DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 2, 2016

Medtronic Neurosurgery
Manas Lele
Senior Regulatory Affairs Specialist
125 Cremona Drive
Goleta, California 93117

Re: K161370
Trade/Device Name: Durepair Dura Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: September 27, 2016
Received: September 28, 2016

Dear Mr. Lele:

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)*
K161370

Device Name
Durepair Dura Regeneration Matrix

Indications for Use *(Describe)*
Durepair is indicated as a dura substitute for the repair of the dura mater.

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

This 510(k) summary is submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Owner:	Medtronic Neurosurgery 125 Cremona Drive Goleta, CA 93117-5503 USA
Contact Name:	Manas Lele Senior Regulatory Affairs Specialist Telephone: (805) 571-8956 Email: Manas.M.Lele@Medtronic.com
Date Summary Prepared:	October 31, 2016
Trade or Proprietary Name:	Durepair Dura Regeneration Matrix
Common Name:	Dura Substitute
Classification Name:	Dura Substitute (21 CFR §882. 882.5910, Product Code GXQ)
Predicate Device:	Durepair Dura Regeneration Matrix (K063117, K041000 and K052211)

Device Description:
Durepair® Dura Regeneration Matrix is a collagen implant for the repair of defects in the dura mater. Durepair is supplied sterile, in a double-peel package, and is intended for single (one-time) use-only. Durepair is available in a variety of sizes intended to be cut by the surgeon to the desired shape.

Indications for Use:
Durepair is indicated as a dura substitute for the repair of the dura mater.

Summary of Technological Characteristics Compared to the Predicate Device:
The proposed Durepair Dura Regeneration Matrix incorporates the same basic technological characteristics as the predicate device. The manufacturing process change relative to the predicate device did not affect the device design, indications of use, material or the fundamental technology of the device.

Table 1 – Summary of Technological Characteristics Comparison between Predicate Durepair Device and Proposed Durepair Device

Technological Characteristic	Predicate Durepair Device	Proposed Durepair Device
Fundamental Technology	Collagen implant for the repair of the defects in the dura mater	Same. The Fundamental Technology has not changed.
Sizes	Durepair is available in different sizes 1" x 1" 1" x 3" 2" x 2" 3" x 3" 4" x 5" 5" x 8"	Same. The length or width sizes or tolerances have not changed
Suturability	Use of suture allowed to secure device	Same. This characteristic has not changed.
Material	Collagen matrix harvested from processed fetal bovine materials	Same. The proposed device is made from the collagen matrix
Cut product to size	Durepair can be cut ot size based on user need	Same. This characteristic has not changed.
Manufacturing Process (Use of Solvents)	Use of organic solvents	No use of organic solvents. Replacement with equivalent processing step.

Table 2 – Summary of Bench Top Testing:

The following bench testing was submitted in support of substantial equivalence.

Test	Test Method Summary for Proposed Durepair device	Results for Proposed Durepair device
Sizes	The specified length or width had a tolerance of ± 5%. Measured with digital calipers and were inspected 100%.	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the physical attributes of the proposed device in comparison to the predicate device.
Tensile Strength	Tensile Strength must be an average 5 MPa minimum. All skins were sampled at the two thinnest corners of each skin representing worst case.	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the strength and stiffness attributes of the proposed device in comparison to the predicate device.
Tensile Stiffness	Tensile Stiffness must have an average 225 MPa maximum. All skins were sampled at the two thinnest corners of each skin representing worst case.	

