October 19, 2021

Winner Medical Co., Ltd.
Haoyuan He
Regulatory Affairs Specialist
Winner Industrial Park, No. 660 Bulong Road,
Longhua District
Shenzhen, Guangdong 518109
China

Re: K202982
Trade/Device Name: Silver Alginate Dressing (Prescription use), Antibacterial Alginate Would Dressing (OTC use)
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 14, 2020
Received: December 21, 2020

Dear Haoyuan He:

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,

Lixin Liu, PhD
Acting Assistant Director
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)*
K202982

Device Name
Silver Alginate Dressing (Prescription use), Antibacterial Alginate Wound Dressing (OTC use)

Indications for Use *(Describe)*
Prescription:
Silver Alginate Dressing (Prescription use) 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:
Antibacterial Alginate Wound Dressing (OTC use) is 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.

***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 is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K202982

1. **Date of Submission**: September 25, 2020

2. **Submitter Identification**

**Winner Medical Co., Ltd.**

Winner Industrial Park, No. 660 Bulong Road, Longhua District, Shenzhen City, Guangdong Province, 518109, China
Establishment Registration Number: 9616433

Contact Person: Haoyuan He

Position: Regulatory Affairs Specialist
Tel: +86-755 28138888
Fax: +86-755 28134588
Email: hyhe@winnermedical.com

3. **Identification of Proposed Device**

Trade/Proprietary Name: Silver Alginate Dressing (Prescription use)
Antibacterial Alginate Wound Dressing (OTC use)
Common name: Silver Alginate Wound Dressing

Regulatory Information

Classification Name: Dressing, Wound, Drug;

Classification: Unclassified;

Product Code: FRO;

Review Panel: General & Plastic Surgery;

4. **Identification of Predicate Device**

Predicate Device:

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.

**5. Device Description**

It is a sterile, single-use dressing composed of calcium alginate and silver antibacterial agent. The dressing absorbs wound exudate and release silver ions within the dressing in the presence of wound fluid to help reduce bacteria within 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 bacteria 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, Bacillus subtilis, Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant Enterococcus (VRE), Serratia marcescens, Pseudomonas aeruginosa, Escherichia coli, and Klebsiella pneumoniae for up to seven days.

**6. Intended Use Statement**

Prescription:

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:

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

**7. Non-Clinical Test Conclusion**

Non clinical tests were conducted. 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 10993-6:2016 Biological Evaluation of Medical Devices- Part 6: Tests for local effects after implantation.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-11:2017 Biological Evaluation Of Medical Devices- Part 11: Tests For Systemic Toxicity.
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- USP <85> Bacterial Endotoxins Test

**8. Clinical Test Conclusion**

No clinical study is included in this submission.

**9. Comparison of Technological Characteristics With The Predicate Device**

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

K172554, LUOFUCON® Extra Silver Alginate Dressing (Prescription Use)/ LUOFUCON® Antibacterial Alginate Wound Dressing (OTC Use), Manufactured by Huizhou Foryou Medical Devices Co., Ltd.

The following table shows similarities and differences of intended use, mechanism, material, and performance between proposed device and its predicate devices. These data came from commercially product labeling and 510(k) summary.

Table 1 Comparison of Intended use, Design and Technological Characteristics

| Item | Subject Device (K202982) | Predicate Device(K172554) | Comparison |
|---|---|---|---|
| Product Code | FRO | FRO | NA |
| Class | Unclassified | Unclassified | NA |

| | | | |
|---|---|---|---|
| Intended Use | Prescription:<br>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.<br>OTC:<br>Antibacterial Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts, minor lacerations, minor scrapes, minor scalds and minor burns. | Prescription:<br>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, and graft and donor sites.<br>OTC:<br>LUOFUCON® Antibacterial Alginate Wound Dressing (OTC) is first aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns. | Same |
| Mechanism | Alginate for absorbing liquid, silver present in the alginate for reducing bacteria in the dressing. | Alginate for absorbing liquid, silver present in the alginate for reducing bacteria colonization in the dressing. | Same |
| Material | Alginate and silver | Alginate and silver | Same |
| Antibacterial Duration | 7 days | 7 days | Same |
| Single Use | Yes | Yes | Same |
| Sterilization | Gamma irradiation<br>SAL:$10^{-6}$ | Radiation<br>SAL:$10^{-6}$ | Same |
| Biocompatibility | Biocompatibility in accordance to 10993-1(breached or compromised surfaces with prolonged contact(>24h to 30d)) | Biocompatibility in accordance to 10993-1(breached or compromised surfaces with prolonged contact(>24h to 30d)) | Same |
| Free Swell Absorption Capacity | 14.2g/g | 13.8g/g | Similar |

The proposed device is compared to the predicate device with respect to intended use, mechanism, material, antibacterial capacity, single use, biocompatibility, free swell absorption capacity. According to the comparison information, most of the characteristics of proposed device are the same as the predicate, one is different, but none of them will raise different questions of safety or effectiveness.

**10. Substantially Equivalent (SE) Conclusion**

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.