October 10, 2025

Winner Medical Co., Ltd.
Ziling Shangguan
Regulatory Affairs Specialist
Winner Industrial Park, No.660 Bulong Road, Longhua Dist.
42nd Floor Building No 2, Huilong Business Center, Longhua
Shenzhen, Guangdong 518109
China

Re: K252001
Trade/Device Name: Collagen Wound Dressing
Regulatory Class: Not Classified
Product Code: KGN
Dated: June 27, 2025
Received: September 12, 2025

Dear Ziling Shangguan:

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252001

Device Name
Collagen Wound Dressing

Indications for Use *(Describe)*
Prescription Use
Collagen Wound Dressing is indicated for the management of exuding wounds including:
Full thickness and partial thickness wounds
Pressure and venous ulcers
Ulcers caused by mixed vascular etiologies
Diabetic ulcers
Partial thickness burns
Donor sites and other bleeding surface wounds
Abrasions
Traumatic wound healing by secondary intention
Dehisced surgical incisions

Over-The-Counter Use
Intended for the management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor 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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510(K) Summary

This 510(K) Summary information is being submitted in accordance with the requirement of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(K) Number: K252001

Date of Submission: June 27, 2025

1. Submitter Identification

Winner Medical Co., Ltd.

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Address 2: 42F, Building No.2, HBC Huilong Business Center, North Station Community, Minzhi Street, Longhua District, Shenzhen City, Guangdong Province, 518109, China

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2. Identification of Proposed Device

Common or Usual Name: Collagen Wound Dressing

Regulatory Information

Classification Name: Wound Dressing With Animal-Derived Material(S)

Classification: Unclassified

Product Code: KGN

Review Panel: General and Plastic Surgery

3. Identification of Predicate Device

Predicate device: Collagen Wound Dressing

510(K) Number: K231152

Manufacturer: Winner Medical Co., Ltd

Classification Name: Wound Dressing With Animal-Derived Material(S)

Classification: Unclassified

Product Code: KGN

Review Panel: General and Plastic Surgery

4. Device Description

Collagen Wound Dressing is a wound care device composed of pure freeze-dried cross-linked bovine collagen. It is a sterile, absorbent, white, porous, topical wound dressing. As a primary wound dressing that can be cut to any size or be used in multi-layers to fit wound. It can also be used in combination with either occlusive or semi-occlusive secondary dressing. The product is biodegradable. Please reapply the dressing as needed based on the patient's wound healing situation.

5. Intended Use Statement

Prescription:

The Collagen Wound Dressing is indicated for the management of exuding wounds including:

Full thickness and partial thickness wounds

Pressure and venous ulcers

Ulcers caused by mixed vascular etiologies

Diabetic ulcers

Partial thickness burns

Donor sites and other bleeding surface wounds

Abrasions

Traumatic wound healing by secondary intention

Dehisced surgical incisions

OTC

The Collagen Wound Dressing is intended for the management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns.

6. Non-Clinical Data/Information

The following non-clinical data and performance data are provided to demonstrate the safety and effectiveness of the proposed device for its intended use and to support a determination of substantial equivalence.

Biocompatibility

Based on Table A.1 of ISO 10993-1 and Table A.1 of "Use of International Standard ISO 10993-1, Biological evaluation of medical devices-Part 1 Evaluation and testing within a risk management process", the proposed device is categorized as surface device for breached or compromised surface with long-term duration, the relevant biocompatibility endpoints were conducted tests or evaluation as required. The results showed that Collagen Wound Dressing meets biocompatibility requirements of the ISO 10993-1 standard and FDA Guidance. The proposed device raised no new safety concerns for biocompatibility to the predicate device.

Biocompatibility tests included: cytotoxicity, acute systemic toxicity, subcutaneous implantation, irritation, subacute systemic toxicity, pyrogenicity, skin sensitization, and chemical characterization.

Performance Test

A series of bench tests were conducted which included an evaluation of physical, chemical, and biological properties. Results of the testing confirm that the proposed device meets all product performance requirements for the intended use and demonstrates substantial equivalence to the predicate device.

The following performance tests were conducted on proposed devices: Appearance, Weight, Free swell absorption, pH value, Heavy metals, Hydroxyproline assay,

Bacterial Endotoxins, Sterility, Scanning Electron Microscope (SEM), Differential Scanning Calorimetry (DSC), Fourier Transform Infrared Spectroscopy (FTIR).

Sterilization and Shelf Life

The proposed device is provided sterile and will subject to an irradiation sterilization process by gamma ray, in its final package to achieve a Sterility Assurance Level (SAL) of 10^{-6}. The validation study for radiation sterilization dose establishment is carried out according ISO 11137-1/-2:2013, ISO11137-3:2017, ISO11737-1:2018, ISO 11737-2:2019. The results for the sterility testing showed that, the products achieved a SAL of 10^{-6} after the irradiation sterilization process.

3 years real time aging test has been completed according to FDA guidance on shelf life. The subject device has a shelf life of three (3) years, when stored in a cool (below 25 °C) place, and avoid excessive light in accordance with the manufacturer's recommendations. The shelf life is based on an assessment of the seal integrity of the sterile barrier packaging and functional testing of device. The results demonstrated that all performance indicators of the proposed device meet the requirements.

