Huizhou Foryou Medical Devices Co., Ltd.
Jie Dong
R&D Engineer
North Shangxia Rd, Dongjiang Hi-tech Industrial Park
Huizhou, Guangdong 516005
China

Re: K221110
Trade/Device Name: LUOFUCON Silver Gelling Fiber Surgical Dressing, LUOFUCON Antibacterial Gelling Fiber Cover Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 8, 2023
Received: December 5, 2023

Dear Jie Dong:

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.

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)*
K221110

Device Name
LUOFUCON® Silver Gelling Fiber Surgical Dressing（Prescription use）
LUOFUCON® Antibacterial Gelling Fiber Cover Dressing（OTC use）

Indications for Use *(Describe)*
Prescription use:
Under the supervision of a healthcare professional:
LUOFUCON® Silver Gelling Fiber Surgical Dressing may be used for the management of surgical wounds as an effective barrier to microbial penetration of the dressing.

OTC use:
LUOFUCON® Antibacterial Gelling Fiber Cover Dressing may be used for:
Minor abrasions;
Minor lacerations;
Minor cuts;
Minor scalds and 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.

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510(k) Summary

1. Submitter

Huizhou Foryou Medical Devices Co., Ltd.

Address: North Shangxia Rd, Dongjiang Hi-tech Industrial Park, 516005, Huizhou, PEOPLE'S REPUBLIC OF CHINA.

Phone: +86-0752-5302185

Contact Person: Jie Dong

Date Prepared: December 21th, 2023

2. Subject Device

Trade Name: LUOFUCON® Silver Gelling Fiber Surgical Dressing (Prescription use); LUOFUCON® Antibacterial Gelling Fiber Cover Dressing (OTC use)

Common Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Code: FRO

Review Panel: General & Plastic Surgery

3. Predicate Device

510(k) Number: K210718

Product Name: LUOFUCON® Extra Silver Gelling Fiber Dressing; LUOFUCON® Silver Antibacterial Gelling Fiber Dressing

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

4. Reference Device

510(k) Number: K091034

Product Name: Aquacel™ Ag Surgical

Manufacturer: Convatec Inc.

5. Device Description

LUOFUCON® Silver Gelling Fiber Surgical Dressing is a sterile post-operative dressing, comprising of polyurethane film, super absorbent fiber non-woven pad, silver gelling fiber non-woven pad (wound contact) containing 1.1% (w/w) ionic silver, and silicone gel. A windowed self-adhesive silicone skin contact layer plays a role of minimizing the trauma on removal, and alleviating the leakage of exudate.

The compliance and the softness of the dressing are improved effectively by using the notched non-woven pad, thus it is easier to apply on the wounds/parts which are difficult to paste. The highly absorbent dressing has a strong exudate management. When absorbing the wound fluid, the dressing will form a soft gel to support a moist wound healing environment. The non-woven pad gelling properties allow intact removal without damage to the closure system e.g. sutures.

Based on in vitro performance data, the LUOFUCON® Silver Gelling Fiber Surgical Dressing is waterproofness and breathable. The polyurethane film of dressing provides a microbial barrier to prevent the microbial penetrating through it, and the silver component prevents the growth of the bacteria within the dressing up to 7 days.

6. Indications for Use

Prescription use:

Under the supervision of a healthcare professional:

LUOFUCON® Silver Gelling Fiber Surgical Dressing may be used for the

management of surgical wounds as an effective barrier to microbial penetration of the dressing.

OTC use:

LUOFUCON® Antibacterial Gelling Fiber Cover Dressing may be used for:

Minor abrasions;

Minor lacerations;

Minor cuts;

Minor scalds and burns.

7. Summary of the conventional information

Items	Subject Device	Predicate Device (K210718)	Reference Device (K091034)
Intended Use	Prescription use: Under the supervision of a healthcare professional: LUOFUCON® Silver Gelling Fiber Surgical Dressing may be used for the management of surgical wounds as an effective barrier to microbial penetration of the dressing.	Prescription: Under the supervision of a healthcare professional: LUOFUCON® Extra Silver Gelling Fiber Dressing may be used for the management of moderate to heavily exuding chronic and acute wounds as an effective barrier to bacterial penetration of the dressing, including: Partial thickness burns (second degree); Diabetic foot ulcers; Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology); Pressure ulcers (partial and full	Under the supervision of a healthcare professional: Aquacel™ Ag Surgical cover dressing may be used for the management of: Wounds healing by primary intent (e.g. traumatic and elective post-operative wounds/incisions) and as an effective barrier to bacterial penetration to help reduce infection.

