DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

August 17, 2017

Re: K172165
Trade/Device Name: Q-Fix Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 17, 2017
Received: July 18, 2017

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,

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)*
K172165

Device Name

Q-Fix Suture Anchor

Indications for Use *(Describe)*

The Q-Fix Suture Anchor is intended to be used for soft tissue to bone fixation for:

Shoulder: Bankart lesion repair; SLAP lesion repair; acromio-clavicular repair; capsular shift/capsulolabral reconstruction; deltoid repair; rotator cuff tear repair; biceps tenodesis

Foot & Ankle: Medial/Lateral repair and reconstruction; midfoot and forefoot repair; Hallux valgus reconstruction; Metatarsal ligament/tendon repair or reconstruction; Achilles tendon repair

Elbow: Ulnar or radial collateral ligament reconstruction; lateral epicondylitis repair; biceps tendon reattachment

Knee: Extra-capsular repair: medial collateral ligament (MCL), lateral collateral ligament (LCL) and posterior oblique ligament; Iliotibial band tenodesis (IBT); patellar tendon repair; vastus medialis obliquus advancement (VMO); joint capsule closure

Hand & Wrist: Collateral ligament repair; Scapholunate ligament reconstruction; Tendon transfers in phalanx; Volar plate reconstruction

Hip: Acetabular labral repair

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

Q-Fix® Suture Anchor

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 17, 2017

Device Name

Proprietary Name:	Q-Fix® Suture Anchor
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

ArthroCare Q-Fix® Suture Anchor: K133727 (cleared January 16, 2014)

Description

The purpose of this submission is to seek clearance for a line extension and additions to the accessory instrumentation used with the previously cleared Q-Fix Suture Anchor (K133727). There are no changes to the previously cleared indications for use, materials, design, technology, method of anchor insertion and or tissue attachment.

The Q-Fix Suture Anchor (Q-Fix) is a bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. This family of suture anchors previously was available in two sizes, 1.8mm and 2.8mm. This submission proposes an additional size of Q-Fix Suture Anchor, the 1.8mm Q-Fix MINI Suture Anchor.

The Q-Fix consists of two primary parts: a 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.

The Q-Fix Suture Anchor consists of the bone anchor and associated instruments for implanting the bone anchor. In accordance with the ArthroCare Product Development Process, testing was performed to demonstrate the proposed device is substantially equivalent to the predicate device. Mechanical testing was performed in accordance with the requirements of the FDA Guidance Document, *Testing Bone Anchor Devices*, April 1996.

Intended Use/Indications For Use

The Q-Fix Suture Anchor is intended to be used for soft tissue to bone fixation for:

Shoulder:	Bankart lesion repair; SLAP lesion repair; acromio-clavicular repair; capsular shift/capsulolabral reconstruction; deltoid repair; rotator cuff tear repair; biceps tenodesis
Foot & Ankle:	Medial/Lateral repair and reconstruction; midfoot and forefoot repair; Hallux valgus reconstruction; Metatarsal ligament/tendon repair or reconstruction; Achilles tendon repair
Elbow:	Ulnar or radial collateral ligament reconstruction; lateral epicondylitis repair; biceps tendon reattachment
Knee:	Extra-capsular repair: medial collateral ligament (MCL), lateral collateral ligament (LCL) and posterior oblique ligament; Iliotibial band tenodesis (IBT); patellar tendon repair; vastus medialis obliquus advancement (VMO); joint capsule closure
Hand & Wrist:	Collateral ligament repair; Scapholunate ligament reconstruction; Tendon transfers in phalanx; Volar plate reconstruction
Hip:	Acetabular labral repair

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.

The test results demonstrate that the Q-Fix 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 devices when used in accordance with labeling.

Clinical Data

No clinical or animal data are included in this submission.

Summary

All testing demonstrates that the Q-Fix performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

The minor differences between the Q-Fix system and predicate device system do not raise any new questions of safety or effectiveness.

Comparison of Technological Characteristics		
Characteristics	**Predicate Devices & System 1.8mm Q-Fix & 2.8mm Q-Fix (K133727)**	**Proposed Devices & System 1.8mm Q-Fix, 2.8mm Q-Fix & 1.8mm Q-Fix MINI**
Intended Use	Fixation of soft tissue to bone	Same
Delivery Method	Arthroscopic and Limited Access	Same
How Supplied	Packaged in thermoform tray with Tyvek lid, Sterile (EtO), Single Use	Same
Suture Material	No. 2 UHMWPE Suture	Same
Anchor Material	Braided Polyester	Same
Inserter Handle Materials	Medical Grade Plastics and Surgical Grade Stainless Steels	Same
Method of Anchor Insertion	Inserted into a predrilled hole	Same
Bone Locking Mechanism	Expandable Compression Fit	Same
Suture Locking Mechanism	Manually tied suture knot	Same
# of Suture Legs	Two (1.8mm) & Four (2.8mm)	Same
Sizes Offered	1.8mm & 2.8mm	1.8mm, 2.8mm & 1.8mm MINI
Deployed Length	15mm for 1.8mm Q-Fix Anchor 20mm for 2.8mm Q-Fix Anchor	15mm for 1.8mm Q-Fix Anchor 20mm for 2.8mm Q-Fix Anchor 10mm for 1.8mm Q-Fix MINI Anchor
Bone hole OD	2.1mm (0.083”) for 1.8mm Q-Fix Anchor 3.1mm (0.121”) for 2.8mm Q-Fix Anchor	Same
Bone hole depth	22.3mm for 1.8mm Q-Fix Anchor 26.8mm for 2.8mm Q-Fix Anchor	22.3mm for 1.8mm Q-Fix Anchor 26.8mm for 2.8mm Q-Fix Anchor 17.1mm for 1.8mm Q-Fix MINI Anchor
Accessory Instruments	Nonsterile, Reusable Drill, Drill Guide, Obturator and Sterile, Disposable Drill, Drill Guide, Obturator	Same
	Bone Punch, Knot Pusher	Same
	1.8mm & 2.8mm PathFinder®	Same
	FirstPass® Suture Passer	FirstPass® Suture Passer FirstPass® ST Suture Passer Accu-Pass® Direct Suture Passer SpeedStitch® Suture Passer