December 11, 2024

ZuriMed Technologies AG
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K241219
Trade/Device Name: FiberLocker System: FiberLocker Implant (SpeedPatch PET), FiberLocker Instrument (FiberLocker Instrument SN)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWX
Dated: November 12, 2024
Received: November 12, 2024

Dear Janice Hogan:

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, MS
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)*

K241219

Device Name

FiberLocker System:

FiberLocker Implant (SpeedPatch PET)

FiberLocker Instrument (FiberLocker Instrument SN)

Indications for Use *(Describe)*

The FiberLocker System 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 FiberLocker System is not intended to replace normal body structures 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) SUMMARY
# ZURIMED's FIBERLOCKER SYSTEM
## K241219

**Submitter**

**ZuriMED Technologies AG**
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Switzerland

Phone: +41 44 552 12 29

Contact Person: Elias Bachmann

Date Prepared: December 6, 2024

**Name of Device: FiberLocker System: FiberLocker Implant (SpeedPatch PET) FiberLocker Instrument (FiberLocker Instrument SN)**

**Common or Usual Name: Surgical Mesh**

**Classification Name: Mesh, Surgical, Non-Absorbable, Orthopaedics, Reinforcement of**

**Tendon Regulation: 21 CFR 878.3300**

**Regulatory Class: Class II**

**Product Code: OWX**

**Predicate Devices**

The FiberLocker System described in this submission is substantially equivalent to the following predicate device:

**Primary Predicate:** Pitch-Patch Tissue Reinforcement Device (K211563)

**Reference Devices:**

Rotation Medical, Inc. Collagen Tendon Sheet-Ddi (K140300) Rotation Medical, Inc. Rotation Medical Soft Tissue Staple (K131637) Covidien Signia Stapler (K160176)

**Device Description**

The FiberLocker System is comprised of two components: (1) the FiberLocker Implant (SpeedPatch PET) and (2) an instrument (FiberLocker Instrument) for fixation of said implant. The implant, a needled textile felt is made out of polyester staple fibers and is non-degradable. The FiberLocker Instrument, a surgical micro-stapling or felting device, is a sterile, single use

device designed for the fixation of medical felt patches in soft tissue.

**Intended Use / Indications for Use**

The FiberLocker System 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 FiberLocker System is not intended to replace normal body structures 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.

**Technological Characteristics**

The FiberLocker System consists of a synthetic non-woven patch that integrates with the patient's soft tissue. The predicate Pitch-Patch is a knitted mesh with fibers. Although there are some differences in the physical properties (e.g., porosity) of the subject implant device and the predicate device, both devices provide adequate mechanical strength and acceptable biological response. Bench and animal testing has been performed to support the equivalence of the two rotator cuff reinforcement systems. The subject and predicate devices are both designed to augment the strength of injured or deficient soft tissue, are non-resorbable and are provided sterile by means of irradiation.

**Performance Data**

The following performance testing has been completed for the FiberLocker System:

- Testing to determine the density and pore size
- Tensile testing
- Suture pull-out testing
- Tear testing
- Biocompatibility
- Safety and performance of the fixation device
- Fixation performance in an ex-vivo animal model
- Human factors testing, including device removal testing
- Corrosion testing

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 FiberLocker System 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 – Animal Studies

In vivo biologic response to the FiberLocker System was characterized in an established ovine infraspinatus tendon model. The evaluation was based on macroscopic observations, radiographic (X-ray) and histological analyses at 6- and 12-weeks post implantation directly comparing the FiberLocker Implant (Test Item) to the control predicate group patch (Reference Item).

Radiograph showed no adverse reactions at the infraspinatus surgical sites for all test groups and time points. From a local reaction perspective of the RI (Pitch-Patch: predicate device) or TI (subject device) patches to the tendon tissue, macroscopic and histological assessments revealed both patches were equivalently biocompatible. In conclusion, under the conditions of this study, the RI and TI tendon repair augmentation patches were found to be equivalent biomechanically, functionally, and from the perspective of the local biological response. Overall, across all 24 animals included in the group analysis, there was no significant biological response at the systemic or local tissue levels.

**Substantial Equivalence**

The FiberLocker System is as safe and effective as the Pitch Patch. The FiberLocker System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the FiberLocker System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the FiberLocker System is as safe and effective as Pitch Patch. Thus, the FiberLocker System is substantially equivalent.

**Conclusions**

Based on the above information the FiberLocker System is substantially equivalent to the rotator cuff tissue re-enforcement predicate device Pitch-Patch (K211563) for use in reinforcement of the rotator cuff following or during surgical repair with suture or suture anchors