December 19, 2024

Collagen Matrix, Inc.
Devin Dragon
Senior Regulatory Specialist
15 Thornton Road
Oakland, New Jersey 07436

Re: K243071
Trade/Device Name: Bovine Dermis Collagen Dermal Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 27, 2024
Received: September 27, 2024

Dear Devin Dragon:

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.

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 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control 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)*
K243071

Device Name

Bovine Dermis Collagen Dermal Matrix

Indications for Use *(Describe)*

Bovine Dermis Collagen Dermal Matrix is indicated for the management of wounds, including:

- Full thickness and Partial thickness wounds
- Chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers)
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, and skin tears)
- Draining wounds
- Partial thickness burns

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.

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1. Contact Details

Applicant Name: Collagen Matrix, Inc.
Applicant Address: 15 Thornton Road
Oakland, New Jersey 07436
Applicant Contact Telephone: (732) 856-2674

Applicant Contact: Devin Dragon
Sr. Regulatory Specialist
ddragon@regenity.com

Date Prepared: December 10, 2024

2. Device Name

Device Trade Name: Bovine Dermis Collagen Dermal Matrix
K243071

Device Common Name(s): Collagen Dermal Matrix

Device Classification Name: Dressing, Wound, Collagen
KGN
Unclassified

3. Legally Marketed Devices to Which Substantial Equivalence is Claimed

Primary Predicate Device: Collagen Topical Wound Dressing
K040211
KGN

Secondary Predicate Devices: **C**ollagen Dental Wound Dressings
K152600
KGN

4. Device Description Summary

Bovine Dermis Collagen Dermal Matrix is an absorbent, porous, collagen matrix engineered from purified collagen derived from bovine dermal tissue. Bovine Dermis Collagen Dermal Matrix should be applied directly to the wound, covering the entire wound surface.

Bovine Dermis Collagen Dermal Matrix is supplied sterile, non-pyrogenic and for single use only.

5. Intended Use

Bovine Dermis Collagen Dermal Matrix is indicated for the management of wounds, including:

- Full thickness and Partial thickness wounds
- Chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers)
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, and skin tears)
- Draining wounds
- Partial thickness burns

6. Indications for Use Comparison

The subject device and the predicate device (Collagen Topical Wound Dressing, K040211) are both intended for the management of wounds. The indications of both devices align with devices within the KGN product code (Dressing, Wound, Collagen).

7. Technological Comparison

Although the subject and predicate devices are both made primarily from purified Type I bovine dermis collagen, the subject device has an additional formaldehyde crosslinking step and a lower sterilization dose than the predicate device, K040211. The subject device's manufacturing process and sterilization dose is identical to the secondary predicate device K152600. The process of crosslinking the device with formaldehyde has been used in many of Collagen Matrix's cleared 510(k)s, including Collagen Dental Wound Dressing, K152600 and is a well-recognized practice in similar medical devices.

Through the manufacturing process and product release testing, the level of residual formaldehyde is monitored and mitigated for safety. The subject device and is crosslinked using formaldehyde under the same processing conditions that is used for the secondary predicate K152600. Due to the larger maximum size of available dressing sizes for the subject device, a risk analysis was performed to demonstrate that the potential content of formaldehyde residuals in the largest available dressing size does not raise new questions of safety.

The subject and predicate device have the same intended use, principle of operation, and identical starting materials. With the exception of the crosslinking step and lower sterilization dose, the subject and predicate devices have similar technical characteristics, manufacturing materials, performance specifications, and packaging materials.

A summary table comparing the subject device to the predicate devices is included on the next page.

Subject Device & Predicate Device(s):	K243071	K040211	K152600
General Device Characteristics	Bovine Dermis Collagen Dermal Matrix	Collagen Topical Wound Dressing	Collagen Dental Wound Dressing
Intended Use	For the management of wounds, including: • Full thickness and Partial thickness wounds • Chronic wounds (e.g. pressure ulcers, venous ulcers, diabetic ulcers, chronic ulcers) • Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) • Trauma wounds (abrasions, lacerations, and skin tears) • Draining wounds • Partial thickness burns	For the management of moderately to heavily exudating wounds, and to control minor bleeding. Collagen Topical Wound Dressing may be used for the management of exudating wounds such as: • pressure ulcers • venous stasis ulcers • diabetic ulcers • acute wounds, for example trauma and surgical wounds • partial-thickness burns	For the management of oral wounds and sores, including: • Denture sores • Oral ulcers (non-infected or viral) • Periodontal surgical wounds • Suture sites • Burns • Extraction sites • Surgical wounds • Traumatic wounds
Tissue source	Bovine dermis	Same	Same
Available Sizes	Up to 700 cm^2 • 2 cm x 4 cm • 5 cm x 5 cm • 10 cm x 10 cm • 10 cm x 20 cm • 20 cm x 35 cm	Up to 114 in^2 (720 cm^2) Width: 2 in – 8 in (5 cm – 20 cm) Length: 2 in – 14 in (5 cm – 36 cm)	Up to 8 cm^2 • 2 cm x 4 cm
Thickness	3 mm	Same	Same
Absorption Capacity	Specification: >18 mL/g Test: 31.0 mL/g	Specification: >10 mL/g Test: 40.2 mL/g	Same
Cross-linked	Yes	No	Yes
Crosslinker	Formaldehyde	N/A	Same
Sterilization Method	Gamma irradiation	Same	Same
SAL	10^{-6}	Same	Sam
Pyrogenicity	Non-pyrogenic	Same	Same
Packaging	Single barrier (Tyvek pouch)	Same	Same or blister tray
Shelf Life	36 months	Same	Same

8. Non-Clinical and/or Clinical Tests Summary & Conclusions

Subject and predicate devices performance data were compared to support the safety of the subject device and demonstrate that the Bovine Dermis Collagen Dermal Matrix perform as intended.
The substantial equivalence of Bovine Dermis Collagen Dermal Matrix to its predicates is demonstrated based on in vitro characterization studies and biocompatibility studies.

In vitro product characterization testing was performed to demonstrate substantial equivalence of the subject device to its predicate devices. A series of bench tests were conducted to evaluate material properties, biological properties, chemical and physical properties. These tests included: Absorbency, pH, Thermal Transition Temperature, Density, Crosslinking Agent Residual Content, and Pyrogenicity.

A series of biocompatibility testing was performed to assess the safety of the Bovine Dermis Collagen Dermal Matrix as a surface device categorized for long term (>30 days) contact with breach and/or compromised skin surfaces. These tests included: Physical and Chemical Information, Cytotoxicity, Sensitization, Irritation, Material Mediated Pyrogenicity, Acute / Subacute / Subchronic / Chronic Toxicity, Implantation, Genotoxicity, and Carcinogenicity.

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

9. Conclusions

The conclusions drawn from the above documentation demonstrate that the proposed device is as safe, effective and performs as well as the legally marketed predicate devices.