June 3, 2026

Roosin Medical Co., Ltd.
℅ Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K253974
Trade/Device Name: Roosin Collagen Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: May 7, 2026
Received: May 7, 2026

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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)*
K253974

Device Name
Roosin Collagen Dressing

Indications for Use *(Describe)*

Roosin Collagen Dressing is intended for the management of burns, sores, blisters, scrapes, ulcers, and other 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.

K253974

510(k) Summary

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

Submitter & Foreign Manufacture Identification

Roosin Medical Co., Ltd.
8 Yuandong Road, KouAn Town, Gaogang,
Taizhou, Jiangsu Province, China 225321
Tel: (086) 523-86908085
Submitter's FDA Registration Number：3007124979

Contact Person

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

Date of Summary: September 15, 2025

Device Name:

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

Predicate Device Information:
(1) K122325: "Skin Temp II Dressing"

Device description:

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

Roosin Collagen Dressing is used as a primary contact layer in dressing for the management of burns, blisters, sores, scrapes, ulcers and other wounds.

All dressings are sterilized and sold directly to users after sterilization by radiation using conditions validated following ISO 11137-2: 2006.

Indications for Use:

Roosin Collagen Dressing is intended for the management of burns, sores, blisters, scrapes, ulcers, and other wounds.

Comparison to Predicate Devices

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

(1) K122325: "Skin Temp II Dressing", manufactured by "Human Biosciences Inc" located in Gaithersburg, Maryland, USA

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

Description	Subject Device	Predicate Device (K122325)	Conclusion
Indication for Use	Roosin Collagen Dressing is intended for the management of bums, sores, blisters, scrapes, ulcers, and other wounds.	The device is intended for the management of bums, sores, blisters, scrapes, ulcers, and other wounds.	Identical
Prescription/OTC	Prescription	Prescription	Identical
Mechanism	Maintain a healthy and hydrated wound bed	Maintain a healthy and hydrated wound bed	Identical
Material	Purified type 1 collagen	Purified type 1 collagen	Identical
Animal Source	Bovine	Bovine	Identical
Form	Sheet	Sheet	Similar
Color	White to off white	White to off white	Identical
Single Use	Yes	Yes	Identical
Sterile	Sterile to 10^6 SAL	Sterile	Identical

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

No-clinical tests were conducted following in house procedures, and results for Roosin Collagen Dressing met all relevant requirements.

The following biocompatibility tests have been evaluated based on the following standards:

Cytotoxicity (ISO 10993-5)
Irritation & Sensitization (ISO 10993-10)
Systematic Toxicity (ISO 10993-11)
Genotoxicity (ISO 10993-3)
Implantation (ISO 10993-6)
Homolysis (ISO 10993-4)
Material-Mediated Pyrogenicity (ISO 10993-11)
Implantation (ISO 10993-6)
Genotoxicity (ISO 10993- 3)
Chemical Charachterization and Toxicological Risk Assesment (ISSO 10993-17 and ISO 10993-18)
Immunotoxicology (ISO 10993-20)

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, and performance, our Roosin Collagen Dressing is substantial equivalent to its predicate devices.