April 21, 2022

Huizhou Foryou Medical Devices Co., Ltd.
Junfeng Zhang
Development Engineer
North Shangxia Rd, Dongjiang Hi-tech Industrial Park
Huizhou, Guangdong 516005
China

Re: K210718
Trade/Device Name: LUOFUCON Extra Silver Gelling Fiber Dressing, LUOFUCON Silver Antibacterial Gelling Fiber Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Junfeng Zhang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter sent on March 23, 2022. Specifically, FDA is updating this SE Letter for an updated IFU form and no date on the SE Letter.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-472-6328, Julie.Morabito@fda.hhs.gov

Sincerely,

Julie A. Morabito -S

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

Huizhou Foryou Medical Devices Co., Ltd.
Junfeng Zhang
Development Engineer
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Huizhou, Guangdong 516005
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Re: K210718
Trade/Device Name: LUOFUCON Extra Silver Gelling Fiber Dressing, LUOFUCON Silver Antibacterial Gelling Fiber Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 13, 2021
Received: December 17, 2021

Dear Junfeng Zhang:

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,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
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and Infection Control Devices
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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)*
K210718

Device Name
LUOFUCON® Extra Silver Gelling Fiber Dressing (Prescription use)
LUOFUCON® Silver Antibacterial Gelling Fiber Dressing (OTC use)

Indications for Use *(Describe)*
Prescription:
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.

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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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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: Junfeng Zhang

Date Prepared: March 22, 2022

2. Subject Device

Trade Name: LUOFUCON® Extra Silver Gelling Fiber Dressing (Prescription use)
LUOFUCON® Silver Antibacterial Gelling Fiber Dressing (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: K121275

Product Name: Aquacel™ Ag Extra™ with Hydrofiber™ Dressing with Silver and Strengthening Fiber

Manufacturer: Convatec Inc.

510(k) Number: K183645

Product Name: Silver High Performance Dressing

Manufacturer: Advanced Medical Solutions Ltd.

4. Device Description

LUOFUCON® Extra Silver Gelling Fiber Dressing is a soft, conformable, non-woven pad or ribbon dressing composed of carboxymethyl cellulose fibers, high-density polyethylene and Polyethylene terephthalate fibers and 1.1% (w/w) ionic silver. Based on in vitro testing, the silver in the dressing inhibits bacterial growth in the dressing and provides a barrier against bacterial penetration through the dressing for up to seven days. This conformable and highly absorbent dressing absorbs wound fluid and creates a soft gel, provides an ideal moist wound healing environment.

These antibacterial claims are based on in vitro testing, no clinical studies have been conducted to support these claims.

5. Indications for Use

Prescription:

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.

6. Summary of Substantial Equivalence

Items	Subject Device	Primary Predicate Device (K121275)	Secondary Predicate Device (K183645)
Intended Use	Prescription: 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;	Prescription: Under the supervision of a healthcare professional: Aquacel™ Ag Extra™ with Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for the management of wounds as an effective barrier to bacterial penetration of the dressing as this may help reduce infection; partial thickness (second degree) burns; diabetic foot ulcers, leg ulcers, (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology) and pressure ulcers/sores (partial & full thickness); surgical wounds left to heal by secondary intention such as dehisced surgical incisions; surgical wounds that heal by primary intent such as dermatological and surgical incisions (e.g. orthopedic and vascular); traumatic wounds; wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided and	Under the supervision of a healthcare professional, Silver High Performance Dressing can be used in the management of moderate to heavily exuding chronic and acute wounds. The dressing is indicated for use on the following wounds: Pressure ulcers (partial and full thickness); Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology); Diabetic foot ulcers; Surgical wounds that heal by primary intent such as dermatological and surgical incisions; Surgical wounds left to heal by secondary intention such as dehisced surgical incisions and donor sites; Traumatic wounds.

