December 21, 2023

Huizhou Foryou Medical Devices Co., Ltd.
Guosheng Tan
R&D Engineer
North Shangxia Road
Dongjiang Hi-Tech Industry Park
Huizhou, Guangdong 516005
China

Re: K223359
Trade/Device Name: LUOFUCON® Ag+ Foam Dressing, LUOFUCON® Ag+ Antibacterial Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 13, 2023
Received: April 13, 2023

Dear Guosheng Tan:

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)*
K223359

Device Name
LUOFUCON® Ag+ Foam Dressing
LUOFUCON® Ag+ Antibacterial Foam Dressing

Indications for Use *(Describe)*
Prescription Use:
LUOFUCON® Ag+ Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds, including leg and foot ulcers, pressure ulcers, diabetic foot ulcers, superficial second-degree burns, donor sites, surgical wounds, lacerations and abrasions.

OTC Use:
LUOFUCON® Ag+ Antibacterial Foam Dressing is indicated for first aid management of minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor 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

This 510(k) Summary information is being submitted in accordance with Title 21, CFR Section 807.92.

I. SUBMITTER:

Huizhou Foryou Medical Devices Co., Ltd.

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

Phone: +86-0752-5302185

Contact Person: Guosheng Tan

Date Prepared: November 3, 2022

II. SUBJECT DEVICE

Trade/Proprietary Names: LUOFUCON® Ag+ Foam Dressing (Prescription use), LUOFUCON® Ag+ Antibacterial Foam Dressing (OTC use)

Common Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Code: FRO

III.PREDICATE DEVICE:

Primary Predicated Device:

510(k) Number: K140954

Product Name: LUOFUCON® Silver PU Antibacterial Foam Dressing

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

Secondary Predicated Device:

510(k) Number: K083133

Product Name: X AFD Dressings

Manufacturer: Andover Healthcare, Inc.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION:

LUOFUCON® Ag+ Foam Dressing/LUOFUCON® Ag+ Antibacterial Foam Dressing is a sterile, single-use wound dressing. The device has a single or multi-layer structure and its foam layer is containing 0.40mg/cm^2 maximum content of ionic silver. According to the different composition of product structure, the device provides three models: Easy, Backing and Adhesive.

(a) The first model, Easy, consist of a single exudate absorption layer (Polyurethane foam containing silver compound).

(b) The second model, Backing, consist of a backing layer (Polyurethane film); an exudate absorption layer (Polyurethane foam containing silver compound).

(c) The third model, Adhesive, consist of a self-adhesive layer (Adhesive tape); an exudate absorption layer (Polyurethane foam containing silver compound); a release liner covers on the adhesive tape.

Depending on its exudate absorption layer, the device can absorb wound exudates and maintain a moist wound healing environment. As wound exudates are absorbed, the silver ions released from the polyurethane foam to assist in inhabiting bacterial growth within the dressing for up to 7days, as demonstrated in vitro. The polyurethane film of dressing is waterproof and breathable which can provide a microbial barrier to prevent the microbial penetrating through it.

V. INDICATIONS FOR USE:

Prescription Use:

LUOFUCON® Ag+ Foam Dressing is indicated for exudate absorption and the

management of partial to full thickness wounds, including leg and foot ulcers, pressure ulcers, diabetic foot ulcers, superficial second- degree burns, donor sites, surgical wounds, lacerations and abrasions.

OTC Use:

LUOFUCON® Ag+ Antibacterial Foam Dressing is indicated for first aid management of minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

LUOFUCON® Ag+ Foam Dressing/LUOFUCON® Ag+ Antibacterial Foam Dressing is Compared with the Predicate Devices in terms of technological characteristics. The following table shows their similarities and differences.

