November 11, 2024

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

Re: K242856
Trade/Device Name: LUOFUCON® Silicone Ag+ Foam Dressing (Prescription use)/ LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing (OTC use) (Bordered, Bordered Lite, Non-Bordered, and Transfer)
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 15, 2024
Received: October 15, 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.

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)*
K242856

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 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.

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 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 Predicate Device：

510(k) Number:	K223360
Product Name:	LUOFUCON® Silicone Ag+ Foam Dressing/LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing
Manufacturer:	Huizhou Foryou Medical Devices Co., Ltd.

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 Device in terms of technological characteristics. The following table shows their similarities and differences.

Item	Subject Device	Primary Predicate Device (K223360)	Similarities and Differences
Regulatory Class	Unclassified	Unclassified	Same
Product Code	FRO	FRO	Same
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 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.	Same
Prescription /OTC	Prescription/OTC	Prescription	Same
Mechanism	Polyurethane foam and absorbent fiber pad for absorbing exudates; Silver compounds present in the foam for reducing bacteria colonization in the	Polyurethane foam and absorbent fiber pad for absorbing exudates; Silver compounds present in the foam for reducing bacteria colonization in the	Same

Item	Subject Device	Primary Predicate Device (K223360)	Similarities and Differences
	dressing; Silicone soft contact layer for self-adhesive; polyurethane film offers waterproofing.	dressing; Silicone soft contact layer for self-adhesive; polyurethane film offers waterproofing.	
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	Same
Size	Max: 50cm×20cm	Max: 25cm×20cm×	Different: The subject device has an additional maximum size in comparison to Non-Bordered and Transfer model of the predicate device.
Antibacterial Duration	7 days	7 days	Same
Single Use	Yes	Yes	Same
Sterilization	EtO SAL:10^{-6}	EtO SAL:10^{-6}	Same

The subject device has the same technological characteristics (i.e., design, material, chemical composition, structure, process, etc.) as the predicate device. However, the only modification made was the addition of a new size to the Non-Bordered and Transfer model of the predicate device. As the material properties of the subject device and predicate device remain the same and the performance specifications are also identical, the difference in size does not affect the effectiveness of the product.
Accordingly, the modification is considered not to affect the Substantial Equivalence between the subject device and predicate device.

VII. PERFORMANCE DATA

The following performance tests were conducted 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

No additional biocompatibility tests were conducted for this submission. All biocompatibility data were leveraged from the predicate device was submitted as part of the original 510(k) submission of the predicate, LUOFUCON® Silicone Ag+ Foam Dressing/LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing (K223360) and include:

- 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>

Clinical Study

No clinical studies were conducted for the subject device.

VIII. CONCLUSIONS

Based on the information provided within this 510(k) submission, the subject device, LUOFUCON® Silicone Ag+ Foam Dressing/LUOFUCON® Silicone Ag+ Antibacterial Foam Dressing is substantially equivalent to the predicate device listed and is as safe, as effective and performs as well as the legally marketed predicate device.