	Minor lacerations; Minor cuts; Minor scalds and burns.	donor sites; oncology wounds with exudate, such as fungoides-cutaneous tumors, fungating carcinoma, cutaneous metastasis, Kaposi's sarcoma, and angiosarcoma; painful wounds and infected wounds. OTC: Aquacel™ Ag Extra™ with Hydrofiber™ Dressing with Silver and Strengthening Fiber may be used for abrasions, lacerations, minor cuts, minor scalds and burns.	
Prescription/ OTC	Prescription and OTC	Prescription and OTC	Prescription
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 bacterial growth in the dressing and provides a barrier against bacterial penetration through the dressing for up to seven days.	The dressing absorbs wound fluid and creates a soft gel, which provides an ideal moist wound healing environment. The silver in the dressing kills wound bacteria held in the dressing and provides a barrier against bacterial penetration of the dressing.	The highly absorbent dressing absorbs exudate from the wound to form a soft gel that intimately conforms to the wound bed and aids in maintaining a moist wound environment. Silver High Performance Dressing contains ionic silver, and effectively manages and suppresses colonization and proliferation of bacteria and yeast within the dressing for up to 7 days.
Design/ Material	Non-woven dressing, consist of carboxymethyl cellulose fiber, ionic silver and enhance fiber(High-density polyethylene and Polyethylene terephthalate)	Non-woven dressing, consist of carboxymethyl cellulose fiber, ionic silver and enhance fiber(regenerated cellulose)	Non-woven dressing, consist of carboxymethyl cellulose fiber, alginate fiber, ionic silver and reinforcement layer (nylon fiber)
Antimicrobial Duration	Seven days	Seven days	Seven days
Antimicrobial Activity	Broad spectrum	Broad spectrum	Broad spectrum
Single Use	Yes	Yes	Yes
Sterilization	Radiation	Radiation	Radiation
Size	Max. 300mm×200mm Min. 50mm×50mm	Max. 300mm×200mm Min. 50mm×50mm	Ranging in area from 28cm^2 to 650cm^2.

Free Swell Absorption Capacity	≥15g/100cm^2	NA	NA
pH Value	5.0-8.0	NA	NA
Silver Content	1.1%（w/w）	1.2%（w/w）	NA
Antibacterial Effectiveness	4 Log Reduction for six organisms up to 7 days (MRSA/VRE/Streptococcus pyogenes/Escherichia coli/ Pseudomonas aeruginosa/Klebsiella pneumonia)	4 Log Reduction for six organisms up to 7 days (MRSA/VRE/Streptococcus pyogenes/Escherichia coli/ Pseudomonas aeruginosa /Klebsiella pneumonia)	4 Log Reduction for nine organisms up to 7 days (MRSE/VRE/Streptococcus mutans/ Staphylococcus aureus/Enterobacter cloacae/ Klebsiella pneumonia/ Serratia marcescens/ Escherichia coli/Candida albicans)

The subject device and its predicate device (K121275) both utilize ionic silver as the antibacterial ingredient and utilize carboxymethyl cellulose fiber for the exudate absorption and wound management. The subject device has the similar intended use with the predicate device.

The secondary predicate device (K183645) is used for supporting the subject device's indications for use (Prescription use), and both subject device and secondary predicate device (K183645) use carboxymethyl cellulose fiber, ionic silver and enhance fiber for the antibacterial dressing.

Both subject device and predicate devices are sterilized by radiation.

The intended use, material, performance are similar to those of the predicate devices and do not raise any new issues concerning safety or effectiveness.

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
- Antibacterial Effectiveness (AATCC TM100)
- Bacterial Barrier Effectiveness

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 10993-10)
- Systemic toxicity (ISO 10993-11)
- Implantation (ISO 10993-6)
- Material-mediated pyrogenicity (USP <151>)

3) Summary of Animal Testing

A porcine full thickness dermal wound healing study was carried out to evaluate cytotoxicity of the subject device. The study demonstrated that there were no biologically relevant differences between subject device and predicate device (K121275) in terms of wound healing performance characteristics and

histopathology after wound creation.

7. Conclusions

Based on the comparison of intended use, design, materials, and performance, the subject device, LUOFUCON® Extra Silver Gelling Fiber Dressing/ LUOFUCON® Silver Antibacterial Gelling Fiber Dressing, is determined to be Substantially Equivalent (SE) to the predicate devices, Aquacel™ Ag Extra™ with Hydrofiber™ Dressing with Silver and Strengthening Fiber (K121275) and Silver High Performance Dressing (K183645) in respect of safety and effectiveness.