DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

August 8, 2016

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

Re: K161278
Trade/Device Name: Cerafix Dura Substitute
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: May 5, 2016
Received: May 10, 2016

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 yours,

Michael J. Hoffmann -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161278

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 4.4 in2 (28.3 cm2) 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.

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.

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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	August 1, 2016
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	K153613 Cerafix® Dura Substitute

Device Description

Cerafix® Dura Substitute is a resorbable implant for repair of dural defects and is to be used with tensionless sutures. 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 4.4 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.

Technological Characteristics

The component material used in the subject device is the exact same as the component material used in the predicate device. The only difference is finished device size.

Based on test results included in this submission, a maximum allowable defect size has been prescribed for the subject device. The subject device has the same technological characteristics as the predicate device in terms of principles of operation, materials of construction, material performance, and biocompatibility. Additionally, side-by-side animal studies show the subject device is equivalent for the indicated use of a dura substitute for the repair of dura mater. The subject device has the same technological characteristics as the predicate device as follows:

Characteristic	**Cerafix® Dura Substitute (subject device)**	**Cerafix® Dura Substitute (predicate device)**	**Comparison**
510(k)	K161278	K153613	N/A
Principles of Operation	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 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.	Equivalent to predicate device
Material of Construction	Porous polymer matrix	Porous polymer matrix	Equivalent to predicate device
Indications for Use	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. This device is indicated for defects of 1.9 in^2 (12.5cm^2) or less in area. For example, 1.2 in x 1.6 in (3 cm x 4 cm) would be an acceptable defect size.	Equivalent to predicate device
Size	1”x1” 1”x3” 2”x2” 3”x3” 4”x5” 5”x7”	1”x1” 1”x3” 2”x2” 3”x3”	Subject device is cut into larger finished device sizes compared to predicate device
Material Composition	Porous PGLA / PDO matrix	Porous PGLA / PDO matrix	Equivalent to predicate device

Surgical Application Restrictions	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, SAL 10^{-6}	Equivalent
Packaging	Double sterile pack. Nested pouch configuration within a chipboard envelope.	Double sterile pack. Nested pouch configuration within a chipboard envelope.	Equivalent to predicate device
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Equivalent
Resorbable	Yes	Yes	Equivalent to predicate device
Biocompatibility	Biocompatible	Biocompatible	Equivalent

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

- Subject device and predicate device are manufactured from the exact same component material; however, the subject device will be cut into larger finished device sizes.

Despite the size differences, the subject device is equivalent in function, indication for use, device classification product code, environment of use, and principles of operation to the predicate device. The sizes of the subject device are equivalent to 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. The subject device is cut from the same component material as the predicate device, and therefore has equivalent mechanical properties per unit area.

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. The subject device is cut from the same component material as the predicate device, and therefore has equivalent biocompatibility.

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

The subject device (test) was compared to the predicate device (control) using a canine bilateral duraplasty model with terminal assessments at 4-weeks and 13-weeks post-operatively. Each time point evaluated 3 test and 3 control animals, each with 2 defects. Animals were observed daily and weighed weekly for signs of general clinical health. Particular attention was paid to the implant sites to assess the presence of hydrocephalus, cerebral spinal fluid (CSF) leakage, hemorrhage, infection, and any other adverse side effects. At each end-point, CSF was obtained from each animal and submitted for analysis. Tissue samples from each defect site were processed by histopathology techniques and analyzed for dural integrity / neoduralization and local tissue reactions according to ISO 10993-6.

All animals in both test and control groups appeared healthy with normal neurological evaluations at both time points. No CSF leaks were observed in either group throughout the duration of both studies. Test and control articles were shown to be similar in the mechanism of neoduralization and absorption, independent of the size of the induced dural defect at both time points. Test and control articles demonstrated signs of resorption with infiltration of fibrovascular connective tissue and successful neoduralization.

In total, both the test and control articles showed equivalent clinical performance at each time point and successfully repaired the induced dural defects independent of defect size. Therefore, the results of these studies indicate that the subject device demonstrates equivalent safety and efficacy when compared to the 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.