July 22, 2022

Xiros Ltd.
Steve Curran
Compliance Director
Springfield House Lane, Whitehouse Lane
Leeds, West Yorkshire LS17 7UE
United Kingdom

Re: K220906
Trade/Device Name: SECURE-LOCK
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, GAT
Dated: June 16, 2022
Received: June 21, 2022

Dear Steve Curran:

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,

Laura C. Rose, 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: 08/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220906

Device Name

SECURE-LOCK

Indications for Use *(Describe)*

The SECURE-LOCK is indicated for fixation of bone to bone or soft tissue to bone, and is intended as a fixation device, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair such as Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) Repair and 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.

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510(k) Summary K220906

In accordance with 21 CFR 807.92, the following information constitutes a 510(k) summary for SECURE-LOCK, Suspensory Fixation Device for ACL/PCL.

Submitter Information

510(k) Submitter:	Xiros Ltd
Address:	Springfield House Whitehouse Lane Leeds LS19 7UE UK
Telephone:	+44 (0)113 238 7200
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Contact (primary correspondent)	Name: Dr. Steve Curran Title: Compliance Director Email: CFS@xiros.co.uk
Date summary was prepared:	July 22, 2022

Device Identification

Name of device:	SECURE-LOCK
Trade Name:	SECURE-LOCK
Model number(s):	102-1377
Common Name:	Pin, Fixation, Smooth / Suture, nonabsorbable, synthetic, polyethylene
Classification:	Class II
Regulation and Classification Name:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener 21 CFR 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture
Classification Panel:	Orthopedic
Product Code:	HTY/ GAT

Purpose of Submission

The purpose of this submission is to obtain clearance for a new orthopedic fixation device for use in the fixation of bone to bone and soft tissue to bone.

Predicate Device Information

The SECURE-LOCK Suspensory Fixation Device for ACL/PCL described in this submission is substantially equivalent to the following predicate device:

- Arthrex ACL Tightrope (K112990)

Reference Device

- XTREME-LOOP (K191053) – The device uses identical Titanium alloy and UHMWPE materials, an identical Flipping suture and the same sterilization process to the SECURE-LOCK.
- SECURE-LOOP (K151601) – The device uses identical Polyester materials in the suture components (Implant Loop, Pulling and Flipping sutures) and the same sterilization process to the SECURE-LOCK.

Device Description

The SECURE-LOCK fixation device consists of a sterile and non-absorbable polyester and ultrahigh molecular weight polyethylene blended braid that forms a loop on a titanium alloy button. The button sits on the cortex over the exit to a bone tunnel, suspending the loop inside the tunnel to provide secure, strong fixation for ligament repair and reconstruction. The SECURE-LOCK fixation device is supplied with polyester sutures that are used to assemble and deliver the device.

Intended Use

The SECURE-LOCK is indicated for fixation of bone to bone or soft tissue to bone, and is intended as a fixation device, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair such as Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) Repair and Reconstruction.

Comparison of Technological Characteristics with the Predicate Device

The SECURE-LOCK has the same basic principles of operation as the predicate device. They both consist of an implantable, titanium alloy button that sits on the exit to a bone tunnel on the cortex, suspending a non-absorbable loop inside a tunnel to provide secure, strong fixation for ligament repair/reconstruction. Both devices utilize sutures to deliver the implant into the body with the only difference being the number of sutures used. Both devices utilize the same core materials, with only minor differences in the material composition of each device component. Any differences are considered minor and do not raise questions concerning safety and effectiveness.

Performance Data

The following performance testing has been completed for the SECURE-LOCK:

- Implant Tensile Strength Tests
- Implant Fatigue Tests
- Pulling Suture Tensile Strength Tests
- Suture Diameter Measurements and Tensile Strength
- Formal assessment of the SECURE-LOCK design in simulated use conditions
- MRI Compatibility
- Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE)
- Biocompatibility testing in accordance with ISO 10993-1

Bacterial endotoxin testing was performed on representative devices, the XTREME-LOOP (K191053) and SECURE-LOOP (K151601) that, together, are identical in materials, formulation, sterilization process and manufacturing facilities to the subject device implantable components. The devices have been tested for pyrogenicity using the Limulus Amoebocyte Lysate (LAL) method in line with the requirements of ANSI/AAMI ST72. The devices were found to have a result that met the FDA requirements of < 20 EU/Device. Final product batch release testing for endotoxins will be carried out on the subject device in accordance with ANSI/AAMI ST72:2019. In addition, the SECURE-LOCK has been tested for rabbit material-mediated pyrogenicity in line with USP <151>, and meets the pyrogen specification limits for this test.

These tests have been conducted in accordance with the following Guidance documents and applicable FDA recognized consensus standards, relevant to the device:

- Surgical Sutures - Class II Special Controls Guidance Document for Industry and FDA Staff
- Characterization of Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices
- Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment
- 6-467 USP-NF M80200_04_01 Nonabsorbable Surgical Suture
- 6-468 USP-NF M99670_02_01 <881> Tensile Strength
- 6-469 USP-NF M99650_02_01 <861> Sutures – Diameter
- Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1": Evaluation and Testing within a risk management process

Conclusion

The intended use of SECURE-LOCK is substantially equivalent to the predicate, Arthrex ACL Tightrope. SECURE-LOCK has the same basic principles of operation and core materials as the predicate. Any differences identified between the subject and predicate device are minor and do not present safety and effectiveness concerns.

The performance testing results demonstrate that the SECURE-LOCK provides appropriate mechanical properties and is relatively safe for its use in the fixation of bone to bone and soft tissue to bone. 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.

The SECURE-LOCK device is substantially equivalent to the Arthrex ACL Tightrope (K112990) for use in fixation of bone to bone and soft tissue to bone.