August 26, 2022

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

Re: K220091
Trade/Device Name: Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL, OWX
Dated: July 26, 2022
Received: July 28, 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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*
K220091

Device Name: Poly-Tape/Infinity-Lock™ Soft Tissue Reinforcement Device

Indications for Use *(Describe)*

The Poly-Tape/Infinity-Lock Soft Tissue Reinforcement device is a single use device intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during soft tissue repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon or other tendons .

The Poly-Tape/Infinity-Lock Soft 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)*

X 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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VII. 510(k) Summary

510(k) Summary
Poly-Tape/Infinity-Lock™
Soft Tissue Reinforcement Device

Submitter Information

Submitter: Xiros, Ltd
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Contact: Dr. Steve Curran

Date Prepared: August 26, 2022

Device Information

Trade Name: Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device
Common Name: Surgical Mesh
Classification: Class II
Regulation: 21 CFR 878.3300
Classification Name: Mesh, Surgical, Polymeric
Classification Panel: General Plastic Surgery
Product Code: FTL, OWX

Predicate/Reference Device Information

The Poly-Tape/Infinity-Lock Soft Tissue Reinforcement device described in this submission is substantially equivalent to the following predicate devices:

PRO series Bioimplants – PROcuff/PROankle (Formerly OrthAdapt) (K112786)
FlexBand Plus (Formerly SPORTMesh)(K192112)
Xylos® MacroPorous Surgical Mesh (K111584)

Infinity-Lock (Reference Device - K171680)

Device Description

The Poly-Tape/Infinity-Lock Soft Tissue Reinforcement device is a woven tape made from Polyethylene Terephthalate (PET) also referred to as polyester. This a nonabsorbable material that has a long history of use in the orthopedic market. These devices are permanent implants for the reinforcement of soft tissues that are repaired by suture or other fixation devices during soft tissue repair surgery.

Intended Use/Indications for Use

The Poly-Tape/Infinity-Lock Soft Tissue Reinforcement device is a single use device intended for reinforcement of soft tissues that are repaired by suture or other fixation devices during soft tissue repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps tendon or other tendons.

The Poly-Tape/Infinity-Lock Soft 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 Poly-Tape/Infinity-Lock Soft Tissue Reinforcement 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:

- 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
- Available in multiple sizes and may be cut to size to meet the surgeon's preference
- Synthetic Material (not OrthAdapt)

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

- Subject device is non-resorbable – 2 of the 3 predicates are partially resorbable.

Performance Data

The following performance testing has been completed:

- Suture Retention Testing
- Ultimate Strength Testing
- Cyclic Testing
- Packaging Testing
- Biocompatibility Testing

The series of tests, listed above, has been conducted and successfully completed. The results demonstrate that the Poly-Tape/Infinity-Lock Soft Tissue Reinforcement device provide adequate mechanical properties for its use in soft tissue reinforcement.

Xiros conducts routine endotoxin (LAL) batch testing to monitor endotoxin levels.

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.

Conclusion

Based on the above information the Poly-Tape/Infinity-Lock Soft Tissue Reinforcement device is substantially equivalent to soft tissue reinforcement predicate devices:

PRO series Bioimplants – PROcuff/PROankle (Formerly OrthAdapt) (K112786)
FlexBand Plus (Formerly SPORTMesh)(K192112)
Xylos® MacroPorous Surgical Mesh (K111584)