January 2, 2026

ZuriMED Technologies AG
% Kelliann Payne
Partner
Hogan Lovells US LLP
1735 Market St., Floor 23
Philadelphia, Pennsylvania 19103

Re: K253867
Trade/Device Name: FiberLocker Implant; FiberLocker Instrument; FiberLocker PowerUnit
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWX, KIJ
Dated: December 3, 2025
Received: December 3, 2025

Dear Kelliann Payne:

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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253867

Please provide the device trade name(s).

FiberLocker Implant;
FiberLocker Instrument;
FiberLocker PowerUnit

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY
ZURIMED's FIBERLOCKER SYSTEM

Submitter

ZuriMED Technologies AG
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Switzerland

Phone: +41 44 552 12 29

Contact Person: Elias Bachmann

Date Prepared: January 2, 2026

Name of Device: FiberLocker Implant; FiberLocker Instrument; FiberLocker PowerUnit

Common or Usual Name: Surgical Mesh (with surgical instrument accessory)

Primary Classification Name: Mesh, Surgical, Non-Absorbable, Orthopaedics, Reinforcement of Tendon
Primary Regulation: 21 CFR 878.3300
Regulatory Class: Class II
Product Codes: OWX; KIJ

Predicate Devices

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

- **Primary Predicate:** FiberLocker System: FiberLocker Implant (SpeedPatch PET), FiberLocker Instrument (FiberLocker Instrument SN) (K241219)

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. The instrument can be powered by either the FiberLocker PowerUnit or the Powermax Elite Shaver.

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.

Substantial Equivalence

The subject and predicate devices have identical indications for use. Accordingly, the subject device satisfies the first criteria of having the same intended use as the predicate.

There are no changes to the FiberLocker Implant and Instrument. Both devices are compatible with the originally cleared accessory device (DYONICS shaver system), but the subject device can alternatively be used with an additional accessory device, the FiberLocker PowerUnit. Key technological characteristics of the two accessory devices are identical, including the functional interface to the FiberLocker Instrument and actuation. There are two minor differences in design that do not introduce additional risks. The first difference is that the PowerUnit operates at a fixed speed of 2500 rpm, as defined in the Instructions for Use (IFU) of the cleared FiberLocker Instrument, whereas the shaver handpiece offers a range of selectable output speeds (500–5000 rpm). The fixed-speed design of the PowerUnit reduces the potential for user error, as it eliminates the need for speed selection during surgery and ensures consistent performance. The second difference is that the PowerUnit is battery powered whereas the cleared shaver system is mains powered. Neither of these differences raise different questions of safety or effectiveness, because the basic mechanism of using electrical energy to power the instrument is maintained. Software validation, bench tests and electrical safety testing have been performed to establish equivalence.

Performance Data

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

- Cleaning validation
- Steam sterilization validation
- Software documentation and validation
- Electrical safety and EMC testing per IEC 6060.

Conclusions

Based on the above information the updated FiberLocker System is substantially equivalent to the predicate FiberLocker System (K241219) for use in reinforcement of the rotator cuff following or during surgical repair with suture or suture anchors