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

June 30, 2017

Xiros, Ltd
Mr. Stephen Seed
Springfield House
Whitehouse Lane, Leeds
LS19 7UE
England

Re: K171680
Trade/Device Name: Infinity-Lock 3, Infinity-Lock 5
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(ethylene terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: June 2, 2017
Received: June 6, 2017

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. 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" (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.

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171680

Device Name
Infinity-Lock 3
Infinity-Lock 5

Indications for Use *(Describe)*

The Infinity-Locks are single use devices intended to be used for soft tissue approximation, including Achilles tendon repair in patients with acute rupture of the Achilles tendon.

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 7. Special 510(k) SUMMARY

In accordance with 21 CFR 807.92, the following information constitutes the Special 510(k) summary for the Infinity-Locks 3 and 5.

I.SUBMITTER INFORMATION

Submitter`s Name:	Xiros Limited
Address:	Springfield House Whitehouse Lane Leeds LS19 7UE England
Telephone Number:	+44 (0)1132387200
Fax Number:	+44 (0)113 2387201
Contact Person 1:	Stephen Seed (Compliance Director)
Contact Person 2:	Manuela Rodrigues (Principal Regulatory Affairs Associate)
Date:	02 May 2017

II. DEVICE IDENTIFICATION

Name of Device(s):	Infinity-Lock 3 Infinity-Lock 5
Trade Name(s):	Infinity-Lock 3 Infinity-Lock 5
Common or usual name:	Non-absorbable Polyester Surgical Tape
Classification Name:	Suture, Non-absorbable, Synthetic, Polyethylene
Regulatory Class:	Class II
Product Code:	GAT
Panel:	General & Plastic Surgery

III. PREDICATE/UNMODIFIED DEVICE

Predicate: Xiros, Ltd, Poly-Tapes K002172.

This predicate has not been subject to a design related recall.

Reference device: Teleflex Medical Inc., polyethylene terephthalate suture (Cottony II green suture polyester) K021019.

IV. DEVICE DESCRIPTION

The Infinity-Locks are non-absorbable, sterile, poly(ethylene terephthalate) sutures. They are prepared from fibres of high molecular weight, long chain, linear polyesters having recurrent aromatic rings as an integral component. Infinity-Locks differ from USP Sutures in being in the form of woven tapes and in exceeding all USP sizes.

The product comprises two sizes of textile implant based on the Neoligaments poly-tape design. The tapes have an integral loop at one end which are used to tie a cow hitch through one end of a ruptured tendon. The tapes have two tails which are then sutured through the separated end (using methods such as the Bunnell technique), thus drawing the two ends together in order to facilitate healing of the tear. One of the tails has a green stripe to aid identification and both taper into a cord to assist with passing through soft tissues.

V. INTENDED USE

The Infinity-Locks are single use devices intended to be used for soft tissue approximation, including Achilles tendon repair in patients with acute rupture of Achilles tendon.

The device subject to modification (Poly-Tapes) has exactly the same intended use as the modified device. The Poly-Tapes are single use devices intended to be used for soft tissue approximation, including Achilles tendon repair in patients with acute rupture of Achilles tendon.

VI. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The substantial equivalence of the Infinity-Locks is supported by the fact that they have the same intended use and they have common technological characteristics to the Poly-Tapes. The same material is used in the manufacture of the proposed modified device (both are made of polyester). Both Poly-Tapes and Infinity-Locks have the same construction; they are woven from polyester, and have the same performance characteristics in accordance with USP requirements.

The modified device retains all the features of the original poly-tapes but includes some new ones to aid usability. These are the: -

- Tapered ends that are intended to aid threading which was previously achieved by adding sutures in theatre.
- Tails that are marked with green weft to aid identification, previously both were plain.
- Addition of an integral loop to make it easier for surgeons to tie a cow hitch knot when required. The previous device was un-looped and the modified device can be simply un-looped when required.

These minor differences in the design of the Infinity-Lock variants do not bring any new questions of safety and effectiveness in accordance with performance data hence do not constitute a change in the fundamental technological characteristics.

VII. PERFORMANCE DATA

Mechanical testing was performed on the modified device and original poly-tape in both knotted and unknotted conditions to determine the ultimate tensile strengths using an internal method, QT010, and following USP 39 NF33:2016 for non-absorbable surgical sutures, where applicable. The modified devices were found to be equivalent or superior in all cases.

Validation was also undertaken by clinicians using cadaveric materials to demonstrate the suitability of the modified device for the intended use which was found to be satisfactory.

The performance data benefit/risk analysis concluded that the differences encountered do not affect the safety and efficacy of the new device variants in relation to the predicate.

Summary: Based on the pre-clinical testing performance, the Infinity-Lock 3 and Infinity-Lock 5 are found to have the same safety and effectiveness profile to the predicate device (Poly-Tapes).

VIII.CONCLUSION

Xiros conclude the Infinity-Lock 3 and Infinity-Lock 5 are substantially equivalent to the Poly-Tapes.