July 2, 2026

Ventris Medical
% Patsy Trisler
Regulatory Consultant
Trisler Consulting, Dba
306 Turnberry Ct.
Lebanon, Indiana 46053

Re: K260596
Trade/Device Name: Collagen Wound Powder
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 1, 2026
Received: June 1, 2026

Dear Patsy Trisler:

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,

TEK N. LAMICHHANE -S

For 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260596

Device Name
Collagen Wound Powder

Indications for Use *(Describe)*
Collagen Wound Powder is indicated for the management of wounds that include:
- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and superficial 2nd degree burns
- Cuts, abrasions and surgical wounds

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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510(k) Summary – K260596

1.0 Submitter Information

Name:	Ventris Medical
Address:	1201 Dove Street, Suite 470 Newport Beach, CA 92660
Telephone:	(949) 706-5551
Contact Person:	Patsy Trisler Regulatory Consultant trisconsult@icloud.com
Date Prepared:	June 1, 2026

2.0 Device Information

Trade Name:	Collagen Wound Powder
Common Name:	Collagen Wound Dressing
Classification:	Unclassified
Device:	Wound Dressing With Animal-Derived Material(S)
Product Code:	KGN

3.0 Predicate Device

510(k) Number	Manufacturer	Device Name
K171645	Strukmyer Medical	CoMatryx Collagen Wound Dressing 1 gram pouch, CoMatryx Collagen Wound Dressing 1 gram vial, CoMatryx Collagen Wound Dressing 10 gram bottle

4.0 Indications For Use

Collagen Wound Powder is indicated for the management of wounds that include:

- Partial and full thickness wounds
- Pressure (stage I-IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and superficial 2nd degree burns
- Cuts, abrasions and surgical wounds

5.0 Device Description

Collagen Wound Powder is an absorbent, low pH, purified Type I collagen powder indicated for the management of wounds. The resorbable microfibrillar collagen, derived from bovine tendon, absorbs wound fluid and maintains a moist wound environment. Collagen Wound Powder is supplied in either a bellows applicator packaged in a blister pack, or an open-barrel syringe packaged in a Tyvek pouch. The final device is supplied terminally sterile, for single use, and is offered in sizes of Small (.015 oz), Large

(.030 oz) and X-Large (.045 oz). The device can be applied to the wound either as a dry powder or in a hydrated form. Collagen Wound Powder can be used as a primary wound dressing in direct contact with the wound or be used in combination with other suitable secondary dressings. The finished device is lot tested for endotoxin per USP <85>.

6.0 Summary of Testing

Non-clinical testing was performed in accordance with recognized consensus standards as applicable. Physical, chemical and functional characterization testing of the collagen raw material and final product was conducted in accordance with relevant requirements of ASTM F 2212-11. Bench testing conducted on the starting collagen material and finished device include: Weight, volume, surface area, particle size, absorbency, pH, hydroxyproline, moisture, and thermal transition temperature.

Collagen Wound Powder has met all biocompatibility requirements in accordance with ISO 10993-1. Biocompatibility tests were selected as appropriate for a surface device with long-term (>30 days) contact with breached or compromised skin. Tests conducted include: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, Material-Mediated Pyrogenicity, Chemical Characterization, and Toxicological Risk Assessment.

Viral Inactivation steps applied to the collagen raw materials used on Collagen Wound Powder meet relevant requirements of ISO 22442 standards.

Collagen Wound Powder is terminally sterilized via gamma irradiation and validated to SAL 10^{-6} in accordance with ISO 11137-2. Expiration dating has been established.

The wound healing response of the Collagen Wound Powder was evaluated in a porcine full-thickness dermal defect model in comparison to predicate and control groups. The full-thickness defect wound model confirmed the biocompatibility and normal healing response associated with the Collagen Wound Powder, and demonstrated an equivalent *in vivo* performance compared to the predicate device

7.0 Conclusion – Substantial Equivalence

As shown in the Substantial Equivalence Comparison table on the following page:

The similarities between Collagen Wound Powder and the predicate device are:

- They have the same intended use,
- They are both derived from Type I bovine collagen.
- They are both provided in powder form.
- They are both provided at a low pH.
- They absorb wound fluid

The technological differences are:

- Collagen source: tendon (subject device) vs. hide (predicate device)
- Packaging materials (see SE table)
- Device sizes (see SE table)
- Sterilization method: gamma (subject device) vs. E-Beam (predicate)

These technological differences do not raise new questions of safety or effectiveness, as demonstrated by the comparative performance evaluation in the porcine full-thickness wound model and the side-by-side comparisons in the SE table. Therefore, the Collagen Wound Powder is substantially equivalent to the predicate device.

Substantial Equivalence Comparison Table

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE
Device Name	Collagen Wound Powder	CoMatryx Collagen Wound Dressing 1 gram pouch, CoMatryx Collagen Wound Dressing 1 gram vial, CoMatryx Collagen Wound Dressing 10 gram bottle
Manufacturer	Ventris Medical	Strukmyer Medical
510(K)	K260596	K171645
Product Code	KGN	KGN
Indications For Use	Collagen Wound Powder is indicated for the management of wounds that include: • Partial and full thickness wounds • Pressure (stage I-IV) and venous ulcers • Ulcers caused by mixed vascular etiologies • Venous stasis and diabetic ulcers • 1st and superficial 2nd degree burns • Cuts, abrasions and surgical wounds	Collagen Wound Powder is indicated for the management of wounds that include: • Partial and full thickness wounds • Pressure (stage I-IV) and venous ulcers • Ulcers caused by mixed vascular etiologies • Venous stasis and diabetic ulcers • 1st and 2nd degree burns • Cuts, abrasions and surgical wounds
Device Sizes	Small (.015 oz), Large (.030 oz), X-Large (.045 oz)	1 gram pouch, 1 gram vial, 10 gram bottle
Physical Form	Collagen Powder	Collagen Powder
Composition	Purified Bovine Type I Collagen, Tendon Derived	Bovine Type I Collagen, Dermis Derived
pH	2.0 – 3.5	≥ 2.5
Moisture %	≤ 17%	≤ 17%
Packaging	Bellows applicator/ blister pack; Syringe applicator/ Tyvek pouch	1 gram pouch, 1 gram vial, 10 gram bottle
Sterilization	Gamma irradiation	E-Beam
Single Use	Single Patient Use Only	Single Patient Use Only
Principles Of Operation	Absorb wound fluid, maintain a moist environment	Absorb wound fluid, maintain a moist environment