	OTC use: LUOFUCON® Antibacterial Gelling Fiber Cover Dressing may be used for: Minor abrasions; Minor lacerations; Minor cuts; Minor scalds and burns.	thickness); Donor sites; Surgical wounds; Traumatic wounds. OTC: LUOFUCON® Silver Antibacterial Gelling Fiber Dressing may be used for: Minor abrasions; Minor lacerations; Minor cuts; Minor scalds and burns.	
Prescription/ OTC	Prescription/OTC	Prescription/OTC	Prescription
Mechanism	Silver gelling fiber for exudate absorption and wound care, silver ion in the non-woven pad for antibacterial effect; absorbent fiber for exudate absorption; Polyurethane film provided waterproofness and breathable function, as an effective barrier to microbial penetration of the dressing; Silicone gel holds the dressing tightly to the wound.	Silver gelling fiber for exudate absorption and wound care, silver ion in the non-woven pad for antibacterial effect, as an effective barrier to bacterial penetration of the dressing;	Silver gelling fiber for exudate absorption and wound care, silver ion in the non-woven pad for antibacterial effect; Polyurethane film provided waterproofness and breathable function, as an effective barrier to bacterial penetration of the dressing; Hydrocolloid holds the dressing tightly to the wound.
Design/Material	Dressing is comprised of polyurethane film, silicone gel, non-woven pad consist of super absorbent fibers, non-woven pad consist of carboxymethyl cellulose fiber, ionic silver and enhance fiber(High-density	Non-woven dressing, consist of carboxymethyl cellulose fiber, ionic silver and enhance fiber(High-density polyethylene and Polyethylene terephthalate)	Dressing is comprised of polyurethane film, hydrocolloid, non-woven pad composed of carboxymethyl cellulose fibers, ionic silver, enhance fiber

	polyethylene and Polyethylene terephthalate)		
Antibacterial Duration	Seven days	Seven days	Seven days
Antibacterial Activity	Broad spectrum	Broad spectrum	Broad spectrum
Single Use	Yes	Yes	Yes
Sterilization	Ethylene oxide	Radiation	Radiation

The subject device used the predicate device(K210718) as the wound contact layer for exudate absorption and inhibition of bacterial growth within the dressing. The subject device has the similar intended use with the predicate device. The intended use, material, performance are similar to those of the predicate device and do not raise any new issues concerning safety or performance.

The reference device (K091034) is used for understanding the structure of subject device. Both subject device and reference device are comprised of barrier Layer, bonding layer, wound-contacting layer.

8. Summary of Biocompatibility Testing

The subject device raised no new safety concerns for biocompatibility. Based on "*Use of International Standard ISO 10993-1, Biological evaluation of medical devices-Part 1_Evaluation and testing within a risk management process*", the subject is categorized as surface devices for breached or compromised surface with prolonged duration. The subject device was evaluated for:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Systemic toxicity (ISO 10993-11)

- Implantation (ISO 10993-6)
- Material-mediated pyrogenicity (USP <151>)

9. Summary of Performance Testing

The following performance tests were conducted on subject device in comparison to the predicate device:

- Appearance
- Size
- Adhesive property (ASTM D6195-03)
- Fluid handling capacity (EN 13726-1)
- Waterproofness (EN 13726-3)
- Conformability (EN 13726-4)
- Silver content
- Antibacterial effectiveness
- Sterility (USP <71>)

10. Summary of Animal Testing

A porcine partial-thickness skin wound healing study was carried out to evaluate cytotoxicity of the subject device. The study demonstrated that there were no biologically relevant differences between subject device and predicate device (K210718) in terms of wound healing performance characteristics and histopathology after wound creation.

11. Conclusions

Based on the comparison of intended use, design, materials, and performance, the subject device, LUOFUCON® Silver Gelling Fiber Surgical Dressing/ LUOFUCON® Antibacterial Gelling Fiber Cover Dressing, is determined to be

Substantially Equivalent (SE) to the predicate device, LUOFUCON® Extra Silver Gelling Fiber Dressing/ LUOFUCON® Silver Antibacterial Gelling Fiber Dressing (K210718) in respect of safety and performance.