



November 18, 2025

Collagen Matrix, Inc.  
Victoria Augustine  
Regulatory Affairs Specialist  
15 Thornton Road  
Oakland, New Jersey 07436

Re: K251191

Trade/Device Name: Collagen Dura Regeneration Membrane - Repair  
Regulation Number: 21 CFR 882.5910  
Regulation Name: Dura Substitute  
Regulatory Class: Class II  
Product Code: GXQ  
Dated: October 20, 2025  
Received: October 20, 2025

Dear Victoria Augustine:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the QS regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the medical device reporting (MDR) regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

XIAOLIN  
ZHENG -S

For Jaime Raben, Ph.D.  
Director  
DHT5A: Division of Neurosurgical,  
Neurointerventional, and  
Neurodiagnostic Devices  
OHT5: Office of Neurological and  
Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K251191

Device Name

Collagen Dura Regeneration Membrane - Repair

Indications for Use (Describe)

Collagen Dura Regeneration Membrane - Repair is indicated 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Collagen Matrix, Inc.
Applicant Address	15 Thornton Road, Oakland, NJ 07436 United States
Applicant Contact Telephone	(1) 646-222-9564
Applicant Contact	Ms. Victoria Augustine
Applicant Contact Email	taugustine@collagenmatrix.com

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Collagen Dura Regeneration Membrane - Repair
Common Name	Dura Substitute
Classification Name	Dura Substitute
Regulation Number	882.5910
Product Code(s)	GXQ

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161370	Durepair Dura Regeneration Matrix	GXQ
K141608	Collagen Dura Membrane	GXQ
K040888	DuraMatrix Collagen Dura Substitute Membrane	GXQ

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

Collagen Dura Regeneration Membrane - Repair is a white, nonfriable, resorbable, membrane matrix consisting of highly purified Type I and Type III collagen from bovine dermis for the repair of defects in dura mater.

Collagen Dura Regeneration Membrane - Repair is provided in various sizes where it can be easily trimmed for an appropriate fit.

Collagen Dura Regeneration Membrane - Repair is supplied sterile, non-pyrogenic and for single use only.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

Collagen Dura Regeneration Membrane - Repair is indicated as a dura substitute for the repair of dura mater.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Collagen Dura Regeneration Membrane - Repair, the predicate device (Durepair Dura Regeneration Matrix, K161370), and the reference devices (Collagen Dura Membrane, K141608 & Duramatrix Collagen Dura Substitute Membrane, K040888) are indicated as a dura substitute for the repair of dura mater. The indications of the devices align with devices within the GXQ product code (Dura Substitute).

The subject and predicate device have the same intended use, principle of operation, starting materials and performance characteristics. There are no significant technological differences between the subject device and the reference devices.

The following technological characteristics of the subject device are compared to the predicate device:

Material:	Fetal bovine dermis
Form:	Intact tissue matrix
Color:	White to off-white
Sizes:	Variety of sizes up to 35 inch <sup>2</sup>
Thickness (mm):	Approximate to native dura $0.72 \pm 0.14$ (subject device); $0.75 \pm 0.20$ (predicate device)
Hydration:	Hydration in saline at room temperature in less than or equal to 3 minutes
Physical Integrity:	Non-friable
Suture Pullout Strength (N):	Suture pullout strength similar to the predicate device
Biocompatibility:	Biocompatible per ISO 10993 standards
Thermal Transition Temperature (°C):	Thermal transition similar to the predicate device
Sterility:	SAL $10^{-6}$ via ethylene oxide
Pyrogenicity:	Non-pyrogenic
Single Use/Reuse:	Single use only
Chemically Cross-linked:	No
Tensile Strength (MPa):	Tensile strength similar to the predicate device
Drapability (a):	Drapability similar to the predicate device

## Non-Clinical and/or Clinical Tests Summary & Conclusions

In vivo and in vitro testing of the subject device was conducted to demonstrate substantial equivalence of the subject device to its predicate device. The following performance data are provided in support of the substantial equivalence determination.

### Biocompatibility:

Biocompatibility testing according to standards set forth in ISO 10993-1 demonstrated that the material is non-irritating, non-pyrogenic, non-mutagenic, non-sensitized, non-hemolytic, and had no evidence of systemic toxicity.

A biological evaluation report was performed based on the requirements of ISO 10993-1:2018. A toxicological risk assessment was performed to evaluate residuals of the manufacturing process. Based upon examination of this information, the risk assessment indicates that exposure to toxicologically significant levels of chemicals is unlikely during clinical use of the device and any patient risks associated with such exposures are negligible.

### Bench Testing:

Product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate. Testing included dimensions, hydration, pyrogenicity, suture pull out, and thermal stability. Each lot of finished devices is tested for bacterial endotoxin for lot release.

### Shelf-Life:

The shelf-life study has been designed to evaluate the stability of the product and packaging over time as packaged and stored under real time aging conditions. The representative product is selected based on the parameters correlating to safety and performance of the device and its packaging, as well as potential risks to such requirements. The product stability assessment simulates the functional and chemical stability tests required for release of the final product. The results of the tests at each time point must meet overall product specifications.

### Animal Testing:

Dural implantation testing of the subject device was performed in a rabbit study to support the subchronic toxicity, implantation, and neurotoxicity of the subject device demonstrating substantial equivalence to the positive control (predicate device) at 4, 8, 13, and 26 week time points.

Clinical performance data was not required to determine substantial equivalence.

The conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to its predicate device. The safety and effectiveness of the subject device has been demonstrated through bench testing, biocompatibility and substantial equivalence comparison to the predicate device.