



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

November 20, 2015

Collagen Matrix, Inc.  
Ms. Gloria Zuclich  
Senior Manager of Regulatory Affairs  
15 Thornton Road  
Oakland, New Jersey 07436

Re: K150825

Trade/Device Name: Collagen Dural Regeneration Matrix  
Regulation Number: 21 CFR 882.5910  
Regulation Name: Dura Substitute  
Regulatory Class: Class II  
Product Code: GXQ  
Dated: November 13, 2015  
Received: November 16, 2015

Dear Ms. Zuclich:

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)

K150825

Device Name

Collagen Dural Regeneration Matrix

Indications for Use (Describe)

Collagen Dural Regeneration Matrix is intended for use as a dura substitute for the repair of 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

### 1. Applicant Information

**Applicant Name:** Collagen Matrix, Inc.  
**Address:** 15 Thornton Road  
Oakland, New Jersey 07436 USA  
**Telephone:** (201) 405-1477 Ext. 317  
**Fax:** (201) 405-1355  
**Contact Person:** Gloria Zuclich  
Senior Manager of Regulatory Affairs  
**Date Prepared:** November 19, 2015

### 2. Name of the Device

**Device Trade Name:** Collagen Dural Regeneration Matrix  
**Device Common Name:** Collagen Dura Substitute  
**Device Classification Name:** Dura Substitute  
Regulation Number 882.5910  
Product Code GXQ  
Device Class II

### 3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

**Predicate Device(s):** DuraGen Plus<sup>®</sup> Dural Regeneration Matrix  
K032693

### 4. Description of the Device

Collagen Dural Regeneration Matrix is a white, non-friable, resorbable and biocompatible type I collagen matrix made from purified bovine Achilles tendon. Collagen Dural Regeneration Matrix is a porous, sponge-like collagen matrix with one smooth surface that conforms to the contours of the defect site. It is supplied sterile, non-pyrogenic, in various sizes, and for single use only.

### 5. Intended Use

Collagen Dural Regeneration Matrix is intended for use as a dura substitute for the repair of dura mater.

### 6. Summary/Comparison of Technical Characteristics

Collagen Dural Regeneration Matrix has been determined to be substantially equivalent to the predicate device having similar technological characteristics as follows:

Parameter	Collagen Dural Regeneration Matrix (This submission)	DuraGen Plus® Dural Graft Matrix
510(k)	K150825	K032693
Indications for Use	Intended for use as a dura substitute for the repair of dura mater.	Intended for use as a dura substitute for the repair of dura mater.
Collagen Source	Bovine Achilles tendon	Bovine Achilles tendon
Form	Porous Collagen Matrix	Porous Collagen Matrix
Color	White to off-white	White to off-white
Physical Integrity	Non-friable	Non-friable
Sizes	Variety of sizes	Variety of sizes
Conformability	Conformable	Conformable
Biocompatibility	Biocompatible	Biocompatible
In Vivo Stability	Gradual resorption	Gradual resorption
Sterility	Sterile, SAL 10 <sup>-6</sup>	Sterile, SAL 10 <sup>-6</sup>
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Single Use/Reuse	Single use only	Single use only
Packaging	Double blister	Double blister

## 7. Discussion of Non-clinical Testing

The substantial equivalence of Collagen Dural Regeneration Matrix and its predicate was demonstrated based on *in vitro* characterization studies, biocompatibility studies, and an animal efficacy study.

Non-clinical testing was performed in accordance with FDA recognized consensus standards and FDA guidelines as follows:

FDA Guidance Document entitled, "Guidance document for Dura Substitute Device: Guidance for Industry", issued on November 9, 2000

ISO 22442-1 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 1 Analysis and Risk Management

ISO 22442-2 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 2 Controls on Sourcing, Collection, and Handling

ISO 22442-3 Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices – Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Agents

ISO 10993-3:2009 Biological Evaluation of Medical Devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests for *in vitro* cytotoxicity

ISO 10993-6:2009 Biological Evaluation of Medical Devices- Part 6: Test for local effects after implantation

ISO 10993-10:2009 Biological Evaluation of Medical Devices- Part 10 Test for local effects after implantation

ISO 10993-11:2009 Biological Evaluation of Medical devices – Part 11 Tests for systemic toxicity

**Non-clinical Testing Conducted**

*In vitro* product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate device. A series of bench tests were conducted to evaluate material properties, biological properties, chemical and physical properties. The comparative bench testing is summarized in the table below.

