December 16, 2024

Huizhou Foryou Medical Devices Co., Ltd.
Taylor Deng
R&D Manager
North Shangxia Rd. Dongjiang Hi-tech Industry Park
Huizhou, Guangdong 516006
China

Re: K240809
Trade/Device Name: LUOFUCON® Silver Collagen Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 15, 2024
Received: November 15, 2024

Dear Taylor Deng:

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)*
K240809

Device Name
LUOFUCON® Silver Collagen Dressing

Indications for Use *(Describe)*
LUOFUCON® Silver Collagen Dressing is intended for the management of wounds that include:
Full thickness and partial thickness wounds
Pressure ulcers
venous ulcers
Ulcers caused by mixed vascular etiologies
Diabetic ulcers
First and second degree burns
Donor sites and other bleeding surface wounds
Abrasions
Trauma wounds healing by secondary intention
Dehisced wounds
Surgical wounds
Dehisced 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

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: K240809

1. Sponsor

Huizhou Foryou Medical Devices CO., Ltd.
Address: No.1 North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, PEOPLE'S REPUBLIC OF CHINA
Phone: +86-752-5302185
Contact Person: Taylor Deng
Email address: tfdeng@foryoumedical.com
Date Prepared: December 11, 2024

2. Subject Device

The Name of Device: Silver Collagen Dressing
Common or Usual Name: Silver Collagen Dressing
Trade or Proprietary Name：LUOFUCON® Silver Collagen Dressing
Classification Name: Dressing, Wound, Drug
Product Code: FRO
Regulatory Class: Unclassified
Review Panel: General & Plastic Surgery

3. Predicate device

The subject device has been found to be substantially equivalent to the legally marketed predicate device.

Predicate device:

The Name of Device: Puracol® Plus Ag MicroScaffold™ Wound Dressing
Trade name: Puracol Plus Ag Collagen Wound Dressing
510(K) Number: K071552
Submitter: Medline Industries, Inc.
Manufacturer: Medskin Solutions
Classification Name: Dressing, Wound, Drug
Product Code: FRO
Regulatory Class: Unclassified
Review Panel: General & Plastic Surgery

4. Device description

LUOFUCON® Silver Collagen Dressing is comprised of bovine collagen and silver chloride intended for the management of wounds. Silver chloride is present to prevent bacteria colonization within the dressing. An in-vitro antibacterial effectiveness test showed that the dressing is effective against bacteria.

LUOFUCON® Silver Collagen Dressing is a sterile, single use, pliable, absorbent and biodegradable wound dressing. In the present of the wound exudate LUOFUCON® Silver Collagen Dressing transforms into a soft, conformable gel sheet, maintains a physically moist environment, to protect the wound and support natural healing.

LUOFUCON® Silver Collagen Dressing can be used as a primary wound dressing in direct contact with the wound, or be used in combination with other suitable secondary dressings.

5. Indication for Use

LUOFUCON® Silver Collagen Dressing is intended for the management of wounds that include:

- Full thickness and partial thickness wounds
- Pressure ulcers
- Venous ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- First and second degree burns
- Donor sites and other bleeding surface wounds
- Abrasions
- Trauma wounds healing by secondary intention
- Dehisced wounds
- Surgical wounds
- Dehisced surgical wounds

6. Substantially Equivalent (SE)

The following table summarizes the similarities and differences of the subject device, and the predicate device in terms of intended use, indications for use, technological characteristics, sterilization, and animal-derived materials safety.

