November 27, 2017

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

Re: K172603
Trade/Device Name: Cerafix Dura Substitute
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: August 29, 2017
Received: August 30, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172603

Device Name
Cerafix Dura Substitute

Indications for Use *(Describe)*
The Cerafix Dura Substitute is indicated as a dura substitute for the repair of dura mater. This device is indicated for defects of 4.9 in2 (31.7cm2) or less in area. For example, 4.0 in x 1.2 in (10.0 cm x 3.1 cm) would be an acceptable defect size.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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 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 Cerafix® Dura Substitute is provided below.

Date Summary Prepared	November 24, 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	Cerafix® Dura Substitute
Common Name	Dura substitute
Code –Classification	**GXQ** 21 CFR 882.5910 : Class II
Primary Predicate Device	K040888 DuraMatrix™ Collagen Dura Substitute Membrane
Reference Device	K153613, K161278 Cerafix® Dura Substitute

Device Description

Cerafix® Dura Substitute is a resorbable implant for repair of dural defects. The device can be applied as an onlay matrix or sutured in place. Cerafix® Dura Substitute is a soft, white, pliable, nonfriable, porous polymer matrix. Cerafix® Dura Substitute is available in a variety of sizes and is supplied sterile and nonpyrogenic in a single-use nested pouch configuration, which is enclosed within a protective chipboard envelope.

Indications for Use

The Cerafix® Dura Substitute is indicated as a dura substitute for the repair of dura mater. This device is indicated for defects of 4.9 in^2 (31.7 cm^2) or less in area. For example, 4.0 in x 1.2 in (10.0 cm x 3.1 cm) would be an acceptable defect size.

Technological Characteristics

The subject device is the exact same device as the previously approved Cerafix® Dura Substitute (K161278, K153613). The only updates pertain to: 1) the method of fixation / application as cited in the surgical technique guide, and 2) the acceptable defect size within the indications for use. Now, the subject device may be applied as an onlay matrix, as well as sutured in place, and utilized in defects up to 4.9 in^2 (31.7 cm^2). This instruction is consistent with the method of fixation used by the primary predicate device as well as other commercially available dural substitutes.

The subject device has identical technological characteristics to the reference device, including the principles of operation, indications for use, sizing, material performance and biocompatibility. The subject device is equivalent to the reference device in terms of materials of construction. Additionally, side-by-side animal studies show the subject device performed equivalently to the predicate device when applied without suture (onlay) in a canine duraplasty model.

The subject device has the following technological characteristics in common with the predicate and reference devices:

Characteristic	**Cerafix® Dura Substitute (subject device)**	**Cerafix® Dura Substitute (Reference Device)**	**DuraMatrix™ Collagen Dura Substitute (Primary Predicate)**	**Comparison**
510(k)	N/A	K153613, K161278	K040888	N/A
Principles of Operation	Device can be cut by surgeon and placed on dural defect and used as an onlay matrix or sutured in place. If sutured, suture line should be 2-3 mm from edge of implant. Implant should be large enough to overlap edge of the remaining dura by at least one (1) centimeter.	Device can be cut by surgeon and placed on dural defect with tensionless suture application. Suture line should be 2-3 mm from edge of implant. Implant should be large enough to overlap edge of the remaining dura by at least one (1) centimeter.	Device can be cut by surgeon and placed on dural defect and used as an onlay membrane or sutured in place.	Equivalent
Material of Construction	Porous PGLA / PDO polymer matrix	Porous PGLA / PDO polymer matrix	Bovine collagen matrix	Equivalent to reference device

Indications for Use	Indicated as a dura substitute for the repair of dura mater. This device is indicated for defects of 4.9 in^2 (31.7 cm^2) or less in area. For example, 4.0 in x 1.2 in (10.0 cm x 3.1 cm) would be an acceptable defect size.	Indicated as a dura substitute for the repair of dura mater. This device is indicated for defects of 4.4 in^2 (28.3cm^2) or less in area. For example, 4.0 in x 1.1 in (10.1 cm x 2.8 cm) would be an acceptable defect size.	Indicated as a dura substitute for the repair of dura mater.	Data included in this submission to justify defect increase
Sizing	1”x1” 1”x3” 2”x2” 3”x3” 4”x5” 5”x7”	1”x1” 1”x3” 2”x2” 3”x3” 4”x5” 5”x7”	1”x1” 1”x3” 2”x2” 3”x3” 4”x5” 5”x7”	Equivalent
Application Restrictions	Device does not have a requirement for specific orientation	Device does not have a requirement for specific orientation	Device does not have a 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 sterile pack. Nested pouch configuration within a chipboard envelope.	Equivalent
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic	Equivalent
Resorbable	Yes	Yes	Not Applicable	Equivalent to reference device
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Equivalent

There are no technological differences between the subject and the reference device.

Non-Clinical Testing – Mechanical

No new mechanical testing was conducted for this submission. All mechanical testing for the Cerafix® Dura Substitute device was submitted in K153613 and K161278.

Non-Clinical Testing - Biocompatibility

No new biocompatibility testing was conducted for this submission. All biocompatibility testing for the Cerafix® Dura Substitute device was submitted in K153613 and K161278.

Non-Clinical Testing – Side-by-Side Animal Study Comparison

Side-by-side animal implantation studies were performed between the subject and predicate device in a canine duraplasty model utilizing dural defects (18 mm x 25 mm) without the use of suture (onlay). Results show equivalent safety and performance between the subject and predicate device.

Conclusions

The subject and predicate device underwent non-clinical evaluation that confirmed device equivalency in the indication for use, device classification, product code, biocompatibility, safety, efficacy, environment of use, and the principles of operation. Therefore, the subject device demonstrates equivalence to the predicate device in dural defects, and can be applied as an onlay matrix or sutured in place.