Item	Subject Device	Primary Predicate Device (K140954)	Secondary Predicate Device (K083133)
Regulatory Class	Unclassified	Unclassified	Unclassified
Product Code	FRO	FRO	FRO
Intended Use	**Prescription:** LUOFUCON® Ag+ Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds, including leg and foot ulcers, pressure ulcers, diabetic foot ulcers, superficial second- degree burns, donor sites, surgical wounds, lacerations and abrasions. **OTC:** LUOFUCON® Ag+ Antibacterial Foam Dressing is indicated for first aid management of minor abrasions, minor cuts, minor	**Prescription:** LUOFUCON® Silver PU Antibacterial Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wound, including leg ulcers, pressure ulcers, diabetic foot ulcers, 2nd degree burns, donor sites, post-operative wound and skin abrasions.	**Prescription:** CoFlex-X AFD® and the CoFlex-X AFD® Pad contact wound dressings are indicated for use in light to heavy exuding partial and full thickness wounds, including decubitus and diabetic ulcers, 1st and 2nd degree bums, and donor sites. These dressings may also be used over debrided and partial thickness wounds. **OTC:** PowerFlex NL-X AFD® and CoFlex-X AFD® First Aid contact wound dressings are indicated for first aid

Item	Subject Device	Primary Predicate Device (K140954)	Secondary Predicate Device (K083133)
	lacerations, minor scrapes, minor scalds and minor burns.		management of minor abrasions, cuts, scrapes, scalds and bums.
Prescription /OTC	Prescription/OTC	Prescription	Prescription/OTC
Mechanism	Polyurethane foam for exudate absorption and wound care, silver ion in the foam for antibacterial effect; polyurethane film is waterproof and breathable which can provide a microbial barrier. Adhesive tape for self-adhesive and holding the dressing tightly to the wound.	Polyurethane foam for exudate absorption and wound care, silver ion in the foam for antibacterial effect.	Polyurethane foam for exudate absorption and wound care, metallic silver in the foam for antibacterial effect; Polyurethane film provided Waterproof and breathable function; Bandage holds the dressing tightly to the wound.
Design /Material	Polyurethane foam containing silver chloride, Polyurethane film, non-woven adhesive tape	Polyurethane foam containing silver chloride, Polyurethane film, non-woven adhesive tape	Polyurethane foam containing metallic silver with x-static fiber, Polyurethane film, cohesive elastic bandage
Antibacterial Duration	7 days	7 days	N/A
Antibacterial Activity	Broad spectrum	Broad spectrum	N/A
Single Use	Yes	Yes	Yes
Sterilization	EtO SAL:10^{-6}	Radiation SAL:10^{-6}	EtO

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench performance testing

- Appearance
- Size
- Water absorbency: conducted with BS EN 13726-1

- pH Value: conducted with USP <791> pH.
- Silver content
- MVTR: conducted with BS EN 13726-2
- Waterproofness: conducted with BS EN 13726-3
- Microbial barrier
- EO and ECH residuals: conducted with ISO 10993-7
- Antibacterial effectiveness: conducted with Modified AATCC TM100.
- Sterility: conducted with ISO 11737-2

Biocompatibility testing

The subject device raised no new safety concerns for biocompatibility. Based on Table A.1 of ISO 10993-1 and 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 is categorized as surface devices for breached or compromised surface with prolonged duration. The device has been demonstrated to safe for its intended use. The series of testing included the following tests:

- Cytotoxicity - ISO 10993-5:2009
- Intracutaneous Reactivity - ISO 10993-10:2010
- Sensitization - ISO 10993-10:2010
- Acute Systemic toxicity - ISO 10993-11:2017
- Material-mediated pyrogenicity - USP <151>
- Sub chronic toxicity - ISO 10993-11:2017
- Implantation - ISO 10993-6:2016

Animal Study

A Porcine Wound Healing Study was conducted to evaluate the effect of the subject device on the wound healing process. Under the conditions of the study,

LUOFUCON® Ag+ Foam Dressing/LUOFUCON® Ag+ Antibacterial Foam Dressing did not affect normal wound healing.

Clinical Study

No clinical studies were conducted for the subject device.

VIII. CONCLUSIONS

Based on the comparison of intended use and technological characteristics with the predicate devices, the subject device, LUOFUCON® Ag+ Foam Dressing/LUOFUCON® Ag+ Antibacterial Foam Dressing, is determined to be Substantially Equivalent (SE) to the predicate devices, LUOFUCON® Silver PU Antibacterial Foam Dressing (K140954) and X AFD Dressings (K083133), with respect of safety and performance.