DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 30, 2017

Huizhou Foryou Medical Devices Co., Ltd.
Guosheng Tan
Development Engineer
North Shangxia Rd.
Dongjiang Hi-tech Industry Park
Huizhou, Guangdong 516005 China

Re: K170077
Trade/Device Name: LUOFUCON Silicone Ag Foam Dressing with Border
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 6, 2017
Received: January 9, 2017

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 (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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
LUOFUCON® Silicone Ag Foam Dressing with Border

Indications for Use *(Describe)*
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.
Silver compounds present in the dressing helps reduce bacterial colonization in the dressing.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

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:

1. **Date of Submission:** 1/6/2017

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

Contact Person: Guosheng Tan

Position: Development Engineer

Tel: +86-0752-5302012

Fax: +86-0752-5302020

Email: gstan@foryougroup.com

3. **Subject Device Identification:**

Device Name:LUOFUCON® Silicone Ag Foam Dressing with Border

Common Name: Silver Foam Dressing

Classification Name: Silicone, Dressing, Wound, Drug;

Product Code: FRO;

Regulation Number: Unclassified;

Review Panel: General & Plastic Surgery;

4. Predicate Device Identification:

First: 510(k) Number: K100029

Product Name: Mepilex Border Ag Dressing

Manufacturer: Mölnlycke Health Care

Second: 510(k) Number: K160022

Product Name: LUOFUCON® Silicone Ag Foam Dressing

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

5. Device Description:

LUOFUCON® Silicone Ag Foam Dressing with Border has a multilayer structure, it consists of a soft silicone wound contact layer, an absorbent polyurethane foam pad containing about 0.25~0.35mg/cm^2 silver ions, a supper absorbent fibre pad, a vapor permeable waterproof film, and release PE films.

LUOFUCON® Silicone Ag Foam Dressing with Border can absorb exudates, maintains a moist wound healing environment and has good antibacterial properties. It has been shown that antibacterial effectiveness within the dressing for up to 7 days, as demonstrated in vitro.

All dressings are sterilized and sold after sterilization by EO using conditions validated following ISO 11135: 2014.

6. Intended Use Statement:

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.

Silver compounds present in the dressing helps reduce bacterial colonization in the dressing.

7. Comparison to the Predicate Device

LUOFUCON® Silicone Ag Foam Dressing with Border is compared with the following Predicate Device in terms of intended use, design, material, specifications, and performance.

- K100029, Mepilex Border Ag Foam Dressing, Manufactured by Mölnlycke Health Care.
- K160022, LUOFUCON® Silicone Ag Foam Dressing, 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 two predicate devices. These data came from commercially product labeling and 510(k) summary.

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

Item	Subject Device	Predicate Device 1 (K100029)	Predicate Device2 (K160022)
Intended Use	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	Mepilex Border Ag dressing 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.	LUOFUCON® Silicone Ag foam dressing 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.

	thickness burns. Silver compounds present in the dressing helps reduce bacterial colonization in the dressing.	Mepilex Border Ag can also be used under compression bandaging. Silver sulfate present in the dressing helps reduce microbial colonization on the dressing.	Silver compounds present in the dressing helps reduce bacterial colonization in the dressing.
Mechanism	Polyurethane foam and super absorbent fibre pad for absorbing liquid, Silver compounds present in the foam for reducing bacteria colonization in the dressing, Silicone soft contact layer for self-adhesive, baking film for waterproof.	Polyurethane foam and super absorbent fibre pad for absorb liquid, Silver compounds present in the foam for reducing bacteria colonization in the dressing, Silicone soft contact layer for self-adhesive, baking film for waterproof.	Polyurethane foam for absorbing liquid, Silver compounds present in the foam for reducing bacteria colonization within the dressing. Silicone soft contact layer for self-adhesive, baking film for waterproof.
Material	Silicone , polyurethane foam containing silver, super absorbent fibre, non- woven fabrics, polyurethane film	Silicone , polyurethane foam containing silver and activated carbon, polyacrylate fibre, non-woven fabrics, polyurethane film	Polyurethane foam containing silver, Silicone and polyurethane film; with border version additional has non-woven fabrics
Antibacterial Duration	Seven days	Seven days	Seven days
Single Use	Yes	Yes	Yes
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

LUOFUCON® Silicone Ag Foam Dressing with Border and its predicate devices (K100029, K160022) utilize silver compound as the antibacterial agent, and utilize polyurethane foam and super absorbent fibre pad for the exudates absorption

and wound management. LUOFUCON® Silicone Ag Foam Dressing with Border is modified from the border version of LUOFUCON® Silicone Ag Foam Dressing (K160022) which had no supper absorbent fibre. These differences do not impact the safety and efficacy of our subject devices, because their functions have no change.

Therefore, LUOFUCON® Silicone Ag Foam Dressing with Border and its predicate devices are made from similar materials, utilize same antibacterial mechanism, and have similar intended use.

Table 5-2 Comparison of Biocompatibility and Performance Testing

Item	Subject Device	Predicate Device 1 (K100029)	Predicate Device2 (K160022)
Cytotoxicity	No Toxic Effect (ISO10993-5)	Non-cytotoxic	No Toxic Effect (ISO10993-5)
Skin Irritation and Sensitization	No Effect (ISO 10993-10)	Non-irritating Non-sensitizing	No Effect (ISO 10993-10)
Systematic Toxicity	No Effect (ISO 10993-11)	/	No Effect (ISO 10993-11)
Antibacterial Activity	>4 log reduction for seven days for all six bacteria	Inactivate representative bacteria up to 7 days	>4 log reduction for seven days for all six bacteria
Antibacterial Duration	Seven days	Seven days	Seven days

LUOFUCON® Silicone Ag Foam Dressing with Border meets biocompatibility requirements per ISO 10993-5, ISO10993-10, and ISO 10993-11. Its physical performance meets the requirements of its pre-defined acceptance criteria and intended use. All dressings are sterilized and sold after sterilization by EO using conditions validated following ISO 11135: 2014.

Modified ASTM E2149-13a was used to evaluate the antibacterial preservative activity of the subject device. Predicate Device 1 also chooses the ASTM E2149 as the test method. Both the subject device and predicate devices can get antibacterial duration of seven days.

Therefore, the performance results are comparable to the predicate devices when the dressings are used for antibacterial preservative 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, and performance, the subject device, LUOFUCON® Silicone Ag Foam Dressing with Border, is determined to be Substantially Equivalent (SE) to the predicate devices, Mepilex Border Ag Foam Dressing (K100029) and LUOFUCON® Silicone Ag Foam Dressing(K160022), in respect of safety and effectiveness.