May 01, 2024

Collagen Matrix, Inc.
Daniel Fernandez
Regulatory Affairs Specialist
15 Thornton Rd.
Oakland, New Jersey 07436

Re: K233203
Trade/Device Name: Soft Tissue Augmentation Resorbable Matrix
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone grafting material
Regulatory Class: Class II
Product Code: NPL
Dated: April 03, 2024
Received: April 04, 2024

Dear Daniel Fernandez:

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 quality systems (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.

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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233203

Device Name
Soft Tissue Augmentation Resorbable (STAR) Matrix

Indications for Use *(Describe)*
The Soft Tissue Augmentation Resorbable (STAR) Matrix is intended to support localized gingival augmentation to increase keratinized tissue.

STAR Matrix is indicated for:

- •Covering of implants placed in immediate or delayed extraction sockets;
- •Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants.

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
Telephone: (201) 405-1477
Fax: (201) 405-1355

Contact Person: Daniel Fernandez
Regulatory Affairs, Specialist
dfernandez@collagenmatrix.com

Date Prepared: May 01, 2024

2. Name of the Device

Device Trade Name: Soft Tissue Augmentation Resorbable (STAR) Matrix

Device Common Name(s): Collagen Dental Membrane

Device Classification Name: Barrier, animal source, intraoral
872.3930
NPL
Class II

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Predicate Device: Geistlich Mucograft®, Geistlich Mucograft Seal®
Geistlich Pharma AG
K210280

Reference Device(s): Collagen Dental Membrane – Porcine Type I Collagen
Collagen Matrix, Inc.
K110600

Porcine Mineral Collagen Composite
Collagen Matrix, Inc.
K202183

4. Description of the Device

The Soft Tissue Augmentation Resorbable Matrix (STAR Matrix) is a cross – linked, resorbable membrane engineered from highly purified Type I collagen fibers derived from Porcine Achilles Tendon for use in periodontal, oral, and maxillofacial surgery. STAR Matrix is composed of two structures: a smooth outer layer that acts as a barrier membrane and a porous matrix layer to allow cell invasion and tissue ingrowth. The product is oriented so that the porous layer is in contact with the host tissue bone/bone graft or periosteum to facilitate tissue integration. The

product is provided sterile, non-pyrogenic, and for single use only. Product is provided in various sizes where it can be easily trimmed for appropriate fit and sutured into place during surgery.

5. Indications for Use

STAR Matrix is intended to support localized gingival augmentation to increase keratinized tissue.

STAR Matrix is indicated for:

- Covering of implants placed in immediate or delayed extraction sockets;
- Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants.

6. Summary/Comparison of Technical Characteristics

The subject device has equivalent technological characteristics as the predicate Geistlich Mucograft® and Geistlich Mucograft Seal® (510(k) K210280) device.

Feature	Soft Tissue Augmentation Resorbable (STAR) Matrix (Subject Device)	Geistlich Mucograft®, Geistlich Mucograft Seal® (K210280) (Predicate Device)	Collagen Dental Membrane – Porcine Tendon Type I Collagen (K110600) (Reference Device)	Device Comparison
Indications for Use	STAR Matrix is intended to support localized gingival augmentation to increase keratinized tissue. STAR Matrix is indicated for: • Covering of implants placed in immediate or delayed extraction sockets; Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants.	Geistlich Mucograft and Mucograft seal are indicated for covering of implants placed in immediate or delayed extraction sockets, localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants, alveolar ridge reconstruction for prosthetic treatment, and recession defects for root coverage.	Collagen Dental Membrane – Porcine Tendon Type I Collagen is intended for use in oral surgical procedures as a resorbable material for placement in the area of dental implants, bone defect or ridge reconstruction to aid in wound healing.	Similar
Product Code & Regulation	NPL 872.3930 Bone Grafting Material	NPL 872.3930 Bone Grafting Material	NPL 872.3930 Bone Grafting Material	Identical
Material Origin	Porcine	Porcine	Porcine	Similar
Material Composition	Primarily Type I Porcine collagen	Primarily Type I Porcine collagen	Primarily Type I Porcine collagen	Similar
Product Form	Smooth outer layer Porous matrix layer	Smooth “outer” surface Porous “inner” structure	Membrane	Identical