Table 1 Comparison information

Item	Subject device	Predicate device

510(k) number	K240809	K071552
Product Code	FRO	FRO
Device Class	Unclassified	Unclassified
Prescription	Yes	Yes
Intended use	LUOFUCON® Silver Collagen Dressing is intended for the management of wounds	Puracol Plus Ag Collagen Wound Dressing is indicated for the management of wounds
Indications for use	Full thickness and partial thickness wounds Pressure ulcers Venous ulcers Ulcers caused by mixed vascular etiologies Diabetic ulcers First and second degree burns Donor sites and other bleeding surface wounds Abrasions Trauma wounds healing by secondary intention Dehisced wounds Surgical wounds Dehisced surgical wounds	Full thickness and partial thickness wounds Pressure ulcers Venous ulcers Ulcers caused by mixed vascular etiologies Diabetic ulcers First and second degree burns Donor sites and other bleeding surface wounds Abrasions Trauma wounds healing by secondary intention Dehisced wounds Surgical wounds Dehisced surgical wounds
Material	Collagen, Silver Chloride	Collagen, Silver Chloride
Physical structure	Porous microstructure	Porous microstructure
Mode of action	In the present of the wound exudate or sterile water LUOFUCON® Silver Collagen Dressing transforms into a soft, conformable gel sheet, maintains a physically moist environment, Silver chloride is present to prevent bacteria colonization within the dressing. An in-vitro antibacterial effectiveness test showed that the dressing is effective against bacteria	Puracol Plus Ag Collagen Wound Dressing forms a soft, conformable moist gel sheet at the wound surface, to provide an ideal environment. Silver chloride is present to prevent bacteria colonization within the dressing.
Sterilization	Terminally sterilized by	Terminally sterilized by

	radiation, SAL 10^{-6}	radiation
Single use	Yes	Yes
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1
Animal-Derived Materials Safety	Complied	Complied

LUOFUCON® Silver Collagen Dressing has the same intended use, indications for use, and very similar technological characteristics to the predicate device.

Both devices are designed as single-layer, sheet form, porous microstructure, single-use, sterile product. The subject and predicate devices employ a similar mode of action in that both devices contain an absorbent nature that maintains a moist wound environment. Silver chloride is present to prevent bacteria colonization within the dressing. An in-vitro antibacterial effectiveness test showed that the dressing is effective against bacteria

7. Non-Clinical Data/Information

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

7.1 Sterilization and Shelf-Life

LUOFUCON® Silver Collagen Dressing was sterilized using Gamma radiation to a sterility assurance level of 10^{-6}. In addition to application of the VDmax[25] methodology, the method of radiation sterilization was established and validated per ISO 11137-1/-2.

Per FDA guidance on shelf life, a real-time aging test was conducted to demonstrate the shelf-life of LUOFUCON® Silver Collagen Dressing.

7.2 Biocompatibility

Based on Table A.1 of ISO 10993-1/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 subject 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 LUOFUCON® Sliver Collagen Dressing meets

biocompatibility requirements of the ISO 10993-1 standard and FDA Guidance. The subject device raised no new safety concerns for biocompatibility to the predicate device.

The following biocompatibility tests were conducted:

- Cytotoxicity
- Irritation
- Sensitization
- Material-mediated pyrogenicity
- Systemic Toxicity
- Genotoxicity
- Implantation
- Acute Systemic Toxicity
- Subchronic Systemic Toxicity
- Chronic toxicity
- Carcinogenicity of subject device is acceptable based on toxicological risk assessment

7.3 Performance Test-bench

A series of bench tests were conducted which included an evaluation of physical, chemical, and biological properties. Parts of bench test were used to compare the subject device against to the predicate device. The results of the testing confirm that the subject 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 subject devices:

- Appearance
- Size
- Loss on drying
- Tensile strength
- Free swell absorption
- pH value
- Silver content
- Sterility
- Antibacterial effectiveness

7.4 Animal-Derived Materials Safety

Based on utilization of animal derived materials in LUOFUCON® Silver Collagen Dressing, the requirements of safety is compliant with FDA guidance document-Medical Devices Containing Materials Derived from Animal Sources (Except for

In Vitro Diagnostic Devices) and ISO 22442 standards.

8. Conclusions

Based on the data provided in this 510(K) submission as summarized above, it can be concluded that the subject device is substantially equivalent to the predicate device concerning intended use, indications for use, technological characteristics, performance data as shown in a series of performance tests and biocompatibility studies. The technological differences between the two devices raise no new issues of safety or effectiveness.