January 28, 2021

Huizhou Foryou Medical Devices Co., Ltd.
Guosheng Tan
Development Engineer
No. 1 Shangxia North Road, Dongjiang Hi-tech Industry Park
Huizhou, Guangdong 516005
China

Re: K201016
Trade/Device Name: LUOFUCON® PHMB Alginate Dressing (Prescription use),
LUOFUCON® PHMB Antibacterial Alginate Wound Dressing (OTC use)
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 15, 2020
Received: April 17, 2020

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. 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,

For Kimberly Ferlin, PhD
Assistant Director (Acting)
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

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)*
K201016

Device Name
LUOFUCON® PHMB Alginate Dressing (Prescription use)
LUOFUCON® PHMB Antibacterial Alginate Wound Dressing(OTC use)

Indications for Use *(Describe)*
Prescription:
LUOFUCON® PHMB 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® PHMB Antibacterial Alginate Wound Dressing is indicated for first aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor 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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510(k) Summary

This 510(k) Summary information is being submitted in accordance with Title 21, CFR Section 807.92.

1. SUBMITTER:

Huizhou Foryou Medical Devices Co., Ltd.

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Phone: +86-0752-5302185

Fax: +86-0752-5302020

Contact Person: Guosheng Tan

Date Prepared: April 15, 2020

2. SUBJECT DEVICE

Name of Device: LUOFUCON® PHMB Alginate Dressing (Prescription use), LUOFUCON® PHMB Antibacterial Alginate Wound Dressing (OTC use)

Common or Usual Name: PHMB Alginate Dressing

Classification Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Code: FRO

3. PREDICATE DEVICES:

510(k) Number: K082296

Product Name: COPA AMD antimicrobial wound dressing

Manufacturer: Kendall, a Division of Tyko Healthcare Group LP

510(k) Number: K172554

Product Name: LUOFUCON® Extra Silver Alginate Dressing (Prescription use)/ LUOFUCON® Antibacterial Alginate Wound Dressing (OTC Use)

Manufacturer: Huizhou Foryou Medical Devices Co., Ltd.

4. DEVICE DESCRIPTION:

LUOFUCON® PHMB Alginate Dressing /LUOFUCON® PHMB Antibacterial Alginate Wound Dressing is a sterile, single-use dressing consisting of calcium alginate fiber impregnated with polyhexamethylene biguanide, and the maximum polyhexamethylene biguanide content is 0.8% w/w. LUOFUCON® PHMB Alginate Dressing/LUOFUCON® PHMB Antibacterial Alginate Wound Dressing can absorb wound exudate. As wound exudate is absorbed, the alginate forms a gel, which provide a moist wound healing environment, and allows intact removal.

Based on in vitro performance data, LUOFUCON® PHMB Alginate Dressing/LUOFUCON® PHMB Antibacterial Alginate Wound Dressing has broad spectrum antibacterial effects, and the polyhexamethylene biguanide prevents colonization and proliferation of bacteria within the dressing for up to seven days.

5. INDICATIONS FOR USE:

Prescription:

LUOFUCON® PHMB 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® PHMB Antibacterial Alginate Wound Dressing is indicated for first aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns.

6. COMPARISON WITH THE PREDICATE DEVICE:

LUOFUCON® PHMB Alginate Dressing/ LUOFUCON® PHMB Antibacterial Alginate Wound Dressing is Compared with the Predicate Devices in terms of intended use, design, material, specifications, and performance. The following table shows their similarities and differences.

Item	Subject Device (K201016)	Primary Predicate Device (K082296)	Secondary Predicate Device (K172554)
Product Code	FRO	FRO	FRO
Class	Unclassified	Unclassified	Unclassified
Indications for use	Prescription: LUOFUCON® PHMB 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® PHMB Antibacterial Alginate Wound Dressing is indicated for first aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns.	Prescription: COPA AMD Dressing are indicated for use in the management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, first and second-degree burns, dermatologic disorders, other wounds inflicted by trauma, and as a secondary dressing or cover dressing for packed wounds.	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.

