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 23, 2015

Huizhou Foryou Medical Devices Company, Ltd.
% Ms. Diana Hong
Mid-Link Consulting Company, Ltd.
P.O. Box 120-119
200120 Shanghai
China

Re: K140954
Trade/Device Name: LUOFUCON® Silver PU Antibacterial Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 9, 2015
Received: March 13, 2015

Dear Ms. Hong:

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,

Jennifer R. Stevenson -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)*
K140954

Device Name
LUOFUCON® Silver PU Antibacterial Foam Dressing

Indications for Use *(Describe)*
LUOFUCON® Silver PU Antibacterial Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds, including leg ulcers, pressure ulcers, diabetic foot ulcers, second-degree burns, donor sites, post-operative wounds and skin abrasions.

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."

510(k) Summary

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

The assigned 510(k) Number: K140954

1. Date of Submission: 03/18/2015

2. Sponsor 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: Wei Lu
Position: Development Engineer
Tel: 86 752 5302013
Fax: 86 752 5302020
Email: wlu@foryougroup.com

3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: LUOFUCON® Silver PU Antibacterial Foam Dressing
Proposed Device Common Name: Silver Containing Wound Dressing

Regulatory Information:
Classification Name: Dressing, Wound, Drug;
Classification: Unclassified;
Product Code: FRO;
Review Panel: General & Plastic Surgery;

Intended Use Statement:
LUOFUCON® Silver PU Antibacterial Foam Dressing is indicated for exudate absorption and the management of partial to full thickness wounds, including leg ulcers, pressure ulcers, diabetic foot ulcers, second-degree burns, donor sites, post-operative wounds and skin abrasions.

5. Predicate Device Identification

510(k) Number: K100218
Product Name: Biatain Ag Foam Dressings
Manufacturer: Coloplast A/S

6. Device Description

The proposed device, LUOFUCON® Silver PU Antibacterial Foam Dressing, is a sterilized, single-use dressing composed of soft, elastic PU foam and antibacterial coating including PVA and ionic silver particles, indicated for exudate absorption and the management of partial to full thickness wounds. The proposed device includes multiple sizes, which are listed in the following Table 1.

Table 1 Device Sizes List

Product Code	Size	Product Code	Size
SD050050AENG101	50×50x3mm	SD050050BENG101	50×50x5mm
SD100100AENG101	100×100x3mm	SD100100BENG101	100×100x5mm
SD120100AENG101	120×100 x3mm	SD120100BENG101	120×100 x5mm
SD120120AENG101	120×120 x3mm	SD120120BENG101	120×120 x5mm
SD150150AENG101	150×150 x3mm	SD150150BENG101	150×150 x5mm
SD200150AENG101	200×150 x3mm	SD200150BENG101	200×150 x5mm

The silver is only present as a preservative within the dressing. And the content of ionic silver of

proposed device is 10.4~12.0 mg/100cm^2 for 3mm thickness, 17.3~20.1 mg/100cm^2 for 5mm thickness.

The antibacterial preservative efficacy of proposed device is tested by gram-positive bacteria and gram-negative bacteria, including Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus faecalis, Klebsiella pneumonia, and Streptococcus pyogenes. The results showed that bacterial reduction of proposed device is greater than 4log for 7 days.

They are provided sterilized with Sterility Assurance Level (SAL) of 10^{-6}.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
ISO 10993-11:2006/(R)2010, Biological Evaluation Of Medical Devices -- Part 11: Tests For Systemic Toxicity.
ISO11137-2: 2012, Sterilization of healthcare products-Radiation-Part2: Establishing the sterilization dose.
ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.
ASTM F1140-07 (Reapproved 2012), Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.
USP 36-NF 31: 2013 <85>Bacterial Endotoxins Test.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 2 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device
Product Code	FRO	FRO
Class	Unclassified	Unclassified
Review Panel	General & Plastic Surgery	General & Plastic Surgery
Intended Use	LUOFUCON® Silver PU Antibacterial Foam Dressing is indicated for exudate absorption and the management of partial	**Biatain Ag Foam Adhesive & Non-Adhesive Dressings** are

	to full thickness wounds, including leg ulcers, pressure ulcers, diabetic foot ulcers, second-degree burns, donor sites, post-operative wounds and skin abrasions.	indicated for use in the management of moderately to highly exuding leg ulcers and pressure sores. The dressing can also be used for 2nd degree burns, donor sites, post operative wounds and skin abrasions. **Biatain Ag Foam Non-Adhesive Dressings** are additionally indicated for diabetic foot ulcers.
Configuration	Foam dressing and antibacterial coating	Foam dressing and antibacterial coating
Single Use	Yes	Yes
Antibacterial	Silver ion	Silver ion
Antibacterial Time	7 days	7 days
Main Material	Polyurethane foam, Polyvinyl Alcohol, Silver sulfate, silver chloride	Polyurethane foam and silver compounds
Biocompatibility	Comply with ISO 10993-5, ISO 10993-10, and ISO 10993-11.	Comply with ISO 10993-5, ISO 10993-10, and ISO 10993-11.
Sterilization	Method: Radiation SAL: 10^{-6}	Method: Radiation SAL: 10^{-6}

Intended Use

Both of proposed device and predicate device are silver containing wound dressing, with function of wound management including leg ulcers, pressure ulcers, diabetic foot ulcers, second-degree burns, donor sites, post-operative wounds and skin abrasions. The difference of intended use is only expression difference. Therefore, the difference is considered not to affect the safety and effectiveness.

Material

The material of proposed device and predicate device are different. But both of them comply with ISO 10993-5, ISO 10993-10, and ISO 10993-11. Therefore, this difference is considered not to affect the Substantially Equivalency (SE) between the proposed and predicate device.

Conclusion

The proposed device, LUOFUCON® Silver PU Antibacterial Foam Dressing, is determined to be Substantially Equivalent (SE) to the predicate device, Biatain Ag Foam Dressings (K100218), in respect of safety and effectiveness.