Test	Test Method	Results
Dimensions	Measurements	Dimensions similar to predicate device
pH	Internal test method using pH meter	pH similar to predicate device
Tensile strength	Internal test method using mechanical test apparatus	Tensile strength similar to predicate device
Conformability	Internal test method to measure drape angle	Conformability similar to predicate device
Hydrothermal transition temperature	Internal test method using differential scanning calorimeter	Hydrothermal transition temperature similar to predicate device.
Liquid Permeability	Internal test method to measure permeability to liquid	Minimally permeable; similar to predicate
Burst strength	Internal test method to measure burst strength	Adequate for cerebrospinal fluid (CSF) pressure

A series of *in vitro* and *in vivo* biocompatibility testing was performed to assess safety of the Collagen Dural Regeneration Matrix as an implantable material. The biocompatibility testing performed is summarized in the table below.

Test	Test Method/ Model	Results
Cytotoxicity	Agarose Overlay, ISO 10993-5	Non-cytotoxic
Sensitization	Guinea Pig Maximization, ISO 10993-10	Under the conditions of this protocol, the test article did not elicit a sensitization response.
Intracutaneous Reactivity	Intracutaneous Reactivity in Rabbit, ISO 10993-10	<u>Polar Extract</u> Under the conditions of the study, there was no erythema and no edema from the test extract injected intracutaneously into the rabbits.

Test	Test Method/ Model	Results
		<u>Non-polar Extract</u> Under the conditions of the study, there was no to very slight erythema or edema from the extract injected intracutaneously into rabbits.
Acute Systemic Toxicity	Acute Systemic Toxicity in Mice, ISO 10993-11	No mortality or evidence of systemic toxicity.
Genotoxicity	Bacterial Reverse Mutagenic Study, ISO 10993-3	Non-mutagenic to <i>Salmonella typhimurium</i> (Test Strains: TA98, TA1535, and TA1537) and to <i>Escherichia coli</i> (Test Strain WP2uvrA)
Genotoxicity	Mouse Lymphoma Assay, ISO 10993-3	The test article extracts did not cause a two-fold or greater increase in the mean mutant frequency of the L5178Y/TK <sup>+/+</sup> cell line either in the presence or absence of metabolic activation. The test article is considered non-mutagenic.
Pyrogenicity	USP (151) Pyrogen Study – Material Mediated	The test article was judged as nonpyrogenic.
Muscle Implantation	Muscle Implantation Study in Rabbits, 2 weeks, ISO 10993-6	The macroscopic reaction was not significant as compared to the sponsor provided control article or to the negative control article. Microscopically, the test article was classified as a non-irritant as compared to the sponsor provided control article and as a slight irritant as compared to the negative control article.
Subchronic Toxicity	Subcutaneous Implantation in Rabbits, ISO 10993-11	Under the conditions of the 13-week study, there was no evidence of systemic toxicity or adverse findings attributed to the test article when compared with the predicate control.
Chronic Toxicity	Subcutaneous Implantation in Rabbits, ISO 10993-11	Under the conditions of the 26-week subcutaneous implant toxicity study, there was no evidence of systemic toxicity or adverse findings attributed to the test article. Based upon the differences between the Test Article Group Average Irritation Scores, the test article was considered non-irritant when compared to the predicate control at 26 weeks.

An animal efficacy study utilizing a rabbit dural defect repair model was conducted to evaluate the device as compared to its predicate device with regards to dura repair and resorption. No clinical tests were performed on the product; however clinical history of the predicate device was referenced in the submission.

A Viral inactivation study was performed to ensure the viral safety of the product.

## **8. Conclusion of Non-clinical Studies**

The predicate device was cleared based on the results of non-clinical data. The subject device demonstrates equivalence to the predicate device.