Test	Test Method Summary for Proposed Durepair device	Results for Proposed Durepair device
Suture Retention Strength	At a pull rate of 20mm/min, 3 mm suture bite using polypropylene 4-0 suture, suture strength must be a Minimum of 5 N. Two suture retention samples were taken from the thinnest (weakest) areas of each skin.	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the ability to maintain a suture on the proposed device in comparison to the predicate device.
Wet Shrink Temperature	Wet shrink Temperature – Hydrated specimens must be 58° - 67° C (an in process specification). A Differential Scanning Colorimeter was used. Indicator that the scaffold has not been damaged during processing.	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the ability to maintain a suture on the proposed device in comparison to the predicate device.
Pore Size	No visible through pores should be seen and this test helps determine the material porosity	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the physical attributes of proposed device in comparison to the predicate device.
Hydration Rate	Time to hydrate must be less than or equal to 3 minutes. Saline solution is used to hydrate at room temperature	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the hydration rate time of proposed device in comparison to the predicate device.
Histology (Wet EBM)	No cells or cellular/nuclear debris evident. To demonstrate the EBM is free of cells and cellular/nuclear debris	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the contents of the proposed device in comparison to the predicate device.
Safety	Must be non-pyrogenic (Less than or equal to 2.15 EU/device) No bacterial endotoxins verified per each production lot.	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the contents of the proposed device in comparison to the predicate device.
Bioburden	No bioburden observed in the final rinse water, 0 CFUs for each lot. Final rinse water samples collected for each lot.	All samples met the acceptance criteria, demonstrating that there are no concerns regarding the contents of the proposed device in comparison to the predicate device.

In all cases, the results of bench testing met applicable pre-established acceptance criteria and raised no concerns regarding safety and effectiveness relative to the predicate device. Therefore, the bench testing summarized above supports the substantial equivalence of Durepair® Dura Regeneration Matrix and the predicate device.

Biocompatibility Testing:

Table 3 – Summary of Biocompatibility Testing:

Test	Test Method Summary	Result
Calcification	No calcification. Samples implanted into weanling rats for 4 weeks, explants were examined grossly and microscopically. Samples were tested for potential for calcification.	Pass. No calcification was present in the samples.
Cytotoxicity	Per ISO 10993-5 Test item considered non-cytotoxic if none of cultures exposed to test item show greater than mild reactivity (grade 2) Lots tested for biological reactivity by exposing mouse fibroblasts to a MEM elution of product.	Pass. None of the cultures showed greater than grade 2 of reactivity.
Skin Sensitization Study (Saline & Cottonseed Oil Extraction)	Per ISO 10993-10 No significant dermal contact sensitization. Extract of EBM was tested for allergenic potential via the guinea pig maximization test	Pass. All test animals scored a 0 and had no significant dermal contact sensitization.
Irritation Study, Intracutaneous Injection (Saline & Cottonseed Oil Extraction)	Per ISO 10993-10 Mean reaction scores for the test articles must be < 1.0 Extract of EBM was evaluated for its potential to produce irritation after Intracutaneous injection in rabbits	Pass. Mean reaction scores for the test articles were <1.0.
Acute Systemic Toxicity, Systemic Injection (Saline & Cottonseed Oil Extraction)	Per ISO 10993-11 No evidence of mortality or acute systemic toxicity. Extract of EBM was evaluated for its potential to cause acute toxicity after intravenous and intra peritoneal injection in mice.	Pass. No test or control animals showed signs of toxicity.
Hemolysis, Rabbit Blood	Per ISO 10993-4 Corrected % hemolytic index for direct and indirect contact must be < 5%. The samples were evaluated for hemolytic activity on rabbit blood via both direct and indirect contact.	Pass. Corrected % hemolytic index for direct and indirect contact was < 5%.
Intramuscular Implantation Study (4 weeks & 12 weeks)	Per ISO 10993-6 Must be non-reactive. Samples evaluated for local tissue responses and the potential to induce local toxic effects after implantation in a rat intramuscular model	Pass. No reaction was seen in the samples.
Genotoxicity, Ames Reverse Mutation Assay	Per ISO 10993-3 No 2X, or greater, increase in the mean number of revertants compared to the negative control. Extracts of EBM were evaluated for potential mutagenicity in certain bacteria via a change in their dependence for histidine or tryptophan.	Pass. None of the test article extracts induced a significant increase in number of revertants as

Test	Test Method Summary	Result
		compared to the negative control.

In all cases, Durepair® passed biocompatibility testing, demonstrating that the Durepair chemical change process does not raise any biocompatibility concerns relative to the predicate device. Therefore, the biocompatibility testing summarized above supports the substantial equivalence of Durepair and the predicate device.

Conclusion:

Based on the indications of use, design and technology similarities, performance testing including bench and biocompatibility testing performed on the proposed device, it can be concluded that the proposed Durepair® Dura Regeneration Matrix is substantially equivalent to the currently marketed Durepair® cleared devices under K063117, K052211 and K041000.