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

July 21, 2015

Ceterix Orthopaedics Incorporated
Mr. Scott King
Senior Director, Regulatory Affairs, Quality Assurance and Compliance
959 Hamilton Avenue
Menlo Park, California 94025

Re: K143356
Trade/Device Name: NovoStitch Plus Meniscal Repair System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: June 12, 2015
Received: June 15, 2015

Dear Mr. King:

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" (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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
For Division of Surgical 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)*

K143356

Device Name

NovoStitch Plus Meniscal Repair System

Indications for Use *(Describe)*

The NovoStitch Plus Meniscal Repair System is intended for approximation of soft tissue in meniscal repair procedures.

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)*

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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CETERIX ORTHOPAEDICS

**510(k) Summary**

Ceterix Orthopaedics

NovoStitch Plus Meniscal Repair System

ADMINISTRATIVE INFORMATION

| | |
|---|---|
| 510(k) Number: | K143356 |
| 510(k) Owner: | Ceterix Orthopaedics, Inc.<br>959 Hamilton Avenue<br>Menlo Park, CA 94025<br>Telephone (650) 316-8660<br>Fax (650) 323-2209 |
| Contact Person: | Scott King<br>959 Hamilton Avenue<br>Menlo Park, CA 94025<br>sking@ceterix.com<br>Telephone (650) 316-8660<br>Fax (650) 323-2209 |
| DATE PREPARED | July 14, 2015 |

DEVICE NAME

| | |
|---|---|
| Trade/Proprietary Name: | NovoStitch Plus Meniscal Repair System |
| Common Name: | Suture, Nonabsorbable, Synthetic, Polyethylene |
| Classification Names: | Suture, Nonabsorbable, Synthetic, Polyethylene |
| Classification Regulation: | 21CFR 878.5000 |
| Device Class: | Class II |
| Panel: | General & Plastic Surgery |
| Product Code: | GAT |

PREDICATE DEVICES

| | |
|---|---|
| Delivery Device Predicate | Cayenne CrossFix II® Meniscal Repair Device (K121413) |
| Suture Implant Predicate | Teleflex Force Fiber® Polyethylene Non-Absorbable Surgical Suture (K063778) |

DEVICE DESCRIPTION

The NovoStitch Plus Meniscal Repair System passes size 2-0 braided, non-absorbable, polyethylene surgical suture through soft tissue in arthroscopic surgery. It is comprised of a handheld surgical instrument to which cartridges preloaded with polyethylene suture are attached.

INDICATIONS FOR USE

The NovoStitch Plus Meniscal Repair System is intended for approximation of soft tissue in meniscal repair procedures.

PERFORMANCE DATA

Product performance testing for NovoStitch Plus Meniscal Repair System was performed in a simulated use environment and device strength and reliability, device insertion, suture deployment, device removal and ability to reload the device with a new suture cartridge and perform additional device insertions, deployments and removals was validated. Bench testing was performed to verify that the device and the implantable suture

CETERIX ORTHOPAEDICS

meet all pre-established acceptance criteria. The verification testing has demonstrated that the device can reliably deliver up to six stitches. This includes the cartridge provided with the handle assembly and up to five additional cartridges. The verification testing included device joint strength, delivery device, suture tensile strength and suture diameter. Suture tensile strength and suture diameter testing was performed per USP requirements for non-absorbable surgical suture. Sterilization, packaging and shelf life were validated. In addition to these performance tests, full biocompatibility testing was conducted to demonstrate compliance with requirements for biocompatibility of permanent implants in contact with tissue and/or bone in accordance with ISO 10993-1.

TECHNOLOGICAL CHARACTERISTICS

- The NovoStitch Plus Meniscal Repair System is a hand-held, disposable surgical instrument coupled with an implantable suture for the approximation of soft tissue in meniscal repair procedures. The system is comprised of a delivery handle and a suture cartridge, both of which are provided sterile.
- Comparison of technological characteristics to the delivery device predicate device

| Characteristic | ***NovoStitch Plus Meniscal Repair System*** | ***CrossFix II Meniscal Repair Device*** |
|---|---|---|
| Method of use | Handheld, manually operated, single procedure, arthroscopic suture placement system | Handheld, manually operated, single procedure, arthroscopic suture placement system |
| Handle material | Polymer delivery handle | Polymer delivery handle |
| Distal end material | Stainless steel distal end | Stainless steel distal end |
| Tissue interaction | Tissue retained by upper and lower jaws | Tissue pierced with two hypotubes |
| Needle characteristics | Flexible, nitinol needle | Flexible, nitinol needle |
| Suture material | Polyethylene, nonabsorbable surgical suture. | Polyethylene, nonabsorbable surgical suture. |
| Sterilization | Sterile, ethylene oxide | Sterile, ethylene oxide |
| Knot tying method | Manually tied knot | Pre-tied knot plus additional manual throws |

- The subject device has the same knot tying method as the suture implant predicate Force Fiber® Polyethylene Nonabsorbable Surgical Suture
- The suture used in the NovoStitch Plus Meniscal repair system is the same suture as the predicate suture cleared under K063778 and the same suture used in the predicate delivery device cleared under K121413

EQUIVALENCE TO MARKETED PRODUCT

The NovoStitch Plus Meniscal Repair Device has demonstrated equivalence to the unmodified predicate devices in the following areas:

- Has the same intended use for approximation of soft tissues in meniscal repair procedures
- Has equivalent technological characteristics
- Has equivalent labeling
- Has demonstrated equivalent usability with respect to handle deployment force
- Has demonstrated product reliability and biocompatibility

In conclusion, the NovoStitch Plus Meniscal Repair System described in this submission is substantially equivalent to the predicate devices with respect to safety, effectiveness and reliability.

959 HAMILTON AVENUE ▪ MENLO PARK, CA 94025
p 650 316 8660 ▪ f 650 323 2209
CETERIX.COM