April 22, 2022

Huizhou Foryou Medical Devices CO., Ltd.
Huiqi Huang
R&D Engineer
North Shangxia Rd., Dongjiang Hi-tech Industry Park
Huizhou, Guangdong 516005
China

Re: K211123
Trade/Device Name: LUOFUCON Silver Wound Gel, LUOFUCON Silver Antimicrobial Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 24, 2022
Received: February 2, 2022

Dear Huiqi Huang:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211123

Device Name
LUOFUCON® Silver Wound Gel (Prescription use)
LUOFUCON® Silver Antimicrobial Wound Gel (OTC use)

Indications for Use *(Describe)*

Prescription:
LUOFUCON® Silver Wound Gel is under the medical supervision of a healthcare professional for the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.

OTC:
LUOFUCON® Silver Antimicrobial Wound Gel is indicated for the topical management of minor abrasions, minor cuts, minor lacerations 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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FORYOU MEDICAL

510(k) Summary

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

1. SUBMITTER:

Huizhou Foryou Medical Devices Co., Ltd.

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Phone: +86-0752-5302185

Fax: +86-0752-5302020

Contact Person: Huiqi Huang

Date Prepared: April 12th, 2021

2. SUBJECT DEVICE

Device Name: LUOFUCON® Silver Wound Gel (Prescription use),
LUOFUCON® Silver Antimicrobial Wound Gel (OTC use)

Common Name or Usual Name: Silver Wound Gel

Classification Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Code: FRO

3. PREDICATE DEVICE:

510(k) Number: K083103

Product Name: AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B,
OTC: AcryDerm Wound Gel Model #B

Manufacturer: AcryMed, Inc.

4. REFERENCE DEVICE:

510(k) Number: K140483

Product Name: ASAP OTC Wound Dressing Gel

Manufacturer: ABL Medical, LLC

5. DEVICE DESCRIPTION:

LUOFUCON® Silver Wound Gel /LUOFUCON® Silver Antimicrobial Wound Gel is a sterile, water-based amorphous gel composed of hydrophilic polymer and silver compound. The gel helps to maintain a moist wound environment. The silver compound acts as a preservative to inhibit the growth of microorganisms in the gel during shelf storage.

LUOFUCON® Silver Wound Gel /LUOFUCON® Silver Antimicrobial Wound Gel is supplied in a tube (collapsible, polypropylene tube, sealed on one end and fitted with a screw cap on the other end).

6. INDICATIONS FOR USE:

Prescription:

LUOFUCON® Silver Wound Gel is under the medical supervision of a healthcare professional for the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears,

surgical incision sites, device insertion site wounds, graft sites, and donor sites.

OTC:

LUOFUCON® Silver Antimicrobial Wound Gel is indicated for the topical management of minor abrasions, minor cuts, minor lacerations and minor burns.

7. COMPARISON WITH THE PREDICATE DEVICE

LUOFUCON® Silver Wound Gel /LUOFUCON® Silver Antimicrobial Wound Gel and the predicate device/reference device consist of different ingredients. However, they have the same intended use, similar designs and performance, and meet the biocompatibility requirements.

The table below compares the subject device to the predicate and reference devices.

Item	Subject Device (K211123)	Predicate Device (K083103)	Reference Device (K140483)
Device name	LUOFUCON® Silver Wound Gel / LUOFUCON® Silver Antimicrobial Wound Gel	AcryDerm Antimicrobial Silver Gel Model #B / OTC: AcryDerm Wound Gel Model #B	ASAP OTC Wound Dressing Gel
Classification Regulation	Unclassified	Unclassified	Unclassified
Product Code	FRO	FRO	FRO
Indications for Use (Rx)	LUOFUCON® Silver Wound Gel is under the medical supervision of a healthcare professional for the management of	Under the supervision of a healthcare professional, AcryDerm Silver Antimicrobial Wound Gel Model #B is indicated for the	N/A

	1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.	management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites, and donor sites.	
Indications for Use (OTC)	LUOFUCON® Silver Antimicrobial Wound Gel is indicated for the topical management of minor abrasions, minor cuts, minor lacerations and minor burns.	AcryDerm Wound Gel Model #B is indicated for the management of minor abrasions, cuts, lacerations and scalds.	ASAP OTC Wound Dressing Gel is indicated for the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.
Composition	Purified water, Carbopol, glycerol, polyethylene oxide, polyvinyl alcohol, silver compound	Hydrophilic polymers and silver salt	Carbopol ETD 2020, triethanolamine, proprietary silver hydrosol suspension
Mechanism	Hydrophilic polymer for maintaining high moisture content, ionic silver for reducing microorganism colonization within the dressing during shelf storage.	Hydrophilic polymer for maintaining high moisture content, ionic silver for reducing microorganism colonization within the dressing during shelf storage.	Hydrophilic polymer for maintaining high moisture content, silver for reducing microorganism colonization within the dressing during shelf storage.
Antimicrobial agent	Silver compound	Silver compound	Element silver

Appearance	Colorless to light yellow, transparent to slightly cloudy	Slightly cloudy	Clear to golden yellow translucent gel
pH Value	5.0-7.5	N/A	6.5-8.0
Silver Content	0.007%-0.012% w/w	N/A	24ppm
Moisture Donation	≥10%	N/A	Greater than 5%
Moisture Absorption	<10%	N/A	Greater than 5%
Preservative Performance	USP <51> preservative effectiveness testing	USP <25> preservative assurance testing	USP <51>
Sterilized	Sterile	N/A	Not provided sterile

8. SUBSTANTIAL EQUIVALENCE DISCUSSION

LUOFUCON® Silver Wound Gel /LUOFUCON® Silver Antimicrobial Wound Gel has been subjected to ISO 10993 biocompatibility studies to demonstrate the device is as safe as its predicate device. The performance tests were conducted to demonstrate that the subject device is as effective as its predicate device.

Performance Testing

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

Appearance

Fluid Affinity: *EN 13726-1 Test methods for primary wound dressings - Part 1: Aspects of absorbency*

Loss on Drying: *USP <731> Loss on Drying*

pH Value: *USP <791> pH*

Preservative Effectiveness: *USP <51> Antimicrobial Effectiveness Testing*

Biocompatibility Testing

Based on Table A.1 of ISO 10993-1 and Table A.1 of FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1_Evaluation and testing within a risk management process", the subject device is categorized as a surface device in contact with breached or compromised surface with prolonged duration. The subject device was evaluated for:

Cytotoxicity

Sensitization

Irritation

Systemic toxicity

Implantation

Material-mediated pyrogenicity

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® Silver Wound Gel /LUOFUCON® Silver Antimicrobial Wound Gel did not inhibit normal wound healing and did not trigger adverse biological reactions.

Clinical Studies

No clinical study was conducted.

9. CONCLUSIONS

Based on the comparison analysis, performance tests, biocompatibility tests and animal study provided in this submission, the subject device, LUOFUCON® Silver Wound Gel /LUOFUCON® Silver Antimicrobial Wound Gel is demonstrated to be as safe and effective as the legally marketed predicate device, AcryDerm Antimicrobial Silver Gel Wound Dressing Model #B /OTC: AcryDerm Wound Gel Model #B (K083103). So, the subject device is considered Substantially Equivalent (SE) to the predicate device.