June 20, 2025

Acera Surgical, Inc.
Tamas Kovacs
Coo
1650 Des Peres Rd.
Suite 120
St. Louis, Missouri 63131

Re: K251224
Trade/Device Name: Restrata Soft Tissue Reinforcement (STR)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OXF
Dated: April 21, 2025
Received: April 21, 2025

Dear Tamas Kovacs:

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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive 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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K251224

Device Name

Restrata Soft Tissue Reinforcement (STR)

Indications for Use *(Describe)*

For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

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 -K251224

Traditional Premarket Notification Submission (510(k) Summary)

Prepared in accordance with 21 CFR 807.92

## 1. Submitter Information

| | |
|---|---|
| Sponsor Name | Acera Surgical, Inc. |
| Address | 1650 Des Peres Rd., Suite 120, St. Louis, MO 63131 United States |
| Telephone | 844-879-2237 |
| Establishment Registration | 3012429393 |

| | |
|---|---|
| Contact | Mr. Tamas Kovacs |
| Title | Chief Operating Officer |
| Email | kovacs@acera-surgical.com |
| Date Summary Prepared | June 19, 2025 |

## 2. Device Information

| | |
|---|---|
| Device Trade Name | Restrata Soft Tissue Reinforcement (STR) |
| Common Name | Surgical Mesh |
| Classification | Class II, Mesh, Surgical, Absorbable, Plastic and Reconstructive Surgery |
| Regulation Number | 878.3300 |
| Product Code | OXF |

## 3. Predicate Device Information

| | |
|---|---|
| Predicate # | K202430 |
| Predicate Trade Name | Kerecis Reconstruct |
| Product Code | OXH |

## 4. Device Description Summary

Restrata Soft Tissue Reinforcement (STR) is an electrospun fiber matrix intended for implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery. Restrata Soft Tissue Reinforcement is composed of resorbable synthetic fibers engineered from biocompatible materials. The fibers comprising Restrata STR are produced from polyglactin 910 (PGLA 90:10) and polydiaxonone (PDO). Contents of the package are provided sterile. The device is intended for one-time use.

## 5. Intended Use/Indications for Use

For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

## 6. Technological Comparison

Both the subject and predicate devices are intended to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery. The devices differ in materials of construction. The subject device is composed of resorbable synthetic polymers. The predicate device is derived from Cod fish skin. The differences in component materials did not raise concerns of safety or effectiveness for the intended use based on results of benchtop performance testing as well as a comparative animal study. The subject device leveraged Restrata® and Cerafix® as reference devices.

## Summary Table of Substantial Equivalence

A comparison of the subject device, predicate device, and reference devices are presented in the table below.

| | Subject Device | Predicate Device | Reference Device | Reference Device | Discussion |
|---|---|---|---|---|---|
| **Company** | Acera Surgical, Inc. | Kerecis | Acera Surgical, Inc. | Acera Surgical, Inc. | N/A |
| **Name** | Restrata Soft Tissue Reinforcement (STR) | Reconstruct | Restrata | Cerafix | N/A |
| **510(k)** | Subject device- K251224 | K202430 | K170300, K193583 | K153613, K161278, K172603 | N/A |
| **Device Classification** | II | II | II | II | Identical |
| **Regulation** | 21 CFR 878.3300 | 21 CFR 878.3300 | Unclassified | 21 CFR 882.5910 | Identical for subject & predicate |
| **Product Code** | OXF | OXH | QSZ | GZQ | Equivalent for subject & predicate |
| **Intended Use/ Indications for Use** | For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery. | For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery. | For use in the management of wounds, including*:<br>• partial and full thickness wounds<br>• tunneled/ undermined wounds<br>• surgical wounds<br>• trauma wounds<br>• burns<br><br>*See device IFU for full list of indications. | For the repair of dura mater. | Identical for subject & predicate |
| **Material** | Polyglactin 910 and polydioxanone (PGLA 90:10 / PDO) | Cod fish skin | Polyglactin 910 and polydioxanone (PGLA 90:10 / PDO) | Polyglactin 910 and polydioxanone (PGLA 90:10 / PDO) | Different for subject & predicate, but performance testing establishes equivalence |

| | | | | | |
|---|---|---|---|---|---|
| **Sizes** | 0.5 x 1 in<br>1 x 1 in<br>1.5 x 2 in<br>1 x 2 in<br>1 x 3 in<br>2 x 2 in<br>3 x 3 in<br>4 x 5 in<br>5 x 7 in<br>0.55 in diameter circle | 4 x 7 cm (1.6 x 2.8 in)<br>7 x 10 cm (2.8 x 3.9 in)<br>7 x 20 cm (2.8 x 7.9 in) | 0.5 x 1 in<br>1 x 1 in<br>1.5 x 2 in<br>1 x 2 in<br>1 x 3 in<br>2 x 2 in<br>3 x 3 in<br>4 x 5 in<br>5 x 7 in<br>0.55 in diameter circle | 1 x 1 in<br>1 x 3 in<br>2 x 2 in<br>3 x 3 in<br>4 x 5 in<br>5 x 7 in | Equivalent for subject and predicate, devices are intended to be trimmed to fit implant site as needed |
| **Sterilization** | E-beam<br>SAL of $10^{-6}$ | EtO<br>SAL of $10^{-6}$ | E-beam<br>SAL of $10^{-6}$ | E-beam<br>SAL of $10^{-6}$ | Equivalent |
| **Shelf-Life** | 2 years | 3 years | 2 years | 2 years | Equivalent |

## 7. Summary of Supporting Data for Substantial Equivalence

Nonclinical testing was performed, including benchtop flexural stiffness, tensile, suture pullout, burst, and tear resistance testing, as well as a comparative animal study. The biocompatibility and other related testing were leveraged from the previously cleared version of the device, as there were no changes to the material or design through to the final finished device.

## 8. Conclusions

Overall, the data provided within this submission supports a determination of substantial equivalence between the subject and predicate devices with regards to intended use, performance characteristics and safety.

For use in reinforcement of soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery, Restrata® Soft Tissue Reinforcement is safe, effective and substantially equivalent to the predicate device.