Feature	Soft Tissue Augmentation Resorbable (STAR) Matrix (Subject Device)	Geistlich Mucograft®, Geistlich Mucograft Seal® (K210280) (Predicate Device)	Collagen Dental Membrane – Porcine Tendon Type I Collagen (K110600) (Reference Device)	Device Comparison
Product Sizes	1.5 x 2.0 cm 2.0 x 3.0 cm 3.0 x 4.0 cm 10 x 20 mm 15 x 15 mm 15 x 25 mm 10 x 40 mm 20 x 40 mm 15 x 45 mm 15 x 40 mm 25 x 45 mm Diameter: 8 - 12 mm	Mucograft: 15 x 20 mm, 20 x30 mm, and 30 x 40 mm Mucograft Seal: 8mm and 12 mm diameter	1.5 x 2.0 cm 2.0 x 3.0 cm 3.0 x 4.0 cm	Similar; The additional potential sizes of the subject device fall within the surface area of the largest device.
Device Thickness	Approx. 1.5 to 5 mm	Approx. 2.5 to 5 mm	0.2 – 0.6 mm	Similar
Thermal Stability	53 ± 8	31.4 ± 0.20	57 ± 7	Different
Suturability (kg)	≥ 0.065	0.166 ± 0.0816	≥ 0.065	Similar
Density	0.047 ± 0.018	0.054 ± 0.003	N/A	Similar
Cross – linking	Crosslinked with formaldehyde	N/A	Crosslinked with formaldehyde	Different
Biocompatibility	Biocompatible Meets ISO 10993 biocompatibility series of testing	Biocompatible Meets ISO 10993 biocompatibility series of testing	Biocompatible Meets ISO 10993 biocompatibility series of testing	Identical
Sterility	Sterile using Gamma Irradiation; SAL 10^{-6}	Sterile using Gamma Irradiation	Sterile using Gamma Irradiation; SAL 10^{-6}	Identical
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic	Identical
Single Use/ Reuse	Single use only	Single use only	Single use only	Identical

7. Performance Data

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.

Viral inactivation to ensure product safety was performed in accordance with ISO 22442-3.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with the testing matrix of ISO 10993-1:

Cytotoxicity, ISO 10993-5

Genotoxicity, ISO 10993-3 and ISO 10993-12

Muscle Implantation, ISO 10993-6

Implantation Assessment in Canine Study, ISO 10993-6

Intracutaneous Reactivity, ISO 10993-10

Acute System Toxicity, ISO 10993-11

Genotoxicity ISO 10993-12

Pyrogenicity ISO 10993-11

A Toxicology Risk Assessment was performed to evaluate formaldehyde residuals. The assessment included an evaluation of information presented in scientific literature and biocompatibility testing conducted on the subject device as well as similar devices. The results of the assessment concluded that the amount of formaldehyde residual for single product use has been addressed. The level of formaldehyde residual present in the subject device is within the acceptable limit as found in previous FDA approved Collagen Matrix, Inc devices.

Bench Testing

- **Purified Collagen Characterization Testing**
  - Hydroxyproline Content
  - Amino Sugar Content
  - Lipid Content
  - SDS page for purified porcine collagen, from reference device K110600, was leveraged in support of characterization testing.
  - Heavy Metals testing was leveraged from reference device K202183 in support of characterization testing.
- **Product Characterization Testing**
  - Suture Pull-out Strength
  - Thermal Transition Temperature
  - Density

Animal Testing

The performance of the device was compared to that of the predicate device, Geistlich Mucograft® in a canine model, and evaluated by gross pathology and histological assessments. Critical soft tissue periodontal defects were made at the alveolar ridge, where devices were then implanted. Measurements of the defects were taken at baseline, 4 weeks, 8 weeks, and 12 weeks, which included anterior, central, and posterior measurements of the keratinized and soft tissue thickness. Measurement and assessment of the keratinized tissue length in the defect site was made at each termination time point. Conclusion of the study indicates the positive healing performance of the device as compared to the predicate, with noticeable return to native structures and complete resorption of the device with no unresolved adverse effects. The results demonstrate performance substantially equivalent to the predicate device with regards to the indications for use.

Clinical Studies

Clinical performance data was not required to determine substantial equivalence.

Sterilization / Shelf Life

The device is provided sterile in following with ISO 11737. Sterilization for the subject device is based off of and leveraged from reference device K110600.
The subject device shelf-life program was developed taking into consideration ISO 11607, ASTM D4169, ASTM F-1886-09, ASTM F1929, ASTM F-88/F88-M15, and ISTA 3A. The shelf life of the subject device is 26 months.

8. Conclusions Drawn from Non-clinical Studies

The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to its predicate devices.