Mechanism	Alginate for absorbing liquid, PHMB in the alginate for reducing bacteria colonization in the dressing.	Polyurethane foam for absorbing liquid, PHMB present in the Polyurethane foam 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 99.2% w/w, PHMB 0.80% w/w	Polyurethane foam 99.5% w/w, PHMB 0.50% w/w	Alginate 99.2%, Silver 0.80% w/w
Antibacterial agent	PHMB	PHMB	Silver
Dressing Use-life	Up to Seven days	Up to Seven days	Up to Seven days
Shelf-life	Two years	/	Two years
Package information	Aluminum foil or paper aluminum plastic pouch, box and Carton	Paper-plastic bag, box and Carton	Aluminum foil pouch, box and Carton
Single Use	Yes	Yes	Yes
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Size	Prescription: Max. 200mm×200mm OTC: Max. 200mm×200mm	Prescription: Max.20.3cm×20.3cm	Prescription: Max. 200mm×200mm OTC: Max. 200mm×100mm
Weight per unit area	120 g/m^2 - 240 g/m^2	N/A	120 g/m^2 - 240 g/m^2
Free swell absorption capacity	≥12g/100cm^2	N/A	≥12g/100cm^2
pH value	4.0-5.0	N/A	4.0-7.0
PHMB content	0.40-0.80% w/w	0.50% w/w	N/A
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 six organisms up to 7 days (MRSA/VRE/ Streptococcus pyogenes/Escherichia coli/ Pseudomonas aeruginosa/ Klebsiella pneumonia)

7. SUBSTANTIAL EQUIVALENCE DISCUSSION:

LUOFUCON® PHMB Alginate Dressing/LUOFUCON® PHMB Antibacterial Alginate Wound Dressing and its predicate devices (K082296, K172554) have the similar

function design and are made of the similar materials. The alginate or polyurethane foam is designed for exudate absorption and wound care, and the PHMB presented in the dressing as an antimicrobial agent is used for antibacterial effectiveness. The biocompatibility of subject device is evaluated according to ISO 10993-1, and the antibacterial effectiveness of both subject device and predicate devices can achieve 4 Log Reduction. Therefore, device materials in the subject device and predicated device do not raise any different question of safety and effectiveness. The predicate device (K172554) is also used for supporting the subject device's performance and indications for use (Prescription use and OTC use), because both subject device and predicate device (K172554) use alginate as the substrate for the antibacterial dressing, both of which have similar performance, such as size, weight per unit area, free swell absorption capacity, pH value.

Performance Testing

The following performance tests were conducted on subject devices in comparison to the predicate devices:

- Appearance
- Size
- Weight per unit area
- Free Swell Absorption Capacity: conducted in accordance with *BS EN 13726-1 Test methods for primary wound dressings-Part 1: Aspects of absorbency.*
- Loss on Drying: conducted in accordance with *USP <731> Lost on Drying*
- pH Value: complied with *USP <791> Ph.*
- PHMB content
- Sterility: conducted in accordance with *ISO 11737-2 Sterilization of medical devices- Microbiological Methods-Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.*
- Antibacterial effectiveness: conducted in accordance with Modified AATCC TM100.

Biocompatibility Testing

Based on Table A.1 of ISO 10993-1 and Table A.1 of *"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 device for breached or compromised surface with prolonged duration. The device has been demonstrated to safe for its intended use. The subject device was evaluated for:

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

Pre-Clinical Studies

A porcine wound healing study was carried out to evaluate the safety for the subject device, and the study results showed that the local tissue response to subject device is addressed for implantation biocompatibility endpoint.

8. SUBSTANTIAL EQUIVALENCE CONCLUSION:

Based on the comparison of intended use, design, materials, performance and biocompatibility testing, the subject device, LUOFUCON® PHMB Alginate Dressing/LUOFUCON® PHMB Antibacterial Alginate Wound Dressing, is determined to be Substantially Equivalent (SE) to the predicate devices, COPA AMD antimicrobial wound dressing (K082296) and LUOFUCON® Extra Silver Alginate Dressing (Prescription use)/ LUOFUCON® Antibacterial Alginate Wound Dressing (OTC Use)(K172554), in respect of safety and effectiveness.