April 3, 2018

Xiros Ltd
Stephen Seed
Compliance Director
Springfield House, Whitehouse Lane
Leeds, West Yorkshire
LS19 7UE
United Kingdom

Re: K180243
Trade/Device Name: Infinity-Lock™ Button System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: January 26, 2018
Received: January 29, 2018

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.

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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)*
K180243

Device Name

Infinity-Lock™ Button System

Indications for Use *(Describe)*

The Infinity-Lock™ Button System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption and as an adjunct in external and intramedullary fixation systems involving plates.

The Infinity-Lock™ Button System is indicated for patients with acromioclavicular separations resulting from disruption to the coracoclavicular ligaments.

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

In accordance with 21 CFR 807.92, the following information constitutes Xiros Ltd. 510(k) summary for the Infinity-Lock™ Button System.

I. SUBMITTER INFORMATION

Submitter`s Name:	Xiros Limited
Address:	Springfield House Whitehouse Lane Leeds LS19 7UE United Kingdom
Telephone Number:	+44 (0)1132387200
Fax Number:	+44 (0)113 2387201
Contact Person:	Stephen Seed (Compliance Director)
Date:	26 January 2018
510(k) document number:	K180243

II. DEVICE IDENTIFICATION

Name of Device:	Infinity-Lock™ Button System
Trade Name:	Infinity-Lock™ Button System
Common or usual name:	Button/suture
Classification Name:	Washer, bolt nut
Regulatory Class:	Class II
Product Code:	HTN
Regulation:	888.3030
Panel:	Orthopedic

III. PREDICATE DEVICE

AC TightRope™ Repair Kit Titanium (AR-2257) manufactured by Arthrex Inc, K052776. This predicate has not been subject to a design related recall.

Reference device 1. for fixation at the clavicle for essentially the same indications for use; Lockdown™ Acromioclavicular (AC) device, manufactured by Surgicraft (Trading name of Mandaco 569 Limited), K091207.

Reference device 2. for materials in Tube-Tape within the very general scope of the reference device intended use for soft tissue approximation; Infinity-Lock 3, Infinity-Lock 5, manufactured by Xiros Limited, K171680.

Reference device 3. for materials in Button for different intended purpose; SECURE-LOOP, manufactured by Xiros Limited, K151601.

IV. DEVICE DESCRIPTION

The Infinity-Lock™ Button System comprises a permanent implantable 240 mm Tube-Tape and titanium alloy Button together with a disposable cannulated drill bit and guidewire. A coracoid passer, such as the Xiros CCHook, is also required.

V. INDICATIONS FOR USE

The Infinity-Lock™ Button System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruption and as an adjunct in external and intramedullary fixation systems involving plates.

The Infinity-Lock™ Button System is indicated for patients with acromioclavicular separations resulting from disruption to the coracoclavicular ligaments.

VI. COMPARISIONS OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Infinity-Lock™ Button System has the same technological characteristics as the predicate device, with respect to intended use (the subject device falls within the scope of the predicate device), labelling, anatomical site, similar basic design consisting of titanium buttons and polymeric sutures and a similar surgical technique using mechanical means to reduce the clavicle to the required position.

VII. PERFORMANCE DATA

The Infinity-Lock™ Button System when tested against the AC TightRope™ Repair Kit Titanium (K052776) for Ultimate tensile strength (UTS), UTS after fatiguing and extension after fatiguing, was not statistically significantly different and determined to be substantially equivalent. Pyrogenicity testing was carried out using LAL testing via the Gel Clot method and a pass result of <20 EU/device obtained. 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 Infinity-Lock™ Button System is found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSION

Testing performed demonstrate that the Infinity-Lock™ Button System is substantially equivalent to the AC TightRope™ Repair Kit Titanium.

Xiros therefore conclude the Infinity-Lock™ Button System is substantially equivalent to the AC TightRope™ Repair Kit Titanium manufactured by Arthrex Inc.