March 27, 2024

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

Re: K223360
Trade/Device Name: LUOFUCON® Silicone Ag+ Foam Dressing, LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 28, 2024
Received: February 28, 2024

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,

Mustafa A. Mazher -S

for 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)*
K223360

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

Indications for Use *(Describe)*
Prescription Use:
LUOFUCON® Silicone 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, 1st and 2nd degree burns, donor sites, traumatic and surgical wounds, lacerations and abrasions.

OTC Use:
LUOFUCON® Silicone 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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K223360

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® Silicone Ag+ Foam Dressing (Prescription use)/ LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing (OTC use)
Common Name:	Silicone Silver Foam Dressing
Classification Name:	Dressing, Wound, Drug
Regulatory Class:	Unclassified
Product Code:	FRO

III.PREDICATE DEVICE:

Primary Predicated Device:

510(k) Number:	K170077
Product Name:	LUOFUCON® Silicone Ag Foam Dressing With Border
Manufacturer:	Huizhou Foryou Medical Devices Co., Ltd.

Secondary Predicated Device:

510(k) Number: K083133

Product Name: Andover Healthcare, Inc. X AFD Dressings

Manufacturer: Andover Healthcare, Inc.

IV. DEVICE DESCRIPTION:

LUOFUCON® Silicone Ag+ Foam Dressing/LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing is a sterile, single-use dressing. The device has a multi-layer structure, and its foam layer contains 0.40mg/cm^2 maximum content of ionic silver. According to the different compositions of product structure, the device provides four models: Bordered, Bordered Lite, Non-Bordered, and Transfer.

(a). The first model, Bordered, consists of a Polyurethane (hereinafter referred to as PU) Film layer, a Super Absorbent Fibre Pad layer, a Non-woven layer, a Silver PU Foam layer, a Perforated Silicone layer, and a Polyethylene (hereinafter referred to as PE) Release Film covered on the Perforated Silicone.

(b). The second model, Bordered Lite, consists of a PU Film layer, a Non-woven layer, a Silver PU Foam layer, a Perforated Silicone layer, and a PE Release Film covered on the Perforated Silicone.

(c). The third model, Non-Bordered, consists of a PU Film layer, a Silver PU Foam layer, a Perforated Silicone layer, and a PE Release Film covered on the Perforated Silicone.

(d). The fourth model, Transfer, consists of a Silver PU Foam layer, a Perforated Silicone layer, and a PE Release Film covered on the Perforated Silicone.

The Non-Bordered model can be freely cut as needed. The Transfer model also can be freely cut and allow using together with a secondary absorbent dressing.

Silver in the dressing is intended to provide antibacterial effectiveness within the dressing for up to 7 days, as demonstrated via in vitro testing. The Bordered, Bordered Lite, and Non-Bordered model dressings are equipped with a PU film that offers waterproofing. The self-adhesive Perforated Silicone wound contact layer plays a role in minimizing the trauma on removal.

V. INDICATIONS FOR USE:

Prescription Use:

LUOFUCON® Silicone 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, 1st and 2nd degree burns, donor sites, traumatic and surgical wounds, lacerations and abrasions.

OTC Use:

LUOFUCON® Silicone Ag+ Antibacterial Foam Wound 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 DEVICE

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

Item	Subject Device	Primary Predicate Device (K170077)	Secondary Predicate Device (K083133)
Regulatory Class	Unclassified	Unclassified	Unclassified
Product Code	FRO	FRO	FRO
Intended Use	**Prescription:** LUOFUCON® Silicone 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, 1st and 2nd degree burns, donor sites, traumatic and surgical wounds, lacerations and abrasions. **OTC:** LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing is indicated for first aid management of minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns.	**Prescription:** LUOFUCON® Silicone Ag Foam Dressing with Border is indicated for the management of exuding wounds, such as leg and foot ulcers, pressure ulcers, traumatic and surgical wounds, superficial and partial thickness burns.	**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 management of minor abrasions, cuts, scrapes, scalds and bums.
Prescription /OTC	Prescription/OTC	Prescription	Prescription/OTC
Mechanism	Polyurethane foam and absorbent fiber pad for absorbing exudates; Silver compounds	Polyurethane foam and absorbent fiber pad for absorbing liquid; Silver compounds	Polyurethane foam for exudate absorption and wound care, metallic silver in the foam for antibacterial

Item	Subject Device	Primary Predicate Device (K170077)	Secondary Predicate Device (K083133)
	present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; polyurethane film offers waterproofing.	present in the foam for reducing bacteria colonization in the dressing; Silicone soft contact layer for self-adhesive; Backing film for waterproof.	effect; Polyurethane film provided Waterproof.
Design /Material	Polyurethane film, polyurethane foam containing silver, absorbent fiber, non- woven fabrics, Silicone, Release film	Polyurethane film, polyurethane foam containing silver, absorbent fiber, non- woven fabrics, Silicone, Release film	Polyurethane foam containing metallic silver with nylon fibre, Polyurethane film, cohesive elastic bandage
Antibacterial Duration	7 days	7 days	N/A
Single Use	Yes	Yes	Yes
Sterilization	EtO SAL:10^{-6}	EtO SAL:10^{-6}	EtO

VII. PERFORMANCE DATA

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

Performance testing

Performance testing was conducted to verify that the subject device met all design specifications was Substantially Equivalent (SE) to the predicate device. The performance of the subject device was tested according to the following standards.

- Adhesive property: conducted with ASTM D6195-03
- Water absorbency: conducted with BS EN 13726-1
- pH Value: conducted with USP <791> pH.
- MVTR: conducted with BS EN 13726-2
- Waterproofness: conducted with BS EN 13726-3
- EO and ECH residuals: conducted with ISO 10993-7
- Antibacterial effectiveness: in vitro simulated use testing.
- Sterility: conducted with ISO 11737-2:2019

Biocompatibility testing

Based on FDA Guidance Document "Use of International Standard ISO 10993-1, Biological evaluation of medical devices-Part 1_Evaluation and testing within a risk

management process", and series of ISO 10993 standards, the subject is categorized as surface devices for breached or compromised surface with prolonged duration. The relevant standards for biocompatibility testing of subject device are listed below.

- Cytotoxicity - ISO 10993-5:2009
- Implantation - ISO 10993-6:2016
- Intracutaneous Reactivity - ISO 10993-10:2010
- Sensitization - ISO 10993-10:2010
- Systemic toxicity - ISO 10993-11:2017
- Material-mediated pyrogenicity - USP 41-N36<151>

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® Silicone Ag+ Foam Dressing/LUOFUCON® Silicone 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® Silicone Ag+ Foam Dressing/LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing, is determined to be Substantially Equivalent (SE) to the predicate devices, LUOFUCON® Silicone Ag Foam Dressing With Border(K170077) and X AFD Dressings (K083133), in respect of safety and effectiveness.