DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 30, 2015

Codman & Shurtleff, Inc.
Ms. Jennifer Siu
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K152481
Trade/Device Name: DURAFORM Dural Graft Implant
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: October 1, 2015
Received: October 2, 2015

Dear Ms. Siu:

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

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)*

K152481

Device Name
DURAFORM Dural Graft Implant

Indications for Use *(Describe)*
The DURAFORM Dural Graft Implant is intended for use in procedures where the repair or substitution of the patient's dura mater is needed.

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

I. Submitter

Codman & Shurtleff, Inc.
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Establishment Registration Number: 1226348

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Secondary Contact: Jocelyn Raposo
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Date of Submission: August 28, 2015

II. Device

Device Proprietary Name	DURAFORM™ Dural Graft Implant
Common Name	Dura Substitute
Classification Name	Dura Substitute (21 CFR 882.5910)
Regulatory Classification	II
Product Code	GXQ

III. Predicate Device

The predicate device for this submission is the CODMAN Dural Graft Implant (K033395), which was cleared on February 25, 2004.

IV. Device Description

The DURAFORM Dural Graft Implant is a single use, sterile collagen implant manufactured from processed bovine tendons. The Duraform Dural Graft Implant is designed to be a sutureless, onlay graft, but tensionless sutures can be used if preferred by the surgeon.

V. Indications for Use

The DURAFORM Dural Graft Implant is intended for use in procedures where the repair or substitution of the patient's dura mater is needed.

VI. Comparison to Predicate Device

The DURAFORM Dural Graft Implant is identical to the predicate device, formerly known as Codman Dural Graft Implant (K033395), with regard to indications for use, design, materials, manufacturing process,

VI. Comparison to Predicate Device (Cont.)

clinical utility, packaging, and sterilization; only the shelf life is different.

Codman is extending the shelf life for the DURAFORM Dural Graft Implant from 12 months to 30 months. The appropriate spectrum of stability testing has been performed to demonstrate substantial equivalence to the CODMAN Dural Graft Implant with a 12-month shelf life.

VII. Performance Data

There were no changes made that affect the DURAFORM Dural Graft Implant's indications for use, design, materials, manufacturing process, clinical utility, packaging, and sterilization.

Device and packaging stability testing for device and packaging characteristics that may be affected by an extended shelf life was performed. All testing was performed on final sterile devices unless otherwise specified.

The following device stability testing was performed at time-zero and after 30 months of real-time aging:

Test	Test Method Summary	Results
Compressibility (Time-Zero and 30-Month)	Compressibility quantifies the ability of a device to be compressed. Compressibility is measured by comparing the compressed thickness to the original thickness of the device. The compressed thickness is measured with a thickness gage after compression at 120 seconds.	Both time-zero and 30-month real-time tests passed the acceptance criterion. Therefore, the proposed device is substantially equivalent to the predicate device and does not raise new issues in safety and effectiveness.
Resilience (Time-Zero and 30-Month)	Resilience quantifies the capability of a device returning back to its original state. Resilience is measured by comparing the recovered thickness after compression to the original thickness of the device. The recovered thickness is measured after the device has been compressed for 120 seconds and left to recover to its original state for 30 minutes.	Both time-zero and 30-month real-time tests passed the acceptance criterion. Therefore, the proposed device is substantially equivalent to the predicate device and does not raise new issues in safety and effectiveness.

VII. Performance Data (Cont.)

Test	Test Method Summary	Results
Imbibition (Time-Zero and 30-Month)	The imbibition quotient measures how much fluid a material is able to absorb. In order to determine imbibition quotient, the dividend of the dry weight of a DURAFORM Dural Graft Implant sample is taken from wet weight of the sample after 10 seconds of irrigation, the procedure representing clinical use.	Both time-zero and 30-month real-time tests passed the acceptance criterion. Therefore, the proposed device is substantially equivalent to the predicate device and does not raise new issues in safety and effectiveness.
Apparent Density (Time-Zero and 30-Month)	Apparent density measures the density of a dural substitute material. Apparent density is measured using the dry weight of the device.	Both time-zero and 30-month real time tests passed the acceptance criterion. Therefore, the proposed device is substantially equivalent to the predicate device and does not raise new issues in safety and effectiveness.
Visual Inspection (Time-Zero and 30-Month)	A visual inspection is performed for the samples to be white in color with no stains visible.	Both time-zero and 30-month real-time tests passed the acceptance criterion. Therefore, the proposed device is substantially equivalent to the predicate device and does not raise new issues in safety and effectiveness.
Tensile Strength (Time-Zero and 30-Month)	Tensile strength testing is performed on the DURAFORM Dural Graft Implant per FDA's guidance on physical and mechanical properties testing for dura substitutes, as outlined in the Guidance Document for Dura Substitute Devices; Guidance for Industry. In order to test tensile strength, each sample is wetted with water, placed into an Instron instrument, and rewetted to ensure the sample has not dried out. Then, the instrument pulls the sample and captures the peak load when failure occurs.	Time-zero testing passed the acceptance criteria; 30-month testing results were deemed acceptable. Therefore, the proposed device is substantially equivalent to the predicate device and does not raise new issues in safety and effectiveness.

VII. Performance Data (Cont.)

The following packaging stability testing, performed at 120 months and 132 months of real-time aging, was leveraged to support packaging integrity for the proposed shelf life at 30 months:

Test	Test Method Summary	Results
Visual Inspection (120-Month and 132-Month)	A visual inspection is performed for any damage to the packaging.	Both 120-month and 132-month tests passed the acceptance criterion. Therefore, packaging integrity will be maintained for the duration of the proposed shelf life at 30 months.
Seal Integrity (Dye Penetration) (120-Month and 132-Month)	Seal integrity (dye penetration) testing was tested in accordance with ASTM F1929-12 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*.	Both 120-month and 132-month tests passed the acceptance criterion. Therefore, packaging integrity will be maintained for the duration of the proposed shelf life at 30 months.
Seal Strength (120-Month and 132-Month)	Seal strength testing was tested in accordance with ASTM F88/F88M-09 *Standard Test Method for Seal Strength of Flexible Barrier Materials*.	Both 120-month and 132-month tests passed the acceptance criterion. Therefore, packaging integrity will be maintained for the duration of the proposed shelf life at 30 months.

Animal Testing:
No animal studies were performed as appropriate validation of the shelf life extension was achieved based on the comparison to the predicate device and from the results of the device and packaging stability studies.

Clinical Testing:
No clinical studies were performed as appropriate validation of the shelf life extension was achieved based on the comparison to the predicate device and from the results of the device and packaging stability studies.

Conclusion:
Based upon the indications for use, design, materials, packaging, comparison to the currently marketed device, and shelf life testing performed by Codman, it is concluded that the DURAFORM Dural Graft Implant with a 30-month shelf life is substantially equivalent to the predicate CODMAN Dural Graft Implant with a 12-month shelf life and therefore, does not raise any new issues of safety and effectiveness.