Acera Surgical, Inc.
% Linda Braddon
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K223725
Trade/Device Name: Restrata® MiniMatrix
Regulatory Class: Unclassified
Product Code: QSZ
Dated: April 17, 2023
Received: April 17, 2023

Dear Linda Braddon:

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,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2023.05.18 08:29:50 -04'00'

for Julie A. Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223725

Device Name
Restrata® MiniMatrix

Indications for Use *(Describe)*

Restrata® MiniMatrix is intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores / ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled / undermined wounds, surgical wounds (e.g., donor site / grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced wounds), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

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.

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510(k) Summary
K223725
Acera Surgical Restrata® MiniMatrix

Date	May 17, 2023
Submitted by	Acera Surgical, Inc. 1650 Des Peres Rd., Suite 120 St. Louis, MO 63131 Phone 844-879-2237
510(k) Contacts	Secure BioMed Evaluations Linda Braddon, Ph.D. Justin Gracyalny, MSE 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 (direct) Regulatory@SecureBME.com
Trade Name	Restrata® MiniMatrix
Common Name	Wound Dressing
Code – Classification	QSZ Unclassified
Primary Predicate Device	Acera Surgical Inc., Restrata® (K170300, K193583)
Reference Devices	ACell Inc., MicroMatrix® (K172399) Aroa Biosurgery Ltd., Myriad™ Particles (K200502)

Device Description
Restrata MiniMatrix is a sterile, single use device intended for the local management of wounds. Restrata MiniMatrix is a form of Restrata Matrix that can be dispersed at the wound site during application. The device is made from synthetic biocompatible materials and was designed to include a fibrous structure with high porosity similar to native extracellular matrix. Restrata MiniMatrix completely degrades via hydrolysis. The device does not contain any human or animal materials or tissues.

Restrata MiniMatrix is supplied in a nested pouch configuration, placed within a shelf-box. The product is terminally sterilized. Contents of the package are guaranteed sterile and non-pyrogenic unless the package has been opened or damaged.

Indications for Use
Restrata MiniMatrix is intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores / ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled / undermined wounds, surgical wounds (e.g., donor site / grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced wounds), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

Technological Characteristics

Restrata MiniMatrix is a form of Restrata Matrix (K170300, K193583) that can be dispersed at the wound site during application. The subject device and predicate device are both indicated for the management of wounds. The subject device is offered in similar packaging and size offerings to those seen in the reference devices (K172399, K200502).

Characteristic	**Subject Device** **Acera Surgical Inc.** **Restrata® MiniMatrix**	**Predicate Device** **Acera Surgical Inc.** **Restrata®** **K170300, K193583**
FDA Product Code	QSZ	QSZ
Device Class	Unclassified	Unclassified
Regulation	Unclassified	Unclassified
Indications for Use	Restrata MiniMatrix is intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores / ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled / undermined wounds, surgical wounds (e.g., donor site / grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced wounds), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.	Restrata is intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores / ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled / undermined wounds, surgical wounds (e.g., donor site / grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced wounds), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.
Principles of Operation	Device permits the ingress of cells and soft tissue formation into the defect space / wound bed.	Device permits the ingress of cells and soft tissue formation into the defect space / wound bed.
Material of Construction	Electrospun, resorbable, synthetic dual polymer matrix comprised of polyglactin 910 and polydioxanone fibers (PGLA 90:10 / PDO), which is then milled.	Electrospun, resorbable, synthetic dual polymer matrix comprised of polyglactin 910 and polydioxanone fibers (PGLA 90:10 / PDO).
Configuration	Particulate matrix	Meshed & non-meshed matrix
Nominal Device Sizes	100mg 250mg 500mg 1000mg 2000mg	0.55” disc (14mm disc) 0.5”x1” (1.3cm x 2.5cm) 1”x1” (2.5cm x 2.5cm) 1.5”x2” (3.8cm x 5.0cm) 1”x2” (2.5cm x 5.0cm) 1”x3” (2.5cm x 7.5cm) 2”x2” (5.0cm x 5.0cm) 3”x3” (7.5cm x 7.5cm) 4”x5” (10.0cm x 12.5cm) 5”x7” (12.5cm x 17.5cm)
Particle Size	<3.15mm	Not applicable
Single Use	Yes	Yes
Prescription Use	Yes	Yes
Resorbable	Yes	Yes
Biocompatibility	Biocompatible	Biocompatible
Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic
Endotoxin	<20 EU/Device	<20 EU/Device

Characteristic	Subject Device Acera Surgical Inc. Restrata® MiniMatrix	Predicate Device Acera Surgical Inc. Restrata® K170300, K193583
Sterilization	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}
Surgical Application Restrictions	Device does not have requirement for specific orientation.	Device does not have requirement for specific orientation.
Packaging	Double sterile pack. Nested pouch configuration within a chipboard unit box.	Double sterile pack. Nested pouch configuration within a chipboard unit box or envelope.

Non-Clinical Testing

Due to the fact that the subject device is made from the exact same component material as the predicate device, pre-existing data pertaining to the predicate device materials are applicable to the subject device. To support the change in device configuration, the subject device particle size was characterized using established imaging techniques, and an evaluation of residual heavy metals was performed. Additionally, a comparative porcine wound healing animal model supports equivalent wound healing performance between the subject, predicate, and reference (K172399) devices.

A biocompatibility evaluation was conducted in accordance with ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and the FDA Guidance Document "Use of International Standard ISO 10993-1. The results of the testing adequately address biocompatibility for the subject device and its intended use. Additionally, a sterilization validation was conducted in accordance with ISO 11137-2 "Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose" and FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" to a sterility Assurance Level (SAL) of $1x10^{-6}$. All test method acceptance criteria were met.

Wound Healing Study

A full thickness porcine wound model was performed. The purpose of this study was to evaluate the local tissue response of the subject device (Restrata MiniMatrix) and show that the device does not cause any delay in the natural wound healing process compared to the predicate/reference devices. Overall, application of the subject device in full thickness wounds showed an equivalent safety and efficacy profile to the comparator devices. The testing data demonstrates comparable wound healing with commercially available devices with the same intended use.

Conclusion

The subject device and the predicate device were initially compared based on product code and intended use and found to be equivalent. Next, the subject device, predicate device, and reference device underwent non-clinical evaluation that confirms equivalence in the intended use of each device, biocompatibility, safety, efficacy, environment of use, and the principles of operation. Therefore, the subject device demonstrates substantial equivalence to the predicate device.