



Food and Drug Administration
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Xiros, Limited
Stephen Seed
Regulatory Manager
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Whitehouse Lane
Leeds
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England

September 9, 2015

Re: K151601

Trade/Device Name: SECURE-LOOP
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 2, 2015
Received: June 12, 2015

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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151601

Device Name
SECURE-LOOP

Indications for Use (Describe)

The SECURE-LOOP is used for fixation of tendons and ligaments during orthopedic 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.

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SECTION 5. 510(k) SUMMARY

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

I. SUBMITTER INFORMATION

Submitter`s Name: Xiros Limited
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England
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Fax Number: +44 (0)113 2387201
Contact Person: Stephen Seed (Regulatory Affairs Manager)
Date: 01.09.2015
510(K) number: K151601

II. DEVICE IDENTIFICATION

Name of Device: SECURE-LOOP
Trade Name: SECURE-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

Smith & Nephew, Inc , Endobutton Continuous Loop (ECL) K980155. This predicate has not been subject to a design related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

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

VI. COMPARISONS OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SECURE-LOOP has the same technological characteristics as the predicate Endobutton Continuous Loop device, with respect to intended use, labelling, material composition, chemical formulation, design, design tolerances, functionality and use the same manufacturing methods.

VII. PERFORMANCE DATA

The SECURE-LOOP when tested against the Endobutton Continuous Loop (K980155) for stiffness, tensile strength, cyclic fatigue testing, and functional testing, was determined to be substantially equivalent. 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 SECURE-LOOP is found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSION

The SECURE-LOOP is composed of the same material and has the same design as the predicate device. It is manufactured in the same manner and uses the same methods of that used to manufacture the predicate device.

Testing performed demonstrate that the SECURE-LOOP is substantially equivalent to the Smith & Nephew Endobutton CL fixation device.

Xiros therefore conclude the SECURE-LOOP is substantially equivalent to the Smith & Nephew Endobutton CL fixation device.