October 7, 2024

Huizhou Foryou Medical Devices Co., Ltd.
Li Jiaqi
R&D Engineer
North Shangxia Rd. Dongjiang Hi-Tech Industry Park
Huizhou, Guangdong 516005
China

Re: K240485
Trade/Device Name: LUOFUCON® Extra Silver Gelling Fiber Dressing Plus (Prescription use),
LUOFUCON® Silver Antimicrobial Gelling Fiber Dressing Plus (OTC use)
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 31, 2024
Received: February 20, 2024

Dear Li Jiaqi:

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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, PhD
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)*
K240485

Device Name
LUOFUCON® Extra Silver Gelling Fiber Dressing Plus
LUOFUCON® Silver Antimicrobial Gelling Fiber Dressing Plus

Indications for Use *(Describe)*
Prescription:
Under the supervision of a healthcare professional:
LUOFUCON® Extra Silver Gelling Fiber Dressing Plus 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 thickness);
Donor sites;
Surgical wounds;
Traumatic wounds.

OTC:
LUOFUCON® Silver Antimicrobial Gelling Fiber Dressing Plus 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.

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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: Jiaqi Li

Date Prepared: Oct 5, 2024

2. Subject Device

Trade Name: LUOFUCON® Extra Silver Gelling Fiber Dressing Plus (Prescription use)；LUOFUCON® Silver Antimicrobial Gelling Fiber Dressing Plus (OTC use)

Common Name: Silver Gelling Fiber Dressing

Classification 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. Device Description

LUOFUCON® Extra Silver Gelling Fiber Dressing Plus is a soft, conformable, sterile dressing composed of carboxymethyl cellulose fibers, high-density polyethylene and polyethylene terephthalate fibers, 1.1% (w/w) ionic silver, and stitched with lyocell fibers. This conformable dressing absorbs wound fluid and creates a soft gel,

provides an ideal moist wound healing environment.

The silver ions help to inhibit microbial growth in the dressing for up to seven days. Additionally, based on in vitro testing, LUOFUCON® Extra Silver Gelling Fiber Dressing Plus also provides a barrier against bacterial penetration.

5. Indications for Use

Prescription:

Under the supervision of a healthcare professional:

LUOFUCON® Extra Silver Gelling Fiber Dressing Plus 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 thickness);

Donor sites;

Surgical wounds;

Traumatic wounds.

OTC:

LUOFUCON® Silver Antimicrobial Gelling Fiber Dressing Plus may be used for:

Minor abrasions;

Minor lacerations;

Minor cuts;

Minor scalds and burns.

6. Summary of Substantial Equivalence

Items	Subject Device	Primary Predicate Device (K210718)
Intended Use	**Prescription:**	**Prescription:**

	Under the supervision of a healthcare professional: LUOFUCON® Extra Silver Gelling Fiber Dressing Plus 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 thickness); - Donor sites; - Surgical wounds; - Traumatic wounds. **OTC:** LUOFUCON® Silver Antimicrobial Gelling Fiber Dressing Plus may be used for: - Minor abrasions; - Minor lacerations; - Minor cuts; - Minor scalds and burns.	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 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 and OTC	Prescription and OTC
Mechanism	The dressing absorbs wound fluid and creates a soft gel, which provides an ideal moist wound healing environment. Based on in vitro testing, the silver in the dressing inhibits microbial growth in the dressing and provides a barrier against bacterial	The dressing absorbs wound fluid and creates a soft gel, which provides an ideal moist wound healing environment. Based on in vitro testing, the silver in the dressing inhibits bacterial growth in the dressing and provides a barrier against bacterial penetration

	penetration through the dressing for up to seven days.	through the dressing for up to seven days.
Device Design	Silver gelling fiber non-woven pad with lines of stitching	Silver gelling fiber non-woven pad
Material Used	Silver gelling fiber non-woven pad is composed of carboxymethyl cellulose fiber, ionic silver and enhance fiber (High-density polyethylene and Polyethylene terephthalate). Lines of stitching are composed of lyocell fibers.	Silver gelling fiber non-woven pad is composed of carboxymethyl cellulose fiber, ionic silver and enhance fiber (High-density polyethylene and Polyethylene terephthalate).
Antimicrobial Duration	Seven days	Seven days
Single Use	Yes	Yes
Sterilization	Radiation	Radiation
Size	Max. 300mm×200mm Min. 50mm×50mm	Max. 300mm×200mm Min. 50mm×50mm
Free Swell Absorption Capacity	≥15g/100cm^2	≥15g/100cm^2
pH Value	5.0-8.0	5.0-8.0
Silver Value	1.1% (w/w)	1.1% (w/w)
Antimicrobial effectiveness within the dressing	4 Log Reduction within the dressing for eight organisms up to 7 days (MRSA/ VRE/ Streptococcus pyogenes/ Escherichia coli/ Pseudomonas aeruginosa/ Klebsiella pneumonia/ Candida albicans/ Aspergillus brasiliensis)	4 Log Reduction within the dressing for six organisms up to 7 days (MRSA/ VRE/ Streptococcus pyogenes/ Escherichia coli/ Pseudomonas aeruginosa/ Klebsiella pneumonia)

The subject device is the same as the predicate device except for the addition of sutures to the material used and the addition of test strains for antimicrobial effectiveness. The performance and biocompatibility testing have shown that these differences do not raise safety and effectiveness concern.

1) Summary of Performance Testing

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

- Free Swell Absorption Capacity (EN 13726-1)
- Fluid Retention Rate
- Shrinkage
- Wet Tensile Strength
- Loss on Drying (USP <731>)
- pH Value (USP <791>)
- Silver Content
- Antimicrobial Effectiveness (AATCC TM100)
- Bacterial Barrier Effectiveness
- Bacterial Endotoxins (USP 85)

2) 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 10993-23)
- Acute systemic toxicity (ISO 10993-11)
- Subchronic systematic toxicity (ISO 10993-11)
- Implantation (ISO 10993-6)
- Pyrogenicity (USP <151>)

3) Summary of Animal Testing

A porcine full thickness dermal wound healing study was carried out to evaluate cytotoxicity and implantation 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 characteristic and histopathology after wound creation.

4) Summary of Antimicrobial Testing

LUOFUCON® Extra Silver Gelling Fiber Dressing Plus has been shown to be effective against a variety of microorganisms, including Gram-positive and Gram-negative bacteria, yeast and mold (tested against VRE (ATCC 51299), MRSA (ATCC 43300), S. Pyogenes (ATCC 19615), P. Aeruginosa (ATCC 9027), E. Coli (ATCC 8739), Klebiella pneumoniae (ATCC 4352), C. albicans (ATCC 10231), and A. brasiliensis (ATCC 16404).

The silver ions help to inhibit microbial growth in the dressing for up to seven days. Additionally, based on in vitro testing, LUOFUCON® Extra Silver Gelling Fiber Dressing Plus also provides a barrier against bacterial penetration.

7. Conclusions

Based on the comparison of intended use, design, materials, and performance, the subject device, LUOFUCON® Extra Silver Gelling Fiber Dressing Plus/ LUOFUCON® Silver Antimicrobial Gelling Fiber Dressing Plus, is determined to be Substantially Equivalent (SE) to the predicate devices, LUOFUCON® Extra Silver Gelling Fiber Dressing / LUOFUCON® Silver Antibacterial Gelling Fiber Dressing (K210718) in respect of safety and effectiveness.