Animal-Derived Materials Safety Information

Based on utilization of animal derivative materials in Collagen Wound Dressing, the relevant requirements of safety are compliant with FDA guidance document-Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices) and ISO 22442 standards. Animal testing, biocompatibility testing, chemical characterization studies and inactivation study of viruses confirmed the safety of proposed device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

The proposed device is compared with the following predicate device in terms of intended use, indications for use, technological characteristics (e.g. design, material, physical structure, technology method, main process, mode of action), sterilization, and animal-derived materials safety. These data of predicate devices came from commercially product labeling and 510(k) summary.

Item	Proposed device	Predicate device
510(k) number	K252001	K231152
Product Code	KGN	KGN
Device Class	Unclassified	Unclassified
Review Panel	General & Plastic Surgery	General & Plastic Surgery
Rx or OTC	Rx and OTC	Rx
Intended use	The Collagen Wound Dressing is indicated for the management of wounds.	The Collagen Wound Dressing is indicated for the management of wounds.
Indications for use	**For prescription use** Full thickness and partial thickness wounds, Pressure ulcers, Venous ulcers, Ulcers caused by mixed vascular etiologies, Diabetic ulcers, Partial thickness burns, Donor sites and other bleeding surface wounds, Abrasions, Traumatic wounds healing by secondary intention, Dehisced surgical incisions. **For Over-the-Counter use** Management of minor cuts, minor scrapes, minor bruises, minor abrasions, minor lacerations, and minor burns	Full thickness and partial thickness wounds, Pressure ulcers, Venous ulcers, Ulcers caused by mixed vascular etiologies, Diabetic ulcers, Partial thickness burns, Donor sites and other bleeding surface wounds, Abrasions, Traumatic wounds healing by secondary intention, Dehisced surgical incisions.
Material	Collagen	Collagen

Animal Source	Bovine	Bovine
Physical structure	Porous microstructure	Porous microstructure
Biodegradable	Yes	Yes
Technology	Reconstructed from purified collagen	Reconstructed from purified collagen
Main processes	Freeze-drying and cross-linking	Freeze-drying and cross-linking
Principle of operation	The Collagen Wound Dressing forms a biodegradable, semitransparent gel sheet, which maintains a physiologically moist microenvironment at the wound surface.	The Collagen Wound Dressing forms a biodegradable, semitransparent gel sheet, which maintains a physiologically moist microenvironment at the wound surface.
Sterilization	Irradiation sterilization	Irradiation sterilization
Packaging	Single barrier	Single barrier
Size	1 x 1 1.5 x 2 2 x 3 2.5 x 2.5 2.5 x 5 2.5 x 7.5 2.5 x 10 2.5 x 20 3 x 3 3 x 4 4 x 5 4 x 6 5 x 5 5 x 5.6 5 x 7.5 5 x 10 5 x 20 6 x 8 7.5 x 7.5 7.5 x 10 7.5 x 15 7.5 x 20 8 x 8 10 x 10	2.5 x 2.5 2.5 x 5 5 x 5 5 x 5.6 2.5 x 7.5 2.5 x 10 5 x 7.5 7.5 x 7.5 5 x 10 7.5 x 10 10 x 10

	10 x 10.8 10 x 11.11 10 x 12.5 10 x15 10 x 18 10 x 20 12.5 x 12.5 12.5 x 15 12.5 x 18 12.5 x 20 15 x 15 15 x 17.5 15 x 18 15 x 20 17.5 x 17.5 18 x 18 18 x 20 20 x 20	
Single use	Yes	Yes
Shelf life	3 years	1 year
Biocompatibility	Comply with ISO 10993	Comply with ISO 10993
Animal experiments	Performed, same in the wound healing rate, no affects the normal healing of the wound.	Complied
Inactivation study of Viruses	Performed, more than 6 logs reduction of viruses	Complied
Chemical Characterization Study and Toxicological Risk Assessment	Performed, the toxicological risk of extractable is acceptable.	Complied

The Collagen Wound Dressing demonstrates substantial equivalence to the predicate devices for their respective intended uses. The proposed device shares the same intended use, similar indications for use and very similar technological characteristics as Predicate Device (K231152), the only differences are the additional size and the indication for OTC use.

All potential new risks raised with the new size have been identified and addressed with verification and validation activities to ensure that substantial equivalence is still established in technological characteristics. These activities include Package Verification, Sterilization Validation, Performance Test, Endotoxin Test, Chemical Characterization and Toxicological Assessment.

The difference in indications from prescription to OTC do not raise different questions of safety or effectiveness. The use of these products for minor wounds is intuitive. Similar products already exist in the OTC market (see K213092).

Critically, both the proposed devices and the predicate device are manufactured from 100% bovine collagen into a single-layer, porous microstructure sheet form. They employ identical core processes (freeze-drying, cross-linking, irradiation sterilization), packaging (single barrier/Tyvek), and are single-use sterile products. Their functional principle is identical: absorbing wound exudate to form a gel that maintains a moist wound environment, thereby supporting natural wound healing. Collectively, this equivalence across materials, structure, manufacturing, sterility assurance, and functional principle firmly confirms substantial equivalence to the predicate devices. The premarket submission of Collagen Wound Dressing is compliant with FDA guidance document-Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices).

9. Substantial Equivalence (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the legally marketed predicate device with regard to intended use, indications for use, technological characteristics, performance tests, animal-derived materials evaluation, and biocompatibility.