December 15, 2022

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

Re: K193583
Trade/Device Name: Restrata®
Regulatory Class: Unclassified
Product Code: QSZ

Dear Linda Braddon:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 25, 2020. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSZ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie 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

September 25, 2020

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

Re: K193583
Trade/Device Name: Restrata®
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 16, 2020
Received: September 17, 2020

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,

Anjana Jain -S

Anjana Jain, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193583

Device Name

Restrata®

Indications for Use *(Describe)*

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 wound (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.

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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Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the Acera Surgical Restrata® is provided below.

Date Summary Prepared	08/25/2020
Submitted by	Acera Surgical, Inc. 10880 Baur Blvd St. Louis, MO 63132 Phone 844-879-2237
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) Regulatory@SecureBME.com
Trade Name	Restrata®
Common Name	Wound Matrix
Code –Classification	**FRO,** Unclassified
Predicate Device	Restrata® Wound Matrix (K170300)
Reference Device	PriMatrix® Dermal Repair Scaffold (K153690)

Device Description

Restrata® is a sterile, single use device intended for use in local management of wounds. Restrata® is a soft, white, conformable, non-friable, absorbable matrix that provides a moist environment for the body's natural healing process to occur. Restrata® is made from synthetic biocompatible materials and was designed to include a fibrous structure with high porosity, similar to native extracellular matrix. Restrata® is a porous matrix with a defined rate of resorption that provides a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis. The device permits the ingress of cells and soft tissue formation in the defect space / wound bed. The device does not contain any human or animal materials or tissues.

Restrata® is terminally sterilized, in a single use double peel package in a variety of sizes in non-meshed and meshed configurations. Contents of the package are guaranteed sterile and non-pyrogenic unless the package has been opened or damaged.

The subject device is a modification of the predicate device to include updated product labeling, a change in product size offerings, and a change in product design offerings.

Indications for Use

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 wound (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

The subject device has the same technological characteristics as the predicate device in terms of principles of operation, intended use, material performance, biocompatibility, material composition and method of action. The only differences between the subject and predicate device are the new smaller size offering of the subject device and the meshed design offerings of the subject device.

The subject device has the same characteristics as the predicate device as follows:

Characteristic	**Restrata® (subject device)**	**Restrata® Wound Matrix K170300 (Predicate device)**	**PriMatrix® Dermal Repair Scaffold K153690 (Reference device)**	**Comparison**
510(k)	K193583	K170300	K153690	N/A
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	Device permits the ingress of cells	Equivalent to Predicate Device
Material of Construction	Resorbable synthetic polymer matrix Dual polymer matrix comprised of polyglactin 910 and polydioxanone fibers (PGLA 90:10 / PDO)	Resorbable synthetic polymer matrix Dual polymer matrix comprised of polyglactin 910 and polydioxanone fibers (PGLA 90:10 / PDO)	An acellular dermal tissue matrix derived from fetal bovine dermis	Equivalent to Predicate Device
Material Composition	Porous, non-woven PGLA:PDO matrix	Porous, non-woven PGLA:PDO matrix	An acellular dermal tissue matrix derived from fetal bovine dermis	Equivalent to Predicate Device

Characteristic	Restrata® (subject device)	Restrata® Wound Matrix K170300 (Predicate device)	PriMatrix® Dermal Repair Scaffold K153690 (Reference device)	Comparison
Indications for Use	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 wound (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 wound (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.	PriMatrix is intended for the management of wounds that include: • Partial and full thickness wounds • Pressure, diabetic, and venous ulcers • Second-degree burns • Surgical wounds – donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence • Trauma wounds – abrasions, lacerations and skin tears • Tunneled/undermined wounds • Draining wounds	Equivalent to Predicate Device
Size	0.55" disc (14mm disc) 1"x1" (2.5cm x 2.5cm) 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)	1"x1" (2.5cm x 2.5cm) 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)	0.2cm x 26.5cm 14mm disc 18mm disc 2cm x 2cm 3cm x 3cm 4cm x 4cm 5cm x 5cm 6cm x 6cm 8cm x 8cm 8cm x 12cm 10cm x 12cm 10cm x 25cm 20cm x 25cm	Equivalent to size range of reference device
Surgical Application Restrictions	Device does not have requirement for specific orientation	Device does not have requirement for specific orientation	Device does not have requirement for specific orientation	Equivalent
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Sterile	Equivalent
Packaging	Double sterile pack. Nested pouch configuration within a chipboard envelope	Double sterile pack. Nested pouch configuration within a chipboard envelope	Double peel packages	Equivalent
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic	Equivalent

Characteristic	Restrata® (subject device)	Restrata® Wound Matrix K170300 (Predicate device)	PriMatrix® Dermal Repair Scaffold K153690 (Reference device)	Comparison
Resorbable	Yes	Yes	Yes	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Equivalent
Configurations	Meshed & non-meshed	Non-meshed	Meshed & non-meshed	Equivalent to reference device

The function, physical appearance, indication, product code, use environment, and principles of operation of Restrata® are exactly the same as the predicate, Restrata® Wound Matrix.

Non-Clinical Testing – Mechanical

No new mechanical testing was conducted for this submission. All mechanical testing for the device was submitted as part of the original 510(k) submission for Restrata® Wound Matrix (K170300). The subject device is manufactured using the exact same components and processes as the predicate, it is cut from the same component material, and therefore has mechanical properties (tensile strength and suture pull-out strength) equivalent to the predicate device.

Non-Clinical Testing - Biocompatibility

No new biocompatibility testing was conducted for this submission. All biocompatibility testing for the device was submitted as part of the original 510(k) submission for Restrata® Wound Matrix (K170300). The subject device is manufactured using the exact same components and processes as the predicate device, it is cut from the same component material, it is packaged and sterilized in the exact same fashion, and therefore has equivalent biocompatibility.

Risk Analysis

A risk analysis of the design controls was conducted in support of substantial equivalence with the predicate device.

Conclusions

The subject device and the predicate device underwent 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.