



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ArthroCare Corporation
Ms. Laura Kasperowicz
Principal RA Specialist
15285 Alton Parkway, Suite 200
Irvine, California 92618

December 11, 2015

Re: K153313

Trade/Device Name: SpeedLock Knotless Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: November 16, 2015
Received: November 17, 2015

Dear Ms. Kasperowicz:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153313

Device Name
SpeedLock Knotless Fixation System

Indications for Use (Describe)

The SpeedLock Knotless Fixation Device 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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ArthroCare® Corporation SpeedLock® Knotless Fixation System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name: ArthroCare Corporation, a Smith & Nephew Company
 Address: 15285 Alton Parkway, Suite 200
 Irvine, CA. 92618
 Contact Person: Laura Kasperowicz
 Principle Regulatory Affairs Specialist
 Phone: 949-585-2406
 Fax: 949-585-2401
 Date Prepared: November 16, 2015

Device Name

Proprietary Name: SpeedLock® Knotless Fixation System
 Common Name: Bone Anchor
 Classification Name: Smooth or threaded metallic bone fixation fastener
 Device Class: Class II
 Product Code: MBI
 CFR Section: 21 CFR 888.3040

Predicate Device

SpeedLock® Knotless Fixation System: K130196 (cleared February 27, 2013)

Description

The SpeedLock Knotless Fixation System is an implantable bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. The SpeedLock is a knotless fixation device, meaning that manually tying surgical knots is not necessary for the fixation of suture to tissue.

The SpeedLock Knotless Fixation System consists of two primary parts: an implantable bone anchor and an anchor inserter, which is preloaded with the anchor. The anchor inserter is a disposable tool.

The entire product is packaged in a tray with a Tyvek® lid, and the finished product is sterilized by ethylene oxide. Both the anchor and inserter are designed for single use only.

Intended Use/Indications For Use

The SpeedLock Knotless Fixation Device 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

Non-Clinical Data

Bench testing was performed on both the proposed and predicate devices in accordance with the FDA Guidance Document, *Testing Bone Anchors*, April 1996. This *in vitro* testing involved insertion of the anchors into a simulated human bone substrate followed by both static and cyclic fatigue testing. Design Verification testing was performed in order to verify the design outputs meet the design inputs. Simulated use testing was performed on the device and accessory devices which will be promoted for use with the SpeedLock system in order to affirm safety and effectiveness.

The test results demonstrate that the proposed SpeedLock meets its design, performance, and safety specifications. Based on the test results, the proposed device performs as intended and mechanical properties are substantially equivalent to the predicate device when used in accordance with labeling.

Clinical Data

No clinical or animal data are included in this submission.

Summary

All testing demonstrates that the proposed SpeedLock performs as intended and mechanical properties are substantially equivalent when used in accordance with the labeling.

As the intended use, operating principle, materials and technological characteristics are comparable to the predicate device, the proposed SpeedLock Knotless Fixation System is substantially equivalent. The minor differences between the proposed SpeedLock and predicate device do not raise any new questions of safety or effectiveness.

Comparison of Technological Characteristics		
Characteristics	Predicate Device SpeedLock (K130196)	Proposed Device SpeedLock
Intended Use	Fixation of soft tissue to bone	Same
Delivery Method	Arthroscopic and Limited Access	Same
How Supplied	Sterile (EtO)	Same
Suture Material	#2 UHMWPE MagnumWire® Suture	Same
Anchor Material	Invibio PEEK Optima® LT1	Invibio PEEK Optima® LT3
Design Technology	Anchor with 9 radial barbs (interference fit)	Same
Suture Locking Mechanism	Plug/Cylinder Compression	Same
Diameter of Anchor Body	3.0 – 3.5 mm	Same
Surface of Cortical Lock	1.25 cm ²	Same
Depth of Barb	0.25 mm	Same
Anchor Deployed Length	12 – 13 mm	Same
Method of Anchor Insertion	Inserted into a drilled hole	Same
Accessory Devices Promoted for use with the SpeedLock System	3.0mm Tapered Twist Drill, 3.0mm ⁺ Tapered Twist Drill, 3.5mm High Visibility Drill Guide, 3.5mm Low Profile Drill Guide, Sharp Tipped Obturator, PathFinder® Obturator	Same and SpeedStitch® Suture Passer