August 13, 2021

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

Re: K211563
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
Dated: May 16, 2021
Received: May 20, 2021

Dear Mr. 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,

for Deborah Fellhauer
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K211563

Device Name
Pitch-Patch Tissue Reinforcement Device

Indications for Use *(Describe)*
The Pitch-Patch is a single use device intended to be used for reinforcement of the rotator cuff following or during repair by suture or suture anchors, where weakness exists in the soft tissue.

The Pitch-Patch is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff. Sutures, used to repair the tear, and sutures or bone anchors, 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
Address:	Springfield House Whitehouse Lane Leeds West Yorkshire LS19 7UE UK
Telephone:	+44(0)1132387200
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Contact:	Dr. Steve Curran
Date Prepared:	May 13, 2021

Device Information

Trade Name:	Pitch-Patch Tissue Reinforcement Device
Common Name:	Surgical Mesh
Classification:	Class II
Regulation:	21 CFR 878.3300
Classification Name:	Surgical Mesh Polymeric
Classification Panel:	General Plastic Surgery
Product Code:	FTL

Purpose of Submission

The purpose of this submission is to gain clearance for a new orthopedic surgical mesh for use during rotator cuff repair to reinforce the tissue during and following repair surgery.

Predicate Device Information

The Pitch-Patch Reinforcement device described in this submission is substantially equivalent to the following predicate devices:

Surgicraft Surgical Mesh System (K072370)
BioMerix Surgical Mesh (K070961)

Device Description

The Pitch-Patch is a permanent implantable device for reinforcement of rotator cuff tears. 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.

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

Intended Use/Indications for Use

The Pitch-Patch is a single use device intended to be used for reinforcement of the rotator cuff, following or during repair by suture or suture anchors, where weakness exists in the soft tissue.

The Pitch-Patch is not intended to replace normal body structure or provide the full mechanical strength to support the rotator cuff. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide mechanical strength for the repair.

Comparison of Principles of Operation & Technological Characteristics
The Pitch-Patch has the same principles of operations as the predicate devices. They are all permanent implants intended to support the rotator cuff during and after a surgical repair.

Performance Data
The following performance testing has been completed for the Pitch-Patch:

- Simple Stitch Pull-Out Testing
- Burst Testing
- Tensile Testing of the base material
- Tear Testing
- Testing to determine the density and pore size
- Biocompatibility

Performance Testing – Bench

A series of tests, listed above, has been conducted and successfully completed in accordance with the Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh; Guidance for Industry and/or for FDA reviewers/ Staff and/or Compliance. The results demonstrate that the Pitch-Patch provides appropriate mechanical properties for its use in soft tissue repair.

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.

Performance Testing – Clinical

The Pitch-Patch device was used in a prospective cohort study of 50 patients. Clinical outcome was evaluated using the Constant-Murley score and the subjective shoulder value. Mean clinical midterm and final follow-up was 22 months (9-35 months) and 52 months (25-74 months), respectively.

The mean Constant-Murley score increased significantly from 36.5 (+/-16.4 standard deviation [SD]) preoperatively to a midterm value of 81.2 (+/-9.6 SD; $P < .0001$) and further improved to a mean of 83.4 (+/-10.8 SD) at final follow-up. The mean subjective shoulder value increased

from 40.3 (+/-24.3 SD) to 89.2 (+/-12.9 SD; P < .0001) at midterm and to 89.6 (+/-15.2 SD) at final follow-up. There were 7 complete re-ruptures (14%). However, re-ruptures did not correlate with revision surgery, which was per-formed in 8 patients. The main reason for revision was frozen shoulder or arthrofibrosis with an intact reconstruction and patch, which was performed in 6 cases.

Conclusion

Based on the above information the Pitch-Patch device is substantially equivalent to rotator cuff tissue re-enforcement predicate devices, Surgicraft Surgical Mesh System (K072370) and the BioMerix Surgical Mesh (K070961) for use in reinforcement of the rotator cuff following or during surgical repair with suture or suture anchors.