



Food and Drug Administration
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August 17, 2016

Huizhou Foryou Medical Devices Co., Ltd.
Guosheng Tan
Development Engineer
North Shangxia Road
Dongjiang Hi-Tech Industry Park
Huizhou, 516005
P.R. China

Re: K160022

Trade/Device Name: Luofucon Silicone Ag Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 13, 2016
Received: July 18, 2016

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" (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.

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

Indications for Use (Describe)

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. 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.

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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: K160022

1. Date of Submission: 12/20/2015

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[®] Silicone Ag Foam Dressing

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: K140954

Product Name: LUOFUCON[®] Silver PU Antibacterial Foam Dressing

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

5. Device Description:

LUOFUCON[®] Silicone Ag foam dressing has a multilayer structure, it consists of a soft silicone wound contact layer, an absorbent polyurethane foam pad containing about 0.25~0.35mg/cm² silver ions, a vapor permeable waterproof film.

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

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

LUOFUCON[®] Silicone Ag foam dressing in this submission consists of two variants:

The first variant, Non-Border Silicone Ag Foam dressing consists of a top layer (Vapor permeable waterproof polyurethane film); a center layer (Absorbent polyurethane antibacterial foam pad containing silver compounds adhered to the top film); a wound contact layer (Perforated silicone gel adhered to the center layer); a release liner covers on the silicone gel.

The second variant, Silicone Ag Foam dressing With Border consists of a top layer (Vapor permeable waterproof polyurethane film); a center layer (A thin non woven and absorbent polyurethane antibacterial foam pad containing silver compounds adhered to the top film, and the top film remained border part); a wound contact layer (Perforated silicone gel adhered to the center layer and top

film); a release liner (covered on the silicone gel).

The dressing has white or light brown appearance and is available in the form of pad and in different sizes of pouch package. All dressings use the same material of backing film, foam pad, silicone gel and release film. With Border version additionally adds a thin non woven as foam auxiliary layer, but it wouldn't impact the product properties.

6. Intended Use Statement:

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.

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

7. Comparison to the Predicate Device

LUOFUCON[®] Silicone Ag Foam Dressing 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.
- K140954, LUOFUCON[®] Silver PU Antibacterial 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 (K160022)	Predicate Device 1 (K100029)	Predicate Device2 (K140954)
Intended Use	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. Silver compounds present in the dressing helps reduce bacterial colonization in the dressing.	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. Mepilex Border Ag can also be used under compression bandaging. Silver sulfate present in the dressing helps reduce microbial colonization on the dressing.	LUOFUCON [®] Silver PU Antibacterial Foam Dressing is indicated for exudates absorption and the management of partial to full thickness wounds, including leg ulcers, pressure ulcers, diabetic foot ulcers, second-degree burns, donor sites, postoperative wounds and skin abrasions.
Mechanism	Polyurethane foam for absorb liquid, Silver compounds present in the foam for reducing bacteria within the dressing. Silicone soft contact layer for self-adhesive, baking film for waterproof.	Polyurethane foam and non woven for absorb liquid, Silver compounds present in the foam for reducing bacteria in the dressing, Silicone soft contact layer for self-adhesive, baking film for waterproof.	Polyurethane foam for absorb liquid, Silver compounds present in the foam for reducing bacteria within the dressing.
Material	Polyurethane foam containing silver, Silicone and polyurethane film; with border version additional has non-woven fabrics	Silicone , polyurethane foam containing silver and activated carbon, polyacrylate fibre, non-woven fabrics, polyurethane film	Polyurethane foam containing silver
Antibacterial preservative Duration	Seven days	Seven days	Seven days
Single Use	Yes	Yes	Yes
Sterilization	Ethylene Oxide	Ethylene Oxide	Irradiation

LUOFUCON[®] Silicone Ag Foam Dressing and its predicate devices (K100029、K140945) utilize silver compound as the antibacterial preservative agent, and utilize polyurethane foam for the exudates absorption and wound management. One difference between subject device and predicate device 1(k100029) is that the predicate device has added a super polyacrylate absorbent fibers used to enhance the product fluid absorption performance. LUOFUCON[®] Silicone Ag Foam Dressing is modified from LUOFUCON[®] Silver PU Antibacterial Foam Dressing (K140945) which had no silicone wound contact layer and sterilized with Irradiation. 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 and its predicate devices are made from similar materials, utilize same antibacterial preservative mechanism, and have similar intended use.

Table 5-2 Comparison of Biocompatibility and Performance Testing

Item	Subject Device (K160022)	Predicate Device 1 (K100029)	Predicate Device2 (K140954)
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 Preservative 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 Preservative Duration	Seven days	Seven days	Seven days

LUOFUCON[®] Silicone Ag Foam Dressing meets biocompatibility requirements per ISO 10993-5, ISO10993-10, and ISO 10993-11. It's physical and 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 AATCC 100-2004 was used to evaluate the antibacterial preservative activity of the subject device. Predicate Device 1 chooses the ASTM E2149-01 as the test method. Both the subject device and predicate devices can get antibacterial preservative 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, is determined to be Substantially Equivalent (SE) to the predicate devices, Mepilex Border Ag Foam Dressing (K100029) and LUOFUCON[®] Silver PU Antibacterial Foam Dressing (K140954), in respect of safety and effectiveness.