, technological characteristics, and comparison to predicated devices, the Spin-Loc Suture Anchor System has been shown to be substantially equivalent to predicate devices as described under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

Ross Creek Medical Inc.
c/o Mr. Michael Kolber
14734 LA Rinconada Drive
Los Gatos, California 95032

Re: K090530
Trade/Device Name: Spin-Loc Suture Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: April 16 2009
Received: April 21, 2009

Dear Mr. Kolber:

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.

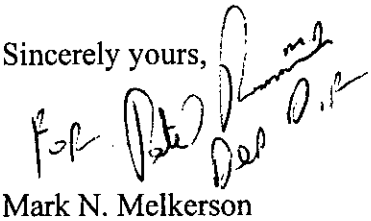
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090530

Device Name: Spin-Loc Suture Anchor System

Indications for Use: The Ross Creek Spin-Loc Suture Anchor System is intended to be used for soft tissue fixation to bone in the shoulder, foot and ankle, knee, and elbow. The anchor is intended for use in the following procedures:

Shoulder
- Rotator Cuff Repair
- Bankart Repair
- SLAP Lesion Repair
- Biceps Tenodesis
- Acromio-Clavicular Separation Repair
- Deltoid Repair
- Capsular Shift/Capsulolabral Reconstruction

Foot and Ankle
- Lateral Stabilization
- Medial Stabilization
- Achilles Tendon Repair
- Hallux Valgus Reconstruction
- Midfoot Reconstruction
- Metatarsal Ligament Repair

Knee
- Medial Collateral Ligament Repair
- Lateral Collateral Ligament Repair
- Patellar Tendon Repair
- Posterior Oblique Ligament Repair
- Illiotibial Band Tenodesis

Elbow
- Biceps Tendon Reattachment

The Ross Creek Spin-Loc Suture Anchor System is intended for single-use only.

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)

Janeta for PhD

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K090530