DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 28, 2016

ArthroCare Corporation
Ms. Katherine Marcaccio
Regulatory Affairs Specialist II
15285 Alton Parkway, Number 200
Irvine, California 92618

Re: K153186
Trade/Device Name: Adjustable 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: November 2, 2015
Received: November 3, 2015

Dear Ms. Marcaccio:

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)*

K153186

Device Name
Adjustable Fixation Device

Indications for Use *(Describe)*

The Adjustable Fixation Device is indicated for soft tissue to bone fixation for:

- ACL/PCL repair / reconstruction
- ACL/PCL patellar bone-tendon-bone grafts
- Double-Tunnel ACL reconstruction
- Extracapsular repair: MCL, LCL, and posterior oblique ligament
- Illiotibial band tenodesis
- Patellar tendon repair
- VMO advancement
- Joint capsule closure

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

ArthroCare® Corporation

Adjustable 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
Address	15285 Alton Parkway, Suite 200 Irvine, CA 92618
Contact Person:	Katherine Marcaccio Regulatory Affairs Specialist II Phone: 508-261-3602 Fax: 978-749-1443
Date Prepared:	2 November 2015

Device Name

Proprietary Name:	Adjustable Fixation Device
Common Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	II
Product Code:	MBI
CFR Section:	888.3040

Predicate Devices

The predicate devices for the Adjustable Fixation Device are:

- Biomet ToggleLoc cleared via 510(k) K083070 and subsequently K130033.
- N8TIVE ACL Reconstruction System cleared via 510(k) K133606.

Description

The Adjustable Fixation Device consists of a graft suspension loop and a titanium cortical button. The suspension loop is threaded through the titanium cortical button to form a graft suspension construction. The device facilitates repair through placement and retention of the soft tissue graft within bone.

Characteristics	**Biomet ToggleLoc** K083070, K130033	**N8TIVE ACL Reconstruction System** K133606	**Adjustable Fixation Device** Proposed Device
Intended Use	*Fixation of soft tissue to bone*	*Same*	Same
How Supplied	*Sterile*	*Same*	Same
Sterilization Method	*Ethylene Oxide*	*Same*	Same
Implant Materials			
• **Cortical Button**	*Titanium (Ti-6AL-4V Alloy)*	*Same*	Same
• **Suspension Loop**	*UHMWPE/Polypropylene/ Polyester*	*UHMWPE/Polyester*	Same as N8TIVE
• **Suture/Suture Tape**	*Not Applicable*	*UHMWPE*	Not Applicable
• **Graft Spacer**	*Not Applicable*	*PEEK Optima®*	Not Applicable
• **Screw**	*Not Applicable*	*Same*	Not Applicable
• **Sheath**	*Not Applicable*	*PEEK Optima*	Not Applicable
• **Tether Sutures**	*Not Applicable*	*UHMWPE*	Not Applicable
Method of Insertion	*Inserted into drilled hole/tunnel*	*Same*	Same
Design Technology	*Graft suspension loop with cortical button*	*Graft Spacer and Suspension Loop with Cortical Button*	Same as Biomet ToggleLoc
Implant Size/Dimensions			
• **Cortical Button**	*13.2mm x 2.0mm x 1.8mm*	*12.1mm x 3.9mm x 1.8mm (Femoral Implant)* *18mm x 11.5mm 6.1mm (Tibial Implant)*	Same as N8TIVE Femoral Implant
• **Suspension Loop**	*Adjustable*	*Same*	Same
• **Graft Spacer**	*Not Applicable*	*23mm x 6mm x 6mm*	Not applicable

• **Screw**	*Not Applicable*	*Range of 29 to 36mm length, 8mm diameter*	Not Applicable
• **Sheath**	*Not Applicable*	*Range of 33 to 40mm length*	Not Applicable

Intended Use

The Adjustable Fixation Device is indicated for soft tissue to bone fixation for:

- ACL/PCL repair / reconstruction
- ACL/PCL patellar bone-tendon-bone grafts
- Double-Tunnel ACL reconstruction
- Extracapsular repair: MCL, LCL, and posterior oblique ligament
- Illiotibial band tenodesis
- Patellar tendon repair
- VMO advancement
- Joint capsule closure

Non-Clinical Data

Bench testing was conducted as follows:

- Comparative testing of the proposed and predicate devices in which the proposed and predicate devices were inserted into a simulated human bone substrate and subjected to cyclic and static loading.
- Design Verification testing to demonstrate conformance to design and performance specifications.

All test results confirm that Adjustable Fixation Device is substantially equivalent to the predicate devices. Additionally, the test results confirm that the devices meet their design, performance, and safety specifications.

Clinical Data

No clinical or animal data are included in this submission.

Summary

All testing demonstrates that the Adjustable Fixation Device performs as intended and has acceptable mechanical properties when used in accordance with the device labeling.

As the intended use, operating principle, materials, and technological characteristics are comparable to the predicate devices, ArthroCare believes the Adjustable Fixation Device is substantially equivalent to the predicate devices. The minor differences between the ArthroCare devices and their predicate devices do not raise any new questions of safety or effectiveness.