DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 26, 2017

Acera Surgical, Inc
% Linda Braddon, Ph.D.
Secure BioMed Evaluations
7828 Hickory Flat Highway, Suite 120
Woodstock, GA 30188

Re: K170300
Trade/Device Name: Restrata Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 30, 2017
Received: January 31, 2017

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017

See *PRA Statement on last page.*

510(k) Number *(if known)*

K170300

Device Name

Restrata™ Wound Matrix

Indications for Use *(Describe)*

Restrata™ Wound Matrix 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, wound dehiscence), 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)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

6 510(k) Summary of Safety and Effectiveness

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

Date Summary Prepared	April 25, 2017
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) 855-MED-DEV1 (office) LGB@SecureBME.com
Trade Name	Restrata™ Wound Matrix
Common Name	Wound Dressing
Code –Classification	**FRO,** Unclassified
Primary Predicate Device	GORE®, BIO-A® Wound Matrix (K132397)
Reference Devices	Cook Biotech, Oasis® Wound Matrix (K061711) Acera Surgical, Cerafix® Dura Substitute (K161278)

Device Description

The Restrata™ Wound Matrix is a sterile, single use device intended for use in local management of wounds. The Restrata™ Wound Matrix is a soft, white, conformable, non-friable, absorbable matrix that acts as a protective covering for wound defects, providing 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™ Wound Matrix is supplied terminally sterile, in a single use double peel package in a variety of sizes. Contents of the package are guaranteed sterile and non-pyrogenic unless the package has been opened or damaged.

Intended Use

Restrata™ Wound Matrix 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, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

Technological Characteristics

The Restrata™ Wound Matrix is composed of a non-woven "fleece" of polymer fibers composed of fully resorbable synthetic polymers. The fibers comprising Restrata™ Wound Matrix are produced from polyglactin 910 (PGLA) and polydiaxonone (PDO), both bioabsorbable polymers utilized in FDA cleared dura substitutes, resorbable sutures, orthopedic implants and other medical devices. Following implantation, both the PGLA and PDO are gradually hydrolyzed and absorbed over time, as new tissue forms in their place.

The subject device, predicate device (GORE® BIO-A® Wound Matrix) and reference device (Oasis® Wound Matrix) are all wound dressings indicated for the management of wounds. The subject device and predicate device are both composed of fully degradable biocompatible polymer materials. The subject device has the same technological characteristics as the predicate device and reference device in terms of principles of operation, intended use, material performance, and biocompatibility.

The subject device is also substantially equivalent to the reference device, Cerafix® Dura Substitute, in terms of design and composition, illustrating its biocompatibility and safety.

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

Characteristic	Restrata™ Wound Matrix (subject device)	GORE® BIO-A® Wound Matrix (K132397) (predicate device)	Cook Biotech, Oasis® Wound Matrix (K061711) (reference device)	Comparison
510(k)	K170300	K132397	K061711	N/A
Principles of Operation	Device serves to protect a wound and facilitate a moist environment for natural healing to occur by forming a physical barrier over the wound bed and providing a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis.	Device serves to protect a wound and facilitate a moist environment for natural healing to occur by forming a physical barrier over the wound bed and providing a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis.	Provides physical scaffold for wound repair.	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 Copolymer matrix comprised of polyglycolic acid and trimethylene carbonate (PGA:TMC)	Minimally processed Porcine SIS Animal-derived, extracelluar matrix	Although resorbable polymers used are different, the biocompat -ibility, performance and safety are equivalent to predicate
Intended Use	Restrata™ Wound Matrix is intended for use in the management of wounds.	The GORE® BIO-A®B Wound Matrix is intended for use in the management of wounds.	Oasis® Wound Matrix is indicated for the management of wounds.	Equivalent to predicate device
Size	2.5cm x 2.5cm (1”x1”) 2.5cm x 7.5cm (1”x3”) 5.0cm x 5.0cm (2”x2”) 7.5cm x 7.5cm (3”x3”) 10.0cm x 12.5cm (4”x5”) 12.5cm x 17.5cm (5”x7”)	7.0cm x 10.0cm 8.0cm x 8.0cm 9.0cm x 15.0cm 10.0cm x 30.0cm 20.0cm x 20.0cm 20.0cm x 30.0cm	3.0cm x 3.5cm 3.0cm x 7.0cm	Equivalent to range set by predicate and reference device
Material Composition	Porous, non-woven PGLA:PDO matrix	Porous, non-woven PGA:TMC matrix	Bovine collagen matrix	Equivalent to predicate 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 to predicate device
Sterility	Sterile, SAL 10^{-6}	Sterile	Sterile	Equivalent
Packaging	Double sterile pack. Nested pouch configuration within a chipboard envelope.	Unknown	Double sterile pack. Nested pouch within a chipboard unit box.	Equivalent to reference device

Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic	Equivalent
Resorbable	Yes	Yes	Not Applicable	Equivalent to predicate device
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Equivalent

The following technological differences exist between the subject and predicate devices:

- Although the subject device and predicate device are both manufactured from resorbable polymers, the subject device is composed of PGLA and PDO fibers, while the predicate device is composed from PGA and TMC fibers.

Although the polymers differ between the subject device and predicate device, both sets of polymers have a long-standing track record in medical device applications, including use in dural substitutes, resorbable sutures, orthopedic implants, and other medical devices. Each of the polymers were proven fully biocompatible, including; non-toxic, non-pyrogenic, non-genotoxic, non-hemolytic, and non-mutagenic. Both the subject device and predicate device are porous, non-woven matrices that serve to protect a wound and facilitate a moist environment for natural healing to occur by forming a physical barrier over the wound bed and providing a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis. So, despite the difference in polymer composition, the subject device is equivalent in function, indication for use, product code, environment of use, and principles of operation to the predicate device.

Performance Data

The subject device has mechanical properties (tensile strength and suture pull-out strength) equivalent or superior to the reference device.

The subject device was also tested against a commercially available wound dressing with the same intended use in a clinically relevant full thickness porcine wound model. Analysis included an assessment of biocompatibility, along with macroscopic assessment of wound healing, planimetric measurement of wound closure, and histopathology. Test results showed that the subject device had an equivalent wound healing response compared to the control article, and exhibited no adverse tissue responses.

Conclusions

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 and reference devices.