May 1, 2018

Huizhou Foryou Medical Devices Co., Ltd.
Huida Huang
Development Engineer
North Shangxia Rd., Dongjiang Hi-tech Industry Park
Huizhou, 516005 Cn

Re: K172554
Trade/Device Name: Luofucon Extra Silver Alginate Dressing (Rx Only), Luofucon Antibacterial Alginate Wound Dressing (OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 29, 2018
Received: March 29, 2018

Dear Huida 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172554

Device Name
Luofucon Extra Silver Alginate Dressing (Rx Only)
Luofucon Antibacterial Alginate Wound Dressing (OTC)

Indications for Use *(Describe)*
Prescription:
Luofucon Extra Silver Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including: postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites.

OTC:
Luofucon Antibacterial Alginate Wound Dressing is first aid to help in minor abrasions, minor cuts, lacerations, scrapes, 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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Section 5 510(k) Summary or 510(k) Statement

This 510(k) Summary information is being submitted in accordance with the requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K172554

1. Date of Submission:

April 25, 2018

2. Submitter Identification:

Huizhou Foryou Medical Devices Co., Ltd.
North Shangxia Rd., Dongjiang Hi-tech Industry Park, 516005, Huizhou, P. R. China.
Establishment Registration Number: 3007735241
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3. Subject Device Identification:

Device Name: LUOFUCON® Extra Silver Alginate Dressing (Prescription use)
LUOFUCON® Antibacterial Alginate Wound Dressing (OTC use)
Common Name: Silver Alginate Dressing
Classification Name: Dressing, Wound, Drug;
Product Code: FRO;
Regulation Number: Unclassified;
Review Panel: General & Plastic Surgery;

4. Predicate Device Identification:

510(k) Number: K120181
Product Name: LUOFUCON® Silver Alginate Dressing (Prescription Use)/ LUOFUCON® Antibacterial Alginate Dressing (OTC Use)
Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

5. Device Description:

LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) is a sterile, single-use dressing composed of calcium alginate and silver antibacterial agent, which absorbs wound exudate and release silver

ions in the presence of wound fluid in the dressing. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The alginate material contains silver which inhibits bacterial growth within the dressing. Based on in vitro laboratory testing, the silver has been shown to protect the dressing against both Gram positive and Gram negative bacteria, such as Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, Methicillin-resistant Staphylococcus aureus (MRSA), and Vancomycin-resistant Enterococcus (VRE). And the silver protects the dressing from a broad spectrum of bacteria up to seven days.

All dressings are sterilized and sold after sterilization by radiation using conditions validated following ISO 11137-2:2013.

6. Intended Use Statement:

Prescription:

LUOFUCON® Extra Silver Alginate Dressing (Rx only) is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites.

OTC:

LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

7. Comparison to the Predicate Device

LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) is compared with the following Predicate Device in terms of intended use, design, material, specifications, and performance.

- K120181, LUOFUCON® Silver Alginate Dressing (Prescription Use)/ LUOFUCON® Antibacterial Alginate Dressing (OTC Use), Manufactured by Huizhou Foryou Medical Devices Co., Ltd.

The following table shows similarities and differences of use, design, material, and processing methods between subject device and its predicate device.

Table 5-1 Comparison of Intended Use, Design and Material

Item	Subject Device (K172554)	Predicate Device (K120181)
Intended Use	Prescription: LUOFUCON® Extra Silver Alginate Dressing (Rx only) is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites. OTC: LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.	Prescription: LUOFUCON® Silver Alginate Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including, postoperative wounds, trauma wounds, leg ulcers, pressure ulcers, diabetic ulcers, graft and donor sites. OTC: LUOFUCON® Antibacterial Alginate Dressing is first aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.
Mechanism	Alginate for absorbing liquid, silver present in the alginate for reducing bacteria colonization in the dressing.	Alginate for absorbing liquid, silver present in the alginate for reducing bacteria colonization in the dressing.
Material	Alginate and silver	Alginate and silver
Antibacterial Duration	Seven days	One day
Single Use	Yes	Yes
Sterilization	Radiation	Radiation

LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) and its predicate device (K120181) utilize silver as the antibacterial agent and utilize alginate pad for the exudates absorption and wound management. So, LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) and its predicate device are made from similar materials, utilize the same antibacterial mechanism, and have the same intended use.

All dressings are sterilized and sold after sterilization by radiation using conditions validated following ISO 11137-2:2013.

The following performance tests were conducted on LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) in comparison to the predicate:

- Free Swell Absorption Capacity

- Loss on Drying
- pH Value
- Silver content
- Antibacterial Activity

LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) raised no new safety concerns for biocompatibility. Assessment was carried out on the final device as per ISO 10993-1:2009 for a surface device; contacting breached or compromised skin for prolonged duration. The device has been demonstrated to safe for its intended use.

LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) was evaluated for:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Implantation
- Material-mediated pyrogenicity

Modified AATCC 100-2012 was used to evaluate the antibacterial activity of the subject device. The predicate device also chooses the AATCC 100 as the test method. The subject device achieves antibacterial duration for seven days while the predicate device achieves one day.

A porcine wound healing study was carried out to evaluate the silver cytotoxicity of subject device. The test results had shown that the silver does not cause cytotoxicity in the healing period or delay normal wound healing.

Therefore, the performance results are comparable to the predicate device when the dressings are used for antibacterial purpose for seven days. The product is safe and effective for its intended use.

Substantial Equivalent Statement

Based on the comparison of intended use, design, materials, performance, biocompatibility, and animal study, the subject device, LUOFUCON® Extra Silver Alginate Dressing (Rx only)/LUOFUCON® Antibacterial Alginate Wound Dressing (OTC), is determined to be Substantially Equivalent (SE) to the predicate device, LUOFUCON® Silver Alginate Dressing (Prescription Use)/ LUOFUCON® Antibacterial Alginate Dressing (OTC Use) (K120181), in respect of safety and effectiveness.