May 31, 2022

Collagen Matrix, Inc.
Peggy Hansen
Senior Vice President
15 Thornton Road
Oakland, New Jersey 07436

Re: K213341
Trade/Device Name: Fibrillar Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: October 5, 2021
Received: October 7, 2021

Dear Peggy Hansen:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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)*

K213341

Device Name

Fibrillar Collagen Wound Dressing

Indications for Use *(Describe)*

Fibrillar Collagen Wound Dressing is indicated for the management of moderately to heavily exudating wounds and to control minor bleeding.

Fibrillar Collagen 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

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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COLLAGEN MATRIX
SCIENCE • TECHNOLOGY • INNOVATION

510(k) Summary

510(k) Number: K213341

1. Applicant Information

Applicant Name: Collagen Matrix, Inc.

Address: 15 Thornton Road
Oakland, New Jersey 07436

Telephone: (201) 405-1477, ext. 304

Fax: (201) 405-1355

Contact Person: Peggy Hansen
GM, Contract Development & Manufacturing
SVP, Regulatory & Clinical Affairs
phansen@collagenmatrix.com

Date Prepared: May 31, 2022

2. Name of the Device

Device Trade Name: Fibrillar Collagen Wound Dressing

Device Common Name(s): Topical Wound Dressing

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
Collagen Matrix, Inc.
K030921

4. Description of the Device

The Fibrillar Collagen Wound Dressing is an absorbent microfibrillar collagen matrix intended for the management of moderately to heavily exudating wounds and the control of minor bleeding. When interacting with the wound fluid, the product immediately begins to absorb the exudates. The Fibrillar Collagen Wound Dressing is applied directly to the secreting wound and protects the wound bed and delicate new tissue. In addition, the product, being comprised of microfibrillar collagen, has intrinsic hemostatic properties, which can be used to control minor bleeding.

The product is available in various sizes and is provided sterile, non-pyrogenic, and for single use only.

5. Intended Use

Fibrillar Collagen Wound Dressing is indicated for the management of moderately to heavily exudating wounds and to control minor bleeding.

Fibrillar Collagen 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, and partial-thickness burns.

6. Summary/Comparison of Technical Characteristics

The subject device has substantially equivalent technological characteristics as the cited legally marketed predicate devices.

Parameter	**Fibrillar Collagen Wound Dressing** (Subject Device)	**Collagen Topical Wound Dressing** K030921 (Predicate Device)
Indications for Use	Fibrillar Collagen Wound Dressing is indicated for the management of moderately to heavily exudating wounds and to control minor bleeding. Fibrillar Collagen 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, and partial-thickness burns.	Collagen Topical Wound Dressing is indicated 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, and partial-thickness burns.
Material	Collagen	Collagen
Biocompatibility	Biocompatible	Biocompatible
Sterility	Sterile	Sterile
Pyrogenicity	Non-Pyrogenic	Non-Pyrogenic
Single Use/Reuse	Single use only	Single use only

Nonclinical tests submitted

The submission included summary-level information demonstrating compliance with design controls, including risk analysis method and Declaration of Conformity with Design Controls. Design validation included performance data to demonstrate conformance with the special controls and to ensure that the modified device would meet user requirements. Safety and performance testing completed on the subject device are shown in the table below:

Test	**Test Method / Model**
Cytotoxicity	L929 MEM Elution, ISO 10993-5

Test	Test Method / Model
Sensitization	Guinea Pig Maximization, ISO 10993-10
Intracutaneous Reactivity	Intracutaneous Reactivity in Rabbits, ISO 10993-10
Acute Systemic Toxicity	Acute Systemic Toxicity in Mice, ISO 10993-11
Pyrogenicity	Rabbit Pyrogen Study, USP <151>

Additional implantation and subchronic toxicity testing of the predicate device was leveraged to support the safety and performance of the subject device.

Conclusions Drawn from Non-Clinical Studies

The conclusions drawn from the design control process demonstrate that the device is substantially equivalent to its legally marketed predicate.