May 31, 2023

Xiros Ltd
% John Mahoney
General Manager
Xiros Inc
20 Cabot Blvd., Suite 300
Mansfield, Massachusetts 02448

Re: K230671
Trade/Device Name: Pitch Patch Tissue Reinforcement Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL, OWX
Dated: March 10, 2023
Received: March 10, 2023

Dear John Mahoney:

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,

Sara S. Thompson -S

For

Yu-Chieh Chiu, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230671

Device Name
Pitch-Patch Tissue Reinforcement Device

Indications for Use *(Describe)*

The Pitch-Patch Tissue Reinforcement Device is a single use device intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon or other tendons.

The Pitch -Patch Tissue Reinforcement Device is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendon or other tendons. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the repair.

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

Pitch-Patch Tissue Reinforcement Device

Submitter Information

Submitter:	Xiros, Ltd
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Contact:	Dr. Steve Curran
Date Prepared:	May 26, 2023

Device Information

Trade Name:	Pitch-Patch Tissue Reinforcement Device
Common Name:	Surgical Mesh
Classification:	Class II
Regulation:	21 CFR 878.3300
Classification Name:	Mesh, surgical polymeric Mesh, surgical, non-absorbable, orthopedics, reinforcement of tendon
Classification Panel:	Orthopedic
Product Code:	*FTL/*OWX

Predicate/Reference Device Information

The Pitch-Patch Tissue Reinforcement Device described in this submission is substantially equivalent to the following:

Predicate/Reference Device Information

Primary predicate: Poly-Tape Soft Tissue Reinforcement Device
Premarket Notification: K220091
Product Code: FTL,OWX

Secondary predicate: FlexBand Plus (FlexBand/FlexPatch)
Premarket Notification: K192112
Product Code: FTL

Reference device: Pitch-Patch Tissue Reinforcement Device
Premarket Notification: K211563
Product Code: FTL, OWX

Device Description

The Pitch-Patch is a permanent implantable device for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon. It is constructed from a warp knitted fabric with integral eyelets. It is reinforced around its perimeter and around each eyelet to increase the security of suture attachment. The Pitch-Patch is available in two sizes, to cover different tear sizes without trimming (30 x 20 mm and 35 x 25 mm). It should not be cut to size. The device is supplied sterile, by Gamma Irradiation to an SAL of 10^{-6}.

The Pitch-Patch is made from Polyethylene Terephthalate (PET) also referred as polyester. This a non-absorbable material that has a long history of use in the orthopedic market.

Intended Use/Indications for Use

The Pitch-Patch Tissue Reinforcement Device is a single use device intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon or other tendons.

The Pitch-Patch Tissue Reinforcement Device is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff, patellar, Achilles, biceps, quadriceps tendon or other tendons. Sutures, used to repair the tear, and sutures or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the repair.

Comparison of Principles of Operation & Technological Characteristics

The Pitch-Patch device has the same principles of operations as the predicate devices. They are all implants intended for the reinforcement of soft tissues that are repaired by suture or other fixation devices. The devices are used in various surgical procedures where soft tissue reinforcement is needed.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Polyester Surgical Mesh
- Implant shares the load placed on the primary repair and provides a structural scaffold for torn or damaged soft tissue
- Provides consistent reinforcement during healing period

The following technological differences exist between the subject and predicate devices:

- The Poly-Tape Soft Tissue Reinforcement Device predicate varies in size from the subject device, but is made from the same material and has the same intended use.
- The FlexBand Plus (FlexBand/FlexPatch) predicate device is made from different material than the subject device, but has the same intended use and is available in similar sizes.

Performance Data

The following performance testing has been completed for the Pitch-Patch Tissue Reinforcement Device:

- Suture Retention Testing
- Ultimate Strength Testing
- Cyclic Testing
- Packaging Testing
- Biocompatibility Testing
- LAL Bacterial Endotoxin Testing (< 20 EU/device)

The series of tests, listed above, has been conducted and successfully completed. The results demonstrate that the Pitch-Patch provides adequate mechanical properties for its use in soft tissue reinforcement.

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 predicates.

Conclusion

Based on the above information the Pitch-Patch is substantially equivalent to other soft tissue reinforcement devices, specifically the predicate devices:

Poly-Tape Soft Tissue Reinforcement Device (K220091) and
FlexBand Plus (FlexBand/FlexPatch) (K192112)