



Food and Drug Administration
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March 24, 2016

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

Re: K153613
Trade/Device Name: Cerafix Dura Substitute
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: December 17, 2015
Received: December 17, 2015

Dear Dr. Braddon:

This letter corrects our substantially equivalent letter of March 16, 2016.

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,

Carlos L. Pena -S 

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153613

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 1.9 in² (12.5 cm²) or less in area. For example, 1.2 in x 1.6 in (3 cm x 4 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.

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510(k) Summary



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

| | |
|--|---|
| <i>Date Summary Prepared</i> | March 16, 2016 |
| <i>Submitted by</i> | Acera Surgical, Inc. 10880 Baur Blvd St. Louis, MO 63132 Phone 844-879-2237 |
| <i>510(k) Contact</i> | 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 |
| <i>Trade Name</i> | Cerafix® Dura Substitute |
| <i>Common Name</i> | Dura substitute |
| <i>Code –Classification</i> | GXQ 21 CFR 882.5910 : Class II |
| <i>Primary Predicate Device</i> | K991413 Ethisorb™ Dura Patch |
| <i>Reference Device</i> | K092388 DuraGen Plus™ Dural Regeneration Matrix |

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 1.9 in² (12.5cm²) or less in area. For example, 1.2 in x 1.6 in (3 cm x 4 cm) would be an acceptable defect size.

Technological Characteristics

The materials used in the subject device are equivalent to the predicate device. Additionally, comparative mechanical testing was performed using the commercially available dura substitute reference device. The comparative mechanical testing showed equivalent performance of the subject device to the reference device. Lastly, physical characteristics are comparable to the predicate device, reference device, and that of native human dura.

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 and reference 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 and reference device as follows:

| Characteristic | Cerafix® Dura Substitute (subject device) | Ethisorb™ Dura Patch (predicate device) | DuraGen™ Plus Dural Regeneration Matrix (reference device) | Comparison |
|--------------------------|--|---|--|--------------------------------|
| 510(k) | K153613 | K991413 | K092388 | 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 a running or interrupted suture application. Avoid tensioning of sutures. Suture line should be 2 mm from edge of implant. | Device can be cut by surgeon and placed on dural defect in either an onlay or tensionless suture application. Implant should be large enough to overlap edge of the remaining dura by at least one (1) centimeter. | Equivalent |
| Material of Construction | Porous polymer matrix | Porous polymer matrix | Bovine collagen 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 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. | Indicated as an absorbable, synthetic implant for bridging defects of the dura mater. | Indicated as a dura substitute for the repair of dura mater. | Equivalent |
| Size | Variety of Sizes | Variety of Sizes | Variety of Sizes | Equivalent |
| Material Composition | Porous PGLA / PDO matrix | Porous PGLA / PDO matrix | Bovine collagen matrix | Equivalent to predicate device |

| | | | | |
|-----------------------------------|--|--|--|--------------------------------|
| Surgical Application Restrictions | Device does not have requirement for specific orientation | On one side the porous structure of the VICRYL fleece allows tissue on-growth while the PDS film coating minimizes leakage of cerebrospinal fluid. | Device does not have requirement for specific orientation | Equivalent to reference device |
| Sterility | Sterile, SAL 10 ⁻⁶ | Sterile, SAL 10 ⁻⁶ | Sterile, SAL 10 ⁻⁶ | Equivalent |
| Packaging | Double sterile pack. Nested pouch configuration within a chipboard envelope. | Foil pouch within a chipboard box | Double sterile pack. Nested thermoformed trays with Tyvek lids within a chipboard 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:

- Subject device is manufactured with non-woven fiber technique versus the predicate device, which is manufactured with a woven technique
- The predicate device has a polymer film dyed with D&C Violet No. 2, while the subject device has neither a film layer nor dyes.
- Subject device does not have a requirement for specific orientation
- The predicate device does not specify how much overlap should exist between the edge of the device and the remaining dura. The subject device specifies a minimum distance of one centimeter. (Note: the reference device specifies a minimum distance of one centimeter as well).
- Although the maximum thickness of the subject device is comparable to the predicate device, the subject device has a lower minimum thickness that is comparable to native dura human dura.
- Subject device needs to be hydrated prior to placement, whereas the predicate device can be used without hydration.

