March 29, 2018

Ceterix Orthopaedics, Inc.
% Ms. Debra Cogan
Regulatory Affairs Consultant for Ceterix
QRAC, LLC
6500 Kaiser Drive, Suite 120
Fremont, California 94555

Re: K180531
Trade/Device Name: NovoStitch Pro 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: February 26, 2018
Received: February 28, 2018

Dear Ms. Cogan:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180531

Device Name
NovoStitch Pro Meniscal Repair System

Indications for Use *(Describe)*
The NovoStitch Pro 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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SECTION 3. 510(K) SUMMARY

Manufacturer and Submitter

Company Name:	Ceterix Orthopaedics, Inc.
Company Address:	6500 Kaiser Drive Suite 120 Fremont, CA 94555 TEL: (650) 316-8660 FAX: (650) 618-2779 Email: dcogan@ceterix.com
Contact Person:	Debra Cogan
Date of Preparation:	February 26, 2018

Device Name and Classification

Trade/Proprietary Name:	NovoStitch Pro Meniscal Repair System
Common Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Classification Name:	Suture, Nonabsorbable, Synthetic, Polyethylene
Regulation Number:	21 CFR 878.5000
Regulatory Class:	II
Product Code:	GAT
Panel:	General & Plastic Surgery

Predicate Device

Device Name:	NovoStitch Plus Meniscal Repair System
510(k) Number:	K143356
Applicant:	Ceterix Orthopaedics

Device Description

The NovoStitch Pro Meniscal Repair System is a next generation of the predicate device, the NovoStitch Plus Meniscal Repair System. The NovoStitch Pro Meniscal Repair System passes size 2-0 braided, nonabsorbable, 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.

Intended Use/Indication for Use

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

Performance Data

Product performance testing for the NovoStitch Pro Meniscal Repair System was performed in a simulated use environment. Device strength, device reliability, device insertion, suture deployment, device removal, and the ability to reload the device with new suture cartridges to perform additional device insertions, deployments and removals were validated. Bench testing was performed to verify that the device and the implantable suture meet all pre-established acceptance criteria. The verification testing has demonstrated that the device can reliably deliver up to six stitches. This includes the preloaded handle assembly and up to five additional cartridges. The verification testing included device joint strength and device performance evaluations. Sterilization, packaging and shelf life were either validated or adopted from previous testing where appropriate. In addition, biocompatibility testing for each element of the NovoStitch Pro Mensical Repair System was conducted to demonstrate compliance with ISO 10993-1. The suture implant met all biocompatibility requirements for permanent implants in contact with tissue and/or bone. The patient contact portions of the delivery handle met all requirements for limited duration contact with tissue and/or bone.

Human factors and usability testing was conducted with the NovoStitch Pro. The evaluation was conducted in conformance with the FDA guidance, "Applying Human Factors and Usability Engineering to Medical Devices", February 3, 2016. In the study, 15 orthopedic surgeons were trained on the use of the NovoStitch Pro per the Instructions for Use, followed by a quantitative assessment of the human factors and usability processes for six essential tasks.

Technological Characteristics

The NovoStitch Pro Meniscal Repair System is a handheld, 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.

Table 3-1.Comparison of technological characteristics to predicate device

Characteristic	NovoStitch Pro Meniscal Repair System	NovoStitch Plus Meniscal Repair System
510(k) #	TBD	K143356
Method Of Use	Handheld, manually operated, single procedure arthroscopic suture placement system	Handheld, manually operated, single procedure arthroscopic suture placement system
Handle Material	ABS/PC blend	Polycarbonate, 10% glass filled
Distal end material	Stainless steel	Stainless steel
Usability	Single patient use, can deliver up to six sutures, disposable	Single patient use, can deliver up to six sutures, disposable
Tissue interaction	Tissue retained by upper and lower jaw	Tissue retained by upper and lower jaw
Needle material	Nitinol	Nitinol

Suture material	Polyethylene, nonabsorbable surgical suture, size 2-0 suture	Polyethylene, nonabsorbable surgical suture, size 2-0 suture
Sterilization	Ethylene oxide	Ethylene oxide
Knot tying method	Manually tied knot	Manually tied knot

Conclusion

The NovoStitch Pro Meniscal Repair System is substantially equivalent to the predicate device with respect to safety, effectiveness and reliability.