DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 6, 2015

ArthroCare Corporation
Ms. Laura Kasperowicz
Principle Regulatory Affairs Specialist
15285 Alton Parkway, Suite 200
Irvine, California 92618

Re: K151897
Trade/Device Name: MultiFIX® P Knotless Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 9, 2015
Received: July 10, 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 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 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" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151897

Device Name

MultiFIX P Knotless Fixation Device

Indications for Use *(Describe)*

The MultiFIX P 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 attachment.

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

MultiFIX® P Knotless Fixation Device

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:	July 9, 2015

Device Name

Proprietary Name:	MultiFIX® P Knotless Fixation Device
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

MultiFIX® P Knotless Fixation Device: K120096 (cleared March 27, 2012)

Description

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

The MultiFIX P 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 irradiation. Both the anchor and inserter are designed for single use only.

Intended Use/Indications For Use

The MultiFIX P 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. The test results demonstrate that the proposed MultiFIX P 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 MultiFIX P performs as intended and has acceptable mechanical properties 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 MultiFIX P Knotless Fixation Device is substantially equivalent. The minor differences between the proposed MultiFIX P and predicate device do not raise any new questions of safety or effectiveness.

Comparison of Technological Characteristics		
Characteristics	**Predicate Device** **MultiFIX P** **(K120096)**	**Proposed Device** **MultiFIX P**
Intended Use	Fixation of soft tissue to bone	Same
Delivery Method	Arthroscopic and Limited Access	Same
How Supplied	Sterile	Same
Brand Name of Qualified Suture	**#2 UHMWPE MagnumWire® Suture Thread**	**#2 UHMWPE MagnumWire® Suture Thread and/or UltraBraid® Suture Thread and/or UltraTape®**
# of Suture Legs **(volume of suture qualified)**	**2, 3 or 4 Suture Thread Legs**	**2, 3 or 4 Suture Thread Legs** **or a maximum of 2 Suture Thread Legs and 2 Suture Tape Legs**
Suture Snare	Single Loop	Same
Anchor Material	Invibio PEEK Optima® LT1	Same
Design Technology	Pound in Anchor	Same
Bone Locking Mechanism	6 barbs	Same
Suture Locking Mechanism	Plug/Cylinder Compression	Same
Diameter of Cortical Lock	4.5 mm	Same
Anchor Deployed Length	14.5 mm	Same
Sterilization Method	Irradiation	Same
Packaging	Sterile / Thermoform Tray with Tyvek Lid	Same