June 3, 2026

Roosin Medical Co., Ltd.
% Charles Shen
Vice President
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07435

Re: K254034
Trade/Device Name: Roosin Collagen Powder
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 16, 2025
Received: December 16, 2025

Dear Charles Shen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MUSTAFA A. MAZHER -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)*
K254034

Device Name
Roosin Collagen Powder

Indications for Use *(Describe)*
Roosin Collagen Powder is used in the management of partial and full thickness wounds, 1st and superficial 2nd degree burns, pressure (stage I-IV) ulcers, scrapes, abrasions, venous ulcers, diabetic ulcers, 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

## 1 Submitter & Foreign Manufacture Identification

Roosin Medical Co., Ltd.
8 Yuandong Road, KouAn Town, Gaogang,
Taizhou, Jiangsu Province, China 225321
Tel: (086) 523-86908085

## 2 Contact Person

Dr. Charles (Chengyu) Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

**Date Prepared:** December 15, 2025

## 3 Device Name:

| | |
|---|---|
| **Trade Name:** | Roosin Collagen Powder |
| **Common Name:** | Collagen Dressing |
| **Classification Name**: | Wound Dressing with Animal-Derived Material(s) |
| **Product Code**: | KGN |
| **Regulation Number:** | Unclassified |
| **Review Panel:** | General & Plastic Surgery |

## 4 Predicate Device Information:

(1) CoMatryx Collagen Wound Dressing (K171645)

## 5 Device description:

Roosin Collagen Powder is a sterile, single use wound dressing. It is a hydrophillic dressing composed of fibrous type I bovine collagen. The device is to be provided in freeze-dried collagen powder.

The device has a white or light yellow appearance and is available in the form of powder. The powders are 0.5g or 1.0g in weight and are packaged in pouches. All powders have the exactly the same material, chemical, and physical properties and are different only in packaging size.

## 6 Indications for Use:

Roosin Collagen Powder is used in the management of partial and full thickness wounds, 1st and superficial 2nd degree burns, pressure (stage I-IV), scrapes, abrasions, venous ulcers, diabetic ulcers, and surgical wounds.

## 7 Comparison to Predicate Devices

"Roosin Collagen Powder" described in this premarket notification is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) CoMatryx Collagen Wound Dressing 1 gram pouch, CoMatryx Collagen Wound Dressing 1 gram vial, CoMatryx Collagen Wound Dressing 10 gram bottle (K171645)

The following table shows similarities and differences of use, design, material, and chemical treatment between our device and the predicate devices.

**Table 5.1: Comparison of Intended Use, Design, and Material**

| **Feature/ Characteristic** | **Subject Device** | **Predicate Device (K171645)** | **Comparison** |
|---|---|---|---|
| Intended Use/ Indications | Roosin Collagen Powder is used in the management of partial and full thickness wounds, 1st and superficial 2nd degree burns, pressure (stage I-IV), scrapes, abrasions, venous ulcers, diabetic ulcers, and surgical wounds. | Used in the management of 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. | Same |
| Prescription/ OTC | Prescription | Prescription | Same |
| Package Sizes | 0.5 gram in pouch<br>1 gram in pouch | 1 gram in vial<br>1 gram in pouch<br>10 grams in bottles | Similar |
| Material | Type I collagen | Type I collagen | Same |
| Animal Source | Bovine | Bovine | Same |
| Physical structure | Powder | Powder | Same |
| Sterile | Yes | Yes | Same |
| Sterilization Method | Radiation | E-Beam | Similar |
| Single Use | Yes | Yes | Same |

Roosin Collagen Powder and its predicate devices are made from similar materials, utilize same principles of operation, and have similar indications for use.

## 8 Summary of Non-Clinical Testing

Performance Testing:

Performance tests were conducted to evaluate the physical and chemical properties of the subject device, such as ignition residue, pH, protein and hydroxyproline content, heavy metal, endotoxin, and sterility. The results met all pre-defined specifications.

Biocompatibility Testing:

The following biocompatibility tests have been evaluated per ISO 19993-1: 2018

| Item | Biological End Point | Standard |
|---|---|---|
| 1 | Cytotoxicity | ISO 10993-5 |
| 2 | Sensitization | ISO 10993-10 |
| 3 | Intracutaneous Reactivity | ISO 10993-23 |
| 4 | Systematic Toxicity | ISO 10993-11 |
| 5 | Pyrogen Test | ISO 10993-11 |
| 6 | Genotoxicity | ISO 10993-3 |
| 7 | Implantation | ISO 10993-6 |
| 8 | Carcinogenicity | ISO 10993-3 |

Sterilization and Shelf Life Testing:

- Sterilization was performed using radiation method. The radiation dose was determined per ISO 11137-2.
- Packaging validation per ISO 11607-1/-2
- One year shelf life of the device was determined based on real time aging test.
- Bacterial endotoxin testing per USP <85>

## 9 Conclusion

Roosin Collagen Powder has the same intended use, design, materials, and performance as the predicate device. The differences between the predicate and subject device do not raise any new or different questions of safety or effectiveness. The non-clinical testing demonstrates that the subject device is as safe, as effective and performs as well as the legally marketed device.