ArthroCare®

APR 0 1 2014

510(k) Summary

ArthroCare® Corporation

N8TIVE™ ACL Anatomic Reconstruction 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
Address	7000 West William Cannon Drive Austin, TX 78735
Contact Person:	Laurie Cartwright Sr. Manager, Regulatory Affairs Phone: 949-585-2465 Fax: 512-895-1489
Date Prepared:	31 March 2014

Device Name

Proprietary Name:	N8TIVE™ ACL Anatomic Reconstruction System N8TIVE™ ACL Femoral Implant N8TIVE™ ACL Tibial Implant
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 N8TIVE ACL Anatomic Reconstruction System are:

- For the N8TIVE ACL Femoral Implant, the Biomet ToggleLoc Femoral Fixation Device cleared under K083070 and K130033.
- For the N8TIVE ACL Tibial Implant, the Arthrex Interference Screws cleared under K052607 and K062466.

The tables on the following page provide a comparison of the technological characteristics for the N8TIVE ACL Implants and the predicate devices.

Comparison of Device Characteristics: N8TIVE ACL Femoral Implant and Biomet ToggleLoc Femoral Fixation Device		
Characteristics	**Biomet ToggleLoc** K083070, K130033	**N8TIVE ACL Femoral Implant** Proposed Device
Intended Use	*Fixation of Soft Tissue to Bone*	Same
How Supplied	*Sterile*	Same
Sterilization Method	*Ethylene Oxide*	Same
Implant Materials		Same
• **Cortical Button**	*Titanium (TI-6AL-4V Alloy)*	Same
• **Suspension Loop**	*UHMWPE/Polypropylene/Polyester*	UHMWPE/Polyester
• **Suture/Suture Tape**	*Not Applicable*	UHMWPE
• **Graft Spacer**	*Not Applicable*	PEEK Optima®
Method of Insertion	*Inserted into drilled hole/tunnel*	Same
Design Technology	*Graft Suspension Loop with Cortical Button*	Graft Spacer and Suspension Loop with Cortical Button
Implant Size/Dimensions		
• **Cortical Button**	*13.2 mm x 2.0 mm x 1.8 mm*	12.1 mm x 3.9 mm x 1.8 mm
• **Suspension Loop**	*Adjustable*	Same
• **Graft Spacer**	*Not Applicable*	23 mm x 6 mm x 6 mm

Comparison of Device Characteristics: N8TIVE ACL Tibial Implant and Arthrex Interference Screws		
Characteristics	**Arthrex Interference Screws** K052607, K062466	**N8TIVE Tibial Implant** Proposed Device
Intended Use	*Fixation of Soft Tissue to Bone*	Same
How Supplied	*Sterile*	Same
Sterilization Method	*Ethylene Oxide*	Same
Implant Materials		
• **Cortical Button**	*Not Applicable*	Titanium (TI-6AL-4V Alloy)
• **Screw**	*PEEK Optima*	Same
• **Sheath**	*Not Applicable*	PEEK Optima
• **Tether Sutures**	*Not Applicable*	UHMWPE
Method of Insertion	*Screwed into drilled hole/tunnel using reusable driver*	Same, using included inserter driver
Design Technology	*Interference Screw*	Same
Implant Size/Dimensions		
• **Cortical Button**	*Not Applicable*	18 mm x 11.5 mm x 6.1 mm
• **Screw**	*Range of 23 to 35 mm length, 6 to 12 mm diameter*	Range of 29 to 36 mm length, 8 mm diameter
• **Sheath**	*Not Applicable*	Range of 33 to 40 mm length

Description

The N8TIVE ACL Reconstruction System is designed for ACL repair and consists of the N8TIVE ACL Femoral and Tibial Implants, as well as various Class I ancillary devices, all of which may be marketed or used individually or in conjunction with one another. The N8TIVE ACL System provides fixation of a soft-tissue graft within the femoral and tibial tunnels to reconstruct the anterior cruciate ligament and is designed to create femoral and tibial tunnels that are "figure-eight" or oval shaped.

The N8TIVE ACL Femoral Implant consists of a polyether etherketone (PEEK) spacer, an ultra-high molecular weight polyethylene (UHMWPE) graft suspension loop, UHMWPE suture tape, and a titanium cortical button. The suspension loop is threaded through the titanium cortical button and the PEEK spacer and forms a symmetrical graft suspension construct. The suspension loop is tightened by pulling each "tail" of the suture to remove the slack and adjust the construct to match the tunnel length. The UHMWPE suture tape is provided to secure the graft to the spacer so that it remains seated during insertion into the bone tunnel.

The N8TIVE ACL Tibial Implant consists of a PEEK screw, a PEEK sheath, and an UHMWPE tether suture pre-threaded through the screw and through an optional titanium cortical button. The Tibial Implant is available in two sizes in order to accommodate specific patient anatomy: a 29 mm length screw with a 33 mm length sheath for smaller tibial anatomy and a 36 mm screw with a 40 mm sheath for larger tibial anatomy.

Both N8TIVE ACL Implants are supplied preloaded onto an inserter handle and are provided sterile, for single patient use only.

The N8TIVE ACL Implants may be marketed and/or used in conjunction with various Class I ancillary instruments. These instruments include both sterile and non-sterile/reusable instrumentation for use in the ACL reconstruction procedure.

Indications For Use

The N8TIVE™ ACL Anatomic Reconstruction System is indicated for use in the fixation of soft tissue grafts to bone during anterior cruciate ligament reconstruction surgeries of the knee.

The indications for use for the N8TIVE ACL System are comprised of a subset of the indications for use cleared for the predicate devices. While the N8TIVE ACL System is specifically designed and intended for use in anterior cruciate ligament reconstruction, the predicate devices may additionally be used for treatment in other anatomic locations. The differences between the predicate device indications for use and the N8TIVE ACL System indications for use do not affect the safety or effectiveness of the N8TIVE ACL System when used in accordance with its labeling.

Non-Clinical Data

Bench testing was conducted as follows:

- Magnetic Resonance Imaging compatibility testing.
- 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.
- Insertion strength testing in a dense bone model.
- Cyclic evaluation of the interface between the UHMWPE suture tape and a graft analog.

- Design Verification testing to demonstrate conformance to design and performance specifications.

All test results confirm that the N8TIVE ACL Reconstruction System 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 N8TIVE ACL Anatomic System 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 N8TIVE ACL Anatomic Reconstruction System 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.

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

April 1, 2014

Arthrocare® Corporation
Mr. Mitchell Dhority
Vice President, Regulatory Affairs
7000 West William Cannon Drive
Building One
Austin, Texas 78735

Re: K133606
Trade/Device Name: N8TIVE™ ACL Anatomic Reconstruction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, JDR
Dated: March 19, 2014
Received: March 20, 2014

Dear Mr. Dhority:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Lori A. Wiggins

for
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 on last page.

510(k) Number *(if known)*
K133606

Device Name
The N8TIVE™ ACL Anatomic Reconstruction System

Indications for Use *(Describe)*
The N8TIVE™ ACL Anatomic Reconstruction System is indicated for use in the fixation of soft tissue grafts to bone during anterior cruciate ligament reconstruction surgeries of the knee.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

Page (1/1)