Pre-clinical testing confirmed that despite differences in manufacturing techniques, the Cerafix® Dura Substitute is equivalent in function, indication for use, device classification product code, environment of use, and principles of operation to the predicate device.

Non-Clinical Testing – Mechanical

The subject device was evaluated in side-by-side bench testing versus the predicate or commercially available reference device. The results showed that the subject device demonstrated equivalent properties in the following areas:

| Test | Test Method Summary | Acceptance Criteria Results |
|--------------------------|---|--|
| Thickness | Comparison of Cerafix® Dura Substitute thickness to other dura substitutes on the market | Equivalent to Predicate or Reference Device PASS |
| Mass per Area | Comparison of Cerafix® Dura Substitute mass per area to other dura substitutes on the market | Equivalent to Predicate or Reference Device PASS |
| Tensile Strength | Comparison of Cerafix® Dura Substitute tensile strength to other dura substitutes on the market | Equivalent to Predicate or Reference Device PASS |
| Suture Pull-Out Strength | Comparison of Cerafix® Dura Substitute suture pull-out strength to other dura substitutes on the market | Equivalent to Predicate or Reference Device PASS |
| Burst Strength | Comparison of Cerafix® Dura Substitute burst strength to other dura substitutes on the market | Equivalent to Predicate or Reference Device; and burst strength greater than anticipated intracranial pressures PASS |
| Shrink Temperature | Evaluation of Cerafix® Dura Substitute stability at various temperatures | Show stability at applicable temperatures PASS |
| Fiber Diameter | Evaluation of Cerafix® Dura Substitute fiber diameter via SEM | Meets Final Device Specification PASS |
| Pore Size | Evaluation of Cerafix® Dura Substitute pore size via SEM | Meets Final Device Specification PASS |

Non-Clinical Testing - Biocompatibility

Biocompatibility testing was performed in compliance with ISO 10993. The results are summarized in the following table:

| Biocompatibility Tests | Results |
|--|---|
| ISO Cytotoxicity MEM Elution According to ISO 10993-5 Biological evaluation of medical devices: Part 5 Tests for In vitro Cytotoxicity | Cell culture treated with test sample exhibited no reactivity. Therefore, non-cytotoxic. |
| Guinea Pig Maximization - Sensitization According to ISO 10993-10 Biological evaluation of medical devices: Part 10 Tests for irritation and delayed hypersensitivity | Albino guinea pigs treated with test sample did not elicit a sensitization response. Therefore, non-irritant. |
| Intracutaneous Irritation Reactivity According to ISO 10993-10 Biological evaluation of medical devices: Part 10 Tests for irritation and delayed hypersensitivity | Rabbits treated with test samples were non-irritating. Therefore, non-irritant. |
| Hemolysis Assay According to ASTM F756-08 FDA Consensus Standard Number 2-154 | Rabbit blood treated with test samples was found to be non-hemolytic. |

| Biocompatibility Tests | Results |
|--|--|
| Genotoxicity In Vitro Mouse Lymphoma Assay ISO 10993-3:2003 | Cell culture with mouse lymphoma cells in the presence of trifluorothymidine exhibited a mean mutant frequency equivalent to the negative control Therefore, non-genotoxic. |
| Genotoxicity In vivo Mouse Micronucleus Assay ISO 10993-3:2003 | Adult CD-1 mice treated with test sample were considered non-mutagenic |
| Genotoxicity Bacterial Mutagenicity Test – Ames Assay ISO 10993-3:2003 | Salmonella typhimurium histidine auxotrophs and E. coli were considered non-mutagenic |
| Pyrogenicity Materials Mediated Rabbit Pyrogen Test | Albino rabbits treated with test samples exhibited a negative response. Therefore, non-pyrogenic. |
| Acute Systemic Toxicity ISO 10993-11 | Albino mice treated with test samples were considered non-toxic. |
| Endotoxin Testing | Less than 2.15 EU/device. Non-pyrogenic. |
| Subchronic Toxicity 90 day animal study | Rabbits treated with test samples for 90 days show the device to be non-toxic. |
| Chronic Toxicity 180 day animal study | Rabbits treated with test samples for 180 days show the device to be non-toxic. |

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

Side-by-side animal implantation studies were performed between the subject and predicate device. 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.