July 15, 2025

Xiros Limited
Corey Robinson
Research, Product and Business Development Director and PRRC - Technical Documentation and Post Market Surveillance
Springfield House
Whitehouse Lane
Yeadon, Leeds LS19 7UE
United Kingdom

Re: K242237
Trade/Device Name: Jewel Soft Tissue Reinforcement Device (102-6005)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: QUW, FTL
Dated: July 15, 2025
Received: July 15, 2025

Dear Corey Robinson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242237

Device Name

Jewel Soft Tissue Reinforcement Device (102-6005)

Indications for Use *(Describe)*

The Jewel Soft Tissue Reinforcement Device is a single-use device intended for reinforcement of soft tissues that are undergoing reconstruction surgery, utilizing autograft or allograft soft tissue grafts, or are to be repaired by suture or other fixation devices during ligament repair surgery. This includes reinforcement of extra-articular ligaments such as, but not limited to, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, and ulnar collateral ligament.

The Jewel Soft Tissue Reinforcement Device is not intended to replace normal body structure or provide the full mechanical strength to support the medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other extra-articular ligaments. Sutures, or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the reconstruction or 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Jewel Soft Tissue Reinforcement Device

Date Prepared: July 15, 2025

Submitter Information

Submitter: Xiros Limited
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FDA Registration Number: 8044102

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Device Information

Device Proprietary Name:	Jewel Soft Tissue Reinforcement Device
Common Name:	Orthopedic Surgical Mesh for Soft Tissue Reinforcement
Device Classification:	Class II
Regulation:	21 CFR 878.3300
Classification Name:	Surgical Mesh
Classification Panel:	Orthopedic
Product Code:	QUW, FTL

Predicate Device Information
The Jewel Soft Tissue Reinforcement Device described in this premarket submission is substantially equivalent to the following device:

Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device (K222978) – Primary Predicate Device

Device Description:

The Jewel Soft Tissue Reinforcement Device is a woven tubular implantable device intended to provide support for soft tissues where weakness exists including soft tissues that have been

repaired using suture or other fixation devices during ligament repair surgery. The tubular structure of the implant is designed to allow insertion of an allograft or autograft inside the mesh structure; or alternately for reinforcement of the native tissue. The Jewel Soft Tissue Reinforcement Device is a gamma sterilized, single use, permanent implant manufactured from Polyester (Polyethylene Terephthalate; PET) a nonabsorbable material that has a long history of use in the orthopedic market. The Jewel Soft Tissue Reinforcement Device is treated with an atmospheric gas plasma process to improve surface wettability of the mesh structure. The Jewel Soft Tissue Reinforcement Device is MRI safe.

Indication for Use:

> The Jewel Soft Tissue Reinforcement Device is a single-use device intended for reinforcement of soft tissues that are undergoing reconstruction surgery, utilizing autograft or allograft soft tissue grafts, or are to be repaired by suture or other fixation devices during ligament repair surgery. This includes reinforcement of extra-articular ligaments such as, but not limited to, medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, and ulnar collateral ligament.
>
> The Jewel Soft Tissue Reinforcement Device is not intended to replace normal body structure or provide the full mechanical strength to support the medial collateral ligament, lateral collateral ligament, spring ligament, deltoid ligament, ulnar collateral ligament or other extra-articular ligaments. Sutures, or other fixation devices, used to attach the tissue to the bone, provide mechanical strength for the reconstruction or repair.

The Jewel Soft Tissue Reinforcement Device is being marketed for the extra-articular ligament indications associated with the cleared Poly-Tape/Infinity-Lock devices. Minor rewording of the indications is meant to improve readability and does not change the scope of these indications. There are no new issues of safety and effectiveness as a result of these changes and they fall within the intended use in ligament reinforcement described under 21 CFR 878.3300 and FDA Product Code QUW.

Comparison of Principles of Operation & Technological Characteristics

The Jewel Soft Tissue Reinforcement Device has the same principles of operation as the predicate device. They are both implants intended to provide support for soft tissues where weakness exists including reinforcement of soft tissues that have been repaired using suture or other fixation devices (21 CFR 878.3300). The devices are used in various surgical procedures where soft tissue reinforcement is needed, inclusive of extra-articular ligament repair and reconstruction (i.e. reinforcement of soft tissue grafts).

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

- Biocompatible Surgical Mesh construct
- Implant shares the load placed on the primary tissue repair or tissue graft reconstruction and provides structural scaffold for torn or damaged tissue

- Implant provides consistent reinforcement during the healing period

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

- Subject Jewel device is treated with an atmospheric gas plasma process to improve surface wettability of the mesh

Performance Data

The following performance testing has been completed for the Jewel Soft Tissue Reinforcement Device:

- Ultimate Tensile Strength
- Stiffness
- Suture Retention Strength
- Knot Strength
- Pull Out Strength
- Permanent Elongation
- Biocompatibility Testing
- Packaging and Shelf-Life Testing

The series of tests listed above have been conducted and successfully completed. The results demonstrate that the Jewel Soft Tissue Reinforcement Device is biocompatible and provides adequate mechanical properties for its intended use in reinforcement of soft tissues where weakness exists including soft tissues that have been repaired using suture or other fixation devices, specifically in ligament repair and reconstruction procedures.

The performance data benefit/risk review concluded that the differences identified do not affect the safety and efficacy of the Jewel Soft Tissue Reinforcement Device when compared to the predicate Poly-Tape/Infinity-Lock device.

Conclusion

Based on the information provided above, the Jewel Soft Tissue Reinforcement Device is substantially equivalent to the soft tissue reinforcement predicate device:

Poly-Tape/Infinity-Lock Soft Tissue Reinforcement Device (K222978)