July 17, 2019

Xiros Ltd
Stephen Seed
Compliance Director
Springfield House
Whitehouse Lane
Leeds, West Yorkshire
LS17 7UE
United Kingdom

Re: K191053
Trade/Device Name: XTREME--LOOP
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 17, 2019
Received: April 19, 2019

Dear Mr. Seed:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K191053

Device Name
XTREME-LOOP

Indications for Use *(Describe)*

The XTREME-LOOP is used for fixation of tendons and ligaments during orthopaedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction.

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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K191053 510(k) SUMMARY

In accordance with 21 CFR 807.92, the following information constitutes Xiros Ltd. 510(k) summary for the XTREME-LOOP.

I.SUBMITTER INFORMATION

Submitter`s Name:	Xiros Limited
Address:	Springfield House Whitehouse Lane Leeds LS19 7UE England
Telephone Number:	+44 (0)113 238 7200
Fax Number:	+44 (0)113 238 7201
Contact Person:	Stephen Seed (Compliance Director)
Date:	17 April 2019

II. DEVICE IDENTIFICATION

Name of Device:	XTREME-LOOP
Trade Name:	XTREME-LOOP
Common or usual name:	Suture retention device; Surgical Button, Polyester Surgical Suture, ACL suspension fixation.
Classification Name:	Fastener, fixation, non-degradable, soft tissue
Regulatory Class:	Class II
Product Code:	MBI
Regulation:	888.3040
Panel:	Orthopaedic

III. PREDICATE DEVICE

SECURE-LOOP manufactured by Xiros, K151601. This predicate has not been subject to a design related recall.

Reference device market leader for essentially the same indications for use; Endobutton Continuous Loop (ECL) manufactured by Smith and Nephew, K980155.

Reference device for loop material for essentially the same indications for use; XO Button manufactured by Conmed Linvatec, K070780.

IV. DEVICE DESCRIPTION

The XTREME-LOOP fixation device consists of a Ultra High Molecular Weight Polyethylene (UHMWPE) continuous loop captured on a titanium alloy button. The button sits on the exit to a bone tunnel on the cortex, suspending the continuous loop inside the tunnel to provide secure, strong fixation for ligament reconstruction. The XTREME-LOOP fixation device is supplied with sutures that are used to pull the graft assembly into place and then flip the button allowing ligament reconstruction to be performed arthroscopically.

V. INDICATIONS FOR USE

The XTREME-LOOP fixation device is used for fixation of tendons and ligaments during orthopaedic reconstruction procedures such as anterior cruciate ligament (ACL) reconstruction.

VI. COMPARISIONS OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The XTREME-LOOP has the same technological characteristics as the predicate SECURE-LOOP, with respect to intended use, labelling, composition of all components except for the continuous loop material, basic design, functionality and uses essentially the same manufacturing methods except for differences in the button manufacture and sterilization method.

VII. PERFORMANCE DATA

The XTREME-LOOP when tested against the SECURE-LOOP (K151601) for strength, stiffness, strength after fatigue, extension at predicate UTS, cyclic fatigue testing, and functional testing, was determined to be substantially equivalent. The device has been tested for pyrogenicity using the turbidimetric Limulus Amoebocyte Lysate (LAL) method in line with the requirements of ANSI/AAMI ST72:2011. It was found to have a result of < 0.1 EU/Device, meeting FDA requirements of < 20 EU/Device. Final product batch release testing for endotoxins will be carried out in accordance with ANSI/AAMI ST72:2011. In addition, the loop has been tested for rabbit pyrogenicity in line with USP, General Chapter <151>, Pyrogen test with a result of a total rise in temperature for three animals over 3 hours of 0.5°C with no single animal above 0.5°C, and was therefore judged to be non-pyrogenic. The testing demonstrated that the differences between the new device and the predicate device do not raise any new issues of safety and efficacy. The performance data benefit/risk analysis concluded that the differences encountered do not affect the safety and efficacy of the new device in relation to the predicate..

Summary: Based on the pre-clinical testing performance, the XTREME-LOOP is found to have a safety and effectiveness profile that is similar to the predicate device.

VIII.CONCLUSION

The XTREME-LOOP is composed of the same materials with the exception of the continuous loop material (manufactured from a different fibre of polymeric material) and has essentially the same basic design as the predicate device. It is manufactured in the same manner and uses essentially the same methods of that used to manufacture the predicate device.

Testing performed demonstrate that the XTREME-LOOP is substantially equivalent to the SECURE-LOOP fixation device.

Xiros therefore conclude the XTREME-LOOP is substantially equivalent to the SECURE-LOOP also manufactured by Xiros.