August 1, 2018

Ceterix Orthopaedics, Inc.
% Mr. Tarhan Kayihan
Director of Quality and Regulatory
6500 Kaiser Drive, Suite 120
Fremont, California 94555

Re: K181772
Trade/Device Name: NovoStitch Pro Meniscal Repair System, CTX-A004 (size 0)
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: July 2, 2018
Received: July 3, 2018

Dear Mr. Kayihan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

David Krause -S

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)*

K181772

Device Name

NovoStitch Pro Mensical Repair System, CTX-A004 (size 0)

Indications for Use *(Describe)*

The NovoStitch Pro Mensical 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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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: tkayihan@ceterix.com
Contact Person:	Tarhan Kayihan

Device Name and Classification

Trade/Proprietary Name:	NovoStitch® Pro Meniscal Repair System, CTX-A004 (size 0)
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 Pro Meniscal Repair System, CTX-A003 (size 2-0)
510(k) Number:	K180531
Applicant:	Ceterix Orthopaedics

Reference Device

Device Name:	Force Fiber® Green Ultra High Molecular Weight Polyethylene Non-Absorbable Surgical Suture
510(k) Number:	K100506
Applicant:	Teleflex Medical

Device Description

The NovoStitch Pro Meniscal Repair System, size 0 is a new configuration of the predicate device. While the predicate device passes size 2-0 suture, this new configuration passes size 0 braided, nonabsorbable, surgical suture through soft tissue in arthroscopic surgery. It is comprised of a handheld surgical instrument to which cartridges preloaded with suture are attached.

Intended Use/Indication for Use

The NovoStitch Pro Meniscal Repair System, size 0 is intended for approximation of soft tissue in meniscal repair procedures.

Technological Characteristics

The NovoStitch Pro Meniscal Repair System, size 0 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, CTX-A004 (size 0)	NovoStitch Pro Meniscal Repair System, CTX-A003 (size2-0)
510(k) #	K181772	K180531
Method of Use	Handheld, manually operated, single procedure arthroscopic suture placement system	Handheld, manually operated, single procedure arthroscopic suture placement system
Delivery Instrument	Identical to predicate device, NovoStitch Pro Meniscal Repair System, CTX-A003 (size 2-0)	As described in K180531
Handle Material	ABS/PC blend	ABS/PC blend
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 0, white with green co-braid	Polyethylene, nonabsorbable surgical suture, size 2-0, white with blue co-braid
Suture supplier	Teleflex Medical	Teleflex Medical
Sterilization	Ethylene oxide	Ethylene oxide
Knot tying method	Manually tied knot	Manually tied knot

Performance Data

Product performance testing for the NovoStitch Pro Meniscal Repair System, size 0 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 Meniscal Repair System, size 0 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.

Conclusion

The NovoStitch Pro Meniscal Repair System, size 0 is substantially equivalent to the predicate device with respect to safety, effectiveness and reliability.